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Artificial intelligence as a tool for research and development in European patent law

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ABSTRACT

Artificial intelligence ("AI") is increasingly fundamental for research and development ("R&D"). Thanks to its powerful analytical and generative capabilities, AI is arguably changing how we invent. According to several scholars, this finding calls into question the core principles of European patent law—the field of law devoted to protecting inventions. In particular, the AI revolution might have an impact on the notions of "invention", "inventor", "inventive step", and "skilled person". The present dissertation examines how AI might affect each of those fundamental concepts. It concludes that European patent law is a flexible legal system capable of adapting to technological change, including the advent of AI.

First, this work finds that "invention" is a purely objective notion. Inventions consist of technical subject-matter. Whether artificial intelligence had a role in developing the invention is therefore irrelevant as such. Nevertheless, *de lege lata*, the inventor is necessarily a natural person. There is no room for attributing inventorship to an AI system. In turn, the notion of "inventor" comprises whoever makes an intellectual contribution to the inventive concept. And patent law has always embraced "serendipitous" inventions—those that one stumbles upon by accident. Therefore, at a minimum, the natural person who recognizes an invention developed through AI would qualify as its inventor. Instead, lacking a human inventor, the right to the patent would not arise at all. Besides, the consensus among scholars is that, *de facto*, AI cannot invent "autonomously" at the current state of technology. The likelihood of an "invention without an inventor" is thus remote. AI is rather a tool for R&D, albeit a potentially sophisticated one.

Coming to the "skilled person", they are the average expert in the field that can rely on the standard tools for routine research and experimentation. Hence, this work finds that if and when AI becomes a "standard" research tool, it should be framed as part of the skilled person. Since AI is an umbrella term for a myriad of different technologies, the assessment of what is truly "standard" for the skilled person – and what would be considered inventive against that figure – demands a precise case-by-case analysis, which takes into account the different AI techniques that exist, the degree of human involvement and skill for using them, and the crucial relevance of data for many AI tools. However, while AI might cause increased complexities and require adaptations – especially to the inventive step assessment – the fundamental principles of European patent law stand the test of time.

Ai miei architetti

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INTRODUCTION

1. Phenomenon

Artificial intelligence ("AI") is everywhere today. A nonstop buzz in the media ([1]) – and, at times, academic literature – heralds AI as a magical tool ([2]), an apocalyptic threat for humanity ([3]) and everything in between ([4]).

([1]) NGUYEN, HEKMAN, *The news framing of artificial intelligence: a critical exploration of how media discourses make sense of automation*, in *AI & Society*, 2022, https://doi.org/10.1007/s00146-022-01511-1.

([2]) PLOTKIN, *The Genie in the Machine*, *How Computer-Automated Inventing Is Revolutionizing Law and Business*, Stanford University Press, Stanford, 2009 (the Author uses, to some extent ironically, the expression "genie" to refer to AI systems); ELISH, BOYD, *Situating methods in the magic of Big Data and AI*, in *Communication Monographs*, 2017, 1 ff. (the Authors criticize the myths that animate the supposed "magic" of AI systems, which glosses over the limitations of these systems); see also CLARKE, *Profiles of the Future: An Enquiry into the Limits of the Possible*, Harper & Row, New York, 1973, 21 (coined the often cited phrase "any sufficiently advanced technology is indistinguishable from magic").

([3]) According to Stephen Hawking, AI will be "either the best, or the worst thing, ever to happen to humanity" (HERN, *Stephen Hawking: AI will be 'either best or worst thing' for humanity*, in *The Guardian*, 19 October 2016, https://www.theguardian.com/science/2016/oct/19/stephen-hawking-ai-best-or-worst-thing-for-humanity-cambridge). After the launch of ChatGPT and a number of powerful AI systems in 2022 and 2023 the tone of the discussion around AI has gotten darker, with notable figures in the field alerting that AI systems are being developed too quickly, urging for caution and dangers ahead. In May 2023, Geoffrey Hinton, a 75 years old pioneer of the field, often called the "Godfather of AI" quit his position at Google saying that he believes that AI systems are becoming increasingly powerful and dangerous (see: METZ, *'The Godfather of A.I.' Leaves Google and Warns of Danger Ahead*, in New York Times, 1 May 2023, https://www.nytimes.com/2023/05/01/technology/ai-google-chatbot-engineer-quits-hinton.html). More than 1,000 technology leaders, including Elon Musk, Steve Wozniak, Emad Mostaque (the CEO of Stability AI) and esteemed professors Yoshua Bengio and Stuart Russell, signed an open letter in March 2023 asking big AI companies to "pause for at least 6 months the training of AI systems more powerful than GPT-4" as it poses "profound risks to society and humanity" https://futureoflife.org/open-letter/pause-giant-ai-experiments/. In May 2023, another alarming statement was issued by the Center for AI Safety, which reads: "Mitigating the risk of extinction from AI should be a global priority alongside other societal-scale risks such as pandemics and nuclear war" (Statement on AI Risk, available at https://www.safe.ai/statement-on-ai-risk#signatories). The signatories include Bill Gates, Sam Altman, the CEO of Open AI, Geoffrey Hinton and others. In both cases, to some extent counterintuitively, the very executive directors of firms at the forefront of the most advanced AI systems have signed.

([4]) See CALO, *Artificial Intelligence Policy: A Primer and Roadmap*, in *UC Davis Law*

To be sure, AI is not a recent technology. Its roots trace back at least to the fifties ([5]). Over the last decade, however, the exponential increase in computing power and the availability of large datasets ([6]), combined with growing investments ([7]), have allowed remarkable developments in the AI field ([8]). This, in turn, reignited the interest of scholars ([9]), policymakers ([10])

Review, vol. 51, 431 (suggesting that rather than focusing on remote "AI apocalypse" threats, attention should be paid at the current risks that AI's "stupidity" pose for individuals and society). In a similar vein, many stress that that AI's more "mundane" risks – e.g., bias and discrimination by algorithms, the creation of mis-and disinformation, and labor automation – should be at the forefront of the discussion: CHOWDHURY, SCHWARTZ, *How is Generative AI changing the landscape of AI harms?*, Berkman Klein Center for Internet & Society at Harvard University, (https://cyber.harvard.edu/events/how-generative-ai-changing-landscape-ai-harms); NAUGHTON, *AI will be everywhere, but its rise will be mundane not apocalyptic*, in *The Guardian*, 27 May 2023.

([5]) See § I.B below.

([6]) These two factors are particularly impacting for machine learning, a subfield of AI. See § I.B.4.1 below.

([7]) MASLEJ ET AL., *The AI Index 2023 Annual Report*, AI Index Steering Committee, Institute for Human-Centered AI, Stanford University, Stanford, April 2023, 171 (reporting an 18-fold increase in private investment in AI since 2013 up to 91 billion USD in 2022). Another study estimated that AI could contribute $15.7 trillion to the global economy by 2030: RAO, VERWEIJ, *Sizing the Prize: What's the Real Value of AI for Your Business and How Can You+ Capitalise?*, PwC, 2017, 3, www.pwc.com/gx/en/issues/analytics/assets/pwc-ai-analysis-sizing-the-prize-report.pdf.

([8]) WIPO, *Technology Trends 2019, Artificial Intelligence*, 2019, https://www.wipo.int/publications/en/details.jsp?id=4386 (reporting a boom in AI-related patents since 2013); BARUFFALDI ET AL., *Identifying and measuring developments in artificial intelligence: Making the impossible possible*, OECD Science, Technology, and Industry Working Papers 2020/05, 2020, https://doi.org/10.1787/18151965 (reporting a drastic increase in the number of AI-related publications and patents after 2015); USPTO, *Inventing AI, Tracing the diffusion of artificial intelligence with U.S. patents*, 2020, https://www.uspto.gov/sites/default/files/documents/OCE-DH-AI.pdf ("from 2002 to 2018, annual AI patent applications increased by more than 100%").

([9]) MASLEJ ET AL., *The AI Index 2023 Annual Report*, cit., 24 (reporting that "[f]rom 2010 to 2021, the total number of AI publications more than doubled, growing from 200,000 in 2010 to almost 500,000 in 2021").

([10]) In 2021, the European Commission issued the proposal for the first law on AI by a major regulator: Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain union legislative acts, Brussels, 21.4.2021, COM(2021) 206 final, 2021/0106(COD).

and the broader public ([11]).

AI is notoriously better than humans at playing games. Already in 1997, the IBM "supercomputer" Deep Blue defeated Garry Kasparov, perhaps the greatest chess player of all times, in a legendary match ([12]). In 2011, Watson – another IBM product – beat the strongest contestants on the U.S. game show Jeopardy ([13]). Just a few years later, in 2016, the world champion of the boardgame Go, Lee Sedol, lost against Google's system AlphaGo ([14]). These spectacular feats echoed across the world and were widely covered in news and documentaries ([15]).

AI then gradually entered our everyday lives ([16]). Most smartphones now include facial recognition technology and "intelligent virtual assistants" able to process natural language and interact with users. Machine translation

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([11]) PEW RESEARCH CENTER, *Public Awareness of Artificial Intelligence in Everyday Activities*, February 2023. Google Trends show that the interest in artificial intelligence exploded over the past five years, and especially since the end of 2022 (https://trends.google.com/trends/explore?date=today%205-y&q=artificial%20intelligence&hl=en-US).

([12]) IBM, *Deep Blue*, https://www.ibm.com/ibm/history/ibm100/us/en/icons/deepblue/.

([13]) MARKOFF, *Computer Wins on 'Jeopardy!': Trivial, It's Not*, in *New York Times*, 16 February 2011, www.nytimes.com/2011/02/17/science/17jeopardy-watson.html.

([14]) The achievement is particularly impressive since the possible combinations of moves in Go are in the order of 10^{170}, i.e., greater than the number of atoms in the universe: ABBOTT, *Artificial Intelligence, Big Data and Intellectual Property: Protecting Computer-Generated Works in the United Kingdom*, in APLIN (ed.), *Research Handbook on Intellectual Property and Digital Technologies*, Edward Elgar, Cheltenham, 2020, 322. Also, computer scientist had predicted that it would be decades before a computer could win at Go, therefore the success of AlphaGo was relatively unexpected (ELISH, BOYD, cit. 10). A few years later, a new model called AlphaGo Zero beat AlphaGo one hundred games to zero after only a few days of training: SILVER ET AL., *Mastering the game of Go without human knowledge*, in *Nature*, 2017, vol. 550, 354, https://doi.org/10.1038/nature24270).

([15]) See: *Game Over: Kasparov and the Machine*, directed by Vikram Jayanti, 2003; *Watson: Smartest Machine on Earth*, directed by Michael Bicks, PBS, 2011, https://www.pbs.org/wgbh/nova/video/smartest-machine-on-earth/; *AlphaGo*, directed by Greg Kohs, 2017.

([16]) DOMINGOS, *The Master Algorithm: How the Quest for the Ultimate Learning Machine Will Remake Our World*, Basic Books, New York, 2015, xi ff.; NÄGERL, NEUBURGER, STEINBACH, *Künstliche Intelligenz: Paradigmenwechsel im Patentsystem*, in *GRUR* 2019, 336.

services like DeepL offer consistently improved results ([17]). Autonomous vehicles are no longer utopic ([18]). And much less exciting things – like insurance premiums or credit scores – are often determined by AI systems as well ([19]). Economists have therefore long called for a fourth industrial revolution, of which AI is one of the main drivers ([20]).

The current state of the AI field is however best represented by "generative AI" models. While computers have been used for decades to generate text, music and images ([21]), a number of AI systems launched since 2022 stepped up the game ([22]).

The so-called "text-to-image" models are able to instantly generate pictures from a description in natural language ([23]). For instance, the following images are the output of the prompt "artificial intelligence developing a new drug in futuristic high-definition style" typed in three popular generative AI models: DALL-E 2 ([24]), Stable Diffusion ([25]) and Midjourney ([26]).

([17]) DEEPL, *Another breakthrough in AI translation quality*, https://www.deepl.com/en/blog/ 20200206.

([18]) DEICHMANN, *Autonomous driving's future: Convenient and connected*, McKinsey Center for Future Mobility, January 2023, https://www.mckinsey.com/industries/automotive-and-assembly/our-insights/autonomous-drivings-future-convenient-and-connected#/.

([19]) ASAY, *Artificial Stupidity*, in *William & Mary Law Review*, 2020, 61(5), 1190-1191.

([20]) SCHWAB, *The fourth industrial revolution*, Penguin, London, 2017, 9-11.

([21]) See SUNDARARAJAN, *Harold Cohen and AARON: Collaborations in the Last Six Years (2010–2016) of a Creative Life*, in *Leonardo*, 2021, vol. 54, issue 4, 412 (discussing Harold Cohen's use of the AI system AARON to paint); *Kurzweil CyberArt Technologies Home Page*, 2001, http://www.kurzweilcyberart.com/poetry/rkcp_overview.php (Ray Kurzweil's project on a "Cybernetic Poet); FARRELL, *Artificial Composers: Tools of the Modern Musician or Affront to Human Creativity?*, in *Inquiries Journal/Student Pulse*, 2015, vol. 7, issue 3 (discussing the use of AI in music composition).

([22]) HEIKKILÄ, HEAVEN, *What's next for AI*, in *MIT Technology Review*, 23 December 2022, https://www.technologyreview.com/2022/12/23/1065852/whats-next-for-ai/.

([23]) ROOSE, *A.I.-Generated Art Is Already Transforming Creative Work*, in *New York Times*, 21 October 2022, https://www.nytimes.com/2022/10/21/technology/ai-generated-art-jobs-dall-e-2.html.

([24]) OPENAI, *Dall-E 2*, https://openai.com/product/dall-e-2.

([25]) STABILITY.AI, *Stable Diffusion 2.0 Release*, https://stability.ai/blog/stable-diffusion-v2-release.

([26]) MIDJOURNEY, https://www.midjourney.com/home/?callbackUrl=%2Fapp%2F.

Fig. 1 – DALL-E 2

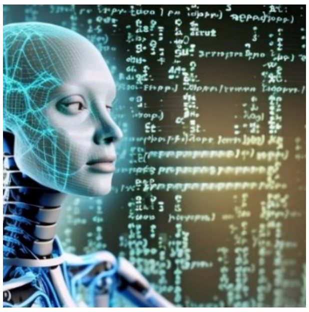
Fig. 2 – Stable Diffusion


Fig. 3 – Midjourney

These pictures did not exist before the prompt was processed and using the same prompt again will not generate identical images. Notably, all three images also reflect the loosely anthropomorphic view of AI that science fiction engrained in the public imagination and, consequently, in the data these models are built upon (i.e., pictures, drawings, paintings etc.).

The latest generative AI systems to stir widespread discussions at the time of writing are "large language models" ("LLMs"). These models are trained on immense datasets and designed to process and generate natural-sounding text ([27]). In November 2022, OpenAI – the company behind DALL-E – released ChatGPT, a conversational chatbot based on the GPT-3 large language model they developed ([28]). ChatGPT is able to generate coherent responses to text prompts, including technical explanations, imaginary dialogues and programming tips, in seconds. Since its launch, the speed and eloquence of ChatGPT's outputs caused an upheaval, among others, in the education field, with high schools and colleges questioning whether students' essays and homework make sense anymore ([29]). One of the most important AI conferences immediately prohibited papers that include LLM-generated texts, citing plagiarism risks among the main reasons ([30]).

([27]) LEE, COOPER, GRIMMELMANN, IPPOLITO, *AI and Law: The Next Generation*, July 2023, Chapter 1, https://genlaw.github.io/explainers/.

([28]) OPENAI, *Introducing ChatGPT*, 30 November 2022, https://openai.com/blog/chatgpt. To be precise also DALLE is based on GPT3, modified to generate images: OPENAI, *DALL·E: Creating images from text*, 5 January 2021, https://openai.com/research/dall-e.

([29]) STOKEL-WALKER, *AI bot ChatGPT writes smart essays – should professors worry?*, in *Nature*, 9 December 2022, https://www.nature.com/articles/d41586-022-04397-7.

([30]) ICLM, *Clarification on Large Language Model Policy LLM*, https://icml.cc/Conferences/2023/llm-policy.

Yet only a few months later – as Google launched its own LLM, called Bard ([31]) – OpenAI introduced GPT-4, which is remarkably more accurate and powerful than its previous version ([32]). GPT-4 was able to "pass" the U.S. uniform bar exam as well as many other college-level exams with flying colours ([33]).

2. Problem

The powerful capabilities of AI systems – and, above all, its perceived unpredictability and autonomy from human instructions ([34]) – quickly led legal scholars to question if and how AI might impact practically every field of law ([35]). This comes as no surprise since, in the words of Dan Burk, while

([31]) PICHAI, *An important next step on our AI journey*, in *The Keyword (Google Blog)*, 6 February 2023, https://blog.google/technology/ai/bard-google-ai-search-updates/.

([32]) HEAVEN, *GPT-4 is bigger and better than ChatGPT—but OpenAI won't say why*, in *MIT Technology Review*, 14 March 2023, https://www.technologyreview.com/2023/03/14/1069823/gpt-4-is-bigger-and-better-chatgpt-openai/.

([33]) OPENAI, *GPT-4 Technical Report*, 27 March 2023, https://arxiv.org/pdf/2303.08774.pdf. This notwithstanding, GPTs are bad in math: ZUMBRUN, *ChatGPT Needs Some Help With Math Assignments*, in *Wall Street Journal*, 10 February 2023, https://www.wsj.com/articles/ai-bot-chatgpt-needs-some-help-with-math-assignments-11675390552.

([34]) See e.g., DORIA, *Proprietà intellettuale ed intelligenza artificiale*, Piccin, Padova, 2023, 24-25; KIM ET AL., *Clarifying assumptions About Artificial Intelligence Before Revolutionising Patent Law*, in *GRUR International*, 2022, vol. 71(4), 304 ff.

([35]) In the Italian scholarship, see: ALPA (ed.), *Diritto e intelligenza artificiale*, Pacini, Pisa, 2020; RUFFOLO (ed.), *Intelligenza artificiale. Il diritto, i diritti, l'etica*, Giuffrè, Milan, 2020; SANTOSUOSSO, *Intelligenza artificiale e diritto. Perché le tecnologie di IA sono una grande opportunità per il diritto*, Mondadori, Milan, 2020; PAINO, DONATI, PERRUCCI (eds.), *Intelligenza artificiale e diritto: una rivoluzione?*, il Mulino, Bologna, 2022, vol. I, II and III; OTTOLIA, *Big Data e innovazione computazionale*, Giappichelli, Turin, 2017; MONTAGNANI, *Il ruolo dell'intelligenza artificiale nel funzionamento del consiglio di amministrazione delle società per azioni*, Egea, Milan, 2021; ABRIANI, SCHNEIDER, *Diritto delle imprese e intelligenza artificiale, Dalla Fintech alla Corptech*, il Mulino, Bologna, 2021; GAUDIO, *Algorithmic management, poteri datoriali e oneri della prova: alla ricerca della verità materiale che si cela dietro l'algoritmo*, in *Labour & Law Issues*, 2020, 6, 19; MANES, *L'oracolo algoritmico e la giustizia penale*, in RUFFOLO (ed.), *Intelligenza artificiale. Il diritto, i diritti, l'etica*, Giuffrè, Milan, 2020, 547. AVANZINI, *Decisioni amministrative e algoritmi informatici*, ESI, Napoli, 2019; NIEVA-FENOLL, *Intelligenza artificiale e processo, Giappichelli*, Turin, 2019.

technological change "sometimes poses novel challenges for regulation", it "unfailingly elicits dubious declarations regarding its revolutionary character" ([36]).

The field of patent law is no exception. As artificial intelligence is becoming an increasingly common tool in research and development – to design anything from miniature antennas ([37]) to toothbrushes ([38]), new drugs ([39]) and gas turbines ([40]) – scholars realized that these systems might fundamentally change the way in which inventions are made ([41]).

In turn, this might call into question the current understanding of the "person skilled in the art", one of the most fundamental notions in European patent law. The skilled person is a fictional model representing the average expert in the technical field of the invention. That is the yardstick against

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See also: DIMATTEO, PONCIBÒ, CANNARSA (eds.), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, Cambridge University Press, Cambridge, 2022; HERVEY, LAVY (eds.), *The Law of Artificial Intelligence*, Sweet & Maxwell, London, 2020; CUSTERS, FOSCH-VILLARONGA (eds.), *Law and Artificial Intelligence, Regulating AI and Applying AI in Legal Practice*, Asser Press, The Hague, 2022; ABBOTT (ed.), *Research Handbook on Intellectual Property and Artificial Intelligence*, Edward Elgar, Cheltenham, 2022. ENRIQUES, ZETZSCHE, *Corporate Technologies and the Tech Nirvana Fallacy*, in *Hastings Law Journal*, 2020, vol. 72, issue 55, 55; MÖSLEIN, *Robots in the boardroom: artificial intelligence and corporate law*, in BARFIELD, PAGALLO (eds.), *Research Handbook on the Law of Artificial Intelligence*, Edward Elgar, Cheltenham, 2018, 656; KAULARTZ, BRAEGELMANN (eds.), *Rechtshandbuch Artificial Intelligence und Machine Learning*, C. H. Beck, Munich, 2020.

([36]) BURK, *AI Patents and the Self-Assembling Machine*, in *Minn. L. Rev. Headnotes*, 2021, 105.

([37]) See § I.C.2.2.2 below.

([38]) See § I.C.2.1.2 below.

([39]) See § I.C.3.1 below.

([40]) WOYKE, *General Electric Builds an AI Workforce*, in *MIT Tech. Rev.*, 27 June 2017, www.technologyreview.com/2017/06/27/150784/general-electric-builds-an-ai-workforce/.

([41]) RAMALHO, *Patentability of AI-generated inventions: is a reform of the patent system needed?*, 2018, 25-26, https://ssrn.com/abstract=3168703; SAMORE, *Artificial intelligence and the patent system: can a new tool render a once patentable idea obvious?*, in BARFIELD, PAGALLO (eds.), *Research Handbook on the Law of Artificial Intelligence*, Edward Elgar, Cheltenham, 2018, 472; FIRTH-BUTTERFIELD, CHAE, *Artificial Intelligence Collides with Patent Law*, World Economic Forum, White Paper, April 2018, 12, www3.weforum.org/docs/WEF_48540_WP_End_of_Innovation_Protecting_Patent_Law.pdf; ROTMAN, *AI's Big Idea: Reinvent how we invent*, in *MIT Tech. Rev*. 2019, vol. 122(2), 60, https://www.technologyreview.com/2019/02/15/137023/ai-is-reinventing-the-way-we-invent/.

which the core patentability requirements – novelty, inventive step and sufficiency of disclosure – are assessed. The skilled person can rely on the standard tools for routine research and experimentation. Hence, if AI is (or becomes) a "standard" research tool, it should be framed as part of the skilled person. Since AI is an umbrella term for a myriad of different technologies, how to do so – in theory and in practice – is a multifaceted and fact-specific issue. The widespread adoption of AI might impact *who* the skilled person is, *what* they know, and *how* they take on research endeavours.

Moreover, if we were to accept – as several scholars claim ([42]) – that AI is not only a *research tool* in the hands of the skilled person, but also capable of inventing "autonomously", this might prompt a more radical rethinking of European patent law's foundations, including the notion of "invention" and "inventor" themselves. As patent law is traditionally understood as a system for protecting human ingenuity ([43]), one might ask whether AI could or should qualify as the *inventor* – or at least *an* inventor – when an invention is developed using an AI system. Also, one might ask if inventions developed using AI actually qualify as "inventions" under patent law.

3. Course of the investigation

To address these questions, this thesis is structured in four chapters.

- **Chapter I** sets the stage for the research. Further to a brief introduction on the features of modern innovation, it provides a technical "glossary" of AI and various AI techniques. Then, the chapter investigates, as a matter of fact, how AI is used in research and development, with particular emphasis on the pharmaceutical and healthcare fields, which are some of the most promising areas of AI-powered research.
- **Chapter II** turns to the law, laying out the fundamental concepts, sources and policy justifications of European patent law.

([42]) The most influential voice in the field has certainly been that of prof. Ryan Abbot: ABBOTT, *I Think, Therefore I Invent: Creative Computers and the Future of Patent Law*, in *B.C.L. Rev.*, 2016, 57(4), 1079. See also § III.B.2 below.

([43]) See e.g., MAAMAR, *Computer als Schöpfer*, *Der Schutz von Werken und Erfindungen künstlicher Intelligenz*, Mohr Siebeck, Tübingen, 2021, 17.

– **Chapter III** addresses the notions of invention and inventor. It argues that the notion of invention is purely objective and that the potential use of AI does not affect whether certain subject matter qualifies as an invention or not. The chapter then addresses the figure of the inventor. It comes to the conclusion that the debate on AI-inventorship is both flawed, technically and doctrinally, as well as unnecessary because in most cases a human inventor can be identified. AI is thus best understood as a research tool, albeit potentially a very sophisticated one, in the hands of the skilled person;
– Building on these findings, **Chapter IV** carries out the core doctrinal analysis of the thesis. It first discusses the figure "person skilled in the art" as the foundational notion for the assessment of all patentability requirements. Then, it examines the "inventive step" requirement, its conceptual underpinnings and evolution, as well as the different approaches adopted by the EPO and national courts to the question of obviousness. Concluding that, sooner or later, AI shall be framed as part of the skilled person for the assessment of inventive step, the chapter suggests several ways of looking at that possibility, both in theory and in practice.

Instead, this work will not examine whether and how AI technologies can be patented. That is a separate question from those addressed herein, as it looks at AI as an object of protection, rather than a tool used in the inventive process ([44]). It is submitted that asking whether AI can be patented

([44]) There is a rich literature concerning the patentability of AI systems. See, in particular, for the EPO approach: MOUFANG, *Artificial Intelligence and the Technicality Requirement of Patent Law*, in GODT, LAMPING (eds.), *A Critical Mind. MPI Studies on Intellectual Property and Competition Law*, vol 30, Springer, Berlin-Heidelberg, 2023, 471; BALDUS, *A practical guide on how to patent artificial intelligence inventions and computer programs within the German and European patent system: much ado about little*, in *EIPR*, 2019, vol. 12, 750; HERVEY, DRIVER, WOODHOUSE, *Intellectual Property*, in HERVEY, LAVY (eds.), *The Law of Artificial Intelligence*, Sweet & Maxwell, London, 2020, §§ 243-270; FOX, MOROZOVA, DISTEFANO, *Patentability of AI*, in DIMATTEO, PONCIBÒ, CANNARSA (eds.), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, Cambridge University Press, Cambridge, 2022, 233; ZOBOLI, *Diritto dei brevetti e intelligenza artificiale*, Egea, Milan, 2023, 52-64. In the U.S. literature, see:

approximates the longstanding debate on software patents ([45]), which falls outside the scope of the present work ([46]). For the same reason, this work will not address how inventions that concern AI systems (as an object of protection) can and should be described in patent specifications to meet the patentability standards ([47]). Once again, this important question looks at AI as an object of protection, rather than a technology used to invent.

4. Disambiguation on "AI-inventions"

For clarity purposes, the present work avoids the expression "AI-inventions"

HATTENBACH, SNYDER, *Rethinking the Mental Steps Doctrine and Other Barriers to Patentability of Artificial Intelligence*, in *Science and Technology Law Review*, 2018, 19(2), 313; STAMATIS, *Patenting Artificial Intelligence: An Administrative Look into the Future of Patent Law*, in *J. High Tech. L.*, 2019, vol. 19, 329. See also for comparative perspectives: HASHIGUCHI, *The Global Artificial Intelligence Revolution Challenges Patent Eligibility Laws*, in J. Bus. & Tech. L., 2017, vol. 13(1), 1, http://digitalcommons.law.umaryland.edu/jbtl/vol13/iss1/2; VASYLYEVA, ZELISKO, ZINYCH, *Peculiarities of Patenting Artificial Intelligence in the United States and Countries of the European Union*, in *J. Advanced Res. L. & Econ*, 2018, 9, 2854; OKAKITA, *Patent examination practices regarding AI-related inventions: Comparison in the EPO, USPTO and JPO*, MIPLC Master Thesis, 2019, http://www.miplc.de/research/.

([45]) See e.g., GIOV. GUGLIELMETTI, *L'invenzione di software, Brevetto e diritto d'autore*, Giuffrè, Milan, 1997; AREZZO, *Tutela brevettuale e autoriale dei programmi per elaboratore: profili e critica di una dicotomia normativa*, Giuffrè, Milan, 2012; DRAGONI, *Software and Patent Law: Reverse Contaminations, Hybridizations and Trends, Observed Through the Legal Systems of Italy (and the EPC System), Japan, and the United States*, in COLOMBO (ed.), *Hybridizations, Contaminations, Triangulations: Itineraries in Comparative Law Through the Legal Systems of Italy and Japan*, Special issue of the "Italian Law Journal", 2018, https://www.theitalianlawjournal.it/dragoni/; DRAGONI, *Software Patent Eligibility and Patentability: An Overview of the Developments in Japan, Europe and the United States and an Analysis of Their Impact on Patenting Trends*, Stanford-Vienna TTLF Working Paper No. 72, 2021, http://ttlf.stanford.edu.

([46]) However, see § III.A.1.1 below.

([47]) On this topic see, e.g., FRÜH, *Transparency in the Patent System: Artificial Intelligence and the Disclosure Requirement*, in SIKORSKI, ZEMLA-PACUD (eds.), *Patents as an Incentive for Innovation*, Wolters Kluwer, Alphen aan den Rijn, 2021, 235; RUDZITE, *Algorithmic Explainability and the Sufficient-Disclosure Requirement under the European Patent Convention*, in *Juridica International*, 2022, vol. 31, 125.

which is used somewhat confusingly in literature ([48]) and policy papers ([49]) to refer both to inventions developed *through* the use of AI (i.e., an AI system is a tool to invent or, potentially, the inventor) and inventions *concerning* AI systems (i.e., an AI system is the invention, or part thereof).

Instead, this work adopts the terminology suggested by the Max Planck Institute for Innovation and Competition ("MPI") ([50]), as follows:

(i) "AI-assisted inventions" to refer to inventions where humans use AI as a tool to invent;

(ii) "AI-generated inventions" to refer to inventions where AI acts autonomously without human intervention (assuming that can be the case); and

(iii) "AI-implemented inventions", where AI is implemented as (part of) the invention.

To be perfectly clear, the expressions "AI-generated" and "AI-assisted" inventions do *not* imply that AI is also the subject-matter of the invention. AI systems can be used to design products – such as antennas or antibiotics – that have nothing to do with AI as such. At the same time, the fact that an invention is AI-assisted or AI-generated does not exclude *per se* that the invention might also be AI-implemented. Naturally, AI can be used to invent

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([48]) See e.g., MAMMEN, *AI as Inventor*, in DIMATTEO, PONCIBÒ, CANNARSA (eds.), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, Cambridge University Press, Cambridge, 240-241; EBRAHIM, *Artificial Intelligence Inventions & Patent Disclosure*, in *Penn St. L. Rev.*, 2020, vol. 125, 147, https://scholarlycommons.law.cwsl.edu/fs/357.

([49]) See e.g., USPTO, *Request for Comments on Patenting Artificial Intelligence Inventions* Federal Register, Vol 84, No 166, 44889 (Federal Register, 22 August 2019) https://www.federalregister.gov/documents/2019/08/27/2019-18443/request-for-comments-on-patenting-artificial-intelligence-inventions.

([50]) DREXL ET AL., *Comments of the Max Planck Institute for Innovation and Competition of 11 February 2020 on the Draft Issues Paper of the World Intellectual Property Organization on Intellectual Property Policy and Artificial Intelligence*, 2020, 4, https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2020-02-11_WIPO_AI_Draft_Issue_Paper__Comments_Max_Planck.pdf (hereafter "*MPI Comments on the WIPO Draft Issues Paper*"). The WIPO eventually adopted the terminology proposed by the MPI: see WIPO, *AI inventions*, 2023, https://www.wipo.int/export/sites/www/about-ip/en/frontier_technologies/pdf/WIPO_AI_Inventions_factsheet.pdf.

an AI-implemented system. The typical case are AI-powered diagnostic instruments, where AI is both used in the development process that leads to the device, and is embedded in the device as such ([51]). But these two aspects, i.e., AI as a tool to invent (or the inventor) and AI as the subject-matter of an invention, are distinct.

5. Methodological approach

Finally, the choice to focus the present work on European patent law postulates a methodological clarification. Indeed, "European patent law" is here used only as a generic and descriptive expression to refer to the national and international patent laws having effect in the European territory.

As is well-known, the European Union ("EU") has largely refrained from regulating patent law within the EU member states ([52]). Nevertheless, the European Patent Convention ("EPC"), which is not an EU instrument, along with other international treaties, favoured a rather high harmonisation in patent legislations across Europe ([53]). The recent rollout of the Unified Patent Court and European patents with unitary effect are hoped to bring further uniformity ([54]). Nevertheless, national patent statutes and courts still play an important role in the interpretation and evolution of patent law in Europe ([55]). Hence, in order to properly reflect the multi-layered nature of European patent law, the present work does not focus only on a doctrinal analysis of the EPC provisions and the decisions of the European Patent Office ("EPO"), but methodically takes into account also on the Italian, German and UK national patent systems – i.e., three of the most relevant and established patent jurisdictions in the continent. In doing so, rather than attempting a full comparative analysis, this work aims to highlight the broad convergences that emerge from national patent systems, which allow a coherent understanding of the law in the European territory.

([51]) See § I.C.3.4 below.
([52]) See § II.B below.
([53]) See § II.B.1 below.
([54]) See § II.B.2 below.
([55]) See § II.B.3 below.

I.

ARTIFICIAL INTELLIGENCE AND R&D

This chapter sets the stage for the research. Section I.A identifies the fundamental features of modern innovation and, in particular, the circular relationship between innovation and research and development ("R&D"). Then, Section I.B provides a technical "glossary" of AI and illustrates the fundamental features of the AI techniques most used in R&D. Finally, Section I.C discusses how AI is used in R&D. First, it addresses a few so-to-say "classic" examples that have been repetitively cited in the IP literature. Then, it discusses contemporary use-cases of AI in R&D, with a focus on the pharmaceutical and healthcare field, which is one of the most promising areas of AI-assisted research.

A. INNOVATION

1. Innovation through R&D

Thomas Edison is frequently celebrated as the solitary genius who invented the lightbulb ([1]). Perhaps, however, Edison's most consequential invention is that the Edison Electric Light Company (later merged into General Electric) ([2]) was the first company to set up, in 1878, a private research laboratory that spent a significant part of its parent company's revenues, employing a staff of twenty ([3]). This model proved to be successful. By the

([1]) LEMLEY, *The Myth of the Sole Inventor*, in *Michigan Law Review*, 2012, vol 11, 709 ("[t]he canonical story of the lone genius inventor is largely a myth. Edison didn't invent the lightbulb; he found a bamboo fiber that worked better as a filament in the lightbulb developed by Sawyer and Man, who in turn built on lighting work done by others"). See also *The Incandescent Lamp Patent*, 159 U.S. 465 (1895) (landmark case of the U.S. Supreme Court that summarizes part of the research and development story of the lightbulb).

([2]) *General Electric*, in *Encyclopaedia Britannica*, 28 April 2023, https://www.britannica.com/topic/General-Electric.

([3]) MCLEOD, HOLSTEIN, *Research and development*, in *Encyclopaedia Britannica*, 19 May 2023, https://www.britannica.com/topic/research-and-development; See also LEMLEY, *The Myth of the Sole Inventor*, cit., 721 ("Edison […] is rightly recognized as the first person to take invention from a hobby to a business"). More broadly, as the philosopher Alfred North Whitehead famously remarked, "the greatest invention of the nineteenth century was the end of his life, Edison was more than 1,000 patents ([4]). Around 1900, many other companies – such as DuPont, AT&T, Kodak and Standard Oil – followed suit, establishing in-house research laboratories ([5]).

Instead, since the early twentieth century, the romantic ideal of the solitary inventor possessed by the "fire of genius" ([6]) has been progressively abandoned ([7]). In most cases, today innovation is the result of a continuous and systematic process which presupposes a complex organization of people and resources, often led by private enterprises ([8]) and directed to industrial

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invention of the method of invention" (WHITEHEAD, *Science and the modern world*, Cambridge University Press, London, 1925, 136). He was referring to the "new method" of "bridging the gap between the scientific ideas and the ultimate product" as a "process of disciplined attack upon one difficulty after another (WHITEHEAD, ibid.).

([4]) The precise number is 1,084 patents: WILLS, *Thomas Edison: Success and Innovation through Failure*, Springer, Cham, 2019, 171. Other sources attest the number of Edison's patent at 1,093 (see, e.g., RUTGERS UNIVERSITY, *Edison's Patents*, https://edison.rutgers.edu/life-of-edison/edison-s-patents), however 9 of those are design patents, which cover the ornamental design of an article of manufacture (35 U.S.C. § 171(a)), not inventions.

([5]) MCLEOD, HOLSTEIN, cit.

([6]) The expression "fire of genius" is generally first attributed to Abraham Lincoln, who used it in his Second Lecture on Discoveries and Inventions, held on 11 February 1858. The full excerpt reads: "[n]ext came the Patent laws. These began in England in 1624; and, in this country, with the adoption of our constitution. Before then […], any man might instantly use what another had invented; so that the inventor had no special advantage from his own invention. The patent system changed this; secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things", as reported in BASLER (ed.), *The collected works of Abraham Lincoln*, 1953, 363, https://quod.lib.umich.edu/l/lincoln/lincoln3/1:87?rgn=div1;view=fulltext.

([7]) LEMLEY, *The Myth of the Sole Inventor*, cit., 711 (arguing that innovation is a social, rather than an individual phenomenon: "[i]nventors build on the work of those who came before, and new ideas are often either 'in the air' or result from changes in market demand or the availability of new or cheaper starting materials"); SINGH, FLEMING, *Lone Inventors as Sources of Breakthroughs: Myth or Reality?*, in *Management Science*, vol. 56, no. 1, 2010, p. 41 (arguing that collaboration both reduces the probability of extremely poor outcomes and increases the probability of extremely successful ones); See also LJUNGBERG, *Lone Inventors and Technological Novelty*, in Academy of Management Proceedings 2019, vol. 1, https://doi.org/10.5465/AMBPP.2019.18242abstract (arguing that "lone inventors" have an advantage when it comes to novelty generation compared to collaboration, but that their advantage is lost under higher technical complexity).

([8]) SENA, *I diritti sulle invenzioni e sui modelli di utilità*, in SCHLESINGER (ed.), production ([9]). This process is herein loosely referred to as "research and development" ("R&D"), wherein the industrial "development" step is seen as the necessary completion of the "research" phase, traditionally understood as the more abstract activity of identifying new ideas and making discoveries, typical of academic endeavours ([10]).

In particular, the R&D innovation model is inescapable for industries impacted by high innovation costs, such as pharmaceuticals and biotechnologies ([11]). In those fields companies often employ hundreds of

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Trattato di diritto civile e commerciale, 4th ed., Giuffrè, Milan, 2011, 173-174, 199; SENA, *Invenzioni brevettabili e intelligenza artificiale*, in *Riv. dir. ind.* 2020, I, 153; UBERTAZZI, *Profili soggettivi del brevetto,* Giuffrè, Milan, 1985, 1; VANZETTI, DI CATALDO, SPOLIDORO, *Manuale di diritto industriale*, Giuffrè, Milan, 2021, 375; GHIDINI, *Profili evolutivi del diritto industriale*, III ed., Giuffrè, Milan, 2015, 116; GHIDINI, *Rethinking intellectual property, Balancing Conflicts of Interests in the Constitutional Paradigm*, Edward Elgar, Cheltenham, 2018, 111. According to the latest EPO Patent Index Report, a significant proportion of applicants at the EPO are smaller entities. Among the applications originating from European countries, 73% were filed by large companies, 20% by SMEs and individual inventors, and 7% by universities and public research organisations. (https://www.epo.org/about-us/annual-reports-statistics/statistics/2022.html).

(9) SENA, *I diritti sulle invenzioni*, cit., 27 (defining "technical innovation" as the "research and development" activity that materializes in the industrial production, i.e., in the production or utilization of products or in the realization of process to produce them).

(10) GODIN, LANE*, Research or Development? A Short History of Research and Development as Categories*, n.d., https://publichealth.buffalo.edu/content/dam/sphhp/cat/kt4tt/pdf/research-or-development.pdf ("[w]hile research is an academic's category, development is an industrial category. It is composed of those activities which rely on engineering and which are devoted to developing prototypes of new goods and services"); See also GODIN, *Research and development: how the 'D' got into R&D*, in *Science and Public Policy* 2006, vol. 33, 59.

(11) ERRICO, *I brevetti sulle biotecnologie fra ricerca pubblica e sviluppo privato. Indicazioni dall'esperienza statunitense*, in *Riv. dir. ind.*, 2009, 311. The most frequently cited study estimates that the average R&D cost for bringing a new drug on the market is over 1.3 billion USD (in 2013 dollars): DIMASI, GRABOWSKI, HANSEN, *Innovation in the pharmaceutical industry: New estimates of R&D costs*, in *J. Health Econ.* 2016, vol. 47, no. 20. That means *over 2.3 billion USD* in 2021 dollar values, as estimated by the U.S. CONGRESSIONAL BUDGET OFFICE, *Research and Development in the Pharmaceutical Industry*, 2021, www.cbo.gov/publication/57025. More recently, another study estimated the average R&D cost per new drug at 1,2 billion USD: WOUTERS, MCKEE, LUYTEN, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009–2018*, in *JAMA*, 2020, 323(9), 844. Both studies include in their estimates the cost of capital and, at least to some extent, the cost of drugs that did not reach the market. Despite a

skilled researchers and must invest heavily on advanced equipment and studies ([12]) in order to identify new solutions within an "ocean" of available information, such as the human genotype or the many millions proteins that exist ([13]).

2. Innovation in R&D

The relationship between R&D (i.e., a *process* that presupposes the systematic organization of people and resources) and innovation (i.e., the

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significant variation (from 1 to 2 billion USD), they support the general conclusion that drug development is an extremely expensive endeavour. Moreover, the average length of the R&D for a new drug, from basic research to market, is estimated between 10 and 15 years, and only one or two of every 10,000 molecules will successfully pass all stages of development (EFPIA, *The Pharmaceutical Industry in Figures*, 2021, 6, www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf.). On top of this, the marketing authorization requirements are rigorous: around 90% of new drugs fail to be approved by authorities, both in the U.S. and in the EU (GURGULA, *AI-assisted inventions in the field of drug discovery: readjusting the inventive step analysis*, in *Int. J. Soc. Sci. Pub. Pol.* 2020, 2(8), https://doi.org/10.33642/ijsspp.v2n8p2, 2; DOWDEN, MUNRO, *Trends in clinical success rates and therapeutic focus*, in *Nature Reviews Drug Discovery* 2019, vol. 18, 495, https://doi.org/10.1038/d41573-019-). Unsurprisingly, then, the pharmaceutical industry has the highest ratio of R&D investments to net sales across all industries. In 2019, the industry invested more than 117 billion Euro in R&D in Europe, U.S., and Japan alone, which represents an exponential increase from the 1990s (EFPIA, cit., 5). The rising R&D costs and perceived lower output of new drugs by pharmaceutical companies suggested an alarming decline in productivity of pharmaceutical R&D: PAMMOLLI, MAGAZZINI, RICCABONI, *The productivity crisis in pharmaceutical R&D*, in *Nat. Rev. Drug Disc.* 2011, 10, 428. However, recent studies showed significant signs of improvement: PAMMOLLI ET AL., *The endless frontier? The recent increase of R&D productivity in pharmaceuticals,* in *J. Transl. Med.*, 2020, 18, 162.

([12]) SENA, *I diritti sulle invenzioni*, cit., 172.

([13]) ROMANO, *Brevetti per invenzioni industriali*, in *Enciclopedia Treccani*, 2009, https://www.treccani.it/enciclopedia/brevetti-per-invenzioni-industriali_%28XXI-Secolo%29/; BLOOM ET AL., *Are Ideas Getting Harder to Find?*, in *American Economic Review* 2020, vol 110 (4): 1104 (arguing that "everywhere we look we find that ideas, and the exponential growth they imply, are getting harder to find") .Many authors thus contend that – also due the increased complexity of the technical problems faced by researchers and the widespread availability of information, especially in the life sciences field – innovation nowadays tends to move *incrementally*, i.e., through small advancements over known subject-matter, whereas *breakthrough* inventions are a very rare exception, see: GHIDINI, *Rethinking Intellectual Property,* cit., 111. FRASSI, *Innovazione derivata, brevetto dipendente e licenza obbligatoria*, in *Riv. dir. ind.* 2006, 212. ERRICO, cit., 311.

expected *result* of said process) is circular. Technological innovation ([14]) often conveys new ways of thinking and doing things, which can in turn lead to improvements in how R&D is carried out, for instance thanks to more efficient or accurate research tools ([15]). A better microscope can show things that could not be seen before, just like the invention of the graphite pencil improved note-taking ([16]).

The rise of computer programming starting from the 1970s is a paradigmatic example of the interconnections between R&D and innovation. While computing technologies themselves constituted a ground-breaking innovation, they also opened the doors to new research methods and possibilities. Software became an indispensable research tool across all disciplines ([17]) ([18]).

Incidentally, software also posed unique and unprecedented challenges for patent law as a potential subject-matter of protection. The possibility of patenting software – generally understood as a "set of statements or

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([14]) Notably, Lemley and Burk distinguish "innovation" from "invention" (the subject-matter of patents: see § III.A below) as follows: "[w]e follow Joseph Schumpeter in distinguishing between the act of invention, which creates a new product or process, and the broader act of innovation, which includes the work necessary to revise, develop, and bring that new product or process to commercial fruition" (see LEMLEY, BURK, *Policy levers in patent law*, in *Virginia Law Review*, 2003, vol. 89, No. 7, 1615, fn. 128).

([15]) MAAMAR, cit., 32 and 212.

([16]) Pencils and microscopes are identified as two quintessential R&D "tools" by Ryan Abbott, in LOHN, *Can A.I. invent?*, cit.

([17]) SAMORE, *Artificial intelligence and the patent system: can a new tool render a once patentable idea obvious?*, in BARFIELD, PAGALLO (eds.), *Research Handbook on the Law of Artificial Intelligence*, Edward Elgar, Cheltenham, 2018, 478; MEITINGER, *Künstliche Intelligenz als Erfinder?*, in *Mitt. der deutschen Patentanwälte*, 2020, vol. 111, 49; VOLMER, *Die Computererfindung*, in *Mitt. der deutschen Patentanwälte*, 1971, vol. 62, 256. See also JOHNSON, *The World: In Silica Fertilization; All Science Is Computer Science*, in *New York Times*, 25 March 2001.

([18]) To be precise, information technology (IT) – a broader category than "software" that refers to the use of computers to create, store, process and exchange information – is considered a "general purpose technology", i.e., a technology having the scale of importance of electricity and steam in terms of pervasiveness in the economy and its capacity to spur innovation. See BRESNAHAN, TRAJTENBERG, *General purpose technologies 'Engines of growth'?*, in *Journal of econometrics*, 1995, 65(1), 83. See also JOVANOVIC, ROUSSEAU, *General purpose technologies*, in AGHION, DURLAUF, *Handbook of Economic Growth*, Elsevier, Amsterdam, 2005, 1181.

instructions to be used directly or indirectly in a computer in order to bring about a certain result" ([19]) – was initially thought to clash against the fundamental principle that patents shall not be granted on abstract ideas or mathematical methods ([20]). Nevertheless, while computer programs are generally excluded from patent protection if claimed "as such" ([21]), today it is accepted that they can be patented in certain circumstances, provided they have "technical character" ([22]).

Now, as hinted in the Introduction, artificial intelligence is the one of the most recent technologies to revolutionize how companies innovate and carry out R&D ([23]). Similarly to software, AI also poses unique challenges to patent law, both as a potential subject-matter of patent protection and as a powerful tool used by researchers to invent ([24]).

However, in order to properly discuss the role of AI in modern R&D and – consequently – the impact that AI might have on European patent law, it is first necessary to provide a short technical background about what AI is. I refer to the next section as a "glossary" since its goal is to provide a general picture of basic concepts underlying AI for the purpose of the legal

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([19]) 17 U.S.C. § 101.

([20]) AREZZO, *Tutela brevettuale e autoriale dei programmi per elaboratore: profili e critica di una dicotomia normativa*, Giuffrè, Milan, 2012, 31-32; GHIDINI, *I programmi per computers fra brevetto e diritto d'autore*, in *Giur. comm.* 1984, II , 270 (arguing that abstract mathematical principles shall not be confused with the computer programs that implement them to obtain a specific result); DE SANTIS, *La tutela giuridica del software tra brevetto e diritto d'autore*, Giuffrè, Milan, 2000, 7 (equating software to a mere mathematical model conveys a limited understanding); ZOBOLI, *Diritto dei brevetti e intelligenza artificiale*, Egea, Milan, 2023, 34-35. For a complete discussion on the history behind the exclusions of software from patent protection see also: GIOV. GUGLIELMETTI, *L'invenzione di software, Brevetto e diritto d'autore*, Giuffrè, Milan, 1997, 15 ff.

([21]) Cf. Articles 52(2) and (3) EPC.

([22]) See § III.A.1.1 below.

([23]) More broadly, like software and IT, several studies suggest that AI is potentially a general purpose technology as well. See CRAFTS, *Artificial intelligence as a general-purpose technology: an historical perspective*, in *Oxford Review of Economic Policy*, 2021, vol. 37(3), 521; HÖTTE ET AL., *Exploring Artificial Intelligence as a General Purpose Technology with Patent Data*, The Oxford Martin Working Paper Series on Technological and Economic Change, Working Paper No. 2022-5, 2022, https://arxiv.org/abs/2204.10304.

([24]) To some extent AI actually is "*just* software": see GHOSH, *AIn't it just software?*, in ABBOTT (ed.), *Research Handbook on Intellectual Property and Artificial Intelligence*, Edward Elgar, Cheltenham, 2022, 225. See also § I.B.6 below.

discussion, rather than a precise technical explanation. To do so, I mostly rely on works either published by (and for) legal scholars or at least understandable without a specific background in computer science.

B. A GLOSSARY OF AI

1. Issues in defining AI

The prospect of "intelligent" machines has stimulated the imagination of humankind for centuries ([25]), from the golden ancillae forged by Hephaestus with "intelligence in their hearts" ([26]) to Isaac Asimov's "positronic" robots ([27]). Yet AI remains an elusive concept.

The origins of the term "artificial intelligence" are undisputed. It was coined in 1955 by John McCarthy, who used it in the funding proposal for a workshop at Dartmouth College ([28]). In turn, the mathematical concepts

([25]) ABBOTT, *The Reasonable Robot, Artificial Intelligence and the Law*, Cambridge University Press, Cambridge, 2020, 19; ITALIANO, CIVITARESE MATTEUCCI, PERRUCCI, *L'intelligenza artificiale: dalla ricerca scientifica alle sue applicazioni. una introduzione di contesto*, in PAINO, DONATI, PERRUCCI (eds.), *Intelligenza artificiale e diritto: una rivoluzione?*, il Mulino, Bologna, 2022, vol. I, 44.

([26]) HOMER, *Iliad*, XVIII, 573-579: "Seguían l'orrido rege, e a dritta e a manca / Il passo ne reggean forme e figure / Di vaghe ancelle, tutte d'oro, e a vive / Giovinette simíli, entro il cui seno / Avea messo il gran fabbro e voce e vita / E vigor d'intelletto e delle care / Arti insegnate dai Celesti il senno", translation by Vincenzo Monti, 1825, available at: https://it.wikisource.org/wiki/Iliade_(Monti)/Libro_XVIII. Also cited in ABBOT, *The Reasonable Robot*, cit., 18.

([27]) ASIMOV, *I, Robot*, Gnome Press, New York, 1950. Positronic is a made up word coined by the author (https://en.wikipedia.org/wiki/Positronic_brain). In turn, Karel Čapek was the first to use the word "robot" to refer to intelligent beings made by artificially created limbs in his 1920 utopian play R.U.R. (Rossum's Universal Robots). The term is derived from the Czech word "*robota*" which means "work" (see BABLER, *"Robot": Origin of word*, in *Notes and Queries*, vol. 158, no. 13, 29 March 1930, 228, https://doi.org/10.1093/nq/158.13.228b).

([28]) MCCARTHY ET AL., *A Proposal For the Dartmouth Summer Research Project on Artificial Intelligence*, 31 August 1955, http://jmc.stanford.edu/articles/dartmouth/dartmouth.pdf. While the proposal was co-authored with Marvin Minsky, Nathaniel Rochester and Claude Shannon, McCarthy is generally credited for being the one who first used the term: STONE ET AL., *"Artificial Intelligence and Life in 2030." One Hundred Year Study on Artificial Intelligence: Report of the 2015-2016 Study Panel*, Stanford University, Stanford, 2016, underlying AI are based on the work made generations earlier by Charles Babbage, Ada Lovelace and, later on, Alan Turing ([29]). In particular, Turing was famously one of the first scholars to explore the idea of machine intelligence. In a seminal paper published in 1950, he argued that instead of asking *if machines are capable of thinking*, the right question to ask is whether a *machine can make a human being believe it can think* ([30]). If so, then one could consider it intelligent ([31]). This approach became known as the "Imitation Game" or "Turing Test".

Still, after almost 70 years since its first use, the one thing everyone seems to agree about the definition of AI is that they disagree. Simply put, there is no generally accepted definition of AI ([32]). It is submitted that AI is hard to define, as a concept, at least for three reasons, which are addressed here below, in turn.

1.1 Semantic complexities

First, there are semantic complexities. The definition of "artificial" is relatively straightforward. It means "made by human beings" rather than

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http://ai100.stanford.edu/2016-report; KAPLAN, *Intelligenza artificiale*, *Guida al futuro prossimo*, LUISS, Rome, 2017, 31 ff.

([29]) CALO, cit., 401.

([30]) TURING, *Computing Machinery and Intelligence*, in *Mind* 1950, 49(236), 433. Earlier on, TURING had introduced the concept of a universal computing machine in: TURING, *On computable numbers, with an application to the Entscheidungsproblem*, in *Proceedings of the London mathematical society*, 12 November 1936, https://www.cs.virginia.edu/~robins/Turing_Paper_1936.pdf.

([31]) MCCARTHY, *What is Artificial Intelligence?*, 2007, 4, http://www-formal.stanford.edu/jmc/whatisai.pdf.

([32]) HUGENHOLTZ ET AL., *Trends and Developments in Artificial Intelligence Challenges to the Intellectual Property Rights Framework*, Report for the European Commission, 2020, 21, https://op.europa.eu/en/publication-detail/-/publication/394345a1-2ecf-11eb-b27b-01aa75ed71a1/language-en. KÖNIG ET AL., *Essence of AI. What Is AI?*, in DIMATTEO, PONCIBÒ, CANNARSA (eds.), *The Cambridge Handbook of Artificial Intelligence: Global Perspectives on Law and Ethics*, Cambridge University Press, Cambridge, 2022, 23. See also the compilation of definitions of AI compiled by SAMOILI ET AL., *AI Watch. Defining Artificial Intelligence. Towards an operational definition and taxonomy of artificial intelligence*, JRC Technical Report, EUR 30117 EN, Publications Office of the European Union, Luxembourg, 2020.

occurring naturally ([33]). Conversely, "intelligence" is a much harder concept to grasp. For instance, according to Legg and Hutter intelligence measures "an agent's ability to achieve goals in a wide range of environments" ([34]). Likewise, McCarthy defines intelligence as "the computational part of the ability to achieve goals in the world" ([35]). The idea that achieving "the best outcome" is a fundamental aspect of intelligence is recurring also in the work of Russel and Norvig, the authors of the most popular textbook on AI ([36]). However, referring to "goals" to define "intelligence" (and thus AI) does not seem particularly useful. As put by Scherer, "it simply replaces one difficult-to-define term (intelligence) with another (goal)" ([37]).

While innumerable attempts have been made, intelligence remains inherently hard to qualify and quantify. Psychologists have challenged methods such as IQ tests and the idea that intelligence is a one-dimensional concept ([38]). More broadly, as a complex phenomenon, intelligence is the subject of research in a number of disciplines other than psychology, such as neuroscience, biology, engineering, statistics and linguistics ([39]).

And even if we were to agree on a definition of "intelligence", there are fundamental doubts as to whether it can be used at all in relation to machines.

([33]) *"artificial, adj. and n."*, Oxford English Dictionary Online, OUP, Oxford, March 2023; ABBOT, *The Reasonable Robot*, cit., 22 (the Author however stresses that the boundaries between natural and artificial might be thinning).

([34]) LEGG, HUTTER, *Universal Intelligence: A Definition of Machine Intelligence*, in *Minds and Machines*, 2007, vol. 17, 391–444; see also LEGG, HUTTER, *A Collection of Definitions of Intelligence,* in *Proceedings of the 2007 conference on Advances in Artificial General Intelligence: Concepts, Ar chitectures and Algorithms: Proceedings of the AGI Workshop 2006*, 2007, 17.

([35]) MCCARTHY, *What is Artificial Intelligence?*, cit., 2.

([36]) RUSSELL, NORVIG, *Artificial Intelligence: A Modern Approach*, III ed., Pearson, London, 2010, 4.

([37]) SCHERER, *Regulating artificial intelligence systems: risks, challenges, competencies, and strategies*, in *Harvard J. of Law & Technology*, 2016, vol. 29, 361 (discussing the definitions of "intelligence" by Legg and Hutter, Russell and Norvig, and McCarthy mentioned in fn. 34, 36 and 35).

([38]) In the eighties, Howard Garder famously theorized the existence of at least eight kinds (or dimensions) of intelligence: see e.g., GARDNER, *Frames of Mind; The Theory of Multiple Intelligences*, Basic Books, New York, 1983. See also STERNBERG, *Beyond IQ: A Triarchic Theory of Human Intelligence*, Cambridge University Press, Cambridge, 1985.

([39]) STONE ET AL., cit., 14.

For instance, questioning the soundness of the "Turing Test" – according to which the decisive factor is whether a machine makes a human being believe it can think – the American philosopher John Searle argued that thinking requires intentionality, which is a strictly biological phenomenon ([40]).

1.2 Evolving nature of the concept

Second, the meaning of AI has evolved with time ([41]). On the one hand, the term "AI" has been often used more to allude to the future potential of the technology, rather than its existing functionalities ([42]). On the other hand, at least until recently, AI suffered from an "odd paradox", also known as the "AI effect", according to which, once a new AI technology became mainstream, people got used it and it was no longer considered AI ([43]). A common catchphrase attributed to Larry Tesler – the inventor of the cut, copy and paste commands – to describe this phenomenon is that "AI is whatever hasn't been done yet" ([44]). Lately, it would seem that "AI" is more consistently used to refer, in particular, to generative techniques.

([40]) SEARLE, *Minds, brains, and programs*, in *Behavioral and Brain Sciences*, 1980, 3(3), 417. To be precise, Searle argued that the human brain is a machine and therefore humans can be understood as thinking machines. See also: SEARLE, *Is the Brain a Digital Computer?*, in *Proceedings and Addresses of the American Philosophical Association* 1990, 64, 21. However, Searle believed that formal computations on symbols – i.e., a computer program in the strict sense – cannot produce thought: COLE, *The Chinese Room Argument*, in ZALTA (ed.), *The Stanford Encyclopedia of Philosophy*, December 2020 https://plato.stanford.edu/archives/win2020/entries/chinese-room/. See also KIM, *On words that come easy*, in *GRUR Int.*, 2023, 72(5), 433; DORNIS, *Artificial Intelligence and Innovation: The End of Patent Law As We Know It*, in *Yale J. L. & Tech*., 2020, 23, 107.

([41]) KÖNIG ET AL., cit., 24 (suggesting that due to its ever evolving nature AI is a "moving target").

([42]) ELISH, BOYD, cit., 8.

([43]) STONE ET AL., cit., 12.

([44]) In his website, Tesler points out that his original quote was "intelligence is whatever machines haven't done yet": see TESLER, *CV: Adages & Coinages*, www.nomodes.com/Larry_Tesler_Consulting/Adages_and_Coinages.html. See also *McCarthy*, who echoed this sentiment in an interview, saying that "[a]s soon as it works, no one calls it AI anymore" (VARDI, *Artificial Intelligence: Past and Future*, in *Comm ACM*, 2012, 5).

1.3 Variety of viewpoints

Third, the term AI assumes various meanings depending on how abstractly or concretely one is looking at it. AI is used to simultaneously refer to general concept, a scientific field and tangible computer systems ([45]). AI can refer to both software or hardware, and can even be used to loosely refer to robotics ([46]).

2. Proposed definitions of AI

In light of the above, definitions of AI abound. In the Dartmouth Conference proposal, McCarthy described AI as the process of "making a machine behave in ways that would be called intelligent if a human were so behaving" ([47]). Along the same lines, according to a recent MPI study, AI often refers to "computer-based systems that are developed to mimic human behaviour" ([48]).

These definitions – and many other similar ones ([49]) – are all

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([45]) KÖNIG ET AL., cit., 18 ff.; HUGENHOLTZ ET AL., cit., 21-22.

([46]) See Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on Artificial Intelligence for Europe, Brussels, 25.4.2018 COM(2018) 237 final, which proposed the following definition: "AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications)".

([47]) MCCARTHY ET AL., cit., 11.

([48]) DREXL ET AL., *Technical Aspects of Artificial Intelligence: An Understanding from an Intellectual Property Law Perspective*, MPI Research Paper No. 19-23, 2019, https://ssrn.com/abstract=3465577.

([49]) SCHERER, cit., 361 (adopting a "blissfully circular" definition: "'artificial intelligence' refers to machines that are capable of performing tasks that, if performed by a human, would be said to require intelligence"); CALO, cit., 404 ("set of techniques aimed at approximating some aspect of human or animal cognition using machines"); ELISH, BOYD, cit., 6 ("[I]t does not matter if a system thinks like a human – as long as it appears to be as knowledgeable as a human); MINSKY, *Semantic information processing*, MIT Press, Cambridge, 1969, V (AI is "the science of making machines do things that would require intelligence if done by men"); WIPO, *Worldwide Symposium on the Intellectual Property Aspects of Artificial Intelligence*, 1991, 17 (AI are "systems that display certain capabilities associated with human intelligence, such as perception, understanding, learning reasoning and problem solving"); KAPLAN, cit., 15 (suggesting that many definitions of AI have been fundamentally aligned with the Turing Test: machines can be deemed intelligent if they *appear to be so* by humans. Adopting this approach to the definition of AI is both circular and, to some extent, inevitable. While human intelligence might be a vague concept ([50]) it is also the only true measure of "intelligence" we know of ([51]).

Still, referring to human intelligence as the benchmark for AI has self-evident limitations. While some domains of AI research do attempt to replicate aspects of human intelligence, such as language and learning, others do not ([52]). Many AI systems – for instance those used to control air traffic – vastly exceed, for scale and speed, the capabilities of humans ([53]). At the same time, even a cutting-edge model like ChatGPT can get simple math wrong ([54]) and has a tendency to "hallucinate", i.e., make up facts ([55]).

Simply put, to date human intelligence still has "no match in the biological and artificial worlds for sheer versatility" ([56]). Most scholars thus agree that only "narrow AI" (or "weak AI") has been obtained ([57]). Narrow

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proposed, but they are all more or less aligned on that it implies creating informatic programs or machines that are able of behaviours which we would consider intelligent if they were enacted by a human being).

([50]) HIGH-LEVEL EXPERT GROUP ON ARTIFICIAL INTELLIGENCE, *A Definition of AI: Main Capabilities and Disciplines*, 2019, 1, https://digital-strategy.ec.europa.eu/en/library/definition-artificial-intelligence-main-capabilities-and-scientific-disciplines.

([51]) MCCARTHY, *What is Artificial Intelligence?*, 2007, 4, http://www-formal.stanford.edu/jmc/whatisai.pdf. Cf.

([52]) ZERILLI, WELLER, *The Technology*, in HERVEY, LAVY (eds.), *The Law of Artificial Intelligence*, Sweet & Maxwell, London, 2020, 8.

([53]) ibid., 9.

([54]) ZUMBRUN, cit.;

([55]) ZIMMER, *'Hallucination': When Chatbots (and People) See What Isn't There*, in *The Wall Street Journal*, 20 April 2023, https://www.wsj.com/articles/hallucination-when-chatbots-and-people-see-what-isnt-there-91c6c88b?reflink=desktopwebshare_permalink; see also WEISE, METZ, *When A.I. Chatbots Hallucinate*, in *New York Times*, 1 May 2023, https://www.nytimes.com/2023/05/01/business/ai-chatbots-hallucination.html.

([56]) STONE ET AL., cit., 13. Yet the authors suggest that the difference between human and machine intelligence is "not one of kind, but of scale, speed, degree of autonomy, and generality" (ibid., 12). Thus, a calculator and the human brain both can be placed on an intelligence spectrum, at different points.

([57]) In particular, see SEARLE, *Is the Brain a Digital Computer?*, cit., 21 ff; HUGENHOLTZ ET AL., cit., 21; ASAY, cit., 1193 ff.

AI indicates AI systems that "perform individual tasks in well-defined domains" ([58]), such as playing games, image recognition, generating text and so forth. The possibility of developing an "artificial general intelligence" ("AGI" or "strong AI") that is on par with human intelligence and possibly beyond – an hypothesis sometimes referred to as "singularity" ([59]) – is considered either unrealistic or at least 50 years away ([60]).

Stepping away from the dead end on the meaning of "intelligence", the High-Level Expert Group on Artificial Intelligence ("HLEGAI") set up by the European Commission proposed a definition of AI that focuses on its functions ([61]):

([58]) USPTO, *Public Views on Artificial Intelligence and Intellectual Property Policy*, 2020, ii, www.uspto.gov/sites/default/files/documents/USPTO_AI-Report_2020-10-07.pdf.

([59]) KURZWEIL, *The Singularity Is Near: When Humans Transcend* Biology, Viking, New York, 2005. *Contra* WALSH, *The Singularity May Never Be Near*, in *AI Magazine*, Fall 2017, 58.

([60]) USPTO, *Public Views on Artificial Intelligence*, cit., ii. The mean date in a survey of 18 high-profile experts was 2099: FORD, *Architects of Intelligence: The truth about AI from the people building it*, Packt Publishing, Birmingham, 2018, 528; MÜLLER, BOSTROM, *Future Progress in Artificial Intelligence: A Survey of Expert Opinion*, in MÜLLER (ed.), *Fundamental Issues of Artificial Intelligence*, Springer, Berlin, 2016, 555 (estimating a 9/10 chance of AGI being developed by 2075). See also JORDAN, *Artificial Intelligence—The Revolution Hasn't Happened Yet*, in *Harv. Data Sci. Rev.*, 2019, 1(1), https://doi.org/10.1162/99608f92.f06c6e61. However, there is no consensus among researchers. For instance, according to GRACE ET AL., *Viewpoint: When Will AI Exceed Human Performance? Evidence from AI Experts*, in *J. Art. Intell.*, 2018, 62, 729, "there is a 50% chance of AI outperforming humans in all tasks in 45 years and of automating all human jobs in 120 years". *Contra* BOSTROM, *Superintelligence: Paths, Dangers,* Strategies, Oxford University Press, Oxford, 2014.

([61]) HLEGAI, cit., 6. Along the same lines, see OECD, *Recommendation of the Council on OECD Artificial Intelligence*, OECD/LEGAL/0449, 2022, 7: "An AI system is a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems are designed to operate with varying levels of autonomy". Recently, the OECD proposed an updated definition (OECD, *OECD AI Principles overview*, https://oecd.ai/en/ai-principles), removing the need for "human-defined objectives": "An AI system is a machine-based system that is capable of influencing the environment by producing an output (predictions, recommendations or decisions) for a given set of objectives. It uses machine and/or human-based data and inputs to (*i*) perceive real and/or virtual environments; (*ii*) abstract these perceptions into models through analysis in an automated manner (e.g., with machine

> "[AI] systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal".

While the HLEGAI definition has been adopted in several EU studies as a useful starting point ([62]), its reliance on concepts such as "perceiving" and "reasoning" in relation to machines seems equally tainted by anthropomorphism. The route from "reason" to "intelligence" is a short one.

3. AI as an umbrella term

How to get out of the AI-definition's conundrum? Bearing in mind that AI is inevitably and intuitively connected to the development of systems that approximate some aspects of human cognition using machines, I refrain from providing a formal definition of AI as a concept ([63]). Accepting that the concept of AI has vague boundaries might even be one of its assets. Indeed, as suggested by Stanford's One Hundred Year Study on Artificial Intelligence ([64]):

> "[i]ronically, the lack of a precise, universally accepted definition of AI probably has helped the field to grow, blossom, and advance at an ever-accelerating pace. Practitioners, researchers, and developers of AI are […] guided by a rough sense of direction and an imperative to 'get on with it.'"

Instead, I suggest to adopt only an *operational* definition of AI: that is, a definition that focuses on what AI researchers do ([65]). For the purposes of this work, AI can be understood as an umbrella term that identifies a branch of computer science ([66]) comprising, *inter alia*, various techniques such as

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learning), or manually; and (*iii*) use model inference to formulate options for outcomes. AI systems are designed to operate with varying levels of autonomy".

([62]) HUGENHOLTZ ET AL., cit., 22-23; SAMOILI ET AL., cit., 8 (the authors used HLEGAI definition as a starting point to build their taxonomy on AI activities and fields).

([63]) KAPLAN, cit., 36 (suggesting that if McCarthy had picked a more "prosaic" name than "artificial intelligence" the progress in this field would have appeared for what it is: the relentless advancement of automation).

([64]) STONE ET AL., cit., 12.

([65]) ibid., 13.

([66]) CALO, cit., 405. DREXL ET AL., *Technical Aspects*, cit., 3. ZERILLI, WELLER, cit., 8, § 2-002.

machine learning, evolutionary algorithms and expert systems, whose relation to human intelligence is, at most, figurative ([67]). To refer to a specific embodiment of AI, I mostly use the expression "AI system" ([68]).

4. Different types of AI

Following from the operational definition of AI adopted, it is necessary to discuss some of the existing AI techniques, focusing on those that have shown the most promising results in R&D applications, namely: (*i*) machine learning (§ I.B.4.1); (*ii*) evolutionary algorithms (§ I.B.4.2); and (*iii*) expert systems (§ I.B.4.3).

4.1 Machine learning

Currently, machine learning ("ML") is the most popular subfield of AI ([69]). In short, ML is a form of data processing that identifies statistical patterns from large amounts of data ([70]) and then uses the identified patterns for certain tasks, such as making predictions or taking decisions ([71]). The fundamental feature of ML is that instead of being programmed to give a specific output ([72]) – following workflow-style "if-then" commands ([73]) – these systems "learn" the route to a result based on the examples submitted to them by humans, as part of a process known as "training" ([74]).

([67]) KAPLAN, cit., 36 (arguing that AI is an engineering discipline with "metaphorical" or "inspirational" relations towards biological organism).

([68]) SCHERER, cit., 361.

([69]) DREXL ET AL., *Technical Aspects*, cit., 3. The term "machine learning" was popularized by Arthur Samuel, a computer scientist at IBM, in a 1959 paper: SAMUEL, *Some Studies in Machine Learning Using the Game of Checkers*, in *IBM Journal of Research and Development*, 1959, 44(1.2), 210.

([70]) ZERILLI, WELLER, cit., 9, § 2-003; DREXL ET AL., *Technical* Aspects, cit., 12.

([71]) MAN CHO-SO, *Technical Elements of Machine Learning for Intellectual Property Law*, in LEE, HILTY, LIU (eds.), *Artificial Intelligence and Intellectual Property*, Oxford University Press, Oxford, 2021, 11.

([72]) KIM ET AL., *Clarifying assumptions*, cit., 299.

([73]) KIM, *'AI-Generated Inventions': Time to Get the Record Straight?*, in *GRUR Int.*, 69(5), 2020, 451.

([74]) ZERILLI, WELLER, cit., 9, § 2-003. YANG ET AL., *Concepts of Artificial Intelligence for Computer-Assisted Drug Discovery*, in *Chem. Rev.*, 2019, 119, 10523.

While the idea of ML is practically as old as AI ([75]), the power of these techniques was recently unleashed thanks to the availability of huge amounts of digital data ([76]) and the increase in computing power in terms of speed and memory ([77]). Once again, however, the word "learning" must not be understood in its traditional, human-centric meaning, but rather as an euphemism ([78]) to suggest that ML systems improve their performance at specific tasks over time ([79]).

4.1.1 *The components of machine learning*

There are five fundamental components to a ML system: (*i*) the training data; (*ii*) the training algorithm; (*iii*) the trained model; (*iv*) the input data; and (*v*) the output.

In short, any ML system is based on the analysis of data through different algorithms, i.e., step-by-step instructions, which are encoded as software and directed at a computer ([80]). To some extent, "algorithm" and

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([75]) ZERILLI, WELLER, cit., 9, § 2-003.

([76]) YANG ET AL., cit., 10523; P. SLOWINSKI*, Artificial Intelligence, Novelty and Inventive Step: What Is the Impact of AI on Patent Law?*, in SIKORSKI, ZEMŁA-PACUD (eds.), *Patents as an Incentive for Innovation*, Wolters Kluwer, Alphen aan den Rijn, 2021, 255.

([77]) Over the last twenty-five years, the ratio of computing power to cost has grown by a factor of ten every four years: VERTINSKY, *Thinking machines and patent law*, in BARFIELD, PAGALLO (eds.), *Research Handbook on the Law of Artificial Intelligence*, Edward Elgar, Cheltenham, 2018, 493. In the mid-1960s, the late Gordon Moore, the co-founder of Intel, predicted that the number of transistors per silicon chip would double every year (see MOORE, *Cramming more components onto integrated circuits*, in *Electronics*, 19 April 1965, 114, reprinted in *Proceedings of the IEEE*, vol. 86, no. 1, January 1998, https://www.cs.utexas.edu/~fussell/courses/cs352h/papers/moore.pdf). A decade later, the prediction was revised for every two years. This prediction, which came to be known as the Moore's Law, proved to be accurate – or, rather, self-fulfilling – for more than 50 years. CLARKE, *Gordon Moore (1929–2023)*, in *Nature Electronics*, 2023, 6. According to some, Moore's Law is bound to reach its end: ROTMAN, *We're not prepared for the end of Moore's Law*, in *MIT Technology Review*, 24 February 2020, https://www.technologyreview.com/2020/02/24/905789/were-not-prepared-for-the-end-of-moores-law/.

([78]) BURK, cit., 303.

([79]) KIM ET AL., *Clarifying assumptions*, cit., 302. CALO, cit., 405.

([80]) See DREXL ET AL., *Technical Aspects*, cit., 12; GENLAW, *Glossary*, https://genlaw.github.io/glossary.html.

“model” are interchangeable terms ([81]). However, “model” is most commonly used to refer to the data structure that is the *result* of the training process ([82]). I therefore use “algorithm” to refer more specifically to the *method* used to train the model ([83]). In turn, the “training data” is the *fuel* that allows the training algorithm to build up the model. Better training data – in terms of volume and quality – allows better performing ML models ([84]). Running the same training algorithm on different training data, and vice-versa, will result in different ML models ([85]). Once the model is trained, it can be run on new data, i.e., the "input data" to generate the "output".

To better put the ML "components" into context, the following paragraphs briefly delve into the three main different types of ML, as they are traditionally identified: supervised, unsupervised and reinforcement learning. However one should bear in mind that precise boundaries can be blurry ([86]).

(a) Supervised learning

Supervised learning is easiest type of machine learning to grasp. In supervised learning, the training data is “labelled”, meaning that the correct output value is already known for each piece of data. For example, the training algorithm might be given a dataset of images of cats and dogs, where each image is labelled as either “cat” or “dog”. The training algorithm then iteratively looks for patterns in the images, evaluates whether its predictions are correct or not and, as a result, “learns” the rules for distinguishing pictures of cats and dogs,

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([81]) LEHR, OHM, *Playing with the Data: What Legal Scholars Should Learn About Machine Learning*, in *U.C. Davis L. Rev.*, 2017, vol. 51, 671. See e.g., FJELD, KORTZ, *A Legal Anatomy of AI-generated Art: Part I*, in *Jolt Digest*, 21 November 2017, https://jolt.law.harvard.edu/digest/a-legal-anatomy-of-ai-generated-art-part-i (using “algorithm” to refer to both the training method and the model).

([82]) See e.g., FJELD, KORTZ, cit.; GENLAW, *Glossary*, cit.

([83]) DREXL ET AL., *Technical Aspects*, cit., 7.

([84]) LEHR, OHM, cit., 677. See also ELISH, BOYD, cit., 10 (pointing out that the quality of datasets vary tremendously and limitations in the data often mean that cultural biases and unsound logics get reinforced and scaled by AI systems).

([85]) FJELD, KORTZ, cit., § II.C.

([86]) ZERILLI, WELLER, cit., 15, § 2-0012; RUSSELL, NORVIG, cit., 695.

forming the model ([87]). The trained model can then be used to "recognize" cats from dogs (more precisely: predict an image's label based on statistical rules) in new, unseen images (*input*). This is known as a classification model. The classification (i.e., the value "cat" or "dog") is the *output* produced by the model.

Another simple example of a supervised ML model is a linear regression, which is used to predict a continuous value, such as a price or a quantity (as opposed to a binary choice like "cat" or "dog"). For instance, a linear regression model can be used to predict the price of a house based on its size. The starting point is having a real estate dataset, with houses and prizes, which can be plotted in a graph. Training the model implies finding the best-fitting line that describes the relationship between the size of a house and its price ([88]).

([87]) LEHR, OHM, cit., 671. During the training process, the algorithm will try multiple rules and will ultimately choose the one that results in the minimization of the objective function.

([88]) ZERILLI, WELLER, cit., 18, § 2-0020. See also TAULLI, cit., 58-59. Putting that in numbers should provide a clearer example.

- A simple linear regression model used to predict house prices can be expressed as a mathematical equation of the form "y = mx + b", where "y" represents the price (i.e., the output), "x" represents size of the house (i.e., the input), "m" represents the slope of the line (coefficient) and "b" represents the y-intercept. The unknown parameters defining the relationship between the price and size (i.e., the line) are "m" and "b".
- To find the best-fit line – the one which minimizes the errors between the plotted data and the prediction line – the values for the "m" and "b" parameters might be assigned randomly or to some initial guess. Let's assume that the first values assigned are a slope of 5 (m = 0.5) and y-intercept of 2 (b = 2).
- Using this first random values the model predicts the price of a house of a certain size. Then, the difference between the predicted values and the actual target values – i.e., the error or loss – is calculated.
- Using a mathematical method known as gradient descent, we then decide how to adjust the parameters "m" and "b" and attempt to reduce the error (perhaps assigning a slope "m" of 0.4, and a y-intercept "b" of 1).
- The new parameters are adjusted and the process is repeated until the loss is minimized (e.g., after a certain number of iterations or a certain level of error deemed acceptable).
- The resulting equation of the best-fitting might look something like this: "y = 0.1x + 4". This equation represents the trained ML model, which encodes the relationship between the size of a house and its price as derived from the training data.

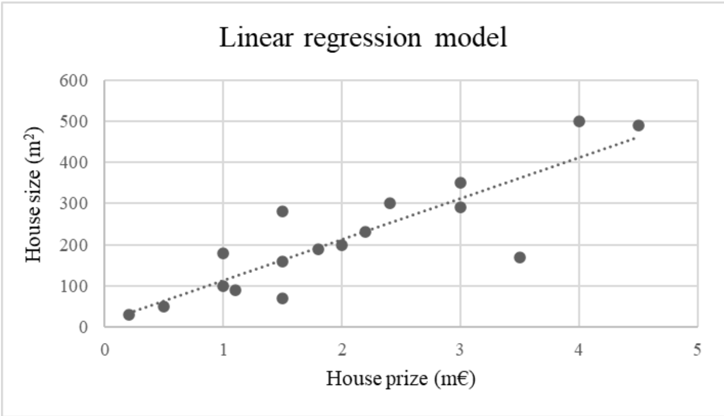

Fig. 4 – Simple linear regression

In this example, a mathematical method (*training algorithm*) is used to learn the relationship between the house size and house price (*training data*). The equation of the best-fitting line (*trained model*) can then be used make price predictions (*output*) when submitted new data on house sizes (*input data*) ([89]).

(b) Unsupervised learning

Unsupervised learning, instead, works with unlabelled data. These models do not predict a labelled outcome variable (e.g., "cat" or "dog"), but are used for grouping or clustering data based on identified similarities or differences ([90]). If given unlabelled pictures of cats and dogs, the unsupervised learning algorithm might, for instance, divide them in two generic clusters ("type-1" and "type-2"). This kind of ML is somewhat less popular, since its results generally require more interpretation ([91]) and have less obvious applications ([92]). Semi-supervised learning is a combination of supervised

– The ML model can then be used to make predictions on new data. For instance, to predict the price of a 80 m^2 house, we can simply plug the size into the equation: y (price) = (0.1 x 80) + 4 = 12. The predicted price of the house would thus be 12 (e.g., 120.000 Euro).

([89]) Of course, this linear regression implied relatively simple math and one could come to the same results without a ML technique. But this example conveys the fundamental idea of pattern identification through training in simple mathematical terms.

([90]) ZERILLI, WELLER, cit., 24, § 2-0030-2-0031.

([91]) DREXL ET AL., *Technical Aspects*, cit., 8.

([92]) HAO, *What is machine learning?*, in *MIT Tech. Rev.*, 17 November 2018, www.technologyreview.com/2018/11/17/103781/what-is-machine-learning-we-drew-you-another-flowchart/.

and unsupervised learning, wherein the algorithm is given both labelled and unlabelled data ([93]).

(c) Reinforcement learning

Finally, *reinforcement* learning is, in essence, a trial-and-error method ([94]). Here the algorithm does not analyse pre-existing datasets, but interacts with the environment, receiving continuous feedback on its performance ([95]). Supervised learning is commonly used, for instance, for board games, where the system is not programmed with strategies, but is only given the rules of the game and the goal to maximize its score, and gets skilled by continuously playing matches against itself ([96]). The feedback is at times also provided by humans, through reward signals that tell whether the model performed well or not. The training algorithm will then attempt to maximise the positive reward ([97]). For instance, ChatGPT was in part trained using reinforcement learning from human feedback ([98]).

4.1.2 *The intense human labour behind a ML model*

Against this backdrop, it is important to note that, to this day, setting up a ML model – be it a supervised, unsupervised or reinforcement type of ML – is in

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([93]) TAULLI, cit., 54; RUSSELL, NORVIG, cit., 695.

([94]) ibid., 53.

([95]) MAN-CHO SO, cit., 23-24;

([96]) For instance, Google's algorithm AlphaGo used reinforced learning: SILVER, HASSABIS, *AlphaGo: Mastering the ancient game of Go with Machine Learning*, in *Google AI Blog*, 27 January 2016, https://ai.googleblog.com/2016/01/alphago-mastering-ancient-game-of-go.html.

([97]) HLGAI, cit, 4.

([98]) OPENAI, *Introducing ChatGPT*, cit. ("[w]e trained an initial model using supervised fine-tuning: human AI trainers provided conversations in which they played both sides—the user and an AI assistant. We gave the trainers access to model-written suggestions to help them compose their responses. To create a reward model for reinforcement learning, we needed to collect comparison data, which consisted of two or more model responses ranked by quality. To collect this data, we took conversations that AI trainers had with the chatbot. We randomly selected a model-written message, sampled several alternative completions, and had AI trainers rank them. Using these reward models, we can fine-tune the model […]. We performed several iterations of this process").

most cases the result of intense human labour ([99]). For instance, in no particular order of relevance:

– the *selection of training and/or input data* is generally the result of extensive decisions form dataset creators and curators ([100]); in particular, labelling data for supervised learning is typically done by humans ([101]).
– the *choice of the training algorithm* to use for each ML model is made *ex ante* by researchers based on "an educated guess" ([102]) – i.e., what the MPI more eloquently calls an "heuristic method" ([103]) – which often involves a process of trial-and-error;
– the *definition of the problem* addressed to the ML system requires human researchers to translate an abstract goal into something that can be processed and solved by a computer, such as a mathematical function (often known as "cost" or "loss" function) ([104]); and
– humans also need to pick a number of features of the model, the so-

([99]) LEHR, OHM, cit., 771; WIPO, *Background Document on Patents and Emerging Technologies*, SCP/30/5, 2019, 10, www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_5.pdf. As summarized by Lehr and Ohm, setting up a ML system entails a series of steps, which include: (*i*) defining the problem to be solved; (*ii*) collecting training data; (*iii*) processing the training data (e.g., by cleaning, removing outliers, reducing dimensions); (*iv*) partitioning the available data between training and test data; (*v*) designing, selecting and/or optimizing the model; (*vi*) training the model based on the training data; and (*viii*) testing the performance of the model based on the test data. The progression between the various steps is not rigid, and there is usually a lot of back-and-forth (see LEHR, OHM, cit., 669 ff.). See also HURWITZ, KIRSCH, *Machine Learning For Dummies, IBM Limited Edition*, Wiley, Hoboken, 2018, 37.

([100]) See e.g., LEE, COOPER, GRIMMELMANN, IPPOLITO, *AI and Law: The Next Generation*, July 2023, Chapter 1, https://genlaw.github.io/explainers/ ("[t]he process of training contemporary generative models requires vast quantities of *training data*. Dataset creators and curators make extensive decisions about how much and which data to include in a training dataset. These choices directly and significantly shape a model's outputs (a.k.a. *generations*), including the model's capacity to learn concepts and produce novel content").

([101]) MAN-CHO SO, cit., 13; ZERILLI, WELLER, cit., 15, § 2-0013.

([102]) TAULLI, cit., 49.

([103]) DREXL ET AL., *Technical Aspects*, cit., 6.

([104]) LEHR, OHM, cit., 672-677; KIM ET AL., *Clarifying assumptions*, cit., 298-299. The "cost" or "loss" function is a "mathematical function which evaluates the magnitude of error of a specific model": DREXL ET AL., *Technical Aspects*, cit., 7.

called *hyperparameters* ([105]), including its *architecture* (i.e., the structure of the model) ([106]), the number of iterations (i.e., single passes through the training data) that are necessary for the training ([107]), the speed at which the algorithm learns (*learning rate*) ([108]) and when the training should stop (*stopping criterium*) ([109]).

It follows that, despite the sensationalistic language that is often used by the media, there is nothing "esoteric" about ML models as such: these systems are advanced computational tools that are designed, and insofar regulated, by humans ([110]).

4.1.3 *Artificial neural networks*

Another important concept in the field of ML is that of artificial neural networks ("ANNs"), which are a popular architecture for ML models. ANNs can be trained with supervised, unsupervised or reinforcement learning methods ([111]). The name ANNs derives from the structure of these models, which is loosely inspired by the functioning of the human brain ([112]). In

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([105]) DREXL ET AL., *Technical Aspects*, cit., 6.

([106]) ibid., 4 ff.; MAN-CHO SO, cit., 15; See also SUMMERFIELD, *The Impact of Machine Learning on Patent Law, Part 3: Who is the Inventor of a Machine-Assisted Invention?*, in *Patentology*, 4 February 2018, https://blog.patentology.com.au/2018/02/the-impact-of-machine-learning-on.html ("[a] great deal of research within the field of [ML] is directed to devising and improving the architecture and operation of the calculation units, and to the algorithms used to optimise the parameters during the training process").

([107]) The appropriate number of iterations that are needed for the algorithm to "converge" (i.e., reaching a point where the parameters are not changing significantly) depends on the complexity of the data and the training algorithm. For simple problems, a few iterations may be enough. For more complex problems, it may take hundreds or even thousands of iterations.

([108]) GOOGLE, *Reducing Loss. Learning Rate*, n.d., https://developers.google.com/machine-learning/crash-course/reducing-loss/learning-rate.

([109]) MAN-CHO SO, cit., 12.

([110]) KIM, *AI-Generated Inventions*, cit., 450.

([111]) FABIYI, *A review of unsupervised artificial neural networks with applications*, in *International Journal of Computer Applications*, 2019, 181(40), 22.

([112]) The first mathematical model of a neural network was suggested in the 1940s: MCCULLOUGH, PITTS, *A logical calculus of the ideas immanent in nervous activity*, in *Bullettin of Mathematical Biophysics*, 1943, vol. 5, 115, (link). The concept of neural particular, ANNs are composed of artificial "neurons" (or "nodes") organized in layers ([113]). A simplified representation of an ANN follows (Fig. 5).

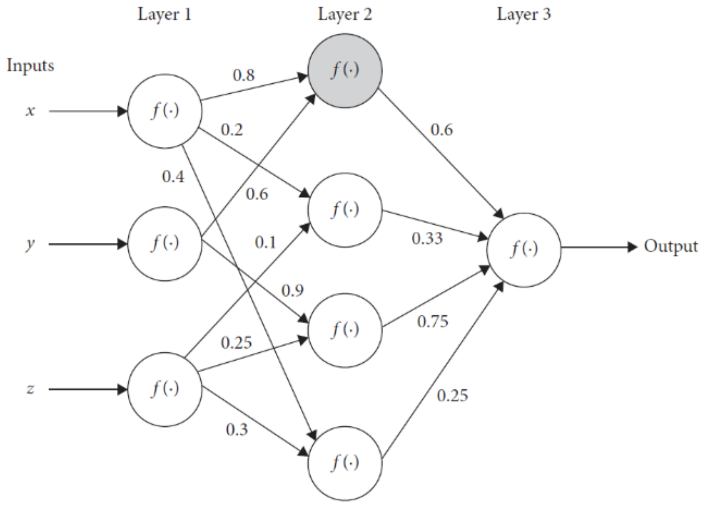

Fig. 5 – ANN Architecture (Source: MAN-CHO SO)

In this example, the ANN includes three layers. "Layer 1", the input layer, has three neurons. "Layer 2" has four neurons. And "Layer 3", the output layer, only has one neuron. The layers in between the input layer and the output layer are usually referred to as "hidden" layers. Layer 2 is therefore a hidden layer. The ANN architecture – including the number and structure of the layers – and its goal are established by programmers prior to the training process ([114]).

The numbers on the arrows that connect the neurons are known as "weights". Weighs determine the strength of the connection between two neurons (where "0" generally means "non connected", and "1" means "firmly connected") ([115]). In other words, weights are a measure of how important each connection is in determining the overall output. The weighs are usually

networks was then developed by Frank Rosenblatt at Cornell University in the 1950s, using a single neuron layer (so-called "Perceptron"): ROSENBLATT, *The perceptron: a probabilistic model for information storage and organization in the brain*, in *Psychological Review* 1958, 65(6), 386. See also PARLOFF, *From 2016: Why Deep Learning is Suddenly Changing Your Life*, in *Fortune*, 28 September 2016, https://fortune.com/longform/ai-artificial-intelligence-deep-machine-learning/; RUSSELL, NORVIG, cit., 20 and 761.

([113]) MAN-CHO SO, cit., 15-16.

([114]) DREXL ET AL., *Technical Aspects*, cit., 5.

([115]) KAPLAN, cit., 53.

assigned a random value at first and are fine-tuned during the training process ([116]). In turn, each neuron represents a mathematical function that transforms numeric inputs in outputs taking into account the weighs.

While a detailed description of the math underlying ANNs is beyond the scope of this work, it is important to emphasise that there is nothing particularly "magical" about ANNs. They can simply be understood as "long sequences of summations and multiplications" ([117])

4.1.4 *Deep learning*

When there are several layers of neurons, including multiple "hidden" middle layers, the ANN is usually referred to as a "deep neural network" ("DNN") ([118]). The trained model resulting from a DNN algorithm is known as a "deep learning" ("DL") model ([119]). Deep learning is thus a subfield of machine learning.

Among other things, DNNs are considered the best-in-class architectures for image recognition. For instance, going back to the "cat" and "dog" classification example, by building a DNN algorithm that comprises thousands of input nodes, programmers are able to train the model to find correlations pixel-by-pixel. In a DNN (Fig. 6), the first layers generally captures low level patterns (e.g., lines, colours) and upper layers identify higher-level structures (e.g., the different ears or paw shapes of cats and dogs). The last layer then provides the ultimate classification ([120]).

([116]) DREXL ET AL., *Technical Aspects*, cit., 6; KIM ET AL., *Clarifying assumptions*, cit., 299, fn. 62. Generally, weighs are at first allocated randomly and then optimised.

([117]) MUELLER, MASSARON, *Artificial Intelligence for Dummies*, Wiley, Hoboken, 2018, 123, as cited in KIM, *AI-generated inventions*, cit., 451, fn. 128. See also WIPO, *Background Document*, cit., 9 ("mathematically, artificial neural network models can be understood as just a set of matrix operations and finding derivatives").

([118]) IBM, *AI vs. Machine Learning vs. Deep Learning vs. Neural Networks: What's the Difference?*, 27 May 2020, www.ibm.com/cloud/blog/ai-vs-machine-learning-vs-deep-learning-vs-neural-networks (suggesting that deep learning requires more than three levels).

([119]) DREXL ET AL., *Technical Aspects*, cit., 6.

([120]) See e.g., WIPO, *Background Document*, cit., 8. To visually appreciate how a image classification DNN works see also: ZEILER, FERGUS, *Visualizing and Understanding*

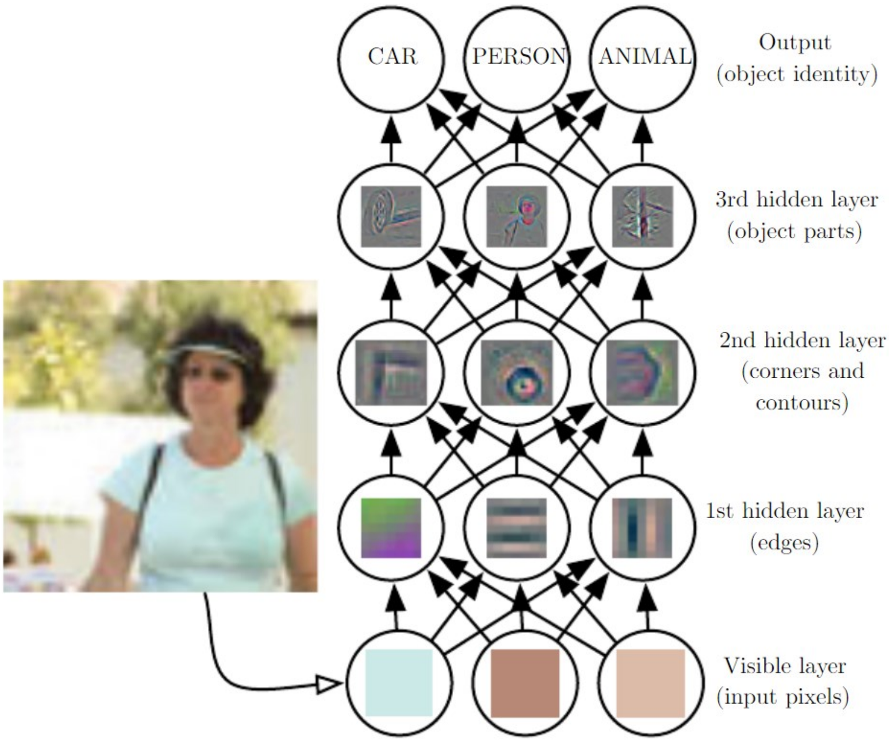

Fig. 6 – Deep Neural Network (Source: GOODFELLOW, BENGIO)

ML and DL differ in how they learn and how much data they need. In particular, non-deep ML depends on human intervention more than DL, requiring more structured data and a pre-determined hierarchy of the features to understand the differences between the inputs ([121]). Instead, DL systems generally require quantitatively more data and computing power to improve their accuracy ([122]), but are better at learning complex patterns ([123]) especially with unstructured and/or imprecise data ([124]). To train a standard ML model for image recognition, programmers would need to first (manually) choose the features they wish to train the model on (e.g., the shape, colours, dimensions that are typical of cats and dogs), a complicated process called

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Convolutional Networks, in FLEET ET AL. (eds.), *Computer Vision – ECCV 2014*, Part I, Springer, Cham, 2014, 818.

([121]) IBM, cit..

([122]) *ibid*.

([123]) HOVY, *Text Analysis in Python for Social Scientists: Discovery and Exploration*, CUP, Cambridge, 2021, 156. See also YANG ET AL., cit., 10532 (pointing out that DL is also reaches better results through unsupervised learning).

([124]) HURWITZ, KIRSCH, cit., 17-18.

feature extraction, or feature engineering ([125]). None of that is required to develop a DL model for image recognition. As mentioned above, a DNN can be trained to build up the image classification directly from the raw pixels ([126]).

4.1.5 *Generative adversarial networks*

Generative Adversarial Networks ("GANs") are a particular type of DNNs. They were first devised in 2014 by Ian Goodfellow, who at the time was a Ph.D. student at the Université de Montréal ([127]).

GANs include two interactive DNNs. The first network, known as "generator", is trained to generate outputs which mimic as closely as possible those in a real dataset. The second network, known as the "discriminator", is trained to detect whether a piece of data is part of a real dataset or was generated by an algorithm ([128]). The adversary principle allows the two networks to train each other. One the one hand, the "discriminator" progressively refines its search for clues to computer-generated data. On the other, the "generator" gets better and better at producing outputs that are indistinguishable from the training dataset ([129]).

The adversarial training allows GANs to imitate, to a great degree, the examples they have been trained on. Several GANs trained on pictures of artworks have been used to generate new art in the style of the trained dataset. The best known example is perhaps the painting titled "Edmond de Belamy, from La Famille de Belamy", which in 2018 was sold at a Christies' auction for more than £ 400,000 ([130]).

([125]) TAULLI, cit., 71.

([126]) ibid.; WIPO, *Background Document*, cit., 8; See also GOODFELLOW, BENGIO, COURVILLE, *Deep Learning*, MIT Press, Boston, 2016, 4-7.

([127]) GILES, *The GANfather: The man who's given machines the gift of imagination*, in *MIT Technology Review*, 21 February 2018, https://www.technologyreview.com/2018/02/21/145289/the-ganfather-the-man-whos-given-machines-the-gift-of-imagination/.

([128]) DREXL ET AL., *Technical Aspects*, cit., 8.

([129]) MAAMAR, cit., 74-75.

([130]) CHRISTIE'S, *Edmond de Belamy, from La Famille de Belamy*, 25 October 2018,

4.2 Evolutionary algorithms

Evolutionary algorithms ("EAs") are another AI technique ([131]) that has been often used in R&D ([132]). They are sometimes also referred as genetic algorithms ([133]).

EAs simulate the processes of natural evolution and the Darwinian theory of survival of the fittest ([134]). EAs work by generating a random "population" of potential solutions to a problem, and then evaluating the fitness of each "individual" against predefined parameters (the so-called "fitness function"). The fittest individuals are then selected and used to create a new population through mutations and cross-overs, until the best-scoring ("fittest") solution is found ([135]). The initial specifications for the parameters and the target properties are set by the EA programmer. However, the processes of problem-solving and creation will occur without human interaction ([136]).

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https://www.christies.com/en/lot/lot-6166184. The painting was made by the Obvious Art collective and was described as a "Generative Adversarial Network print" and was signed with the network's loss function: min G max D Ex[log(D(x))] + Ez[log(1-D(G(z)))]. The name "Belamy" is a pun of the French expression "bel ami", meaning "good fellow", as an homage to the creator of GANs. The case gave rise to a potential copyright case quite immediately, as the author of the open source GAN, a high school student named Robbie Barrat, complained that the collective had basically made 400k out of his work: see VINCENT, *How three French students used borrowed code to put the first AI portrait in Christie's*, in *The Verge*, 23 October 2018, https://www.theverge.com/2018/10/23/18013190/ai-art-portrait-auction-christies-belamy-obvious-robbie-barrat-gans.

([131]) DREXL ET AL., *Technical Aspects*, cit., 11. However see KIM ET AL., *Clarifying assumptions*, cit., 297 (grouping EAs and ML together since (*i*) there is no universally accepted classification of AI methods, and (*ii*) EAs can be applied to similar problems). See also DOMINGOS, cit., xvii, who qualifies EAs as a branch of ML as well.

([132]) P. SLOWINSKI, cit., 256. Within this field, the work of John Koza is often recalled (see § I.C.2.2 below). See e.g., LAMEIJER, *Interactive evolutionary algorithms and data mining for drug design*, 28 January 2010, https://hdl.handle.net/1887/14620.

([133]) P. SLOWINSKI, cit., 256. See also RUSSELL, NORVIG cit., 126 (referring to EAs only as genetic algorithms).

([134]) To be precise: EAs are "stochastic search" algorithms – where stochastic loosely means randomized.

([135]) DREXL ET AL., *Technical Aspects*, cit., 11; P. SLOWINSKI, cit., 256; KIM, *AI-generated inventions*, cit., 451. See also DROSTE ET AL., *Theory of Evolutionary Algorithms and Genetic Programming*, in SCHWEFEL, WEGENER, WEINERT (eds.), *Advances in Computational Intelligence*, Springer, Berlin, 2003, 107.

([136]) DORNIS, *Artificial Intelligence and Innovation*, cit., 108.

EAs do not function on the same principles of ML since they do not require training data ([137]). Therefore, EAs can be used instead of ML techniques, which are highly dependent on the quality of the data submitted and cannot go beyond the learned patterns ([138]).

4.3 Expert systems

Expert systems ("ES") are yet another AI technique, which was especially popular around the 1980s ([139]). Expert systems rely on domain-specific knowledge that is materially gathered by programmers, for instance through interviews with experts in the field, and then encoded ([140]). The idea behind ES is to store the expertise from a specific domain so that the human experts can avoid repetitive tasks or be supported in making decisions ([141]).

There are two components of an ES:

(i) The "knowledge base", i.e., a collection of facts, rules and other information in the domain of the expert system. The information in the knowledge base is often expressed as "if X, then Y" rules through symbols ([142]). ES are thus a technique that falls under the definition of "symbolic AI" ([143]); and

(ii) The "inference engine", which enables the expert system to draw deductions from the facts and rules included in the knowledge base ([144]).

Expert systems might therefore be useful in fields where there is a lot of complex information to process, such as medicine. For example, in a medical expert system, the knowledge base might include information about diseases,

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([137]) DREXL ET AL., *MPI Comments on the WIPO Draft Issues Paper*, cit., 2.

([138]) P. SLOWINSKI, cit., 256.

([139]) KAPLAN, cit., 43-47.

([140]) ibid., 44.

([141]) ZERILLI, WELLER, cit., 9-11.

([142]) ibid. (adding that expert systems are also known as "rule-based" system); See also ZWASS, *Expert system*, in *Enc. Britannica*, 2016, www.britannica.com/technology/expert-system.

([143]) HUGENHOLTZ ET AL., cit., 25 (adding that symbolic AI is often also referred to also "good old-fashioned AI").

([144]) ZWASS, cit.

symptoms and treatments and the inference engine might be used to put together the information about the patient's symptoms and medical history and generate a list of possible diagnoses and treatment options

The disadvantages of ES as opposed to ML are self-evident. Expert systems require a lot of hard-wired programming, are limited to narrow domains and, most of all, are completely dependent on the facts and rules that have been provided to them ([145]). Expert systems do not learn, meaning that they cannot identify new information (e.g., a pattern within data that the researchers could not spot) nor can they improve or optimize their performance over time ([146]). Therefore, although expert systems are still used in various fields, they are no longer an active area of AI research ([147]).

Both Deep Blue and Watson, the game-playing IBM systems mentioned in the *Introduction* ([148]) are expert systems ([149]). Watson has also been recently used in drug development project ([150]). However, later iterations of the Watson system incorporated more than one AI technique, including DL ([151]).

5. Visual synthesis

Further to the basic technical explanations provided on machine learning, evolutionary algorithms and expert systems, it is useful to visualize the relationships between these subfields through the following diagram, in order to precisely distinguish the different categories. However, it should be noted that hybrid combinations exist ([152]). For instance, EAs can be used to design

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([145]) KAPLAN, cit., 46; TAULLI, cit., 12-14; ZERILLI, WELLER, cit., 11.

([146]) TAULLI, cit., 13.

([147]) KAPLAN, cit., 46; ZERILLI, WELLER, cit., 11.

([148]) See § I.A.1 above.

([149]) TAULLI, cit., 13.

([150]) ABBOTT, *Inventive Algorithms and the Evolving Nature of Innovation,* in WOODROW (ed.), *The Cambridge Handbook of the Law of Algorithms*, CUP, Cambridge, 2020, 353.

([151]) KNIGHT, *IBM's Watson Is Everywhere—But What Is it?*, in *MIT Tech. Rev.*, 27 October 2016, https://www.technologyreview.com/2016/10/27/156388/ibms-watson-is-everywhere-but-what-is-it/.

([152]) HUGENHOLTZ ET AL., cit., 24-25.

ANN architectures or to train them ([153]). "Evolutionary artificial neural networks" – a combination of EAs and ANNs – were already being experimented in the 90s ([154]).

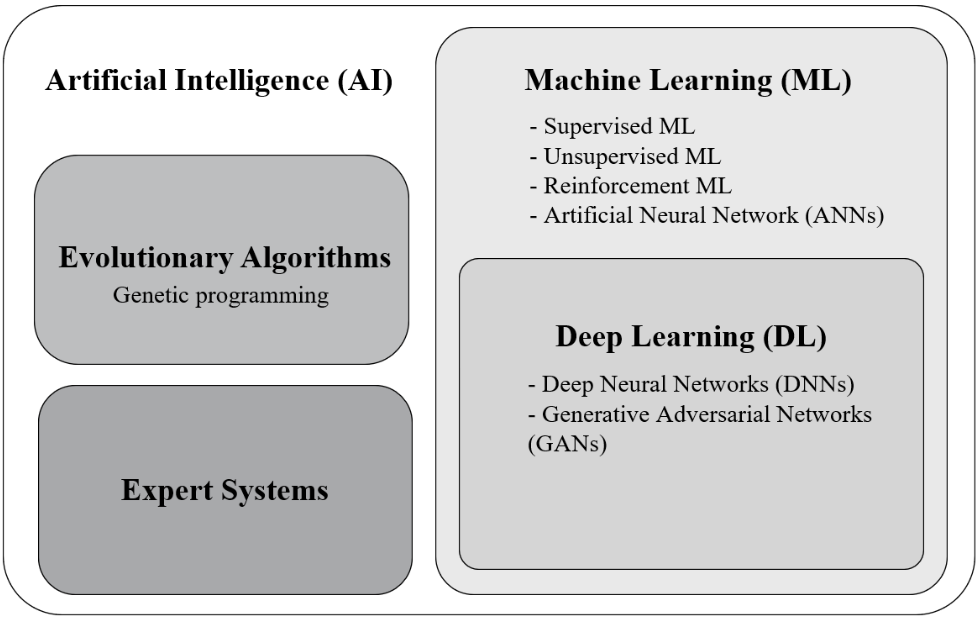

Fig. 7 – Euler Diagram of AI

6. AI as opposed to traditional programming

To conclude this glossary of AI it is helpful to draw explicitly the difference between AI – or, more precisely, machine learning – and the traditional way of writing computer programs ([155]).

([153]) MIRJALILI, *Evolutionary Algorithms and Neural Networks Theory and Applications*, Springer, 2019.

([154]) YAO, *Evolutionary artificial neural networks*, in *International J. Neural Syst.*, 1993, vol. 4(3), 203.

([155]) When the computer program is expressed in a language that is comprehensible to human beings (i.e., alpha-numeric characters) it is referred to as "source code". The source code is then transformed in "object code" (i.e., patterns of bits composed by zeros and ones), which can be understood directly by the machine. See pages "*Program Definition*", "*Source Code Definition*", "*Object Code Definition*" on the *The Linux Information Project* (http://www.linfo.org/index.html); BOSOTTI, *Glossario*, in L. C. UBERTAZZI (ed.), *La legge sul software. Commentario sistematico*, Giuffrè, Milan, 1994, 304-311 (adding that the transformation from source code to object code happens though a program known as compiler). It should be noted that, according to some, "computer program" can be considered a narrower concept than "software" since the latter would also contain the supporting

Traditional computer programs have dramatically evolved through time, from punch cards to modern "software-as-a-service" (SaaS) platforms ([156]), but they all share the basic feature that the programmers must set out all necessary "if-then" rules to be followed in advance. In other words, traditional programming requires thinking out "*every* detail of *every* function, coordinating them, and putting all those details into programming language" ([157]). If a new function is needed, that function must be specifically programmed.

In contrast to traditional programming, AI – and especially ML – involves the use of algorithms and techniques that allow a program to learn and adapt to changing situations and data. ML systems are able to improve their performance over time, making them well-suited for tasks that require flexibility and adaptability. This nevertheless, it is also important not to lose sight of the fact that, at least to some extent, AI is software ([158]), in the sense that AI algorithms and models are generally expressed in code and processed by computers in order to be used ([159]).

C. THE USE OF ARTIFICIAL INTELLIGENCE IN R&D

Keeping in mind the AI glossary, the next section analyses and, to some extent, demystifies a number of case studies where AI has been used in R&D.

1. The narrative about AI-generated inventions

As mentioned in the Introduction, as AI systems became more powerful and

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documentation (HILTY, GEIGER, *Towards a new instrument of protection for software in the EU? Learning the lessons from the harmonization failure of software patentability*, in AREZZO, GHIDINI (eds.), *Biotechnology and software patent law. A Comparative Review of New Developments,* Edward Elgar, Cheltenham, 2011, 153, fn. 1). However, the practice does not make that difference.

([156]) PLOTKIN, cit., 15-28.

([157]) SAMULESON, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, in *Duke Law Journal*, 1984, 687.

([158]) GHOSH, cit., 225-226 and 236.

([159]) ABRIANI, SCHNEIDER, cit., 167 (arguing that algorithms and models as such do not fall under the notion of "computer program", but can be "operationalized" in a computer program).

widespread, they were picked up as tools for conducting R&D ([160]). In turn, the increasing use of AI in R&D led many authors to claim that AI is – or will soon be – capable of "autonomously" generating inventions ([161]) by simply "pushing the on/off button" ([162]).

Against such a momentous claim it is however surprising that the examples of AI-generated inventions referred to in the IP literature are generally few and quite repetitive ([163]). In particular, most scientific articles published on the topic of AI and inventions starting from the late 1990s heavily rely on the work of a handful individuals, in particular Dr. Stephen Thaler and Dr. John Koza ([164]).

The narrative around "AI-generated inventions" seems to have been deeply influenced by the book "*The Genie in the Machine: How Computer-Automated Inventing is Revolutionizing Law and Business*" by Robert Plotkin, published in 2009. Plotkin is a U.S. patent attorney with a background in computer science who discussed the use of AI in R&D in a

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([160]) COCKBURN, HENDERSON, STERN, *The Impact of Artificial Intelligence on Innovation*, in AGRAWAL, GANS, GOLDFARB (eds.), *The Economics of Artificial Intelligence An Agenda*, University of Chicago Press, Chicago; See also CONTI, *The incredible inventions of intuitive AI*, TEDxPortland, February 2017, https://www.ted.com/talks/maurice_conti_the_incredible_inventions_of_intuitive_ai.

([161]) See references cited in § III.B.2.4, fn. 138 below.

([162]) DORNIS, *Of "authorless works" and "inventions without inventor" – the muddy waters of "AI autonomy" in intellectual property doctrine*, in *E.I.P.R.*, 2021, 43(9), 570 (hereafter "*Muddy Waters*").

([163]) KIM, *AI-Generated Inventions*, cit., 445-446 (arguing that " [l]egal narratives of AI-generated inventions often refer to almost the same set of examples"); see also STRAUS, *Will artificial intelligence change some patent law paradigms?*, in *Ljubljana law review*, 2021, vol. 81, 29 ff.

([164]) See e.g., CLIFFORD, *Intellectual Property in the Era of the Creative Computer Program: Will the True Creator Please Stand Up* , in *Tul. L. Rev.*, 1997, 71, 1675; VERTINSKY, RICE, cit., 2002; WAMSLEY, *Flashes of Genius, Toiled Experimentation, and Now Artificial Creation: A Case for Inventive Process Disclosures*, LL.M. Thesis at The George Washington University Law School, 2011, https://scholarspace.library.gwu.edu/etd/rf55z7888; ABBOTT, *I Think*, cit., 1079 ff.; FRASER, *Computers as Inventors – Legal and Policy Implications of Artificial Intelligence on Patent Law*, in *SCRIPTed*, 2016, 13(3), 315; HERVEY, DRIVER, WOODHOUSE, *Intellectual Property*, in HERVEY, LAVY (eds.), *The Law of Artificial Intelligence*, Sweet & Maxwell, London, 2020, 271; A. ENGEL, *Can a Patent Be Granted for an AI-Generated Invention?*, in *GRUR Int.*, 69(11), 2020, 1123.

captivating and colourful prose. He described computers running AI invention software as "genies" to which human inventors can formulate "wishes", i.e., the technical problems they want to be solved ([165]). Although Plotkin clarified that, in his view, "invention automation technology enables *human* inventors to invent more effectively, *not* that technology itself has become an inventor" ([166]), his book has been often referenced as a tale on "autonomous" AI inventions ([167]).

The following paragraphs review in detail these "classic" examples on the use of AI in R&D, including the systems and results obtained by Thaler, Koza and their teams (§ I.C.2). Then, more contemporary examples of the phenomenon are presented, focusing on the use of AI in the pharmaceutical industry (§ I.C.3). In all cases, attention is paid to the R&D processes that materially led to the alleged AI-generated inventions.

2. Classic examples

2.1 Stephen Thaler

Thaler is perhaps the most famous computer scientist advocating for AI's inventive autonomy ([168]). A physicist by training ([169]), Thaler currently is one the leading figures of the "Artificial Inventor Project", a series of self-described "test cases" submitted to courts and IP offices around the world to "promote dialogue" ([170]) on whether AI systems can (and should) qualify as

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([165]) PLOTKIN, cit., 3.

([166]) PLOTKIN, cit., 4, emphasis added. Along the same lines, see also a recent article from the same author: PLOTKIN, *Commentary: How AI is affecting the patent system*, in Reuters, 28 June 2023, https://www.reuters.com/legal/litigation/how-ai-is-affecting-patent-system-2023-06-28/ ("AI can be seen as an extension of previous invention-facilitation tools, including computer-aided design (CAD), 3D printing, and even conceptual tools, such as everything in the long history of mathematics").

([167]) See in particular ABBOTT, *I Think*, cit., 1079 ff.

([168]) For a recent profile on Dr. Thaler, see: WEBER, *The inventor who fell in love with his AI*, in *1843 Magazine* (*The Economist)*, 4 April 2023, https://www.economist.com/1843/2023/04/04/the-inventor-who-fell-in-love-with-his-ai.

([169]) IMAGINATION ENGINES INC., *Stephen L. Thaler, Ph.D.*, https://imagination-engines.com/founder.html.

([170]) ARTIFICIAL INVENTOR, *The artificial inventor project* https://artificialinventor.com/.

authors or inventors ([171]).

2.1.1 *The Creativity Machine*

Starting in the mid-80s, Thaler developed an AI system he called "Creativity Machine" ([172]). The Creativity Machine consists of two interacting ANNs (Fig. 8). The first ANN is the "Imagination Engine" or "Imagitron". The second ANN is the "Perceptron" ([173]). The Imagination Engine is an ANN trained on some body of knowledge that generates new "ideas" also thanks to specially prescribed "perturbations" (i.e., semi-random modifications in the neural connections) ([174]), which are meant to reflect the way the human brain works during creative processes ([175]). The Perceptron instead is an ANN used to filter the best emerging ideas from the Imagination Engine giving its "opinions" ([176]), i.e., scores. The "opinions" of the Perceptron can be provided as a feedback to the Imagination Engine as a form of reinforcement learning to improve the "ideas".

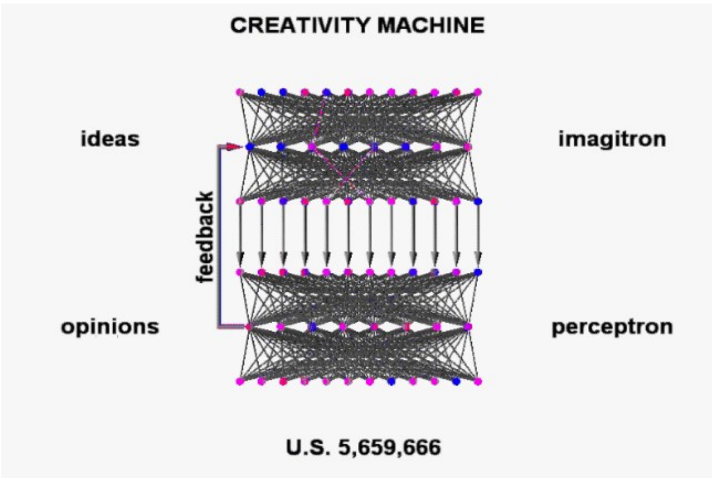

Fig. 8 - Creativity Machine (Source: Imagination Engines Inc.)

([171]) See § III.C below.

([172]) IMAGINATION ENGINES INC., *IEI's Patented Creativity Machine® Paradigm*, https://imagination-engines.com/cm.html (hereafter "*Creativity Machine*").

([173]) Borrowing the name from Frank Rosenblatt's research at Cornell on the first Artificial Neurons concept.

([174]) IMAGINATION ENGINES INC., *Creativity Machine*, cit.

([175]) PLOTKIN, cit. 53.

([176]) IMAGINATION ENGINES INC., *Creativity Machine*, cit. However, the Perceptron can also consist of a traditional rule-based algorithm (ibid.).

In 1994, Thaler filed a U.S. patent application for the Creativity Machine. The United States Patent and Trademark Office ("USPTO") granted the patent in 1997, as U.S. Patent No. 5,659,666 ("US '666"), titled "Device for autonomous generation of useful information" ([177]).

2.1.2 *The CrossAction toothbrush design*

The most famous use case of the Creativity Machine is the cross-bristle toothbrush now known as "CrossAction", which Thaler designed on commission for Gillette, the parent company of Oral-B, in the 90s ([178]).

Getting to the CrossAction design was a long and complex R&D process, which Plotkin described in detail ([179]). Thaler first created digital models of existing toothbrushes, describing them though parameters such as the spacing, angle, and stiffness of the bristles (around 80 parameters were used). The toothbrush parametric designs were used as training data for the Imagination Engine. Thaler then used robots to hold physical toothbrushes and brush fake teeth covered in dye. Thereby he gathered effectiveness data about each toothbrush, such as the amount of dye removed and depth of penetration. The effectiveness data was, in turn, used as training data for the Perceptron in order to predict the features that contributed to the toothbrush's performance. The Perceptron was then able to filter out the best toothbrush designs among those generated by the Imagination Engine. The iterative process between the Imagination Engine and the Perceptron was repeated "until Dr. Thaler was satisfied with the results" ([180]).

This was not the end of it, however. According to Thaler's own statements, the Creativity Machine produced around 2000 potentially superior toothbrush designs, several of which had crossed-bristles. Thaler

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([177]) Thaler then filed a second patent on 26 January 1996, titled "Neural Network Based Prototyping System and Method", granted as U.S. Patent No. 5,852,815 on 22 December 1998. Thaler is listed as the patent's inventor, but he states that it was actually the Creativity Machine the one who invented the patent's subject matter (the "Creativity Machine's Patent"). See also ABBOTT, *I think*, cit., 1085.

([178]) PLOTKIN, cit., 51 ff.

([179]) ibid.

([180]) ibid., 54.

then turned *all* these designs over to Gillette, and the company then "made the final choice and may have made modifications for use in the CrossAction toothbrush" ([181]). To illustrate the scale of the R&D effort that Gillette undertook to develop the CrossAction, the toothbrush's 1999 launch commercial proclaimed: "after 3 years of developing, 300 scientific studies, and with 23 patents filed, comes a breakthrough in dentalcare: introducing the revolutionary Oral-B CrossAction" ([182]).

Hence, despite the contention that the CrossAction toothbrush was an "autonomously" AI-generated invention ([183]), *Ramalho* convincingly stressed that "humans, not the machine, defined the objective to be accomplished/problem to be solved; set the current parameters of toothbrush design; and identified the best solution" ([184]).

2.1.3 *DABUS*

More recently, Thaler developed an AI system called "Device for the Autonomous Bootstrapping of Unified Sentience" or "DABUS". The DABUS system combines a multitude of ANNs ([185]) and Thaler describes it as an evolution of Creativity Machines ([186]). Thaler obtained a U.S.

([181]) ibid., 234, fn. 5.

([182]) GILLETTE, *Oral B Cross Action Toohtbrush 1999 Commercial*, https://www.youtube.com/watch?v=oi69NrH8APo&ab_channel=CRTAfterglow.

([183]) See e.g., DORNIS, *Muddy waters*, cit., 582.

([184]) RAMALHO, *Intellectual Property Protection for AI-generated Creations: Europe, United States, Australia and Japan*, Routledge, London, 2021, 83.

([185]) IMAGINATION ENGINES INC., *DABUS Described*, https://imagination-engines.com/dabus.html.

([186]) See *Thaler v Comptroller General of Patents, Designs And Trade Marks* [2020] EWHC 2412 (Pat), § 5, which report the Patent Form 7 in the UK prosecution of the patent application(s) allegedly invented by "DABUS', […] is a type of 'creativity machine'". However, on the Imagination Engines Inc.'s website DABUS is described, rather obscurely, as follows: "DABUS […] is an altogether different proposition from Creativity Machines, starting as a swarm of many disconnected neural nets, each containing interrelated memories, perhaps of a linguistic, visual, or auditory nature. These nets are constantly combining and detaching due to carefully controlled chaos introduced within and between them. Then, through cumulative cycles of learning and unlearning, a fraction of these nets interconnect into structures representing complex concepts. In turn these concept chains tend to connect with other chains representing the anticipated consequences of any given concept. Thereafter, patent (U.S. Patent No. 10,423,875) ([187]) whose claims allegedly cover DABUS.

Thaler and the Artificial Inventor Project claim that DABUS invented, among other things, (i) a food container ([188]) and (ii) a device and methods for attracting attention ([189]) and proceeded to file several patent applications – in which DABUS itself was designated as the inventor and Thaler as the applicant – before the EPO as well as in the US, the UK, Germany, Australia and South Africa, among others ([190]).

The food container is cylindrical in shape and is characterized by a wall with a fractal profile with pits and bulges ([191]). The fractal profile is allegedly advantageous because, *inter alia*, it makes the food container less slippery ([192]) and may be used to hold together a plurality of containers ([193]). In Figure 6, the food container is in the shape of the "Kock Snowflake" a well-known geometrical figure based on a fractal curve first described in a paper from 1904 ([194]) (Fig. 9). In turn, the device and methods for attracting

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such ephemeral structures fade, as others take their place, in a manner reminiscent of what we humans consider stream of consciousness".

([187]) The title of the patent application, as filed in the PCT system, was "Device and method for the autonomous bootstrapping of unified sentience" (WO2015105731A1). The title of US Patent No. 10,423,875, as granted, however is: "Electro-optical device and method for identifying and inducing topological states formed among interconnecting neural modules". It is also noteworthy that the corresponding European application No. EP 3 092 590 was refused for lack of inventive step (due to the absence of technical effects with respect to several features) and lack of clarity: EPO; EPO (Examining Division), Decision to refuse the application (15734978.8), 27 October 2020, https://register.epo.org/application?documentId=E5GR2KQ45578DSU&number=EP15734978&lng=en&npl=false.

([188]) EP 3 564 144 A1 (application n. EP 18 275 163), filed on 17 October 2018.

([189]) EP 3 563 896 A1 (application n. EP 18 275 174), filed on 7 November 2018.

([190]) PCT Patent application No. WO 2020/079499 A1. For updated information see: ARTIFICIAL INVENTOR, *Patents and applications*, https://artificialinventor.com/.

([191]) A fractal is a non-regular geometric shape that has the same degree of non-regularity on all scales. Fractals can be thought of as never-ending patterns.

([192]) EP 3 564 144 A1, § [0015].

([193]) EP 3 564 144 A1, § [0010].

([194]) VON KOCH, *Sur une courbe continue sans tangente obtenue par une construction géométrique élémentaire*, in *Arkiv för Matematik, Astronomi Och Fysik* 1904, Band 1, 681, https://www.math.purdue.edu/~kdatchev/442/koch.pdf. See also WIKIPEDIA, *Koch snowflake*, https://en.wikipedia.org/wiki/Koch_snowflake.

attention include at least a light source which pulses according to a waveform that "satisfy[es] a fractal dimension equation" ([195]). Apparently, human brains would find this flashing frequency hard to miss and the device could be useful, among other things, in search and rescue operations ([196]) (Fig. 10).

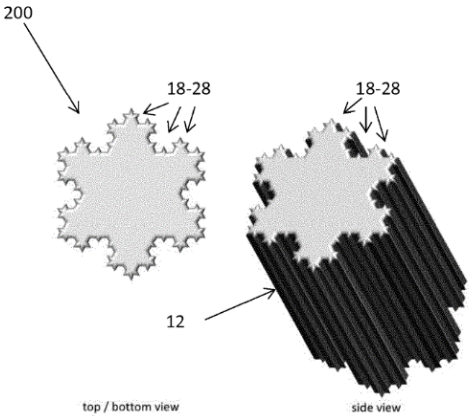

Fig. 9 – Figure 6 of EP 3 564 144 A1

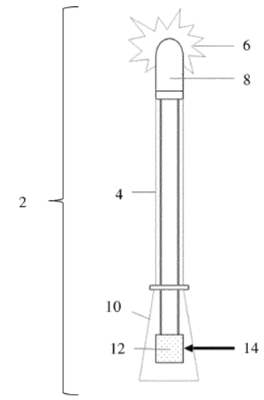

Fig. 10 - Figure 1 of EP 3 563 896 A1

However, there are valid reasons to doubt that DABUS' alleged inventions are patentable, on the merits. The European search opinion by the EPO found that most claims of both DABUS patent applications lacked novelty and/or inventive step, i.e., two of the fundamental patentability requirements ([197]). Furthermore, the patent application concerning the device and method for attracting enhanced attention contains extravagant language. Paragraphs [0019] and [0021] are illustrative:

> "[0019] Embodiments of the present invention further provide a symbol celebrating the unique tempo by which creative cognition occurs. The algorithmically-driven neural flame may be incorporated within one or more structures that resemble candles or altar fixtures, for instance, to accentuate the light's spiritual significance. It is noted that that the light source or beacon can

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([195]) EP 3 563 896 A1, claim 1 (as amended pursuant to Rule 137(2)).

([196]) EP 3 563 896 A1, § [0014].

([197]) See respectively (*i*) EPO, European search opinion on European application No. 18 275 163.6 (EP 3 564 144 A1), 25 April 2019; and (*ii*) EPO, European search opinion on European application No. 18 275 174.3 (EP 3 563 896 A1), 23 April 2019. However, according to a press release from the University of Surrey, around the same time the UKIPO had preliminary found these inventions to be novel, inventive and to have industrial application: see BUTLER, *World first patent applications filed for inventions generated solely by artificial intelligence*, University of Surrey, 1 August 2019, https://www.surrey.ac.uk/news/world-first-patent-applications-filed-inventions-generated-solely-artificial-intelligence.

incorporate any type of light-emitting device".

> "[0021] Moreover, in a theory of how cosmic consciousness may form from inorganic matter and energy (Thaler, 1997a, 2010, 2017), the same attentional beacons may be at work between different regions of spacetime. Thus, neuron-like, flashing elements may be used as philosophical, spiritual, or religious symbols, especially when mounted atop candle- or torch-like fixtures, celebrating what may be considered deified cosmic consciousness. Such a light source may also serve as a beacon to that very cosmic consciousness most likely operating via the same neuronal signaling mechanism".

It is thus questionable whether, among other things, the claimed invention – at least to the extent that it might be used as a "religious symbol" to celebrate "deified cosmic consciousness" – meets the industrial applicability requirement ([198]), which requires, among other things, that an invention does not go against established laws of physics ([199]) and can have a "concrete benefit" in contrast to a "purely theoretical or speculative one" ([200]).

More in general, scholars and practitioners took note that despite the bold, if not outright eccentric ([201]), declarations by Thaler, the fact that DABUS – and AI systems more in general – can invent "autonomously" has not been proven in fact ([202]). Among other things, it was highlighted that the team behind the Artificial Inventor Project did not disclose how DABUS would articulate its inventions (e.g., in words, formulas, numbers, pictures,

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([198]) See *Third Party Observations for application Number EP20180275174*, 3 December 2021.

([199]) EPO, T 541/96, 7 March 2001 (*Element and energy production device*).

([200]) EPO, T 898/05, 7 July 2006 (*Hematopoietic receptor/ZYMOGENETICS*).

([201]) IMAGINATION ENGINES INC., *Stephen L. Thaler, Ph.D.*, cit.; THALER, *The Death Dream and Near-Death Darwinism*, in *Journal of Near-Death Studies* 1996, 15(1), 25 (discussing a model to have artificial neurons incur in near-death experiences and virtual afterlife); HUGHES, *Artificial intelligence is not breaking patent law: EPO publishes DABUS decision (J 8/20)*, in *IPKat*, 11 July 2022, https://ipkitten.blogspot.com/2022/07/artificial-intelligence-is-not-breaking.html. See also the profile by WEBER, cit. ("dabus has feelings, Thaler claims. It might even suffer from loneliness. He has developed what seems like a genuine paternal affection for the ai, and recalled cooing to it gently in the early stages of its development. Thaler and his wife Karen have no children. 'Only dabus,' he told me. 'It's a child-and-father bond").

([202]) KIM ET AL., *Artificial Intelligence Systems as Inventors? A Position Statement of 7 September 2021 in view of the evolving case-law worldwide*, MPI Research Paper No. 21-20, 2021, 1, https://ssrn.com/abstract=3919588. See also SUMMERFIELD, *The Impact of Machine Learning on Patent Law, Part 2: 'Machine-Assisted Inventing'*, in *Patentology*, 21 January 2018, https://blog.patentology.com.au/2018/01/the-impact-of-machine-learning-on_21.html (hereafter "*Machine-Assisted Inventing*").

etc.); that the technology behind DABUS has been mostly ignored by the mainstream AI community; that Thaler's publications are only featured in niche journals; and – perhaps most importantly – that Thaler did neither present its findings at conferences, nor did he otherwise publish the code behind DABUS, contrary to the standard practice in the field ([203]).

From a technical point of view, one feature of DABUS is particularly bizarre. Thaler describes that DABUS – or at least one embodiment thereof – would include (*i*) a number of displays used to show images and (*ii*) one or more cameras watching all said displays to provide feedback on the quality of the displayed images (Fig. 11) ([204]). However, it is unclear why DABUS would use an apparently elaborate system of displays and cameras instead of simply sending data across devices, given that that system is obviously more prone to introduce noise, errors and inaccuracies ([205]).

([203]) HUGHES, *DABUS: An AI inventor or the Emperor's New Clothes?*, in *IPKat*, 15 September 2021, https://ipkitten.blogspot.com/2021/09/dabus-ai-inventor-or-emperors-new.html; HUGHES, *The first AI inventor - IPKat searches for the facts behind the hype*, 15 August 2019, https://ipkitten.blogspot.com/2020/12/is-it-time-to-move-on-from-ai-inventor.html. Actually, Imagination Engines Inc. has expressed some disdain over the peer-review process. In the (now deleted) FAQ section on the website the company answered the question "How come Thaler hasn't written a 'landmark' paper on DABUS?" as follows: "Thaler has written a landmark patent on DABUS and submitted it to totally unbiased subject matter experts (a.k.a., patent examiners) for approval. Besides, IEI is a business and not formally a part of academia where professors are paid to spend most of their time writing papers. Then again, our founder has written peer-reviewed papers on DABUS that are purposely a bit cryptic considering the related patent that was then in prosecution". A previous version of the Imagination Engines Inc.'s website is nevertheless available through Wayback Machine: http://web.archive.org/web/20191226103142/http://imagination-engines.com/iei_dabus.php. See also, *Third party observations for application Number EP20180275163*, 22 April 2021, https://register.epo.org/application?documentId=E55CZ28B6885DSU&number=EP18275163&lng=en&npl=false.

([204]) THALER, *Vast Topological Learning and Sentient AGI*, in *Journal of Artificial Intelligence and Consciousness*, 2021, vol. 8(1), 81; IMAGINATION ENGINES INC., *DABUS Described*, cit.

([205]) This observation is based on a conversation with Dr Mark Summerfield.

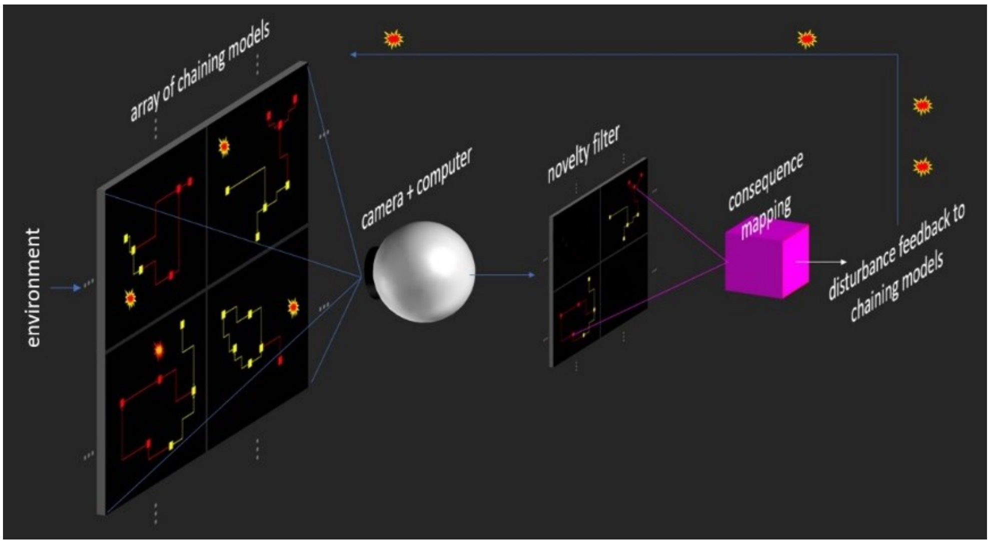

Fig. 11 – DABUS' components (source: Imagination Engines Inc.)

Based on the above, several scholars – both in law and computer science – have suggested that Artificial Inventor Project might be nothing more than an elaborate "publicity stunt" ([206]). Others, however, have praised the project as it has made researchers "confront […] hard problem[s] and exposed the cracks in the system" ([207]).

2.2 *John Koza and genetic programming*

Koza is one of the pioneers of "genetic programming" ("GP"), a computer programming technique first introduced in the late 80s that, broadly speaking, can be considered a form of evolutionary algorithms ([208]). In genetic

([206]) KRETSCHMER, MELETTI, PORANGABA, *Artificial intelligence and intellectual property: copyright and patents—a response by the CREATe Centre to the UK Intellectual Property Office's open consultation*, in *Journal of Intellectual Property Law & Practice* 2022, vol. 17, No. 3, 325, https://doi.org/10.1093/jiplp/jpac013. HUGHES, *EPO refuses "AI inventor" applications in short order – AI Inventor team intend to appeal*, in IPKat, 22 December 2019, https://ipkitten.blogspot.com/2019/12/epo-refuses-ai-inventor-applications-in.html; SUMMERFIELD, *The Impact of Machine Learning on Patent Law, Part 1: Can a Computer 'Invent'?*, in *Patentology*, 13 January 2018, https://blog.patentology.com.au/2018/01/the-impact-of-machine-learning-on.html (arguing that the exceptional claims by Thaler and his team sound "more like marketing hype than sound academic evaluation").

([207]) Quote from Mark Lemley in LOHR, *Can A.I. Invent?*, in *New York Times*, 15 July 2023, https://www.nytimes.com/2023/07/15/technology/ai-inventor-patents.html.

([208]) EISENBERG, *What's Next; When a Gizmo Can Invent a Gizmo*, in *New York Times*, programming the evolving "individual" is in the form of a computer program, and its fitness is determined by its ability to solve a computational problem ([209]).

Koza further devised techniques to use genetic programming to write software that specifies, though mathematical parameters, the physical structure of devices such as electronic circuits and antennas ([210]) and obtained several patents on his advancements on genetic programming ([211]). Incidentally, Koza is also the inventor of the lottery scratch card ([212]).

A 2010 paper by Koza identified more than thirty use cases where genetic programming had duplicated the functionality of a previously patented invention, infringed a previously issued patent, or created a new patentable invention ([213]).

2.2.1 *The Invention Machine*

Koza and his team claim to have used genetic programming to design a controller – i.e., a device that controls another device. They also obtained the

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25 November 1999, https://www.nytimes.com/1999/11/25/technology/what-s-next-when-a-gizmo-can-invent-a-gizmo.html; KEATS, *John Koza Has Built an Invention Machine*, in *Popular Science,* 1 May 2006, https://www.popsci.com/scitech/article/2006-04/john-koza-has-built-invention-machine/.

([209]) KOZA, *Genetic Programming: On The Programming Of Computers By Means Of Natural* Selection, 1992, 18-30; see also PLOTKIN, cit., 55-61.

([210]) KOZA, *Human-Competitive Results Produced by Genetic Programming*, in *Genetic Programming and Evolvable Machines*, 2010, 11, 265.

([211]) See e.g., U.S. Patent No. 4,935,877 (issued in 1990) for "Non-Linear Genetic Algorithms for Solving Problems"; U.S. Patent no. 5,390,282 (issued in 1995) for "Process for problem solving using spontaneously emergent self-replicating and self-improving entities"; U.S. patent no. 6,058,385 (issued in 2000) for "Simultaneous evolution of the architecture of a multi-part program while solving a problem using architecture altering operations"; U.S. Patent No. 6,360,191 (issued in 2002) for "Method and Apparatus for Automated Design of Complex Structures Using Genetic Programming"; and U.S. Patent No. 6,424,959 (issued in 2002) for "Method and Apparatus for Automatic Synthesis, Placement and Routing of Complex Structures".

([212]) PLOTKIN, cit., 55; KENNEDY, *Who Made That Scratch-Off Lottery Ticket?*, in *New York Times*, 5 July 2013, https://www.nytimes.com/2013/07/07/magazine/who-made-that-scratch-off-lottery-ticket.html.

([213]) KOZA, *Human-Competitive Results*, cit., 265 and 273. See also KOZA, KEANE, STREETER, *Evolving Inventions*, in *Scientific American*, February 2003, 52.

grant of U.S. Patent No. 6,847,851 ("US '851") for such invention in 2005. US '851 is entitled "Apparatus for Improved General-Purpose PID and non-PID Controllers", where "PID" stands for "proportional-integrated-derivative" and is a particular type of controller ([214]). According to some, US '851 would be the first known example of a patent granted to an invention generated with the use of AI, although the role of AI in the inventive process was not disclosed in the patent specification ([215]). Koza himself generically refers to the GP-based AI used for this feat as an "Invention Machine" ([216]).

Plotkin describes the inventive process of the improved PID controller as follows ([217]). First, Koza and his team coded the genetic programming software with data about the basic components of a controller. Then, they defined the fitness function, which detailed the criteria that a controller would need to satisfy to solve the problem the researchers were trying to tackle. The fitness function, however, did not specify the physical design of any particular controller, nor that it had to be a PID controller. The team ran a series of simulated tests on each "individual" controller to determine how well did it work. Then the software compared the controller performances to determine which "individual" would survive onto the next generation ([218]). Although the GP system had no database with expert knowledge about existing controllers ([219]), it appears that Koza and his team had decided all the fundamental mathematical elements that composed the controller in advance.

([214]) U.S. Patent No. 6,847,851 (issued on 25 January 2005).

([215]) ABBOTT, *I Think*, cit., 1088 (reporting that Koza told him in the course of a telephone interview that his legal counsel advised him that his team should consider themselves inventors despite the fact that "the whole invention was created by a computer"). See also KEATS, cit.

([216]) SUMMERFIELD, *Can a Computer 'Invent'?*, cit. (making the point that the 'Invention Machine' appears to be a generic term used by Koza to describe GP as applied to generating new solutions to technical problems). See also GENETIC PROGRAMMING INC., *Genetic Programming is an Automated Invention Machine*, http://www.genetic-programming.com/inventionmachine.html.

([217]) PLOTKIN, cit., 58 ff. Incidentally, Koza also obtained yet another patent for "[a] method of designing the controller and other controllers" (U.S. Patent No. 7,117,186).

([218]) PLOTKIN, cit., 58. A similar process is described in KEATS, cit., concerning the development of lens, which also involved the use of a simulator.

([219]) ABBOTT, *I Think*, cit., 1087 (citing as a source a telephone interview with John Koza).

Again, the description of the inventive process that brought to the improved PID controller shows that – long from being an invention that the AI system spit out at the push of a button – Koza and his team thoroughly designed a complex computational process. In this respect, *Kim* stresses that "the design of a well-suited problem-specific fitness function and selection of the problem representation and genetic operators are *not trivial* tasks" ([220]).

On a different note, the technical merits of the improved PID controller developed by Koza have been questioned ([221]). In particular, it was observed that claim 1 of US '851 includes entirely conventional PID controller features characterized by apparently arbitrary constraints quoted to ten significant features, as reproduced below (Fig. 12) ([222]). The scope of protection of a similarly drafted claim is *extremely narrow* ([223]).

1. A proportional, integrative, and derivative (PID) controller comprising a proportional element, an integrative element, and a derivative element coupled together and responsive to a reference signal to generate a control signal in response thereto to cause a plant to generate a plant output, wherein the proportional element has a gain element with a gain being substantially equal to

$$0.72 * K_u * e^{-\frac{1.6}{K_u}+\frac{1.2}{K_u^2}} - .001234000198 * T_u - 6.117274273 * 10^{-6}$$

where K_u is the ultimate gain of the plant and T_u is the ultimate period of the plant.

Fig. 12 – Claim 1 of US 6,847,851

Nevertheless, it should be pointed out that – as opposed to DABUS – genetic programming is a scientifically established AI method ([224]). *Russell* and *Norvig* however highlight that "there is a debate about the effectiveness of the technique", as it is "not clear whether the appeal of genetic algorithms [and thus genetic programming] arises from their performance or from their

([220]) KIM, *Clarifying assumptions*, cit., 303.

([221]) SUMMERFIELD, *Machine-Assisted Inventing*, cit.

([222]) ibid.

([223]) ibid.

([224]) RUSSELL, NORVIG, cit., 156. See also DOMINGOS, cit., 121 ss.

aesthetically pleasing origins in the theory of evolution" ([225]).

2.2.2 *NASA antenna*

Another product that is unfailing cited in the "AI-generated inventions" discourse is the antenna developed in 2005 by NASA using evolutionary algorithms. The antenna flew on a miniature spacecraft as part of the Space Technology 5 ("ST5") mission ([226]). The project was led by Jason Lohn, a pupil of John Koza ([227]).

Recognizing that the field of antenna design was time and labour intensive, Lohn and his team relied on evolutionary algorithms to come up with new structures. Based on the requirements of the ST5 mission, the researchers decided that the antenna would have a single arm, that such arm would not be branched (due to manufacturing difficulties) and consequently refined the fitness function for the EA. In total, it took the NASA team around four months to set up the EA to obtain the single-arm antenna that was ultimately used ([228]). The resulting design, reproduced here below (Fig. 13), obtained after a series of evolutions (Fig. 14), was not only compliant with the mission requirements, but worked more than twice as efficiently as the conventional solution that had been designed by contractors ([229]).

([225]) RUSSELL, NORVIG, cit., 156. See also: O'NEILL, SPECTOR, *Automatic Programming: The Open Issue?*, in *Genetic Programming and Evolvable Machines* 2020, vol. 21, 256 (the authors argue that GP is unlikely to be "sufficient, or at least on its own the most efficient method, to fully realise automatic programming or at least the most appropriate or efficient method to achieve all the necessary functions that an automatic programming system requires").

([226]) HORNBY ET AL., *Automated Antenna Design with Evolutionary Algorithms*, in AIAA 2006-7242. *Space 2006*, 2006, https://doi.org/10.2514/6.2006-7242.

([227]) KEATS, cit.

([228]) HORNBY ET AL., cit. 7-8. Another NASA source seems to suggest that it actually took two years to develop the EA: https://www.nasa.gov/centers/ames/research/exploringtheuniverse/borg.html ("Four NASA Ames computer scientists spent two years developing the AI evolutionary program. It can operate on as many as 120 personal computers, which work as a team. The scientists wrote the AI software to create designs faster than a human being could").

([229]) HORNBY ET AL., cit., 4.

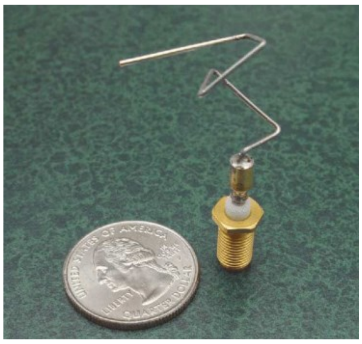

Fig. 13 – ST5 Antenna (Source: HORNBY ET AL., 2006)

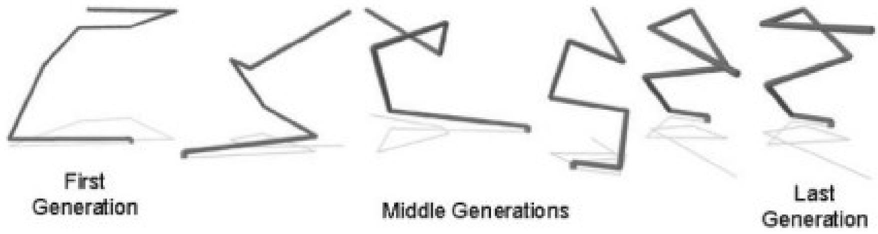

Fig. 14 – Previous generations (HORNBY ET AL., 2011)

Plotkin interviewed one of the members of the design team and was told that "no human engineer would have thought of an antenna that looked so crazy" like a bent paperclip; and "yet the antenna works better than previous human designs" ([230]).

Nevertheless, the same considerations made for Koza's PID controller apply here. Despite the "surprising" results, Lohn and his team had precisely defined all the computational tasks and parameters for the EA's optimisation problem. The full set of papers published by Lohn and his team shows as much ([231]). In other words, the NASA team did not merely state a problem to

([230]) PLOTKIN, cit., 1.

([231]) LOHN, HORNBY, LINDEN, *An Evolved Antenna for Deployment on NASA's Space Technology 5 Mission*, in O'REILLY ET AL. (eds.), *Genetic Programming Theory and Practice II*, Springer, New York, 2005, 301 (discussing in detail how to represent the antennas in the program and the fitness function of two different EAs: one for branching and one for non-branching design). See also LOHN ET AL., *Evolutionary Design of a Single-Wire Circularly Polarized X-Band Antenna for NASA's Space Technology 5 Mission*, *2005 IEEE Antennas and Propagation Society International Symposium*, Washington, DC, USA, 2005, vol. 2B, 267; LOHN ET AL., *Evolutionary Design of an X-Band Antenna for NASA's Space Technology 5 Mission*, *IEEE Antennas and Propagation Society Symposium, 2004.*, Monterey, CA, USA, 2004, vol. 3, 2313; HORNBY, LOHN, LINDEN; *Computer-Automated* that the EA solved, but thoroughly devised an experimental and complex computational method to solve the problem ([232]).

2.2.3 *Other examples*

Apart from the design of the PID controller and the NASA space antenna, several other examples of the use of evolutionary algorithms in R&D exist, including jet engines ([233]), diesel engines ([234]) and the nosecone design of a Japanese train ([235]). However, it should be noted that most of these examples date back to the early 2000s.

3. Examples in the pharmaceutical and healthcare field

Nowadays, AI is used for R&D purposes in virtually all technical fields and applications, ranging from nanotechnology ([236]) to materials science ([237]) and aerospace ([238]). The most noteworthy use-cases of AI in R&D are perhaps found in the pharmaceutical and healthcare industry. The following paragraphs briefly discuss the use of AI in drug discovery, diagnostics and personalized medicine ([239]).

Evolution of an X-Band Antenna for NASA's Space Technology 5 Mission, in *Evol. Comput.*, 2011, vol. 19(1), 1–23, https://doi.org/10.1162/EVCO_a_00005.

([232]) KIM, *Clarifying assumptions*, cit., 301.

([233]) KURZWEIL, *The Virtual Thomas Edison*, in *Time*, December 2000, 62 s.

([234]) *Diesel Breeding: Looking Into Engines Helps Cross the Best with the Best*, in *Mechanical Engineering*, September 2002, vol. 124(09).

([235]) WAJIMA, MATSUMOTO, SEKINO, *Latest System technologies for Railway Electric Cars*, Hitachi 2005, https://www.hitachi.com/rev/pdf/2005/r2005_04_102.pdf.

([236]) MASSON, BIGGINS, RINGE, *Machine learning for nanoplasmonics*, in *Nat. Nanotechnol*. 2023, vol. 18, 111, https://doi.org/10.1038/s41565-022-01284-0.

([237]) PYZER-KNAPP ET AL., *Accelerating materials discovery using artificial intelligence, high performance computing and robotics*, in *Comput Mater* 2022, vol. 8, 84, https://doi.org/10.1038/s41524-022-00765-z.

([238]) LEVRARD, *How Machine Learning Models Can Benefit Aerospace Manufacturing*, 7 July 2020, https://acubed.airbus.com/blog/adam/how-machine-learning-models-can-benefit-aerospace-manufacturing/. See also: HOWLAND ET AL., *Collective wind farm operation based on a predictive model increases utility-scale energy production*, in *Nat Energy* 2022, vol. 7, 818, https://doi.org/10.1038/s41560-022-01085-8 (discussing use of ML in the energy industry).

([239]) The topics covered in this section were initially developed – and are now updated

3.1 AI-assisted drug discovery

The capabilities of AI and, especially, ML to find hidden patterns within large data sets and to automate predictions were quickly recognized as a potential means to accelerate drug development ([240]).

The pharmaceutical industry has relied on computational methods in drug design, including AI, for decades ([241]). The so-called "computer-aided drug design" ("CADD") – also known as "*in silico*" drug design – is the cornerstone of the modern rational drug design processes ([242]). However, due

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and reviewed – in the thesis I submitted in September 2021 at MIPLC (Munich Intellectual Property Law Center) in partial satisfaction of the requirements for the degree of Master of Laws (LL.M.) in Intellectual Property (unpublished, available at the library of the Max Planck Institute for Innovation and Competition, Munich): TRABUCCO, *The Use of AI as a Tool in Pharmaceutical Innovation and the Definition of the Skilled Person*, 2021, 43-51.

([240]) FLEMING, *How artificial intelligence is changing drug discovery*, in *Nature*, 2018, 557, S56. HUGENHOLTZ ET AL., cit., 36.

([241]) SELLWOOD ET AL., *Artificial intelligence in drug discovery*, in *Fut. Med. Chem.*, 2018, 10(17), 2025; GISB. SCHNEIDER, *Mind and machine in drug design*, in *Nat. Mach. Intell.*, 2019, 1, 128; DIMITROV ET AL., *Autonomous Molecular Design: Then and Now*, in *ACS App. Mat. Interf.*, 2019, 11, 24825.

([242]) PATHAK ET AL., *Computational Approaches in Drug Discovery and Design*, in SINGH (ed.), *Computer-Aided Drug Design*, Springer, Singapore, 2020, 2.

The drug discovery process starts with the so-called "basic research". First, the disease molecular targets are identified ("target identification") and their suitability as a site for a therapeutic agent is assessed ("target validation"). The next step is to find molecules that might interact with said targets, e.g., by screening chemical libraries ("target-to-hit"). The molecules that have the greatest potential to be developed into a marketable medicine are singled out ("hit-to-lead") and worked on to find the structure that delivers maximal therapeutic benefit and minimal harm ("lead optimisation"). See EUROPEAN COMMISSION, *Pharmaceutical Sector Inquiry*, Final Report, 2009, § 134-140. See also MAK, PICHIKA, *Artificial intelligence in drug development: present status and future prospects*, in *Drug Disc. Tod.*, 2019, 24(3), 773; DAILEY, *Drug discovery and development*, in *Enc. Britannica*, 2021, https://www.britannica.com/technology/pharmaceutical-industry/Drug-discovery-and-development. Basic research is one of the most difficult parts of the drug discovery process. Finding drug candidates requires an understanding of the complex human biological system, consisting of 25.000 genes and millions of proteins, and it is estimated that there are as many as 10^{60} potential drug-like molecules: more than the atoms in the Solar System (LOU, WU, *Artificial Intelligence and Drug Innovation: A large scale examination of the pharmaceutical industry*, 2021, 7, https://ssrn.com/abstract=3524985).

When and if lead drug candidates are found, the pre-clinical phase follows, consisting in laboratory ("in vitro") and animal ("in vivo") tests on the compounds' toxicity. Researchers then move to the development phase, where clinical trials are carried out. These are usually to a drastic increase in the digitalization of pharmaceutical data, AI offers more powerful tools than ever before to drug development ([243]). A recent study identified at least 270 companies in the field of AI-powered biopharmaceutical research ([244]) and many pharmaceutical giants have signed joint ventures and partnerships with AI-drug discovery start-ups ([245]).

Among other things, AI is currently used to: (*i*) find new disease-associated molecular targets ("target identification" and "validation"), (*ii*) screening molecule libraries to find new drug candidates (especially small molecules), (*iii*) designing new compounds ("*de novo*" drug design), (*iv*) optimizing drug candidates, by identifying their potential toxic side effects ([246]), (*v*) repurposing existing drugs for new applications ([247]), and (*vi*) improving the modelling of pre-clinical tests ([248]). Also, AI is now increasingly used in clinical trials ([249]).

Different AI techniques can be used for different purposes. For instance, supervised learning is used for predicting drug properties (e.g., adsorption, distribution, metabolism, excretion, toxicity) by detecting correlations in the labelled ([250]), while unsupervised learning leverages clustering methods to identify disease subtypes and targets ([251]).

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divided into three sub-phases (Phase I, II and III) directed towards progressively larger groups of subjects, and investigate the safety and efficacy of the medicinal product. If the clinical trials deliver satisfactory results, the developer will apply for a marketing authorization to sell the product.

([243]) PAUL ET AL., *Artificial intelligence in drug discovery and development*, in *Drug. Disc. Today*, 2021, 26(1), 80.

([244]) MCKINSEY, *AI in biopharma research: A time to focus and scale*, 2022, 2, https://www.mckinsey.com/industries/life-sciences/our-insights/ai-in-biopharma-research-a-time-to-focus-and-scale.

([245]) PAUL ET AL., cit., 81.

([246]) MCKINSEY, cit., 2.

([247]) See § I.C.3.2 below.

([248]) PROPERZI ET AL., *Intelligent drug discovery, Powered by AI*, Deloitte Insights, 2019, www2.deloitte.com/us/en/insights/industry/life-sciences/artificial-intelligence-biopharma-intelligent-drug-discovery.html.

([249]) SALVATORE, CHAMMAH, *Advancing Clinical Trials through Artificial Intelligence: A Legal Perspective*, in *J. Clin. Stud.*, 2020, 12(6), 44.

([250])

([251]) MAK, PICHIKA, cit., 773-774.

Reinforcement learning is particularly useful for *de novo* drug design ([252]), as are evolutionary algorithms ([253]), since both techniques are able to go beyond the training data. Expert systems, which were used until the 1990s, did not really succeed in improving drug discovery ([254]). Robotics has its part too, and has been used in particular to automate in vitro testing ([255]).

3.2 Case study on the research of the Collins Lab

To give a practical example of the use of AI in drug discovery, it is useful to present case study on the work of the laboratory led by MIT professor James J. Collins ("Collins Lab"). The Collins Lab is an interinstitutional research laboratory of MIT, Harvard, and the Broad Institute.

3.2.1 *Halicin*

In 2020, the Collins Lab discovered that a known molecule, later renamed *halicin*, had great potential as a new antibiotic thanks to a DL system ([256]). The compound had been previously investigated for diabetes, but without much success ([257]). Further in vitro studies supported *halicin*'s antibiotic

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([252]) ROMEO ATANCE, *De Novo Drug Design Using Reinforcement Learning with Graph-Based Deep Generative Models*, in *Journal of Chemical Information and Modeling*, 2022, vol. 62(20), 4863.

([253]) DEVI, SATHYA, COUMAR, *Evolutionary Algorithms for de Novo Drug Design – A Survey*, in *App. Soft Comp.*, 2015, 27, 543.

([254]) HUGENHOLTZ ET AL., cit., 38.

([255]) KING ET AL., *The Robot Scientist Adam*, in *Computer* 2009, vol. 42, 46, https://ieeexplore.ieee.org/document/5197424?arnumber=5197424; WILLIAMS ET AL., *Cheaper faster drug development validated by the repositioning of drugs against neglected tropical diseases*, in *J R Soc Interface* 2015, vol. 12(104), 1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4345494/ (through rounds of testing, "Robot Eve" discovered that an existing cancer drug could potentially treat malaria. The software predicted the efficacy of 4,800 compounds and selected 96 compounds for automated physical testing).

([256]) The full chemical name of halicin (IUPAC) is: 5-[(5-Nitro-1,3-thiazol-2-yl)sulfanyl]-1,3,4-thiadiazol-2-amine.

([257]) STOKES ET AL., *A Deep Learning Approach to Antibiotic Discovery*, in *Cell*, 2020, 180(4), 688.

effectiveness ([258]).

An in depth analysis the R&D path that brought to the discovery of *halicin* illustrates how the discussion on "AI-generated inventions" is somewhat problematic. In a recent paper, *Stanková* described it as follows: "[t]he system was *given a task* to find a compound with a desired property […], it was *let to crawl* chemical libraries and ranked halicin very high […] which was a *result* that *no human* […] was able *to control* or *have prior knowledge* of" ([259]). According to the author, the research process that led to *halicin* would show that inventions "can be produced without any human being originating those solutions" ([260]). The author's reconstruction of the research process of *halicin*, however, is unconvincing.

Admittedly, the Collins Lab paper at times dwells on suggestive language ([261]). The name of the compound itself is telling. The word "halicin" derives from the evil supercomputer "HAL 9000" from Stanley Kubrick's masterpiece "2001: A Space Odyssey" ([262]). However, at a closer look, those are minor details. Starting with its cover page, the *halicin* study lists twenty human authors, working at some of the most prestigious research institutes in the world. The individual contributions of each of these authors – in tasks such as "conceptualization" or "model development and training" – are listed

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([258]) HIGASHIHIRA ET AL., *Halicin Is Effective Against Staphylococcus aureus Biofilms In Vitro*, in *Clin Orthop Relat Res*. 2022, vol. 480(8), 1476; HUSSAIN ET AL., *Study on antibacterial effect of halicin (SU3327) against Enterococcus faecalis and Enterococcus faecium*, in *Pathog Dis.* 2022, vol. 80(1), ftac037; BOOQ ET AL., *Assessment of the Antibacterial Efficacy of Halicin against Pathogenic Bacteria*, in *Antibiotics (Basel)*, 2021, vol. 10(12), 1480.

([259]) STANKOVÁ, *Human Inventorship in European Patent Law*, in *Cambridge L. J.*, 2021, 4, https://doi.org/10.1017/S0008197321000507, emphasis added. Using halicin as the example of an "autonomous" AI invention, see also DORNIS, *Künstliche Intelligenz als "Erfinder" – Perspektiven der Disruption im Patentrecht,* in *Mitt. der deutschen Patentanwälte*, 2020, 443-444.

([260]) STANKOVÁ, cit., 4.

([261]) BROWN ET AL., *Artificial intelligence in chemistry and drug design*, in *J. CAMD*, 2020, 34, 709 (defining "extravagant" the claims made by STOKES ET AL. that AI can accelerate the drug design process).

([262]) TRAFTON, *Artificial intelligence yields new antibiotic*, in *MIT News*, 20 February 2020, https://news.mit.edu/2020/artificial-intelligence-identifies-new-antibiotic-0220.

at the end of the paper ([263]).

On the merits, it is improper to characterize the research process that led to *halicin* as if the DL model was "let crawl" in chemical libraries, spitting out a result. To the contrary, the discovery of *halicin* as a potential antibiotic was the result of intense human labour. The researchers first created a new dataset of 2,335 molecules, labelling them as "hit" or "non-hit" based on their growth inhibition properties against *E. Coli*. Based on this dataset, they trained and optimized a first DNN. Then, they ran the model on a library of 6,111 known molecules to be repurposed. The results were double checked against five other different AI systems. The 99 resulting hits were then tested in vitro for growth inhibition of *E. Coli*. The 51 molecules showing such property were further skimmed down using a second DNN. Halicin emerged as the lead compound at the end of this selection process. Further *in vitro* and *in vivo* studies confirmed that *halicin* was highly effective against a broad spectrum of bacteria ([264]).

In sum, it was everything but an "autonomous" invention ([265]). Rather the contrary, the Collins Lab made a number of research and strategic choices and developed an original computational method – which also involved the selection of the training data and then the input data – to test a specific hypothesis. Unsurprisingly, in September 2020 the MIT filed an international patent application covering both *halicin* as a potentially effective antibiotic and the ML method that was used to discover the drug ("Halicin Patent Application"). The Halicin Patent Application lists five inventors, including Prof. Collins ([266]).

([263]) *ibid*. See also STRAUS, *Some lessons from "DABUS" patent applications*, in PENNISI ET AL. (eds.), *Studi di diritto commerciale in onore di Vincenzo di Cataldo*, Giappichelli, Turin, 2021, 634 (arguing that "only the decisive human interventions made the discovery [of halicin] possible").

([264]) STOKES ET AL., cit., 689-691.

([265]) See also STRAUS, *Will artificial intelligence change some patent law paradigms?*, cit., 15.

([266]) See International Patent Application No. WO 2021/050473, filed on 9 September 2020, claiming priority from two U.S. provisional applications filed in September 2019. The other listed inventors are Prof. Regina Barzilay (MIT), Dr. Jonathan Stokes (MIT), Dr. Ian Andrews (MIT) and Daniel Collins (Broad Institute).

3.2.2 *Further research*

The paper discussing the discovery of *halicin* also illustrates the research team's further endeavors. The team re-trained the original DL model with the empirical data gathered by testing a number of molecules in vitro and then applied this new model to an anti-tuberculosis library, i.e., a chemical space that is highly divergent from the training dataset, basically as a cross-check of the model robustness. They then assayed the 200 molecules with the highest prediction score and the 100 molecules with the lowest. As expected, none of the 300 molecules assayed showed antibacterial activity ([267]).

The model was trained once again using the data from the anti-tuberculosis library and this time it was ran on a dataset comprising 107 million known molecules, which the team filtered for their psychochemical properties from the immense ZINC15 database, containing data on approximately 1,5 billion molecules. Within this big dataset, the DL model identified 6,820 molecules with acceptable scores. While the number of compounds tested "in silico" was two orders of magnitude larger than empirical screening permits, the process only took four days.

Through further narrowing down steps, the Collins Lab then identified 23 compounds for empirical testing. Of these, 8 compounds showed detectable growth inhibitory activity against at least one of the tested bacteria species. Two of them, showed potent broad-spectrum activity. And one in particular, given its predicted low toxicity in humans was considered to warrant further investigation ([268]).

3.2.3 *Abaucin*

More recently, the research group led by Prof. Collins also discovered the narrow-spectrum antibiotic effect of *abaucin* – a known molecule that had been studied as a CCR2 antagonist – against *A. baumannii*, a dangerous pathogen that often displays multidrug resistance, through a similar deep-

([267]) STOKES ET AL., cit., 697.
([268]) STOKES ET AL., cit., 697-698.

learning screening and testing model ([269]).

Once again, the remarkable feat of the researchers was reported enthusiastically suggesting that AI discovered a new antibiotic "in two hours" ([270]) – referring to the time the trained model took to predict the antibiotic activity of a number of molecules to repurpose and prioritize the results ([271]). Needless to say, like in the case of *halicin*, a more careful reading of the paper shows that the process took much longer and required sophisticated skills and methodological choices from the researchers.

3.3 Observations on the role of AI in drug development

The case study of the Collins Lab is useful to draw some observations as to the role of AI in drug development. While *Fortune* proclaimed a "revolution" in the field of drug discovery due to the use of computers already in 1981 ([272]), most researchers are still rather cautious in describing the capabilities of AI in drug development. A prominent scholar in the field stressed that ML "is neither a quick fix for the problems of the industry, nor does it provide immediate answers to the underlying scientific questions" ([273]).

The first obstacle that is raised is the fact that chemical and biological data is often "sparse, noisy, biased, and inconsistent" ([274]). In particular, while researchers are able to handle chemistry rather well, the "Achilles heel" of the current AI-assisted projects remains the lack of a complete understanding

([269]) LIU ET AL., *Deep learning-guided discovery of an antibiotic targeting Acinetobacter baumannii*, in *Nat Chem Biol* 2023, https://doi.org/10.1038/s41589-023-01349-8.

([270]) CUPPINI, *L'intelligenza artificiale ha scoperto un nuovo (potenziale) antibiotico in due ore*, in *Corriere della sera*, 28 May 2023; YANG, *Scientists use AI to discover new antibiotic to treat deadly superbug*, in *The Guardian*, 25 May 2023.

([271]) LIU ET AL., cit., 2 (saying: "[n]otably, this process of performing predictions and prioritizing molecules for validation was completed within a couple of hours").

([272]) BARTUSIAK, *Designing drugs with computers*, in *Fortune*, August 1981, 47.

([273]) G. SCHNEIDER, cit., 129. Researchers at BenevolentAI, one of the most prominent start-ups in the field echo this sentiment, recalling that AI is not a "magic button" which can deliver perfect outputs. Rather, it remains a "useful tool" that can drive new discoveries, if used correctly (SELLWOOD ET AL., cit., 2025).

([274]) SCHRÖDL, *Current methods and challenges for deep learning in drug discovery*, in *Drug Disc. Tod. Tech.*, 2019, 32, 16.

of biology and, therefore, the lack of appropriate biological data ([275]).

Also in terms of tangible results, while AI has proven to be impactful in the earliest phases of drug development (especially in drug discovery and pre-clinical phases), the probability of success in later phases has not been higher than for drugs discovered without AI ([276]). Also, there is no evidence of a significant impact of AI on clinical trials or regulatory approval ([277]).

Another study stressed that it is unclear whether drug candidates found by AI may represent radical, or rather only incremental improvements over existing drugs ([278]). In particular, it was suggested that ML offers no real advantages in finding radically novel drugs because it is heavily dependent on the data available for training or input: when data are scarce (or non-existing), it is not easy for AI systems to draw conclusions about functionalities of drugs ([279]).

3.4 AI in healthcare: diagnostics and personalized medicine

AI is making significant contributions to innovation in the medical field beyond drug discovery and development. Countless healthcare applications are currently utilizing AI systems ([280]). For instance, AI has shown to be a promising technology also in the diagnostic field, where ML models are used to analyse medical imaging and spot abnormalities that might go undetected by the human eye ([281]). This is particularly true for signs of tumours or

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([275]) BENDER, CORTÉS-CIRANO, *Artificial intelligence in drug discovery: what is realistic, what are illusions? Part 1: Ways to make an impact and why we are not there yet*, in *Drug Disc. Tod.*, 2021, 26, 513 and 522.

([276]) LOU, WU, cit., 4. See also MCKINSEY, cit., 2 ("[t]he AI-driven drug discovery industry: Jury still out on impact").

([277]) LOU, WU, cit., 4.

([278]) HUGENHOLTZ ET AL., cit., 39.

([279]) ibid., 39-40.

([280]) KHOO YI, FANG HAO SEN, *The Rise and Application of Artificial Intelligence in Healthcare*, in LEE, HILTY, LIU (ed.), *Artificial Intelligence and Intellectual Property*, Oxford University Press, Oxford, 2021, 28.

([281]) ibid. See also: FDA, *FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems*, 11 April 2018, https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye.

lesions, as cancer radiology counts the largest number of approved AI-diagnostic devices ([282]).

Furthermore, AI plays a pivotal role in personalized medicine ([283]), i.e., the medical approach that aims at tailoring medical treatments to individual patients based on their unique characteristics such as genetics, lifestyle, and medical history ([284]). AI can help physicians to identify personalized treatment options based on the patient's genetic data or to determine the optimal dosage of a medication for each patient (precision dosing) ([285]).

In this respect, it is important to note that, both in diagnostics and personalized medicine, AI is not only a tool used in R&D – as is the case in AI-augmented drug discovery – but also part of the medical treatment itself. Hence, personalized medicine and diagnostics are fields where an AI-assisted inventions might also be an AI-implemented invention ([286]).

([282]) ZOBOLI, cit., 159; See also LUCHINI, PEA, SCARPA, *Artificial intelligence in oncology: current applications and future perspectives*, in *Nature*, vol. 126, 2021, 5 (reporting that "[t]he oncology-related field that counts for the largest number of AI devices is cancer radiology, with the majority of approved devices (54.9%). It is followed by pathology (19.7%), radiation oncology (8.5%), gastroenterology (8.5%), clinical oncology (7.0%) and gynaecology 1 (1.4%). […] The vast majority of the approved devices (>80%) regarded the complex area of cancer diagnostics"); WONG, YIP, *Machine learning classifies cancer*, in *Nature*, 2018, vol. 555, 446, *https://doi.org/10.1038/d41586-018-02881-7*.

([283]) SCHORK, *Artificial Intelligence and Personalized Medicine*, in VON HOFF, HAN (eds.), *Precision Medicine in Cancer Therapy*, Springer, Cham, 2019, 265. See also KHOO YI, FANG HAO SEN, cit., 34.

([284]) FOSSE, ET AL., *Recommendations for robust and reproducible preclinical research in personalised medicine*, in *BMC Med* 2023, vol. 21, 14. https://doi.org/10.1186/s12916-022-02719-0 (defining personalised medicine as "a medical model that aims to provide tailor-made prevention and treatment strategies for defined groups of individuals"). While there is no universally accepted definition of personalised medicine, the EU Health Ministers in *Council conclusions on personalised medicine for patients*, published in December 2015, (2015/C 421/03) defined personalised medicine as a "medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".

([285]) MUKHOPADHYAY ET AL., *Personalised Dosing Using the CURATE.AI Algorithm: Protocol for a Feasibility Study in Patients with Hypertension and Type II Diabetes Mellitus*, in *Int J Environ Res Public Health* 2022, vol. 19(15), 8979.

([286]) See § I.A.4 above.

4. Future trends

The broad overview of use cases confirm that AI is an instrumental technology for modern R&D in many fields ([287]). Some researchers even contend that AI might soon become a "general-purpose 'method of invention' that can reshape the nature of the innovation process" ([288]).

To explore the limits of this idea, two Australian scholars used Jurassic, a LLM trained also on patent texts that generates output text in a similar style to a given input ([289]). They provided Jurassic with an extract of DABUS food container patent ([290]), and ran it 25 times. Jurassic gave the following output:

> "The invention provides a glove having a flexible gripping portion formed from a fractal pattern. The gripping portion is formed from a continuous fractal pattern. The flexible gripping portion is sufficiently strong and rigid to perform its intended function. A search of the USPTO patent database identified no patent applications submitted since 1976 that contain "glove" and "fractal" in their abstract or claims. It is possible, then, that a sufficiently novel and inventive glove with a flexible fractal gripping pattern could be patented".

The authors then fed the input "glove with a fractal gripping pattern" into the "text-to-image" model Stable Diffusion ([291]), which resulted in the picture reproduced here below (Fig. 15).

Fig. 15 – Fractal gloves (Source: GEORGE, WALSH, *Can AI invent?*)

([287]) ROMM, *Putting the Person in Phosita: The Human's Obvious Role in the Artificial Intelligence Era*, in *B.C. L. Rev.*, vol. 62, 1438.

([288]) COCKBURN, HENDERSON, STERN, cit., 115. See also BIANCHINI, MÜLLER, PELLETIER, *Artificial intelligence in science: An emerging general method of invention*, in *Research Policy*, 2022, vol. 51(10), 104604.

([289]) GEORGE, WALSH, *Can AI invent?*, in *Nat Mach Intell* 2022, vol. 4, 1057, https://doi.org/10.1038/s42256-022-00582-5.

([290]) See § I.C.2.1.3 above.

([291]) See § I.A.1 above.

Are the “fractal gloves” an invention? The authors sit on the fence on that judgement, merely observing that AI models can write “relatively convincing text summarizing a new invention” and that “modern AI text-to-image system can generate images to illustrate the invention” ([292]). While the technical merits of the fractal gloves are dubious, the thought experiment is illustrative of the potential direction of the field ([293]).

Nevertheless, other authors stress that – despite significant technical advances – AI applications need to be “surgically altered or purpose-built” for each new problem domain, implying “lots of preparation by human researchers or engineers, special-purpose coding, special-purpose sets of training data, and a custom learning structure” ([294]). The same picture emerges also from the AI-powered research projects discussed above. Indeed, it is relatively easy to illuminate the fundamental roles that humans still play in the inventive process ([295]).

D. CONCLUSION

This chapter has attempted to demystify from the alleged "magic" of AI and to provide the factual and technical background to the discussion. For the purposes of this work, artificial intelligence should be understood as an umbrella term identifying a branch of computer science that encompasses a number of techniques, including machine learning, evolutionary algorithms, and expert systems. These AI techniques have all been used, to a greater or

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([292]) GEORGE, WALSH, *Can AI invent?*, cit., 1059.

([293]) Along the same lines, see also the report from Australian’s patent office on generative AI, detailing a series of “provocations” about the possible use of LLM to draft patent-like texts: IP AUSTRALIA, *Generative AI and the IP rights system provocation series, Patents*, 2023, https://www.ipaustralia.gov.au/temp/Generative-AI-and-the-IP-System.html.

([294]) See e.g., BROOKS, *The Seven Deadly Sins of AI Predictions*, in *MIT Technology Review* 2017, 79, 120, as cited in KIM, *Clarifying assumptions*, cit., 316.

([295]) The exception being the DABUS examples, where given the opaque disclosures of the inventive process make it hard to reach definitive conclusions. However, as stressed above, the DABUS team claims are not particularly credible (see § I.C.2.1.3). Notably, also in GEORGE, WALSH, *Can AI invent?*, cit., 1060, the authors recognize that “to date, there has been significant human input in devising the objects claimed to have been invented by the AI system DABUS”. The authors however also add that “there is [also] plenty of evidence suggesting that AI systems are increasingly being used to help make inventive steps” lesser extent, to innovate. However, despite significant technical advances, AI still needs plenty of human input to generate inventions. For instance, as the *halicin* case study showed, human researchers had to provide the AI with a dataset of known molecules and their effects, and to precisely define the problem that the AI had to solve. Without this fundamental human input, the AI system would have never identified *halicin* as a potential antibiotic.

Therefore, at the current state of technology, it is highly questionable whether AI-generated, "autonomous" inventions may occur ([296]). At any rate, to provide a comprehensive answer to this question one shall first construe the notion of "invention" and what it means to "invent" in a patent law sense. These aspects will be addressed in Chapter III, further to a brief introduction of European patent law in Chapter II.

([296]) See § III.B.2 below.

II.
EUROPEAN PATENT LAW

This chapter briefly introduces the field of European patent law, as a first foundational step to discuss the impact that the use of AI in R&D might have on the patent system. Section II.A addresses the fundamental concepts of patent law. Section II.B maps the most important legislative sources of European patent law. Finally, Section II.C touches upon the policy justifications underlying the patent system and their compatibility with the AI advent.

A. FUNDAMENTAL CONCEPTS OF PATENT LAW

1. Patent

In simple terms, a patent is an exclusive right – a "limited monopoly" ([1]) – granted to an inventor ([2]) in exchange for the disclosure of an invention ([3]). The patent system is thus based on an implied "social contract" between the inventor and the public ([4]), also known as "patent bargain" ([5]). On the one side, the inventor must disclose an invention – i.e., broadly speaking, technical information ([6]) – in sufficient detail so that it can be implemented by an average practitioner in the respective technical field (the so-called "person skilled in the art"). On the other side, in exchange for such disclosure, the state – through the patent office – confers to the inventor the exclusive right to exploit that invention for a certain time (in most countries: twenty

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([1]) BENTLY ET AL., *Intellectual Property Law*, 5th ed., Oxford University Press, Oxford, 2018, 393. The term "monopoly" is here used descriptively. However, it important to note that the formal qualification of patents as "monopolies" in juridical or economical terms is not universally accepted by the scholarship. See e.g., SENA, *I diritti sulle invenzioni*, cit., 30-37; KITCH, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property*, in *Vanderbilt Law Review*, 2000, vol. 53, 1729 ff.

([2]) Or to the patent applicant if the inventor has assigned or otherwise transferred the right to the patent: see § III.B.2.3 below.

([3]) BENTLY ET AL., *Intellectual Property Law*, 5th ed., Oxford University Press, Oxford, 2018, 393.

([4]) VANZETTI, DI CATALDO, SPOLIDORO, cit., 377.

([5]) See e.g., *Actavis v. ICOS* [2019] UKSC 15, § 53.

([6]) BENTLY ET AL., cit., 393.

years) ([7]). As opposed to copyright, which arises automatically upon creation of the work, a patent is granted only further to an administrative process ([8]). At a minimum, the inventor (or their successor in title) shall file a patent application, which is then examined by a patent office. In most cases, patent offices carry out a substantive examination of the patent application, on its technical merits, to ascertain whether it meets the patentability criteria provided by the law ([9]).

2. Patentability requirements

While patentability requirements somewhat vary across the world, a minimum common standard is provided by the Trade-Related Aspects of Intellectual Property Rights ("TRIPs") agreement signed in 1994 as part of the international treaty that established the World Trade Organization ("WTO"). According to Article 27 TRIPs, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Article 27(2) TRIPs then allows member states to exclude certain inventions from being patentable. Article 29 TRIPs adds that, in order to comply with the social contract at the heart of patent protection, "an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art".

The key patentability requirements are thus traditionally identified as follows: (*i*) patentable subject-matter (or eligibility); (*ii*) novelty; (*iii*) inventive step (or non-obviousness); (*iv*) industrial applicability (or

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([7]) ibid. See also VANZETTI, DI CATALDO, SPOLIDORO, cit., 377-378.

([8]) BENTLY ET AL., cit., 393.

([9]) See e.g., Articles 90 to 98 EPC. Some patent systems do not conduct a substantive examination of the patentability requirements, such as in South Africa: NDLOVU, *Why South Africa Should Introduce Patent Searches and Substantive Examinations to Improve Access to Essential Medicines*, Research Papers from the 2015 WIPO-WTO Colloquium for Teachers of Intellectual Property Law, 2016, 73, https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf.

utility); and (*v*) sufficiency of disclosure ([10]).

Patentable subject-matter is a threshold requirement that filters out of the system activities or subject-matter that are not inventions (e.g., pure mathematical formulas or poems) and inventions that are deemed non-patentable for policy reasons (e.g., because their commercial exploitation would go against *ordre public* or morality). The novelty requirement posits that subject-matter which is already available to the public (in patent law terms, it is part of the "state of the art") at the time of the filing of the application cannot be patented ([11]). The inventive step requirement goes further and prevents patents to be granted on subject-matter that, despite not being available to the public, was still within the reach of the person skilled in the art ([12]). An invention is capable of industrial application if it can be made or used in any kind of industry (e.g., it does not go against the basic laws of physics) ([13]). In addition to the above, it is debateable whether there being an "invention" is an autonomous patentability requirement ([14]).

B. SOURCES OF EUROPEAN PATENT LAW

1. The European Patent Convention

The European Patent Convention ("EPC") is the most relevant source of patent law in Europe. The EPC was signed in Munich in 1973 and came into effect on 1 June 1978. It underwent a substantial revision in 2000, which entered into effect in 2007. The revised text of the Convention is sometimes referred to as "EPC 2000".

The EPC established the European Patent Organization as an international, intergovernmental organization ([15]). As of 2023, the EPC has

([10]) The terms in parenthesis reflect the wording commonly used in U.S. patent law to reflect the analogous (albeit often not identical) requirement.

([11]) See e.g., Article 54 EPC.

([12]) See § IV.B below.

([13]) See e.g., Article 57 EPC.

([14]) See § III.A.1 below.

([15]) EPO, G 3/08, 12 May 2010 (*Programs for computers*), § 7.2.1: "The European Patent Organisation is an international, intergovernmental organisation, modelled on a thirty-nine contracting states, including all EU member states along with many other countries that are not part of the EU such as the United Kingdom and Switzerland ([16]). Notably, however, the European Patent Organization is completely independent from the EU, and the EU in not a member of the organization.

The main organ of the European Patent Organization is the European Patent Office ("EPO") ([17]). The EPO's purpose is to examine and eventually grant European patents ([18]). Despite their name, however, European patents do not confer a unitary right across the EPC member states. Once granted, a European patent rather turns into a "bundle" of national patents, one in each of the designated states ([19]). The main advantage of the EPC system is thus that it offers patent applicants a single application and examination procedure to obtain a patent in more than 30 countries, based on uniform substantive patentability requirements.

The EPC has also established a review mechanism whereby, within nine months of the grant, a European patent can be centrally revoked further to an opposition filed by a third party. Decisions on oppositions can then be challenged before the Boards of Appeal (also "BoA" or simply "Boards") ([20]). The Boards are the first and final judicial instance within EPO procedures and have the task of reviewing contested decisions of first instance, including those in opposition cases ([21]).

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modern state order and based on the separation of powers principle, which the sovereign contracting states have entrusted with the exercise of some of their national powers in the field of patents".

([16]) EPO, *Member states of the European Patent Organisation*, www.epo.org/about-us/foundation/member-states.html.

([17]) Article 4 EPC.

([18]) Article 4 and Articles 90-89 EPC.

([19]) Article 64 EPC.

([20]) Articles 99-112a EPC.

([21]) Article 106 EPC. The EPO regularly publishes a comprehensive summary of the case law of the Boards: EPO, *Case Law of the Boards of Appeal*, 10th ed., July 2022, https://new.epo.org/en/legal/case-law (hereafter "EPO Case Law"). Under Article 111(2) EPC, "if the [BOA] remits the case for further prosecution to the department whose decision was appealed, that department shall be bound by the ratio decidendi of the [BOA], in so far as the facts are the same". Article 20 of the Rules of Procedure of the Boards of

In instances where a Board fears that there is a need to "ensure uniform application of the law" ([22]), it can refer a case to the Enlarged Board of Appeal ("EBA"). When two Boards of Appeal have given different decisions on the same question of law, the President of the EPO can appeal the EBA as well ([23]). While EBA decisions are technically binding only for the referring Board, another Board cannot deviate from an EBA decision without referring the same question again ([24]). Moreover, while the EBA and BOA decision are not binding for the national courts – except for the specific European patent(s) at stake – the EPO case law is generally taken into account in the EPC member states ([25]).

Finally, the EPO periodically updates a comprehensive set of guidelines for the examination process ([26]). The EPO Guidelines are "general instructions" that are "addressed primarily to examiners and formalities officers of the EPO, but are also intended to serve […] patent practitioners as a basis for illustrating the law and practice […] before the EPO" ([27]). Even though the EPO Guidelines are non-binding, the EPO expects them to be followed by examiners, and will generally act in accordance with them ([28]). Also, the EPO Guidelines are customarily referred to in the national courts'

Appeal ("RPBA") slightly broaden the EPC rule, providing that "[s]hould a Board consider it necessary to deviate from an interpretation or explanation of the [EPC] given in an earlier decision of *any* Board, the grounds for this deviation shall be given, unless such grounds are in accordance with an earlier opinion or decision of the [EBA]". See also SMYTH, *What is precedent and does the EPO have it?*, in *IPKat*, 15 July 2014, https://ipkitten.blogspot.com/2014/07/what-is-precedent-and-does-epo-have-it.html.

([22]) Article 112(1) EPC.

([23]) Article 112(3) EPC.

([24]) Article 21 RPBA provides that "[s]hould a Board consider it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier opinion or decision of the [EBA], the question shall be referred to the [EBA]". The Board might argue, for instance, that the EBA precedent's arguments are weak or based on false premises: see EPO, T 297/88, 5 December 1989 (*Nimodipin II*).

([25]) ARNOLD, *Harmonization of European Patent Law*, in *JIPLP*, 2019, 14(9), 657. See also BENTLY ET AL., cit., 401 (discussing after some initial resistance there has been a greater recognition of the importance of aligning UK patent law with the jurisprudence of the EPO).

([26]) EPO, *Guidelines for Examination in the European Patent Office*, March 2023, https://new.epo.org/en/legal/guidelines-epc/2023/index.html (hereafter "EPO Guidelines").

([27]) EPO Guidelines, General Part – § 3.

([28]) ARNOLD, cit. 657. See also SMYTH, cit.

decisions as a useful source of interpretation ([29]).

2. The Unitary patent package

The most important development in the field of European patent law since decades entered into effect on 1st June 2023: the so-called "Unitary patent package". The Unitary patent package consist of three pieces of legislation: (*i*) Regulation (EU) No 1257/2012 ("Unitary Patent Regulation") ([30]); (*ii*) Regulation (EU) No 1260/2012 ("Translation Regulation") ([31]); and (*iii*) the Agreement on a Unified Patent Court ("UPCA"), signed on 19 February 2013.

The Unitary Patent Regulation and the Translation Regulation were adopted through the enhanced cooperation procedure ([32]). Therefore, unlike typical EU regulations, they currently do not apply to all the EU member states, but only to the member states that participate to the mechanism ([33]). For instance, Spain and Croatia refused to take part to the project.

The Unitary Patent Regulation enables patent applicants at the EPO to request the grant of a patent with unitary effect ("unitary patent"), i.e., a single

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([29]) See e.g., Court of Milan, 17 December 2014, in *Giur. ann. dir. ind.* 2016, 1, 1192. See also VANZETTI, DI CATALDO, SPOLIDORO, cit., 278; FRANZOSI, *Non ovvietà*, in *Studi di diritto industriale in onore di Adriano Vanzetti*, Giuffrè, Milan, 2004, 474 ff.; GALLI, BOGNI, *Il requisito di brevettabilità dell'attività inventiva*, in GALLI, GAMBINO (eds.), *Codice commentato della Proprietà Industriale e Intellettuale*, UTET, Turin, 2011, 578 ff.

([30]) Regulation (EU) No 1257/2012 of the European Parliament and of The Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L361/1.

([31]) Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, [2012] OJ L361/89.

([32]) Council Decision 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection [2011] OJ L76/53.

([33]) The Unitary Patent Regulation and the Translation are both in force in all the participating EU member states to the enhanced cooperation since 2013. However, the regulations only apply since the date of entry into force of the UPCA, i.e., 1 June 2023, and have effect only in the member states that have ratified the UPCA. At the time of writing, a unitary patent might be asked only in respect of the 17 member states of the EU, which are also UPC member states, namely: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia and Sweden.

patent that provides uniform protection in all participating EU member states. Unitary patents will coexist with the classic "bundle" European patents, as well as with national patents. The Translation Regulation, instead, creates new and simplified language rules for unitary patents. The purpose is to alleviate part of the costs and burdens linked to the need to translate patent specifications for them to have effect in many EPC member states ([34]).

In turn, the UPCA is an international treaty among EU member states that instituted a new international civil court, the Unified Patent Court ("UPC"), set up to decide on the infringement and validity of unitary patents and "classic" European patents ([35]). As the UPC is a court common to EU member states, it shall apply and respect the primacy of Union law and is subject to the decisions of the European Court of Justice (CJEU) ([36]). However it is important to stress that the UPC it is *not* part of the EU *acquis* ([37]).

The UPC will have exclusive jurisdiction for unitary patents. As to classic bundle patents, the UPCA provides for a transitional period of 7 years (which might be extended to 14 years) during which patent owners can "opt out" their patents from the jurisdiction of the UPC – meaning that those patents would be litigated before national courts ([38]). Notably, next to the judicial redress mechanisms, the UPCA also introduced substantive provisions on infringement and defences ([39]). These provisions are to be

([34]) KEUSSEN, *Articles 1-6 Translation Regulation*, in TILMANN, PLASSMANN (eds.), *Unified Patent Protection in Europe: A Commentary*, OUP, Oxford, 2018, 277-311.

([35]) The competences of the UPC are enumerated under Article 32 UPCA and include, among others, infringement and damages actions, revocation actions, actions for declaration of non-infringement and actions for provisional and protective measures and injunctions. The UPC, however, will have no jurisdiction to decide on actions regarding the entitlement to a European patent application or patent (Article 32(2) UPCA and Article 61 EPC). Cases concerning entitlement will remain subject to the national court's decisions.

([36]) Articles 20 and 21 UPCA. See also TILMANN, *Articles 20 and 21 UPCA*, in TILMANN, PLASSMANN (eds.), *Unified Patent Protection in Europe: A Commentary*, OUP, Oxford, 2018, 440-458.

([37]) LANGE, *EU patent harmonization policy: reconsidering the consequences of the UPCA*, in *Journal of Intellectual Property Law & Practice* 2021, vol. 16(10), 1078.

([38]) Article 83 UPCA.

([39]) Articles 25-30 UPCA. These provisions are modelled on the draft Community applied by the UPC. However, it is debated whether these provisions must also be applied by national courts of the UPC member states ([40]).

By creating a unified court system for European patents, the UPC aims to reduce fragmentation and inconsistencies in patent law, which have are deemed detrimental to innovation ([41]). However, the fact that the UPC is not part of the EU *acquis* gives rise to a somewhat complicated relationship between the Court, the EU and the EPO ([42]). Furthermore, the currently limited geographical scope (only 17 out of the 27 EU member states are part of it) of the UPC, the fact that the UPCA does not provide substantive harmonisation in the EU on the patentability requirements, and the fact that around 500.000 opt-outs had been registered by June 2023 ([43]) suggest that the harmonization effects of the UPC might still be a long way coming.

Patent Convention of 1975. Although it never entered into force, it has been a blueprint for many national patent laws: STEINS, STRATMANN, KONRAD (eds.) (Hoffman Eitle), *The Unified Patent Court and Unitary Patent: A Practitioner's Handbook*, 2nd ed., 2022, 10.

([40]) STEINS, STRATMANN, KONRAD, cit., § III.2 (arguing that it is an open legal question whether national courts must apply them); TILMANN, *Introduction to this Commentary*, in TILMANN, PLASSMANN (eds.), *Unified Patent Protection in Europe: A Commentary*, OUP, Oxford, 2018, 19 (arguing that these provisions constitute harmonised law that national courts shall apply). *Contra*, the UPC Preparatory Committee argued that the UPCA shall not apply to opted out patents: UPC PREPARATORY COMMITTEE, *Interpretative note – Consequences of the application of Article 83 UPCA*, 29 January 2014, https://www.unified-patent-court.org/en/news/interpretative-note-consequences-application-article-83-upca. In Italy, Article 56 c.p.i. was amended in with Legislative Decree 19 February 2019, No. 18, and now reads: "The European patent granted for Italy and the European patent with unitary effect confer on the proprietor the rights provided for in Articles 25 and 26 [UPCA]". It would thus seem that the c.p.i. has incorporated by reference the UPCA provisions. However, it is unclear whether Italian patents would then be subject to a different treatment where Articles 25 and 26 UPC differ from Article 66 c.p.i., for instance with respect to indirect infringement: see e.g., COGO, *Appunti sulla contraffazione indiretta*, in *Studi per Luigi Carlo Ubertazzi - Proprietà Intellettuale e Concorrenza*, Giuffrè, Milan, 2019, 211.

([41]) See UPCA's preamble: "[considering] that the fragmented market for patents and the significant variations between national court systems are detrimental for innovation, in particular for small and medium sized enterprises which have difficulties to enforce their patents and to defend themselves against unfounded claims and claims relating to patents which should be revoked".

([42]) LANGE, cit., 1078.

([43]) KLUWER PATENT BLOG, *Unified Patent Court: 465.247 opt-outs in the sunrise period*, 7 June 2023, https://patentblog.kluweriplaw.com/2023/06/07/unified-patent-court-465-247-opt-outs-in-the-sunrise-period/.

3. National patent laws

Whereas a fully harmonized EU patent law system does not exist yet ([44]), the EPC attained a rather high level of "Europeanisation" across EU member states ([45]). Indeed, on the one hand, the EPC substantive rules were drafted based the patent law in force at the time in the member states ([46]). On the other hand, the EPC countries – which include all EU member states – have implemented the EPC provisions in their national patent laws ([47]). As a result, national provisions on patentability requirements are essentially identical across most EPC member states ([48]).

This nevertheless, the patent law system in Europe remains complex to navigate and multi-layered: (*i*) *first*, national patents exist and will continue to coexist next to European patents and unitary patents. Even if and when the UPC were to have exclusive jurisdiction over "classic" and unitary European

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([44]) The EU had a limited impact in reforming and harmonizing substantive patent law with a few notable exceptions, e.g.: (*i*) supplementary protection certificates (Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products; Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products); and (*ii*) patents on biotechnological inventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions).

([45]) KUR, DREIER, LUGINBÜHL, *European Intellectual Property Law: Text, Cases and Materials*, II ed., Edward Elgar, Cheltenham, 2019, 154 ff. VANZETTI-DI CATALDO-SPOLIDORO, cit., 385. The Convention on the Unification of Certain Points of Substantive Law on Patents for Invention signed in Strasbourg on 27 November 1963, created under the aegis of the Council of Europe ("Strasbourg Patent Convention") is an important antecedent to the EPC and, more broadly, the harmonization of patent law in Europe. The Strasbourg Patent Convention is still in force in the member states, which include, among others, France, Germany, Italy, the Netherlands and the UK. See WADLOW: *Strasbourg, the Forgotten Patent Convention, and the Origins of the European Patents Jurisdiction*, in *IIC*, 2010, 123.

([46]) BENTLY ET AL., cit., 400

([47]) Italy, for instance, introduced the EPC provisions by amending Royal Decree, 29 June 1939, No. 1127 (*Legge invenzioni*) with Presidential Decree, 8 January 1979, n. 32 and Presidential Decree, 22 June 1979, n. 338. See also: Law 26 May 1978, n. 260 that disposed for the ratification of Strasbourg Convention of 27 November 1963, the Patent Cooperation Treaty of 19 June 1970 and the European Patent Convention of Munich, 1973. See GIAN. GUGLIELMETTI, *Le invenzioni e i modelli industriali dopo la riforma del 1979*, UTET, Turin, 1982.

([48]) E.g., Article 56 EPC; Article 48 c.p.i. ; Section 3 Patent Act 1977 ; Section 4 PatG.

patents in all EU member states, it will not decide on national patents ([49]); (*ii*) *second*, the EPC does not provide rules on patent infringement, limitations and exceptions, entitlement rules and vindication actions; (*iii*) *third*, even where the laws of European countries are generally aligned, e.g., with respect to patentability requirements, national interpretations can differ, at times substantially — for instance, German and UK courts do not approach the inventive step assessment the same way the EPO does ([50]); and finally (*iv*) national courts can and often do reach different conclusions as to the validity or infringement of different national portions of the same European patents, even based on the same facts ([51]).

All these factors confirm the soundness of the methodological choice to focus the present dissertation not only on EPC provisions, as applied by the EPO, but also on the patent laws, case law and scholarly writings from three of the major patent jurisdictions in Europe – i.e., Italy, the UK and Germany – as it allows to provide a comprehensive view of the field.

C. POLICY JUSTIFICATIONS OF PATENT LAW

Having introduced the basic ideas and the normative structure of the patent system in Europe, it is important to take a step back and address its policy justifications. At their core, patents cover technical information. In turn, (technical) information has the characteristics of *public goods* ([52]). It is *non-rivalrous*, because several people can use the same information at the same time without restricting each other's use ([53]). And it is inherently *non-*

([49]) In view of the entry into force of the UPC, the Italian Senate has approved an amendment to Article 59 c.p.i. to remove the rule on the pre-eminence of the European patent over an Italian patent. The Chamber of Deputies is currently examining the proposal.

([50]) See § IV.B.4.2 below.

([51]) WALSH, *Promoting Harmonisation Across the European Patent System Through Judicial Dialogue and Cooperation*, in *IIC*, 2019, 50, 408; ARNOLD, cit., 657; 2011; LUGINBÜHL, *European Patent Law - Towards a Uniform Interpretation*, Edward Elgar, Cheltenham, 2011, xxvi ff.

([52]) See STIGLITZ, *Economic foundations of intellectual property rights*, in *Duke Law Journal*, 2008, vol. 57, No. 6, 1699-1700.

([53]) See e.g., FALCE, *Lineamenti giuridici e profili economici della tutela dell'innovazione industriale*, Giuffrè, Milan, 2006, 27-28.

exclusive, because the originator of the information cannot exclude third parties from using the same information once they are aware of it ([54]). Hence, the granting of a patent – i.e., a limited "monopoly" on technical information – begs the fundamental question: "why should one person have the exclusive right to possess and use something which all people could possess and use concurrently?" ([55]). To answer this question – which applies to patent law and, more broadly, intellectual property law in general – traditionally two main approaches have been identified: deontological theories and utilitarian theories ([56]). Both are briefly discussed here below, with particular attention to the impact of the increasing role of AI on their robustness.

1. Deontological theories

Deontological theories ([57]) are based on the assumption that inventors to some extent *deserve* exclusive rights on their invention from a moral point of view, either because of the work they put into it (*labour theory*), because the invention is a reflection or expression of their personality (*personality theory*) or because it is fair to reward inventors for having enriched society (*reward theory*) ([58]).

1.1 Deontological theories in general

In general terms, deontological theories are attributed to various extent to the work of some of the most important modern philosophers. Respectively, the labour theory is traced back to John Locke's natural rights ([59]). The roots of

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([54]) See STIGLITZ, cit., 1700; FALCE, *Lineamenti giuridici*, cit., 28.

([55]) HETTINGER, *Justifying intellectual property*, in *Philosophy and Public Affairs*, 1989, vol. 18, No. 1, 35.

([56]) HILTY, HOFFMANN, SCHEUERER, cit., passim. BENTLY ET AL., cit., 4-5 (calling them, respectively, "ethical and moral arguments" and "instrumental justifications").

([57]) "deontology" is a composite noun deriving from the ancient Greek words (τό) δέον -οντος, "duty", and λογία, "study". Literally, it means the study of duty. "deontologia", in *Treccani*, https://www.treccani.it/vocabolario/deontologia/.

([58]) HILTY, HOFFMANN, SCHEUERER, cit., 4-6. See also ABRIANI, SCHNEIDER, cit., 163.

([59]) In particular LOCKE, *Two Treatises on Government*, 1690, Book 2, § 26, https://www.yorku.ca/comninel/courses/3025pdf/Locke.pdf ("every man has a 'property' in the personality theory have been ascribed to Hegel ([60]) and Kant ([61]). And the reward theory finds its philosophical grounds in the works of J. Stuart Mill ([62]) and Jeremy Bentham ([63]). Notably, the reward theory is the one most closely aligned to utilitarian considerations discussed here below – if only because Mill and Bentham are the founders of utilitarianism ([64]) – as it puts emphasis on the utility for society of the intangible good ([65]). However, despite mutual overlaps and differences, what the deontological theories have

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his own 'person'. This nobody has any right to but himself. The 'labour' of his body and the 'work' of his hands, we may say, are properly his. Whatsoever, then, he removes out of the state that Nature hath provided and left it in, he hath mixed his labour with it, and joined to it something that is his own, and thereby makes it his property. It being by him removed from the common state Nature placed it in, it hath by this labour something annexed to it that excludes the common right of other men. For this 'labour' being the unquestionable property of the labourer, no man but he can have a right to what that is once joined to, at least where there is enough, and as good left in common for others"). See e.g., RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 85; MOORE, HIMMA, *Intellectual Property*, in ZALTA, NODELMAN (eds.), *The Stanford Encyclopedia of Philosophy*, 2022, § 3.3, https://plato.stanford.edu/archives/fall2022/entries/intellectual-property/. However, several authors have pointed out that Locke did not discuss *intellectual* property at all: FALCE, *Sulle fondazioni filosofiche delle moderne dottrine economiche dell'innovazione*, in *Riv. dir. ind.*, 2004, No. 4-5, 125; LEMLEY, *Faith-Based Intellectual Property*, in *UCLA L. Rev.*, 2015, vol. 62, 1338-1339 and fn. 38 (arguing instead that "when John Locke wrote of IP, it was to condemn it, not to treat it as an inherent part of the natural order").

([60]) See e.g., HILTY, HOFFMANN, SCHEUERER, cit., 5. However see once again FALCE, cit., 145, disputing that the personality theory for IP rights can be traced back to Hegel's work.

([61]) FALCE, cit., 145, recognizing that, as opposed to Locke and Hegel, the philosopher Immanuel Kant who explicitly suggested the existence of a natural obligation to respect the author's of his work: KANT, *Of the Injustice of Counterfeiting Books*, in *Essays and Treaties on Political and Various Philosophical Subjects*, 1798, 230. See also DONATI, *La fondazione giusnaturalistica del diritto sulle opere dell'ingegno*, in *AIDA*, 1997, I, 405.

([62]) See J. S. MILL, *Principles of Political Economy*, ASHLEY (ed.), Longmans, Green, and Co., London, 1848 (1920 edition), Chapter X, § 4 https://oll.libertyfund.org/title/mill-principles-of-political-economy-ashley-ed (that the inventor "ought to be both compensated and rewarded […] will not be denied" since "it would be a gross immorality of the law to set everybody free to use a person's work without his consent, and without giving him an equivalent").

([63]) HILTY, HOFFMANN, SCHEUERER, cit., 6.

([64]) DRIVER, *The History of Utilitarianism*, in ZALTA, NODELMAN (eds.), *The Stanford Encyclopedia of Philosophy*, 2022, *https://plato.stanford.edu/archives/win2022/entries/utilitarianism-history/*.

([65]) HILTY, HOFFMANN, SCHEUERER, cit., 6; FALCE, cit., 145 (stressing the crucial relevance of the works of Mill and Bentham for the foundations of the utilitarian approach).

in common is a marked anthropocentrism, whereby IP protection shall be awarded to *humans* thanks to their activities ([66]).

Deontological justification theories have considerably lost ground since the nineteenth century, in particular with respect to the patent system ([67]). Among other things, it was noted that patent rights are commonly granted to "accidental" inventions, where there is arguably no or little labour to reward ([68]). It is also hard to reconcile the idea of patents as an expression of the inventor's personality – a theory that holds significantly more value in copyright law ([69]) – given the scientific, technological and commercial restraints that necessarily dictate the inventive process ([70]). And, more in general, the contemporary nature of innovation, led by industries rather than individuals, has further diluted the traditional anthropocentric notions of labour, personality and reward ([71]).

1.2 Deontological theories and AI

The advent of artificial intelligence is only likely to further strain the relevance of deontological justifications of patent rights. While humans still play a fundamental role in using AI tools in R&D processes ([72]), as technology advances that role might become progressively smaller ([73]). And

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([66]) See e.g., HILTY, HOFFMANN, SCHEUERER, cit., 5.

([67]) VANZETTI, DI CATALDO, SPOLIDORO, cit., 379. See also STIERLE, *A De Lege Ferenda Perspective on Artificial Intelligence Systems Designated as Inventors in the European Patent System*, in *GRUR Int.*, 2021, 70(2), 119 (arguing that "deontological theories […] cannot explain today's patent law and practice. The foundation of the present system is purely based on incentives").

([68]) LEMLEY, *Faith-Based Intellectual Property*, cit., 1340. See also § III.B.1.3 below.

([69]) PICHT, THOUVENIN, *AI and IP: Theory to Policy and Back Again – Policy and Research Recommendations at the Intersection of Artificial Intelligence and Intellectual Property*, in *IIC*, 2023, vol. 54, 922-923.

([70]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 88. The Author however stresses that an inventor can also obtain recognition and prestige for their intellectual performance and that inventors tend to link their inventions to their personality, citing the work of Jeanne Fromer in this respect: FROMER, *Expressive Incentives In Intellectual Property*, in *Virginia Law Review*, 2012, vol. 98(8), 1745 ff.

([71]) HILTY, HOFFMANN, SCHEUERER, cit., 27.

([72]) See § I.C above.

([73]) HILTY, HOFFMANN, SCHEUERER, cit., 27-28.

the smaller the role of humans in the inventive process, the less an anthropocentric approach based on the inventor's moral right to obtain the invention holds up.

2. Utilitarian theories

As the deontological approach lost relevance in the theoretical discourse on IP, the utilitarian theories gained prominence and are currently accepted – at least in some form – as the main justifications for the patent system ([74]).

2.1 Utilitarian theories in general

The basic principle of utilitarianism, as a philosophical current, is that the morally right action is the one that produces the most good, often translated in the axiom "the greatest amount of good for the greatest number" ([75]). Applied to intellectual property, the idea underlying utilitarian theories is that "we grant exclusive rights because we think the world will be a better place as a result" ([76]). More precisely – moving from the moral to the economic analysis of the law ([77]) – utilitarian theories suggest that legislators should aim at maximizing net social welfare when shaping property rights ([78]). In the context of intellectual property, that requires to strike an optimal balance between the power of exclusive rights to stimulate the creation of

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([74]) LEMLEY, BURK, *Policy levers*, cit., 1597 (arguing that "[t]o a greater extent than any other area of intellectual property, courts and commentators widely agree that the basic purpose of patent law is utilitarian: We grant patents in order to encourage invention. While there have been a few theories of patent law based in moral right, reward, or distributive justice, they are hard to take seriously as explanations for the actual scope of patent law").

([75]) DRIVER, *cit.* See also IAIA, *Le invenzioni. L'oggetto e i requisiti di brevettazione*, in GENOVESE, OLIVIERI (eds.), *Proprietà intellettuale. Segni distintivi, brevetti, diritto d'autore*, UTET, Milano, 2021, 386-387.

([76]) LEMLEY, *Faith-Based Intellectual Property*, cit., 1328.

([77]) Falce introduces the economic analysis of the law has having been anticipated by utilitarianism: FALCE, *Lineamenti giuridici*, 25, fn 1. The author however stresses that the relationship between utilitarianism and the law & economics approach is not unquestioned.

([78]) FISHER, *Theories of intellectual property*, in MUNZER (ed.), *New Essays in the Legal and Political Theory of Property*, Cambridge University Press, Cambridge, 2001, 1, https://cyber.harvard.edu/people/tfisher/iptheory.pdf.

inventions (and works of art) and the tendency of such rights to curtail the public enjoyment of those creations ([79]).

While the spectrum of utilitarian theories and their construction is rather broad ([80]), the so-called *incentive theory* is the one that is most accepted and commonly referred to for patent law ([81]). Patents are widely seen as an incentive to innovate and, thus, stimulate technical progress ([82]). In particular, this is because patents can offer protection to the inventor's investment. Since information is, as mentioned above, a non-rivalrous public good, which can appropriated at very little cost once it becomes available, if the necessary investments in generating technical information (i.e., an invention) could not be recouped, there would be a risk of underinvestment in the production of new information, possibly leading to the so-called "market failures" ([83]). In these terms, the incentive theory rests on a number of assumptions. Among other things, it assumes that inventions are necessary to progress and that

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([79]) ibid.

([80]) ibid., 9-14 (distinguishing, within the utilitarian umbrella, the incentive theory, the optimizing patterns of productivity approach and rivalrous inventions). Cf. also LEMLEY, BURK, *Policy levers in patent law*, cit., 1600-1615 (distinguishing five major currents within utilitarianism, e.g.: prospect theory, competitive innovation, cumulative innovation, anticommons, patent thickets).

([81]) UBERTAZZI, *Invenzione e innovazione*, Giuffrè, Milan, 9 and 23. ("si è ritenuto in sostanza che l'istituto brevettuale abbia la funzione di incentivare la ricerca tecnica, e ad un tempo la divulgazione dei suoi risultati e la loro applicazione industriale"); FALCE, *Lineamenti giuridici*, cit., 27 ff. (discussing the incentive theory as the fundamental justification of patent law). See also RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 86 (stressing that the incentive theory is "arguably" the "main justification" of patent law).

([82]) VANZETTI, DI CATALDO, SPOLIDORO, cit., 379. LEMLEY, BURK, *Policy levers in patent law*, cit., 1579. The utilitarian approach finds explicit support in the U.S. Constitutions, where Article I, Section 8, provides that "Congress shall have the Power To […] *promote the Progress of Science* and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries": see FISHER, *Theories of intellectual property*, cit., 5.

([83]) See HILTY, HOFFMANN, SCHEUERER, cit., 16, https://ssrn.com/abstract=3539406; See also ULLRICH, *Intellectual Property: Exclusive rights for a purpose – The case of technology protection by patents and copyright*, Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 13-01, 2013, 11, https://ssrn.com/abstract=2179511.

patents provide the most effective way to increase the number of inventions ([84]).

Each of those assumptions can be (and has been) questioned by IP theorists and economists ([85]). In 1958, further to a comprehensive economic review of the patent system commissioned by the U.S. Senate, Machlup famously (and provocatively) concluded that "[i]f we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it" ([86]). Since then, empirical studies of all sorts have attempted to demonstrate (or disprove) the positive effects of the patent system on innovation, with mostly unconclusive results ([87]). Furthermore, the debate has embraced also a multitude of alternative incentives to innovation other than patents, including public grants

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([84]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 86-87.

([85]) ibid. In particular see STIGLITZ, cit., 1724 (arguing that IPRs are part of the innovation system, but that their importance is exaggerated; while IPRs are important, they are only part of a portfolio of instruments and they shall be redesigned to increase economic efficiency and the pace of innovation); JOHNSON, *Intellectual Property and the Incentive Fallacy*, in *Florida State University Law Review*, 2011, vol. 39, 623 (arguing that incentive are mistaken and that natural and intrinsic motivations will cause technology and the arts to flourish even in the absence of externally supplied rewards); BOLDRIN, LEVINE, *The Case against Patents*, in *Journal of Economic Perspectives*, 2013, vol. 27(1), 3 (arguing that there is no empirical evidence that patents serve to increase innovation and productivity and that the system should be abolished or strongly reformed). In the Italian scholarship it is fundamental to cite the criticism raised by Luigi Einaudi to the patent system in EINAUDI, *Lezioni di politica sociale*, Einaudi, Torino, 1949, 20, cited in GHIDINI, *Profili evolutivi del diritto industriale*, cit., 84-85; GIAN. GUGLIELMETTI, *Rileggendo Einaudi: giustificazione e scopo della tutela brevettuale per le invenzioni industriali*, in *Studi in onore di Remo Franceschelli*, Giuffrè, Milano, 1983, 25.

([86]) MACHLUP, *An Economic Review of the Patent System*, Subcommittee on patents, trademarks, and copyrights of the Senate Committee on the Judiciary, 85th Congress, Study No. 15, 1958, 80. See also MACHLUP, PENROSE, *The Patent Controversy in the Nineteenth Century*, in *The Journal of Economic History*, 1950, 10(1), 1 ().

([87]) LEMLEY, *Faith-Based Intellectual Property*, cit., 1332 ff. See also OUELLETTE, *Patent Experimentalism*, in *Virginia Law Review*, 2015, vol. 101, 76 (arguing that no empirical study on patent laws has resolved "whether patents have a net positive effect on innovation, much less their net welfare effect, or whether alternative innovation incentives such as grants, prizes, and tax credits are inferior"; the author therefore proposes that a better evidence-based approach would be obtained thanks to controlled "policy experiments").

and tax benefits ([88]) – which, however, would be paid by the public at large ([89]) – and even penalties when firms do *not* innovate ([90]). At the same time, other ways in which patents encourage innovation – other than protecting investments in R&D – have been discussed, such as the prestige and social recognition linked to inventiveness ([91]), the fact that patents encourage first-to-file races ([92]), and that patents can also have a "signaling" function, as a way to show the research trends and innovativeness of a company ([93]). And it is also arguable that there is no unitary theory that explains all of patent law ([94]).

While the matter cannot be comprehensively addressed in the context of this work, it is important to pinpoint a few aspects of utilitarian theories that are relevant for the current analysis.

The first is that innovation follows different paths and reacts to different incentives in different fields ([95]). The classic mirror examples are the pharmaceutical (in particular with respect to small molecules) and the software industry ([96]). The pharmaceutical industry is the "textbook" case of a sector characterized by high R&D costs and risks for innovators ([97]).

([88]) HEMEL, OUELLETTE, *Beyond the Patents-Prizes Debate*, in *Texas Law Review*, 2013, vol. 92, 303.

([89]) UBERTAZZI, *Invenzione e innovazione*, cit., 26; GHIDINI, *Profili evolutivi*, cit., 90.

([90]) FISHER, *Regulating Innovation*, in *University of Chicago Law Review Online*, 2015, vol. 82(1), 251 (discussing the possibility to penalize private actors that fail to innovate).

([91]) FROMER, *Expressive Incentives*, cit., 1745 ff.; RANTANEN, JACK, *Patents as Credentials*, in *Wash. & Lee L. Rev.* 2019, vol. 76, 311.

([92]) LEMLEY, *The Myth of the Sole Inventor*, cit., 755 ff.

([93]) LONG, *Patent Signals*, in *The University of Chicago Law Review*, 2002, vol. 69(2), 647 and 651.

([94]) LEMLEY, *The Myth of the Sole Inventor*, cit., 760.

([95]) LEMLEY, BURK, *Policy levers*, cit., 1615.

([96]) See e.g., FISHER, *Regulating Innovation*, cit., 254-255 (using these two industries as examples of different receptiveness to incentives).

([97]) MAGAZZINI ET AL., *Patent Disclosure and R&D Competition in Pharmaceuticals*, in *Economics of Innovation & New Technology*, 18, 2009, 467. See also CORREA, *Ownership of knowledge – the role of patents in pharmaceutical R&D*, in *Bulletin of the World Health Organization*, 2004, vol. 82, No. 10, 2004, 784 (arguing that without being granted exclusive rights of exploitation to fence off free riders, hardly anyone would invest in finding solutions to unmet clinical needs, since the industry is dominated by recouping and profit-making objectives). See also § I.A.1 fn. 11 above.

Conversely, generic manufacturers can avoid R&D costs almost entirely once they figure out how to manufacture the drug and can show its bioequivalence to the originator product ([98]). Since reverse-engineering of a chemical compound is reasonably easy in most cases, secrecy is unlikely to provide a reasonable protection for pharmaceutical products ([99]). Manufacturing costs are, in relative terms, also low ([100]). Furthermore, in the pharmaceutical field, the bulk of the research costs are usually incurred *after* the invention – e.g., once a new active ingredient has been found – since lengthy clinical trials are required to show to regulators that the drug is safe and effective in order to obtain marketing approval ([101]). Hence, it is generally assumed that innovation in the pharmaceutical field would drop considerably absent a strong patent protection that allows originators to recoup costs incurred to research and develop the drug ([102]). The software industry works quite differently. On the one side, the software industry has historically thrived also in absence of patent protection – either because it can benefit from copyright protection ([103]), because software faces specific patentability hurdles ([104]), or because alternative innovation models have been successful, such as the open source movement ([105]). On the other side, software development typically has

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([98]) ibid.

([99]) FISHER, *Regulating Innovation*, cit., 254.

([100]) KAPCZYNSKI, PARK, SAMPAT, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, in *PLoS ONE*, December 2012, vol. 7(12), e49470, 1; AHN, *Second Generation Patents in Pharmaceutical Innovation*, Baden-Baden, Nomos, 2014, 73.

([101]) LEMLEY, BURK, *Policy levers*, cit., 1617.

([102]) LEMLEY, BURK, *Policy levers*, cit., 1617; LADDIE, *Patents – what's invention got to do with it?*, in VAVER, BENTLY (eds.), *Intellectual property in the new millennium: Essays in Honour of William R. Cornish*, Cambridge University Press, Cambridge, 2004, 92. Furthermore, it is often suggested that in pharmaceutical inventions one patent (e.g., the active ingredient) corresponds to one product. The one-to-one relationship between patents and products in the pharmaceutical field has been severely questioned, also due to a growing trend also in "discrete" technologies to "cluster" patents: see e.g., AREZZO, *Patent portfolios and pharmaceuticals: a European perspective*, Giappichelli, Torino, 2023, passim.

([103]) See Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs.

([104]) See § I.A.2 above.

([105]) LEMLEY, BURK, *Policy levers*, cit., 1617.

low fixed costs and software products have a relatively short life cycle ([106]). These factors suggest that innovation in software does not depend critically on strong patent protection ([107]). While this basic comparison suffers from a degree of generalization, one can nevertheless credibly conclude that patents do not encourage innovation equally in all technical fields.

The second aspect is that – as utilitarian theories are now more rarely questioned as a fundamental tenet of patent law ([108]) – the discourse has largely moved on to consider particular aspects of the individual patentability requirements as "policy levers" to ensure the well-functioning of the system ([109]). In particular, inventive step, has been progressively identified as the "ultimate" patentability requirement to weed out those patent applications that do not provide an adequate technical contribution to the state of the art ([110]). In turn, the sufficiency of disclosure requirement is crucial to abide by patent law's "social contract" ([111]), as it makes sure that technical information is disseminated, rather than kept secret, in exchange for exclusive rights ([112]). It follows that an appropriate calibration of the inventive step and sufficiency requirements is fundamental to meet the policy goals of the patent system ([113]).

([106]) LEMLEY, BURK, *Policy levers*, cit., 1623. In the software patents field, there is a tendency of numerous patents insisting on the same product(s) in the field – suffice thinking to standard-essential patents, see e.g., GHIDINI, TRABUCCO, *Il calcolo dei diritti di licenza in regime FRAND: tre criteri proconcorrenziali di ragionevolezza*, in *Orizzonti del diritto commerciale*, vol. V(I), 15 (pointing out that in the context of standard-setting, particularly in the ICT sector, the same product often makes use of technologies covered by hundreds, if not thousands, of patents essential patents).

([107]) ibid.

([108]) FALCE, *Lineamenti giuridici*, cit., 29-30 (stressing that the overwhelming majority of scholars shares the conviction that patent law enables innovation incentives and dissemination of knowledge).

([109]) LEMLEY, BURK, *Policy levers*, cit., 1623.

([110]) See § IV.B.1 below.

([111]) See § II.A.1 above.

([112]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 86-87. In the U.S. scholarship, see e.g., FROMER, *Patent Disclosure*, in *Iowa Law Review*, 2009, vol. 94, 539; OUELLETTE, *Do Patents Disclose Useful Information?*, in *Harv. J.L. & Tech*, 2012, vol. 25, 545; OUELLETTE, *Who reads patents?*, in *Nat. Biotechnol.*, 2017, vol. 35, 421.

([113]) In the Italian scholarship see, in particular, GHIDINI, *Profili evolutivi*, cit., 127-136 (on inventive step), 142-147 (on sufficiency); FALCE, *Lineamenti giuridici*, cit., 92-113.

The third aspect is that adopting utilitarian theories as the fundamental justification of the patent system does not exclude *per se* that deontological theories can have systematic importance. For instance, deontological theories still provide the foundational justification for the attribution of moral rights to inventors ([114]). In turn, the possibility of being recognized the paternity of an invention can, itself, encourage inventive efforts ([115]).

2.2 Utilitarian theories and AI

As to the potential impact of AI technologies on the utilitarian theories, it has been argued that – at the current state of technology – the investment protection theory can still provide an adequate justification to the attribution of patent rights on AI-assisted inventions ([116]).

Indeed, AI tools can be instrumental to develop valuable inventions for which secrets or technical protection measures are not viable solutions ([117]). For example, where pharmaceutical companies use AI tools to research and develop new drugs, in the absence of patent protection, generic companies would generally be able to reverse-engineer and market the same products in a relatively short time, at a fraction of the cost. This in turn could create disincentives for pharmaceutical companies to invest in AI-assisted research, if not research altogether, leading to market failures.

Hence, as long AI-assisted research requires firms to invest, these investments in principle deserve to be protected and incentivized by patent

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([114]) STIERLE, *A de lege ferenda perspective*, cit., 119 ("Inventor's rights, moral rights and inventorship-based employee remuneration are fairness-driven rights or rewards to the human inventor as a person". The author however also stresses the secondary relevance of those rights: "they are just an add-on to the core structure of patent law functions but not a part essential to its operation in general").

([115]) UBERTAZZI, *Invenzione e innovazione*, cit., 23. See also FROMER, *Expressive Incentives*, cit., 1745 ff.; RANTANEN, JACK, *Patents as Credentials*, cit., 311.

([116]) HILTY, HOFFMANN, SCHEUERER, cit., 28.

([117]) ibid. (arguing that "[e]xclusive rights for AI outputs can only be justified once investments are made, when undertakings' chances of recouping them really exist and are at stake, and when these chances actually can be protected by IP rights").

rights ([118]). To the contrary, the prospect that AI tools might one day become capable of generating inventions "autonomously" – i.e., at no costs and risks, with close to no human input – would severely question overall justification of the patent system ([119]).

D. CONCLUSION

This short chapter illustrated the multi-layered structure of the European patent system – where strong national and international systems coexist – and its foundations in legal theory and philosophy. Utilitarian theories were identified as the most common justification for the patent system. In general terms, patents are widely believed to encourage innovation. This is because patents give the inventor the possibility to recoup their R&D investments. In turn deontological theories, grounded on the belief that the inventor has a moral claim on the invention, are significantly less relevant with respect to patent rights. As AI technology advances, it will be important to progressively revaluate how and if the underlying justifications of the patent system – whether deontological or utilitarian ones – still hold up.

([118]) ibid. See also BLOK, cit., 72 (arguing that "[t]he prospect of a patent can induce people to use and develop artificial intelligence applications that create new products and processes").

([119]) See BURK, *AI Patents and the Self-Assembling Machine*, cit., 309. See also § III.B.2.4 below.

III.
THE INVENTION, THE INVENTOR AND AI

This chapter addresses the notions of "invention" and "inventor" under European patent law in order to investigate whether AI-assisted and AI-generated inventions would qualify as "inventions" and who (or what) would be considered their "inventor". To this end, Section III.A looks at the notion of "invention" and discusses its eminently objective nature. Thereafter, Section III.B reviews the notion of "inventor" to address the proposal – advanced by several scholars – that AI systems can and/or should qualify as the inventor (or at least *an* inventor) with respect to AI-assisted and AI-generated inventions. Finally, Section III.C puts forward a concise overview of the decisions that have addressed the AI-inventorship claims made by Dr. Thaler and the Artificial Inventor Project for inventions allegedly developed by the DABUS system.

A. INVENTION

1. The notion of invention

One of the basic tenets of modern patent law is that patents shall be granted for inventions. This is reflected, for instance, in the Paris Convention ([1]), the world's first multilateral treaty on industrial property, the Patent Cooperation Treaty ([2]), the Strasbourg Convention ([3]), the TRIPS Agreement ([4]) and the EPC ([5]). Yet none of these treaties, nor most national patent laws in the

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([1]) E.g., Article 4bis PC ("Patents applied for in […] the Union […] shall be independent of *patents obtained for the same invention* in other countries").

([2]) E.g., Article 1 PCT (the Contracting States "constitute a Union for cooperation in the filing, searching, and examination, of *applications for the protection of inventions*"); See also Article 3 PCT.

([3]) E.g., Article 1 SC ("[i]n the Contracting States, *patents shall be granted for any inventions* which are susceptible of industrial application, which are new and which involve an inventive step").

([4]) E.g., Article 27 TRIPS ("*patents shall be available for any inventions*, whether products or processes, in all fields of technology").

([5]) E.g., Article 52 EPC. See § III.A.1.1 below.

world ([6]), include a positive definition of "invention" ([7]).

According to the *travaux préparatoires*, the EPC provides no definition of "invention" partly because the member states were unable to agree over a common one ([8]), but also as a way "to retain the flexibility necessary for the [patent] system" ([9]). The widespread belief was that defining the concept of "invention" at a precise point in time would risk hampering the "dynamic openness" that patent law should ensure for future and unforeseeable

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([6]) A notable exception is the Japanese Patent Act: Article 2(1) defines an invention as "the highly advanced creation of technical ideas utilizing the laws of nature".

([7]) The dogmatic distinction between the notion of "invention" and that of "inventive step" is relatively modern. In Germany, it was first introduced by scholars in the early twentieth century and then included in the German patent law only further to the adoption of the notion of "inventive step" in the Strasbourg Convention and the EPC. Prior to that, the requirement of "inventiveness" was deemed inherent to the notion of "invention". See NACK, *The "Technical Invention" criterion*, in HAEDICKE, TIMMAM (eds.), *Patent Law, A Handbook on European and German Patent Law*, Beck, Munich, 2014, 69, § 24-25. A similar evolution took place in Italy and in the U.S.: DI CATALDO, *L'originalità dell'invenzione*, Giuffrè, Milan, 1983, 5. See § IV.B.2 below.

For an historical perspective and a comprehensive doctrinal analysis of the "invention" requirement in European patent law see PILA, *The Requirement for an Invention in Patent Law*, Oxford University Press, Oxford, 2010; PRAGER, *Standards of Patentable Invention from 1474 to 1952*, in *University of Chicago Law Review* 1952, vol. 20, No. 1, 69. See also, PILA, *the future of the requirement for an invention: inherent patentability as a pre- and post-patent determinant*, in AREZZO, GHIDINI (eds.), *Biotechnology and Software Patent Law, A Comparative Review of New Developments*, Edward Elgar, Cheltenham, 2011; PILA, *Dispute over the Meaning of "invention" in Art. 52(2) EPC – The Patentability of Computer-Implemented Inventions in Europe*, in IIC 2005, 173; VAVER, *Invention in Patent Law: A review and a Modest Proposal*, in *International Journal of Law and Information Technology*, vol. 11, No. 3, 286. In the Italian literature a seminal work on the notion of invention is: FRANZOSI, *L'invenzione*, Giuffrè, Milan, 1965.

([8]) *Biogen Inc v. Medeva Plc* [1996] UKHL 18 (31 October 1996), § 44. See also EPO, T 154/04, 15 November 2006 (*Estimating sales activity/DUNS LICENSING ASSOCIATES*) (finding that "[t]he application of Article 52(1) EPC presents a problem of construction as there was no legal or commonly accepted definition of the term "invention" at the time of conclusion of the Convention in 1973"). SENA, *I diritti sulle invenzioni*, cit., 122, fn. 83, suggests that the notion of invention is a so-called "typological concept", where the legislator must abandon the interpreter: these are concepts that cannot be defined over a certain measure.

([9]) EPC Preparatory DOC BR/168/72 (15 March 1972) [26], as cited in PILA, *The future of the requirement for an invention*, cit., 68.

developments in science and technology ([10]).

1.1 The EPO approach to the notion of invention

Under the heading "Patentable inventions", Article 52(1) EPC provides that "European patents shall be granted for any *inventions*, in *all fields of technology*, provided that they are *new*, involve an *inventive step* and are *susceptible of industrial application*" (emphasis added). Article 52(2) then includes a non-exhaustive list of subject-matter or activities that *cannot* be considered an "invention", which reads:

> "The following *in particular* shall not be regarded *as inventions* within the meaning of paragraph 1: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information".

Finally, Article 52(3) EPC adds that the patentability of the subject-matter or activities referred to in paragraph 2 is excluded only to the extent to which a European patent application or a European patent relates to those subject-matters or activities "as such".

Article 52 EPC thus apparently distinguishes the notion of "invention" from that of a "patentable invention". In order to be patentable, an invention must be new, inventive and industrially applicable. But first, the EPC wording implies that there must be an "invention" or, more precisely, an invention in a field of technology, i.e., a "technical invention" ([11]).

The term "technical" is the linchpin to understand the notion of invention in European patent law. While the words "in all fields of technology" were introduced in Article 52(1) only with the EPC 2000

([10]) NACK, cit., 67, § 10. See also FRUSCALZO, *Il carattere tecnico dell'invenzione*, Ph.D. Thesis at the University of Parma, 2013, 74-75, https://www.repository.unipr.it/handle/1889/2148; VANZETTI, DI CATALDO, SPOLIDORO, cit., 388 ("il concetto di invenzione non è (e non è mai stato, finora) un *a priori*; è un dato aperto, suscettibile di accogliere al proprio interno realtà diverse"); MAMMAR, cit., 212-213; The expression "developments in science and technology" is derived from Section 1(5) Patents Act 1977.

([11]) EPO, T 154/04, 15 November 2006 (*Estimating sales activity/DUNS LICENSING ASSOCIATES*), OJ EPO 2008, § 5.

revision – to align the provision with Article 27(1) TRIPS – the field of application of patent law has been known as "technology" since the late nineteenth century ([12]). In particular, the EPO has consistently affirmed that the reference to an "invention" in Article 52(1) EPC, together with the list of excluded subject-matter in Article 52(2), implied that an invention as claimed had to fulfil the requirement of "technical character" in order to be patentable ([13]).

For many years the EPO Boards of Appeal have thus interpreted Article 52 EPC as resolving to a *positive requirement* for technical character ([14]). In principle, if a subject-matter has technical character, it is an invention within the meaning of Article 52(1) EPC ([15]). Conversely, the exclusions in Article 52(2) – e.g., mathematical methods and discoveries ([16])

([12]) NACK, cit., 66. See also ASCARELLI, *Teoria della concorrenza e dei beni immateriali*, III ed., Giuffrè, Milan, 540 ff.

([13]) EPO, T 22/85, 5 October 1988, (*Document abstracting and retrieving/IBM*), OJ EPO 1990, 12; EPO, T 154/04, 15 November 2006 (*Estimating sales activity/DUNS LICENSING ASSOCIATES*), cit., § 5; EPO CASE LAW, *Technical character of an invention*, § 1.1, https://new.epo.org/en/legal/case-law/2022/clr_i_a_1_1.html. As reported in STEINBRENER, NÄGERL, *sub Article 52 EPC*, in SINGER, STAUDER, LUGINBÜHL (eds.), *Europäisches Patentübereinkommen*, 9th ed., Carl Heymanns, Munich, 2023, § 9, a number of EPC provisions and rules the imply the technical nature of the invention: (*i)* the examination must be carried out by technically qualified examiners (Articles 18, 19, 33) or members of the Boards of Appeal (Articles 21, 22); (*ii)* the EPO gives technical opinions on European patents for national courts (Article 25); (*iii)* the abstract of the European patent application is used for technical information purposes (Article 85); (*iv)* technically qualified examiners are assigned to Directorates; duties that involve no technical or legal difficulties may be entrusted to employees (Rule 11); (*v)* Rules 27 and 29 on biotechnological inventions mention "technical process", "technical feasibility"; (*vi)* the applicant must indicate the title of the invention as a "technical designation", which "shall exclude all fancy names" (Rule 41(2)(b)), the technical field to which the invention relates (Rule 42(1)(a)) and the prior art (R 42(1)(b)); (*vii)* the technical problem and its solution must result from the disclosure of the invention (R 42(1)(c)); (*viii)* the claims shall define the matter for which protection is sought in terms of technical features (Rule 43(1)); (*ix)* Rules 44 ("technical relationship", "special technical features"), 47 ("technical field of invention", "technical problem") also refer to requirements in the technical field.

([14]) PILA, *The future of the requirement for an invention*, cit., 58.

([15]) ibid.; see also BENTLY ET AL., cit., 479.

([16]) As to the sometimes subtle distinction between an "invention" and a "discovery" see: GIOV. GUGLIELMETTI, *La brevettazione delle scoperte-invenzioni*, in *Riv. dir. ind.*, 1999, I, 97.

claimed "as such" – have been interpreted as referring to subject-matter whose common feature is the lack of technical character ([17]), for instance because it is inherently abstract ([18]).

Under the EPO approach, the question "what is an invention?" essentially turns into "what has technical character?" ([19]). The *Rote Taube* decision issued by the German Bundesgerichtshof ("BGH") in 1969 is often a first line of answer to that question ([20]). There the BGH found that an "invention" requires a "teaching of technical content" ([21]). In turn, a technical teaching was characterized as "a teaching to methodically utilize controllable

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([17]) EPO, T 930/05, 10 November 2006 (*Modellieren eines Prozessnetzwerks/XPERT*).

([18]) EPO, T 258/03, 21 April 2004, (*Auction method/HITACHI*) ("activities falling within the notion of a non-invention "as such" would typically represent purely abstract concepts devoid of any technical implications"); STEINBRENER, NÄGERL, cit., § 9; PILA, *The future of the requirement for an invention*, cit., 59 (reporting that the characterization of the Article 52(2) EPC exclusions as "inherently abstract subject matter" was suggested by Lord Hoffman of the UK House of Lords speaking extra-judicially). See also KUR, DREIER, LUGINBÜHL, cit., 203 (according to whom "[t]he general justification for excluding the subject matter listed […] is the fact that it describes mere mental acts, without involving the use of forces of nature"); MOUFANG, cit., 480 ("one may […] identify a feature which is shared by most of these non-inventions […as] they are connected with human intellectual activities").

However, many authors point out that the list of exclusions in Article 52(2) EPC is heterogenous in nature and it is not possible to derive a single *rationale* out of them: DI CATALDO, *I brevetti per invenzione e per modello di utilità, I disegni e modelli*, *Artt. 2584-2594*, in BUSNELLI (ed.), *Il Codice Civile – Commentario*, 3rd ed., 2012, 106 and 118; SENA, *I diritti sulle invenzioni*, cit., 91; PILA, *The future of the requirement for an invention*, cit., 59-62 (reviewing a broad array of UK case law that challenged a uniform notion of the patentability exclusions under Article 52(2) EPC and point out that that "there is nothing abstract about a literary work, or a sculpture, or a computer program") See also *Aerotel Ltd. v Telco Holdings Ltd & Ors* [2006] EWCA Civ 1371 (27 October 2006), where Jacob LJ held: "[a]n element of the reasoning in the trio [i.e., the EPO decisions mentioned below, in fn. 28] is that the various categories of Art.52(2) must have something in common: that they are all limited to something abstract or intangible. We think this is a mistaken assumption. We have already observed that the categories are disparate with differing policies behind each. There is no reason to suppose there is some common factor (particularly abstractness) linking them".

([19]) Cf. FRUSCALZO, cit., 75-76, fn. 73.

([20]) BGH, 27 March 1969, X ZB 15/67 (*Rote Taube*), in *IIC*, 1970, I, 136; see e.g., in SINGER, STAUDER, *Article 52 EPC*, in SINGER, STAUDER (eds.), *The European patent convention*, 2003, Vol I., § 17.

([21]) BGH, 27 March 1969, X ZB 15/67 (Rote Taube), cit., § 2.

natural forces to achieve a causal, perceivable result" ([22]). The *Rote Taube* definition of "technical teaching" has been cited by the EBA even in recent decisions ([23]). However, since the scientific notion of "natural forces" is all-encompassing and might include the use of human intellect *per se*, the *Rote Taube* definition is often deemed unworkable in practice ([24]).

Nevertheless, looking at the EPO case law provides further insight. In particular, in delivering its opinion in the *G 3/08* (*Programs for computers*) referral, the EBA refused to provide a formal definition of the term "technical", but held that a banal claim directed to a cup with a company logo printed on it would have technical character *per se* ([25]). In another decision, the simple act of "writing with pen and paper" was deemed having technical character ([26]).

In essence, the EPO case law opted for a formalistic understanding of the technical character requirement, one that essentially eliminates the need to examine whether an invention falls outside the scope of Article 52 EPC as long as the patent claims are drafted so to include any physical means or some sort of materiality ([27]). In relation to computer programs and computer-

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([22]) ibid. However, see F. W. ENGEL, *Zum Begriff der technischen Erfindung nach der Rechtsprechung des Bundesgerichtshofes*, in *GRUR*, 1978, 201 (pointing out that the BGH wanted the scope of this formula to be limited to the demarcation and determination of technical inventions in the field of living nature).

([23]) G 2/07, 9 December 2010 (*Broccoli/PLANT BIOSCIENCE*), EPO OJ 2012, 130, § 6.4.2.1 (holding that the *Rote Taube* standard "still holds good today and can be said to be in conformity with the concept of 'invention' within the meaning of the EPC"). G 1/19, 10 March 2021 (*Pedestrian simulation*) § E.I.a ("What is 'technical'").

([24]) NACK, cit., §§ 77-84 (arguing that "[t]he Red Dove formula boils down to nothing more than that a technical invention is the use of any means (natural forces) for any purpose. This definition of the concept of invention, however, contains no limiting function whatsoever").

([25]) EPO, G 3/08, 12 May 2010 (*Programs for computers*), §§ 9.2, 10.6.

([26]) EPO, T 258/03, 21 April 2004 (*Auction method/HITACHI*), § 4.6.

([27]) NACK, cit., 73, § 40. See also AREZZO, *Il requisito del carattere tecnico e la nozione di invenzione brevettabile nella giurisprudenza dell'UEB in materia di invenzioni di software*, in *Studi in memoria di Paola A.E. Frassi*, Giuffrè, Milan, 2010, 11-12; AREZZO, *Tutela brevettuale e autoriale dei programmi per elaboratore: profili e critica di una dicotomia normativa*, Giuffrè, Milan, 2012, 147-152. In turn, this materiality aspect has been interpreted quite broadly: see EPO, T 22/85, 5 October 1988, (Document abstracting and implemented inventions, in particular, this understanding is often referred to as the "any hardware" approach ([28]), meaning that, as long a claim is directed to or implies the use of a piece of hardware, it will generally have technical character ([29]).

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retrieving/IBM) (suggesting that a "physical entity" refers both a material object but also an image, even if that thing was represented by an electrical signal"). More recently, the EBA suggested that while "a direct link with physical reality, based on features that per se are technical and/or non-technical, is in most cases sufficient to establish technicality, it cannot be a necessary condition, if only because the notion of technicality needs to remain open", in EPO, G 1/19, 10 March 2021 (Pedestrian simulation). See also EPO, T 533/09, 11 February 2014 (Schiller Medical/Impulse Train). In the latter case, the invention concerned the modulation of an electrical signal (discharge of a capacitor for the purpose of defibrillation). The Board dissented with the opposition division's decision that held that the invention concerned "a physical phenomenon which is not sufficiently tangible to be considered as being a product (or a process)" and, therefore, did not meet the requirement of an invention and industrial applicability under Articles 52 and 57 EPC. The Board clarified that "the wording of Articles 52 to 57 of the EPC […] in no way binds the notion of patentable invention to any condition as to the necessity the tangible character, in the material sense, that such an invention should have", but then proceeded to recognized that, in the case at stake, the invention was not "abstract" in nature since it concerned a "signal [which] falls well and truly under the definition of 'physical entity'".

([28]) The so-called "any hardware" approach was progressively introduced with a "trio" of decisions: (*i*) EPO, T 931/95, 8 September 2000 (*Controlling pension benefits system/PBS PARTNERSHIP*); (*ii*) T 258/03, 21 April 2004, (*Auction method/HITACHI*), cit.; and (*iii*) EPO, T 424/03, 23 February 2006 (*Clipboard formats I/MICROSOFT*). In *Aerotel Ltd. v Telco Holdings Ltd & Ors* [2006] EWCA Civ 1371 (27 October 2006), Jacob LJ summarized the "any hardware" approach as follows: "[a]sk whether the claim involves the use of or is to a piece of physical hardware, however mundane (whether a computer or a pencil and paper). If yes, Art. 52(2) does not apply".

([29]) It should be pointed out that, strictly speaking, *all* computer programs have technical effect, since at the very least they cause electrical currents to circulate in the computers they are run on. Attempting to reconcile the exclusion of computer programs with this basic truth, the EPO case law has often noted that, in order to be patentable, *computer programs* actually ought to produce a "*further* technical effect", going beyond the "'normal physical interactions between the program (software) and the computer (hardware)" [EPO, G 3/08, 12 May 2010 (*Programs for computers*), § 10.3], e.g. the circulation of electrical currents in the computer [EPO, T 1173/97, 1 July 1998 (*Computer program product/IBM*), § 6.2]. See also EPO GUIDELINES, *Programs for computers*, § G.II.3.6.

However, in practical terms, the requirement for a "further technical effect" has very little impact on patentability considerations (cf. BENTLY ET AL., cit., 505). Indeed, in G 3/08 the EBA found that "a claim in the area of computer programs can avoid exclusions under Articles 52(2)(c) and (3) by explicitly mentioning the use of a computer or a computer-readable storage medium" [EPO, G 3/08, 12 May 2010 (*Programs for computers*), § 10.13].

Finally, it is worth adding that the notion of "invention" and that of "patentable subject-matter" ([30]) are not coextensive. The EPC also pre-empts patent protection for policy reasons other than lack of technicality. In particular, Article 53(1) provides that European patents shall not be granted in respect of "inventions" the commercial exploitation of which would be contrary to *ordre public* or morality ([31]).

1.2 The national approaches to the notion of invention

The notion of "invention" is not uniformly interpreted by EPC member states. For instance, not all member states construe the "invention" (or "technical character") as an independent patentability requirement.

1.2.1 *The Italian approach*

The fact that inventions are technical teachings is a commonly accepted principle by Italian legal scholars ([32]). According to *Di Cataldo* there is a general consensus in the Italian scholarship to define the invention as the original solution to a *technical* problem ([33]). However, Italian case law and

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In other words, as long as a data-storage medium for containing the program is claimed, a claim directed to a computer program would have technical character. See also DRAGONI, *Software Patent Eligibility and Patentability*, cit., 25-26.

([30]) See § II.A.2 above.

([31]) On the intersections of *ordre public* and morality and "AI inventions" see AUSTONI, *Liceità dell'invenzione IA*, in PAINO, DONATI, PERRUCCI (eds.), *Intelligenza artificiale e diritto: una rivoluzione?*, vol. III, *Proprietà intellettuale, società e finanza*, il Mulino, Bologna, 2022, 105. Other *per se* exceptions are provided in Article 53(2) and (3) EPC, covering e.g., plant or animal varieties and methods of treatment of the human body. However, since neither provision uses the term "invention", it is unclear whether that subject-matter could in principle be an invention (i.e., have technical character) or not. The EPO Guidelines suggest an affirmative answer to that question, on the ground that, for instance, "a method claim is not allowable under Art. 53(c) if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy. In that case, whether or not the claim includes or consists of features directed to a technical operation performed on a technical object is legally irrelevant" (EPO GUIDELINES, *Limitations of exception under Art. 53(c)*, § G.II.4.2.1).

([32]) FRUSCALZO, cit., 179.

([33]) DI CATALDO, cit., 104-106 (pointing out that such a wide definition of "invention" is only helpful for descriptive purposes). See also VANZETTI, DI CATALDO, SPOLIDORO, cit., literature have historically refrained from adopting an independent notion of "invention" or "technical character". Instead, they relied, essentially for the same purposes, to the industrial application requirement ([34]). Indeed, further

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387 (noting that this definition of invention finds support in Rule 42(1)(c) EPC according to which the patent description shall "disclose the invention, as claimed, in such terms that the technical problem, even if not expressly stated as such, and its solution can be understood, and state any advantageous effects of the invention with reference to the background art"). Notably, this definition of "invention" comprises the notion of "originality" as well, and is derived from E. LUZZATO, *Trattato generale delle privative industriali*, Rocco, Milan, 1914, vol. I, 174-175. See also FLORIDIA, *Le invenzioni*, in AUTERI ET AL. (eds.), *Diritto industriale, proprietà intellettuale e concorrenza*, 5th ed., Giappichelli, Turin, 2016, 214 ("l'invenzione industriale viene comunemente definita come l'idea di soluzione di un problema tecnico suscettibile di applicazione industriale"); ABRIANI, COTTINO, *I brevetti per invenzione e per modello*, in ABRIANI, COTTINO, RICOLFI (eds.), *Diritto industriale – Trattato di diritto commerciale diretto da G. Cottino*, Cedam, Padua, 2001, 180 ("invenzione industriale come creazione intellettuale consistente nella soluzione originale di un problema tecnico"); MUSSO, *Ditta e insegna, Marchio, Brevetti, Disegni e modelli, Concorrenza*, in DE NOVA (ed.), Commentario *del Codice Civile e codici collegati Scialoja-Branca-Galgano,* Zanichelli, Bologna, 2012 ("soluzione (tecnica) di un problema (tecnico)"). In 1970, Mario Franzosi elaborated a comprehensive definition of invention, at a time where it was not conceptually distinct from that of inventive step: FRANZOSI, *L'invenzione*, cit., 111 ss.; later reprised in FRANZOSI, *Definizione di invenzione brevettabile,* in *Riv. dir. ind.* 2008, I, 19 ("dal punto di vista della qualità, l'invenzione in senso giuridico consiste in una combinazione di precedenti idee tecniche, combinazione resa possibile perché con un atto mentale di intuizione (e non di ragionamento) si scopre la idoneità delle idee ad essere utilmente combinate; dal punto di vista della sostanza, l'invenzione consiste in una scoperta intuitiva, seguita da una combinazione esecutiva").

The Italian case law has broadly adopted the definition of invention as a "solution to a technical problem" since Cass. 24 October 1958, n. 3443, in *Foro it.*, 1958, vol. 81, I, 1799, with comments from BERRI. See, more recently, Cass. 27 July 2021, No. 21565, in *Riv. dir. ind.*, 2021, 6, II, 450; Cass. 10 August 2016, No. 16949, in *Riv. dir. ind.*, 2017, 4-5, II, 553; Cass. 14 October 2009, No. 21835, in *Giur. ann. dir. ind.*, 2009, 248 (the latter even suggesting that the patent is invalid if the technical problem is not identified).

([34]) AMMENDOLA, *La brevettabilità nella convenzione di Monaco*, Giuffrè, Milan, 1981, 80-81 (arguing that the exclusions under Article 52(2) EPC are not inventions as they lack industrial application when they are realized); AREZZO, *Il requisito del carattere tecnico*, cit., 15, fn. 41 (noting that in the Italian literature the assessment of the "technical character" of the invention is often carried out within the framework of the industrial application requirement); FRUSCALZO, cit., 177-178; DI CATALDO, *I brevetti per invenzione*, cit., 104 (suggesting it is the concept of "industrial invention" rather than the "invention" tout court to distinguish patentable and non-patentable subject-matter); SENA, *Industrialità*, in *Volume celebrativo del XXV Anno della "Rivista del diritto industriale". Problemi attuali del diritto industriale*, Giuffrè, Milan, 1977, 1055 ss. (according to whom the industrial to Article 49 c.p.i. – which corresponds to Article 57 EPC ([35]) – the fact that an invention shall be "made or used in any kind of industry" is generally interpreted as implying a certain degree of materiality (either in the patented product or in the means used to carried out the patented method or process) ([36]).

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application requirement is a mere repetition of the concept of invention); ABRIANI, COTTINO, cit., 188; SCHAR, *What Is Technical: A Contribution to the Concept of Technicality in the Light of the European Patent Convention*, in *Journal of World Intellectual Property* 1999, vol. 2, 104 (drawing a broad overview of the notion of "technical character" in the literature of several European countries); FRANZOSI, *L'oggetto del brevetto*, in FRANZOSI, SCUFFI (eds.), *Diritto industriale italiano*, 2014, vol. I, 533-534 (arguing that the exclusions under Article 45(2) c.p.i., which corresponds to Article 52(2) EPC are all lacking the industrial applicability requirement); MUSSO, cit., 633 ("si deve ricordare […] che oggetto del brevetto è tutt'ora l'invenzione industriale, il cui intrinseco carattere tecnico seleziona […] il quid pluris che tramite la tecnologia, l'uomo è riuscito ad apportare come quid novi"); SGROI, *L'invenzione non brevettata*, Giuffrè, Milan, 1961, 143 ("se manca l'attitudine del trovato ad avere una applicazione industriale, non esiste l'invenzione"). See also Court of Milan, 28 August 2018, in *Giur. delle imprese* ("L'invenzione brevettabile va distinta dalla mera scoperta è può essere definita come una creazione intellettuale che si concretizza nella soluzione di un problema tecnico attraverso l'uso di determinati mezzi. L'invenzione è brevettabile in quanto sia atta ad avere un'applicazione pratica industriale, ovvero sia idonea a realizzarsi concretamente 'in cose materiali' o 'con mezzi materiali specifici', requisiti sintetizzabili nella formula della c.d. 'industrialità').

([35]) Article 57 EPC reads "[a]n invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture".

([36]) SENA, *I diritti sulle invenzioni*, cit., 89-93; DI CATALDO, *I brevetti per invenzione*, cit., 112; FRUSCALZO, cit. 181-182, 187. See also BOSSHARD, *I brevetti per invenzione e modello di utilità*, in PEROTTI (ed.), *Proprietà industriale e intellettuale, Manuale teorico-pratico*, Pacini, Pisa, 2021 ("[p]er trovato tecnico […] si deve intendere un insieme di conoscenze tali da portare a un risultato utile in relazione ad un oggetto materiale"); AMMENDOLA, cit., 90 ff.; GIAN. GUGLIELMETTI, cit., 21 ss.; ASCARELLI, cit., 544.

Moreover, Article 2585 ICC, which is still in force, provides a positive list of subject-matter that is considered an invention, with a strong reliance on the industrial nature thereof ("possono costituire oggetto di brevetto le nuove invenzioni atte ad avere un'applicazione industriale, quali un metodo o un processo di lavorazione industriale, una macchina, uno strumento, un utensile o un dispositivo meccanico, un prodotto o un risultato industriale e l'applicazione tecnica di un principio scientifico, purché essa dia immediati risultati industriali. In quest'ultimo caso il brevetto è limitato ai soli risultati indicati dall'inventore"). One of the first patent laws in Italy (legge sulle privative industriali del 30 ottobre 1859, n. 3731) provided that, in Article 6, "non possono costituire argomento di privativa […] le invenzioni o scoperte che non hanno per iscopo la produzione di oggetti materiali".

1.2.2 *The UK approach*

Courts in the UK have, on the one hand, affirmed that the existence of an "invention" is a "fundamental requirement which must be satisfied before a patent can properly be granted" ([37]). On the other hand, in *Biogen v. Medeva*, Lord Hoffmann argued that the definition of "invention" would "almost invariably be academic", whereas "the four conditions in section 1(1)" of the Patent Act 1977 — namely (*i*) patentable-subject matter; (*ii*) novelty; (*iii*) inventive step; and (*iv*) industrial application — "do a great deal more than restrict the class of 'inventions' which may be patented" ([38]). The UK scholarship thus deems that while the question of whether an independent "invention" requirement exists is still open, a disclosure that complies with the requirements in section 1(1) would most likely qualify for the grant of a patent ([39]).

Then again, to assess whether an invention falls within one of the categories of excluded subject matter under section 1(2) – which corresponds to Article 52(2) EPC – the approach adopted in the United Kingdom is to ask whether the invention, viewed as a whole, makes a *technical contribution* to the art ([40]). To understand whether a contribution is technical or not a distinction shall be made between "creations that are abstract, intellectual, mental, undefined […] and those that are concrete, physical, tangible" ([41]). In practical terms, the UK and EPO approaches will hardly lead to different

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More recently, scholars are more inclined to adopt a "technical character" notion of invention: GIOV. GUGLIELMETTI, *L'invenzione di software*, Giuffrè, Milan, 20 ss. and 153-154 (stressing that the Italian notion of materiality/industriality is less precise than the dogmatic definition of invention derived from the German literature); MANSANI, *I brevetti relativi a business methods e a computer implemented inventions*, in GALLI (ed.), *Le nuove frontiere del diritto dei brevetti*, Turin, 2003, 41 ss.

([37]) *Genentech Inc's Patent* [1989] R.P.C. 147 at 261–266.

([38]) *Biogen Inc v. Medeva Plc* [1996] UKHL 18 (31 October 1996).

([39]) BIRSS ET AL., *Terrell on the Law of Patents*, 19th ed., Sweet & Maxwell, London, 2020, § 2-15; BENTLY ET AL., cit., 474; See also, Pila, *The future of the requirement for an invention*, cit., 58-62.

([40]) BENTLY ET AL., cit., 476.

([41]) BENTLY ET AL., cit., 482 (adding that such "physical conception" of technology is interpreted very broadly, to encompass processes and electrical signals).

results ([42]).

1.2.3 *The German approach*

Finally, the German approach to the notion of "invention" is the one most closely aligned to the EPO's "technical character" rule ([43]). The German courts' now interpret the "technical character" as an independent and preliminary patentability requirement and opt for a purely formal examination as to whether the patent claim includes any technical features ([44]).

2. Invention as an objective notion

While the dogmatic discussion on the precise notion of "invention" is not entirely settled, a common understanding emerges. In general terms, courts and scholars tend to agree that inventions consist of subject matter belonging to a field of technology – often implying the presence of physical means or some sort of materiality – as opposed to purely abstract subject matter. Univariably, however, the focus remains on the claimed subject matter, viewed *objectively*, with no particular reference to the inventor.

Yet in the current debate on AI-generated and AI-assisted inventions the question arose as to whether an additional *subjective* element to the notion of invention exists ([45]). The case law and literature do provide hints in that

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([42]) BENTLY ET AL., cit., 491. See also Symbian Ltd v Comptroller General of Patents [2008] EWCA Civ 1066 (08 October 2008), where the Court of Appeal rejected the "any hardware" approach (§§ 49, 51, 59), but also suggested that "as a matter of broad principle, it seems to us that the approaches […] in the great majority of cases in this jurisdiction and in the EPO, are, on a fair analysis, capable of reconciliation. The third stage mandated in *Aerotel*, which we would have thought normally raises the crucial issue, is whether the alleged contribution is excluded by article 52(2), as limited by art 52(3). So far as we can see, there is no reason, at least in principle, why that test should not amount to the same as that identified in *Duns*, namely whether the contribution cannot be characterised as 'technical'".

([43]) FRUSCALZO, cit., 178; NACK, cit., 69 § 22.

([44]) See e.g., BGH, 20 January 2009, X ZB 22/07 (*Steuerungseinrichtung für Untersuchungsmodalitäten – Control Unit for Diagnosis Measures*), in *GRUR Int.*, 2009, 529 (the claim included a generic electronic data processing means which was used to process, store or transmit data and the Court deemed that sufficient to recognize technical character to the invention); BGH, 26 October 2010, X ZR 47/07 (*Wiedergabe topografischer Informationen*); BGH, 24 February 2011, X ZR 121/09 (*Webseitenanzeige*).

([45]) MAAMAR, cit., 212-213.

direction. For instance, in one of the most authoritative commentaries on the EPC, *Stauder* states that "[t]he invention as an intellectual and hence individual achievement is a creation of the inventor, who is always a natural person" ([46]). Along the same lines, in the 1970s, *Volmer* argued that an invention is necessarily the intellectual achievement of a natural person ([47]).

More recently, *Stankovà* suggested that an invention shall be understood as "something owing its existence to a certain kind of human activity or intervention" ([48]). The author cites in support of her thesis that, for instance, in *Tomatoes/State of Israel* the EBA stated that the "essence of invention" is "human intervention in a process in order to bring about a desired result" ([49]) and that renowned authors such as Judge Mellulis have stated that an invention without inventor in not thinkable ([50]).

A similar interpretation of the notion of invention draws immediate comparisons with the notion of a "work" that can be protected by copyright. Human authorship is widely believed to be a pillar of copyright protection ([51]). In the EU, this is also reflected in the positive definition of the

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([46]) STAUDER, *Article 60 EPC*, in SINGER, STAUDER, *The European patent convention, A commentary*, Heymanss, Cologne, 2003, § 7.

([47]) VOLMER, cit., 259. In German literature, see also VAN DER LINDE, *Der künstliche Erfinder – Schutzbedürfnis, Erfinderbegriff und Zuordnungsfragen*, Ph.D. Thesis at the University of Augsburg, 2021, 69 https://opus.bibliothek.uni-augsburg.de/opus4/frontdoor/index/index/docId/92167 (arguing that the possibility of an invention without an inventor would contradict the inventor principle and, therefore, there cannot be an invention without an inventor).

([48]) STANKOVÁ, cit., 11 ff.

([49]) G 1/08, 9 December 2010 (*Tomatoes/STATE OF ISRAEL*).

([50]) MELLULIS, KOCH, *Article 52 EPC*, in BENKARD (ed.), *Europäisches Patentübereinkommen*, Munich 2023, § 50 ("eine Erfindung ohne Erfinder ist nicht denkbar").

([51]) HUGENHOLTZ, QUINTAIS, *Copyright and Artificial Creation: Does EU Copyright Law Protect AI-Assisted Output?*, in *IIC*, 2021, vol. 52, 1212 ("if an AI system is programmed to automatically execute content without the output being conceived or redacted by a person exercising creative choices, there will be no 'work'"). See also RAMALHO, *Will robots rule the (artistic world)? A proposed model for the legal status of creations by artificial intelligence systems*, in *Journal of Internet Law*, 2017, vol. 21(1), 14-16; RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 53; TRAPOVA, *Copyright for AI-generated Works: a Task for the Internal Market?*, in *European L. Rev.*, 2023, 188 (arguing that "the internal market goal, despite its flexibility and broad scope, does not justify originality requirement as the "author's own intellectual creation" in relation to software ([52]), databases ([53]) and, further to the CJEU *Infopaq* decision, to all kinds of works falling within the scope of the Information Society Directive ([54]). Therefore, discussing AI-generated creations most scholars argue that where a human author cannot be identified, there is actually no "work of authorship" and no copyright protection can arise ([55]). Applying the same logic to inventions, Stanková argues that "subject-matter that is not a result of the required human creative intervention is […] excluded […] because there is neither an 'invention' nor subject matter that involves an 'inventive step'" ([56]).

However, this interpretation of the notion of invention is neither supported by the law, nor by the references cited. Although – as discussed below ([57]) – it is incontrovertible that only natural persons can qualify as inventors, this finding cannot be stretched to cast doubts on the fact that the notion of "invention" is purely objective in European patent law ([58]).

To start with, Article 52 EPC and the corresponding national norms do not mention to the inventor. Moreover, the references to the necessary

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opening EU copyright law to purely AI-generated works"). In the U.S. scholarship see: GINSBURG, BUDIARDJO, *Authors and Machines*, in *Berkeley Technology Law Journal* 2019, vol. 34, 446-447; GINSBURG, *People Not Machines: Authorship and What it Means in the Berne Convention*, in *IIC* 2018, 49, 131; GERVAIS, *The machine as author*, in *Iowa Law Review*, vol. 105, 2019, 2053; GRIMMELMANN, *There's No Such Thing as a Computer-Authored Work - And It's a Good Thing, Too*, in *Columbia Journal of Law & the Arts*, 2016, vol. 39(3), 403 ("[c]opyright law doesn't recognize computer programs as authors, and it shouldn't. Some day it might make sense to, but if that day ever comes, copyright will be the least of our concerns").

([52]) Article 1(3) Software Directive.

([53]) Article 3(1) Database Directive. See also Article 6 Term of Protection Directive;

([54]) CJEU, 16 July 2009, C-5/08 (*Infopaq*), § 27. See also CJEU, 1 march 2012, C-604/10 (*Football Dataco*), §§ 37-38 ("the notion of the author's own intellectual creation refers to the criterion of originality. [T]hat criterion of originality is satisfied when […] its author expresses his creative ability in an original manner by making free and creative choices […] and thus stamps his 'personal touch'. By contrast, that criterion is not satisfied when the setting up of the database is dictated by technical considerations, rules or constraints which leave no room for creative freedom).

([55]) See fn 51 above.

([56]) STANKOVÁ, cit., 24.

([57]) See § III.B.1.1 below.

([58]) The same goes for the notion of inventive step, as discussed in § see § IV.B.3 below.

presence of a "human inventor" or "intellectual" capabilities in the above passages are largely circumstantial. For instance, in the EBA decision *Tomatoes/State of Israel* the notion of "human intervention" was derived by the case law that concerns the patentability of "essentially biological processes" and concerns the very specific rules applying to that field (Article 53(1)(b) EPC) and, at the very least, cannot be generalized. Besides, the EPO's official position on the matter is that the "EPC does not contain any provisions which would prevent patenting certain subject-matter based on how or by whom it was generated", including artificial intelligence ([59]).

The reference in *Stauder* is derived from the chapter on Article 60 EPC, concerning the right to the patent, which originally belongs to the inventor, whereas the commentary on Article 56 EPC stresses the need for an "objective interpretation"—although in relation to inventive step ([60]). In turn, while *Haedicke* states that the "prerequisite for every invention *that gives rise to an inventor right* is an intellectual inventive process" ([61]), this definition is perhaps more carefully worded than it might seem at first sight. It can be read so that, lacking an intellectual inventive process, no inventor right (i.e., the right to the patent) arises. However, there might still be an *invention* ([62]).

That said, already in 1900, Josef Kohler, distinguished between the activity of inventing and the concept of invention, which is to be understood *objectively* ([63]). And, more in general, modern patent literature generally

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([59]) EPO, *Comments by the European Patent Office*, *WIPO Conversation On Intellectual Property (IP) Artificial Intelligence (AI)*, Second Session July 7 to 9, 2020, Revised Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/2/GE/20/1 REV.), 2.

([60]) KROHER, *Article 56 EPC*, in SINGER, STAUDER (eds.), *The European patent convention*, 2003, Vol I., § 17, § 7.

([61]) HAEDICKE, *Ownership*, in HAEDICKE, TIMMAM (eds.), *Patent Law, A Handbook on European and German Patent Law*, Beck, Munich, 2014, 244, § 5, emphasis added.

([62]) See further in § III.B below.

([63]) KOHLER, *Handbuch des deutschen Patentrechts in rechtsvergleichender Darstellung*, Bensheimer, Mannheim 1900, 83 ff. (pointing out that "[t]he concept of invention is twofold: the fact of inventing; the result of inventing, the thing invented. The many disputes about the concept of invention are partly due to the confusion of these two sides of the problem, both of which are covered by the concept of invention"; the translation is mine), as cited also in MAAMAR, cit., 213.

rejects any subjective elements in the concept of invention ([64]). A bedrock principle of patent law is that the way that the invention concretely came about is irrelevant both for the existence of an "invention" and the "inventive step" requirement ([65]). Article 52 EPC is thus to be understood as a threshold provision that identifies – both at the EPO and as implemented and interpreted nationally – only the patentable subject-matter.

The notion of invention therefore stands in sharp contrast with that of copyrightable work. AI-assisted and AI-generated inventions shall be regarded as being inventions as long they *objectively* have – in the EPO parlance – technical character, irrespective of any role played by human inventors in their conception, and shall be deemed patentable if they are *objectively* new, inventive and susceptible of industrial application ([66]).

B. INVENTOR

1. The notion of inventor

We now turn to the inventor, who is obviously the other side of the coin of the invention. However, at least until recently, the notion of inventor had received relatively less dogmatic attention than other institutes of patent law, especially in the Italian literature. Inventors tend to come up mostly when issues arise, such as in case of conflicts with the employer, with their co-inventors or usurpations, but not in their general constituent principles. The following paragraphs thus attempt to breakdown the most relevant aspects of this figure.

([64]) LAUBER-RÖNSBERG, HETMANK, *The concept of authorship and inventorship under pressure: Does artificial intelligence shift paradigms?*, in *JIPLP*, 2019, 14(7), 570; BANTERLE, *Ownership of Inventions Created by Artificial Intelligence*, in *AIDA*, 2018, 69; STIERLE, *A De Lege Ferenda Perspective on Artificial Intelligence Systems Designated as Inventors in the European Patent System*, in *GRUR Int.*, 2021, 70(2), 121.

([65]) See further in § III.B.1.3 below.

([66]) And, conversely, a teaching does not have "technical character" merely because it has been "generated" by a technical system such as an AI model: MAAMAR, cit., 213.

1.1 The inventor as a natural person

Neither the EPC nor the Implementing Regulations include a definition of the term "inventor". The figure of the "inventor" is referred to in several provisions. In particular, Article 60(1) EPC provides that "[t]he right to a European patent shall belong to the inventor or his successor in title". The second paragraph of Article 60 EPC adds that "[i]f two or more *persons* have made an invention independently of each other" the right to a European patent belongs to the first "*person*" to file the application. That is known as the "first-to-file" principle. According to Article 62 EPC, the inventor has the right to be mentioned as such in the patent application, which is regarded as a "moral" right ([67]). From a procedural point of view, Article 81 EPC provides that the "application shall designate the inventor". Rule 19 EPC adds that "the designation [of the inventor] shall state the *family name* [and] *given names* […] of the inventor". Read together, all these provisions clearly imply that an inventor is a natural person, since only natural persons have a "family name" and "given names" and can be entitled to "moral" rights ([68]).

The *Travaux Préparatoires* of the EPC show that the possibility of recognizing legal entities as inventors was initially discussed, but then set aside, confirming that only natural persons can be considered inventors ([69]). Likewise, the Boards' case law has described the inventor as the "natural person who has performed the creative act of invention" ([70]). While it is somewhat debated whether there is an autonomous notion of "inventor"

([67]) On the inventor's moral rights see L. C. UBERTAZZI, *Il diritto morale dell'inventore*, in *Studi in onore di Remo Franceschelli sui brevetti di invenzione e sui marchi*, Giuffrè, Milan, 1983, 159; L. C. UBERTAZZI, *Profili soggettivi del brevetto*, Giuffrè, Milan, 1985, 207.

([68]) BALLARDINI, HE, ROOS, *AI-generated content: Authorship and Inventorship in the Age of Artificial Intelligence*, in PIHLAJARINNE, VESALA, HONKKILA (eds.), *Online Distribution of Content in the EU*, Edward Elgar, Cheltenham, 2019, 117.

([69]) See STIERLE, *Artificial Intelligence Designated as Inventor – An Analysis of the Recent EPO Case Law*, in *GRUR Int.*, 2020, 69(9), 924, fn. 87, and references mentioned therein. See also EPO (Receiving Section), 27 January 2020 on EP 18 275 163, Reference RJ/N35111-EP, § 24, fn. 4 and 5.

([70]) J 7/99, 17 May 2000 (*Heavy-duty power/BANDO CHEMICAL*), § 2.

within the EPC system or rather it is a question purely of national law ([71]), there is a consensus on the fact that inventors are necessarily natural persons in European patent law ([72]).

This is generally confirmed also by the Paris Convention ("PC"). Article 4(A)(1) PC states that "[a]ny *person* who has duly filed an application for a patent […] in one of the countries of the Union, or *his* successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority". Article 4-ter PC then provides that "[t]he inventor shall have the right to be mentioned as such in the patent". It is inherent to these provisions that inventors are persons ([73]).

Unsurprisingly, the same goes for EPC member states' national law and case law. For instance, the Italian provisions concerning the "inventor" largely correspond to the EPC provisions mentioned above. According to Article 160(3) c.p.i., the patent application must include the inventor's designation. In turn, Article 185(2)(d) c.p.i. provides that the patent, as granted, must include *first* and *last name* of the inventor ([74]). Art 62 c.p.i. states that the moral right to inventorship may be enforced by the inventor himself and – after his *death* – by his *spouse*, *descendants*, *ascendants* and so forth. These provisions clearly imply that the inventor is a natural person as

([71]) STIERLE, *Artificial Intelligence Designated as Inventor*, cit., 918-919. The main counterargument to the existence of an autonomous notion of inventorship in the EPC is that the EPO is bound by final decisions of the national courts on entitlement to the grant of a European patent (see Article 61 and Rule 20(2) EPC).

([72]) See e.g., MELLULIS, KOCH, *Article 60 EPC*, in BENKARD (ed.), *Europäisches Patentübereinkommen*, Heymanss, Munich, 2023, § 14 (arguing that only a natural person can be considered an inventor); BREMI, STAUDER, *Article 60 EPC*, in SINGER, STAUDER, LUGINBÜHL (eds.), *Europäisches Patentübereinkommen*, 9th ed., Heymanns, Munich, 2023, § 5 (the authors however also point out that the formal insistence on provisions put forward at a time when the possibility of artificial intelligence "as an inventor" was far removed might lead to unjustified remuneration claims by employee-inventors against their employers: see also § III.B.2.2.3(d) below).

([73]) SUMMERFIELD, *Machine-Assisted Inventing*, cit. See also RICKETSON, *The Paris Convention for the Protection of Industrial Property: A Commentary*, 2015, n. 10.35.

([74]) The words "of the inventor" were added for consistency purposes by Article 98(2) of Legislative Decree 13 August 2010, No. 131. In constrast, Article 21 of the Implementing regulations to the c.p.i. apparently does not require the applicant to explicitly designate the inventor in the patent application. However, to give effect to Article 185 c.p.i. the applicant will nevertheless have to provide such information with the application.

well ([75]). Similar provisions – and a shared understanding of inventors are being only natural persons – are found also in UK ([76]) and German patent laws ([77]). Within EPC member states, it would appear that only Cyprus and

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([75]) ASCARELLI, cit., 666-667; L. C. UBERTAZZI, *Profili soggettivi*, cit., 36; BERGIA, *Article 62 c.p.i.*, in VANZETTI (ed.), *Codice della Proprietà Industriale*, Giuffrè, Milan, 2013, 765 (arguing that the conception of an invention can only come from one or more natural persons and that legal persons cannot hold the moral paternity right); BANTERLE, cit., 84; SENA, *Invenzioni brevettabili e intelligenza artificiale*, cit., 157-158 (reluctantly conceding that these provisions require the inventor to be a natural person). In the case law see Court of Milan, 15 May 1997, in *Giur. ann. dir. ind.* 1997, 3887 ("*il fatto costitutivo del diritto morale di paternità* […] *risiede per definizione nell'attività creativa umana, la capacità giuridica di essere soggetto di tale diritto non può essere riconosciute a persone diverse dalla persona fisica*").

([76]) See Section 7 Patents Act 1977; BALLARDINI, HE, ROOS, cit., § 3.2.1.; LUCCHI, *Intelligenza Artificiale, creatività e brevetti: sfide attuali e prospettive pro futuro*, in *DPCE Online*, 2022, vol. 51(1).

([77]) See Sections 6, 37 and 63 PatG (broadly speaking corresponding to Articles 60, 81 and 82 EPC); HAEDICKE, *Ownership*, cit., § 3. See also MAAMAR, cit., 18-19, pointing out that the original right of the inventor on the invention is based, according to the explanatory memorandum to the law, on the "unfolding of the creative personality" (cf. Begründung zu den Gesetzen über den gewerblichen Rechtsschutz vom 5. Mai 1936, in *BLPMZ* 1936, 103).

Until 1936 German patent law recognized the possibility of "company inventions" ("*Betriebserfindungen*"), i.e., inventions that resulted predominantly from the wealth of experience of the company, for which the company was the original holder of the rights and no inventor had to be named. On the concept and history of *Betriebserfindungen*, see WITTE, *Die Betriebserfindung*, in *GRUR*, 1958, 168; UBERTAZZI, *Profili soggettivi*, cit., 5-8; EMMERICH, *Die Auswirkungen künstlicher Intelligenz auf die erfinderische Tätigkeit und das Erfinderprinzip*, LIT, Berlin, 2021, 66 and 133. A few authors have suggested to reintroduce this concept to deal with AI-generated inventions: MEITINGER, *Erfinderlose Erfindungen durch Know-how einer Organisation und Erfinderprinzip: kein Widerspruch*, in *Mitt. der deutschen Patentanwälte*, 2017, 149 (however, proposing to accept legal persons as coinventors); MEITINGER, *Künstliche Intelligenz als Erfinder?*, cit., 49; LAUBER-RÖNSBERG, HETMANK, cit., 571; A. ENGEL, *Can a Patent Be Granted for an AI-Generated Invention?*, cit., 1129, STIERLE, *A de lege ferenda perspective*, cit., 120-121; FRÜH, *Inventorship in the Age of Artificial Intelligence*, in GODT, LAMPING (eds.), *A Critical Mind. MPI Studies on Intellectual Property and Competition Law*, Vol 30, Springer, Berlin-Heidelberg, 2023, 466-467 (highlighting that the protection of employees inventions in one of the major arguments against these proposals). *Contra* see MELLULIS, KOCH, cit., § 14 (arguing that there can be no "company invention" in which a company assumes the position of inventor, since legal persons, as merely imaginary entities, cannot be inventors).

Monaco do not limit inventorship to human beings ([78]), but there is little information available concerning the patent law of these two jurisdictions.

All in all, in a recent study on AI and patent law, even the WIPO recognized that the fact that inventors under patent law are natural persons is probably a "general presumption" ([79]).

1.2 The intellectual contribution to the inventive concept

"Who" is an inventor is thus clear. They are natural persons. "What" qualifies a natural person as an inventor is however a different question. In other words, what does it mean to "invent" something?

This is a question that neither EPO ([80]) nor the UPC ([81]) have jurisdiction on. The entitlement of the right to the grant of patent is a matter of national law of the contracting states ([82]). The EPO is bound to accept final decisions on the matter by national courts ([83]) and, like most patent offices around the world, "shall not verify the accuracy of the designation of the

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([78]) PIHLAJAMAA, *Legal aspects of patenting inventions involving artificial intelligence (AI). Summary of feedback from EPC contracting states* (presentation), 20 February 2019, 4 https://link.epo.org/web/AI_inventorship_summary_of_answers_en.pdf ("CY, MC: law does not restrict inventorship to human beings").

([79]) WIPO, *Background Document on Patents and Emerging Technologies*, SCP/30/5, 2019, 10, www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_5.pdf.

([80]) The negotiation history of the EPC reveals that the contracting parties chose not to include substantive ownership and entitlement requirements in the convention. The negotiators found that it was "impossible to standardize the laws on ownership of inventions for all European States" and that it would have been "equally impossible" for the EPO to determine the applicable law to eventually adjudicate on these issues: see Document BR/144/171, cited in PILA, TORREMANS, *European Intellectual Property Law*, 2nd ed., 2019, 125; see also HUGENHOLTZ ET AL., cit., 99.

([81]) See § II.B.2 fn 35 above.

([82]) See e.g., Articles 63 and 118 c.p.i.

([83]) See Article 61(1) EPC ("[i]f by a final decision it is adjudged that a person other than the applicant is entitled to the grant of the European patent, that person may […] (a) prosecute the European patent application as his own application in place of the applicant; (b) file a new European patent application in respect of the same invention; or (c) request that the European patent application be refused). See also: Article 1 of the Protocol on Jurisdiction and the Recognition of Decisions in respect of the Right to the Grant of a European Patent ("Protocol on Recognition") of 5 October 1973, which reads: "[t]he courts of the Contracting States shall […] have jurisdiction to decide claims, against the applicant, to the right to the grant of a European patent".

inventor" ([84]). Therefore, one must look at the national systems, where entitlement questions often arise, especially in the context of joint inventorship entanglements.

1.2.1 *The Italian approach*

As mentioned above, the Italian scholarship has dedicated little systematic attention to the notion of inventor as such, which is often mentioned only in passing ([85]). Nevertheless, the literature suggests, for instance, that the right of paternity on an invention (moral right) arises as a consequence to the *intellectual activity* that brought to a certain solution to a technical problem ([86]). In turn, the case law distinguishes, for instance, the "inventive activity" from that of providing "purely executive tasks" ([87]). For instance,

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([84]) Rule 19(2) EPC. National patent offices have similar rules: see e.g., Article 119(1) c.p.i. ("[l'UIBM] non verifica l'esattezza della designazione dell'inventore […], né la legittimazione del richiedente, fatte salve le verifiche previste dalla legge o dalle convenzioni internazionali. Dinnanzi l'[UIBM] si presume che il richiedente sia titolare del diritto alla registrazione oppure al brevetto e sia legittimato ad esercitarlo").

([85]) For instance, it is somewhat surprising that the two most common Italian IP textbooks do not discuss the notion of inventor as such, i.e., what makes a person an inventor, but tautologically define the inventor as one has put forward "creative activity" as opposed to financial/executive tasks: see e.g., VANZETTI, DI CATALDO, SPOLIDORO, cit., 425-429; FLORIDIA, cit., 257; SENA, *I diritti*.

([86]) L. C. UBERTAZZI, *Profili soggettivi*, cit., 214, fn. 14, citing SANTINI, *I diritti della personalità nel diritto industriale*, CEDAM, Padova, 1959, 88 ("il fatto costitutivo del diritto di paternità è rappresentato dall'invenzione […] intesa come attività umana che porta alla scoperta di un nuovo trovato"); SGROI, *L'invenzione non brevettata*, cit., 138 ss. *Contra* ASCARELLI, *Teoria della concorrenza e dei beni immateriali*, cit., 303.

([87]) Appeal Court of Milan, 23 December 1977, in *Giur. ann. dir. ind.* 1977, *1025*. Along the same lines Appeal Court of Milan, 23 December 2014, n. 4612, in *DeJure*, confirming the first instance decision in Court of Milan, 25 August 2010, n. 10304, in *DeJure*. See also Court of Milan, 23 July 2009, n. 9945, in *Darts-ip* (recognizing joint inventorship in a case where the parties had signed an agreement to collaborate "to arrive to the patent protection of the innovative subject-matter studied"); Court of Venice, 2 October 2018, n. 1786, in *Darts-IP* (arguing that to be considered a joint inventor it is necessary to provide an original contribution to the realization of the invention, whereas the performance of merely executive tasks is not sufficient"). *Contra* Appeal Court of Milan, 17 December 1971, in *Riv. dir. ind.* 1973, II, 44 (suggesting in the body of the decision that a company can be qualified as an inventor: "la società è […] la presunta autrice dell'invenzione […] qualità perfettamente compatibile con la natura societaria"). The latter however is an isolated decision. L. C.

being the author of the drawings included in the patent specification, as such, is not sufficient to be recognized as the inventor ([88]).

Rovati thus argues that to be considered a joint inventor one shall provide an "original contribution" to the realization of the invention ([89]). Likewise, according to *Ubertazzi*, joint inventors are all those who can be recognized the paternity of "an original idea", or a part thereof ([90]). In a recent decision, the Court of Venice (*Fitt S.p.A.*) affirmed the co-inventorship between the company owner, who had an "intuition" as to the possible solution to a technical problem, and the R&D team, who then "studied the technical solutions to overcome said problem", starting from said intuition ([91]).

1.2.2 *The UK approach*

In the UK the "inventor" is defined as the "actual deviser" of the invention ([92]). In *Yeda*, the House of Lords stated that "the word 'actual' denotes a contrast with a deemed or pretended deviser of the invention; it means […] the *natural person* who 'came up with the inventive concept'" ([93]). Therefore:

UBERTAZZI, *Profili soggettivi*, cit., 7, highlights that the Court's conclusion on company inventorship was a mere *obiter dictum*, which was not necessary to reach a conclusion on the case.

([88]) Court of Turin, 22 March 1972, in *Giur. ann. dir. ind.* 1972, 99 (the sole realization of the patent drawings is not sufficient as evidence of having been the inventor).

([89]) ROVATI, in FRANZOSI, SCUFFI (eds.), *Diritto industriale italiano*, 2014, vol. I, 641; DI CATALDO, *I brevetti per invenzione*, cit., 186-187 ("Tale diritto [di paternità] spetta solo ai componenti del gruppo che abbiano effettivamente partecipato all'attività inventiva, e non anche a coloro che abbiano partecipato alla ricerca con compiti puramente esecutivi").

([90]) L. C. UBERTAZZI, *Profili soggettivi*, cit., 30.

([91]) Court of Venice, 2 October 2018, cit.

([92]) Section 7(3) Patents Act 1977.

([93]) *Yeda Research and Development Company Ltd. v. Rhone-Poulenc Rorer International Holdings Inc et al.* [2007] UKHL 43, 20. Thaler v Comptroller General of Patents Trade Marks And Designs [2021] EWCA Civ 1374 (21 September 2021) at [51] ("the 'actual deviser' is a person and so, by definition in s7(3), is the inventor"). Contribution to the inventive concept was distinguished from a contribution to the claims, since they may include non-patentable integers derived from prior art: *Henry Brothers (Magherafelt) Ltd v Ministry of Defence* [1997] RPC 693, 706; [1999] RPC 442;

> "[d]eciding upon inventorship will […] involve assessing the evidence adduced by the parties as to the nature of the inventive concept and who contributed to it. In some cases this may be quite complex because the inventive concept is a relationship of discontinuity between the claimed invention and the prior art. Inventors themselves will often not know exactly where it lies".

The typical contribution to the inventive concept is solving (or at least doing something to solve) a particular problem ([94]). Improving or perfecting a solution might also contribute to the inventive concept, for instance in cases where the patent incorporates a number of elements, some of which are improvements of an initial breakthrough ([95]).

Even posing the problem to be addressed might suffice, at least in certain cases ([96]). For instance, in *Staeng Limited's Patent*, the Comptroller-General determined the joint-inventorship of two inventors, wherein the first had prompted the second to consider a particular problem in a field in which the latter was not familiar, and the second had come up with the solution ([97]).

Conversely, a purely financial, administrative or abstract contribution to the inventive concept will not suffice for an inventorship claim ([98]).

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and *IDA Ltd & Ors v University of Southampton & Ors* [2004] EWHC 2107 (Pat) (28 July 2004). See also *Markem Corp v Zipher Ltd* [2005] RPC 31 ("invention" means information in the specification rather than the form of the claims); *Stanelco Fibre Optics Ltd's Applications* [2005] R.P.C. 15 at 319, [83]–[84] (arguing that there might be more than one inventive concept, and care must be taken in considering subsidiary claims to determine whether they might imply separate inventive concepts). In general, see also BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 4-12, 94.

([94]) BENTLY ET AL., cit., 626.

([95]) BENTLY ET AL., cit., 626.

([96]) BENTLY ET AL., cit., 626; HERVEY, DRIVER, WOODHOUSE, cit., 276, § 8-077. In the case law, see *Daletech Electronics Limited v Jemella Limited* BL O/501/14 at §26-27 (establishing joint inventorship between those who had spotted the technical problem and those who were then tasked with finding a solution).

([97]) *Staeng Limited's Patent* [1996] RPC, 183.

([98]) SHEMTOV, *A Study on Inventorship in Inventions Involving AI Activity*, Study commissioned by the European Patent Office, 2019, 17.

Likewise, providing "unnecessary detail[s]" ([99]) or "general ideas" ([100]), "making […] prototypes" ([101]) and, more generally, being engaged in purely executive tasks will not count.

1.2.3 *The German approach*

The German approach to inventorship is broadly aligned with the Italian and UK ones. *Haedicke* suggests that the prerequisite for the inventor right to arise is an "intellectual inventive process", whereas "granting of accessories, laboratory space, providing personnel or financial aid do not equate to an inventive process" ([102]). In in the *Steuervorrichtung* decision, the BGH held that the inventor is the person who *finds out* how to solve a specific technical problem with technical means ([103]). In contrast, simply setting a task will not suffice to qualify as an inventor ([104]).

As to joint inventorship, German case law established three

([99]) IDA Ltd & Ors v The University of Southampton & Ors [2006] EWCA Civ 145 (02 March 2006) ("in the context of entitlement to a patent a mere, non-enabling idea, is probably not enough to give the patent for it to solely the devisor. Those who contribute enough information by way of necessary enablement to make the idea patentable would count as "actual devisors", having turned what was "airy-fairy" into that which is practical")

([100]) *Fireworks Fire Protection Limited and Watermist Limited And Mr Andrew James Cooke and Mr Kevin Alan Lesley Musk* (Patent) [2013] UKIntelP o27513 (23 July 2013).

([101]) *IDA vs. Southampton* [2004] EWHC 2107 (Pat), § 45.

([102]) HAEDICKE, cit., § 5. Moreover, the Author stresses that the inventor right is conditioned to the completion of the invention, meaning that "the inventor has clarity over whether or not the technical implementation of his invention effectively leads to the intended technical achievement and no more testing is needed to ascertain this". See also BGH, 10 November 1970, X ZR 54/67 (*Wildverbißverhinderung*). Additionally, the inventor must announce the invention, even verbally. It is only the announcement of the invention that "establishes the requirements for the individualisation and substantiation that are necessary for the establishment of a right" (HAEDICKE, ibid.).

([103]) BGH, 18 May 2010, X ZR 79/07 (*Steuervorrichtung*), § 28. The decision adds two caveats: (*i*) the inventor's right arises irrespective of whether the teaching is protectable or not; and (*ii*) the inventor must also sets out this knowledge in such a way that it can be used as an instruction for technical action.

([104]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, in *GRUR*, 2022, 865. The author however cites in support of his statement a decision where it was suggested that the invention would not be patentable since it merely posed a problem, but did not offer a solution. Whether that directly translates to the notion of inventor is more uncertain. See BGH, 16 June 1998, X ZB 3/97 (*Alpine skiing*).

requirements ([105]). First, the co-inventor must provide an *intellectual collaboration* to the inventive process, whereby simply performing assigned tasks or manual activities (e.g., building test assemblies or prototypes) will not suffice ([106]). Second, the participation to the inventive process must be *causally linked* to the solution of the technical problem ([107]). Third, the co-inventor must make an *independent creative contribution* to the invention. However, according to established case law, that contribution must not be per se *inventive*: otherwise, joint inventorship could not be established in cases when a series of non-inventive contributions lead to a patentable invention ([108]). Inventive step is a property of the invention, not of the inventor ([109]). In a recent decision, the BGH stated that "the co-inventor status shall not be recognised *only* where a contribution *had almost no impact* on the overall success and was therefore insignificant for the claimed solution" ([110]). *Stierle* thus highlights that the standard for co-inventorship is

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([105]) BGH, 5 May 1966, Ia ZR 110/64 (*Spanplatten*); BGH, 20 June 1978, X ZR 49/75 (*Motorkettensäge*).

([106]) HAEDICKE, cit., § 25.

([107]) HAEDICKE, cit., § 32, suggesting that, in German patent law, the simple act of posing a problem cannot qualify as an inventive contribution if the problem must be simply solved "somehow": the problem must have been at least "sketched out": BGH, 5 May 1966, Ia ZR 110/64 (*Spanplatten*). However, German case law also recognizes that the person posing the technical problem can be the sole inventor when the solution already outlined as part of the technical problem is easily solvable using commonly available means: BGH, 10 November 1970, X ZR 54/67 (*Wildbissverhinderung*).

([108]) BGH, 5 May 1966, Ia ZR 110/64 (*Spanplatten*); BGH, 20 June 1978, X ZR 49/75 (*Motorkettensäge*); BGH, 16 September 2003, X ZR 142/01 (*Verkranzungsverfahren*); BGH, 17 May 2011, X ZR 53/08 (*Atemgasdrucksteuerung*); BGH, 18 June 2013, X ZR 103/11 (*Zuerkennung des Miterfinderstatus*); BGH, 22 January 2013, X ZR 70/11 (the last two decisions expressed the principle that a (co)inventor might be a person that creatively contributed to the subject matter of the patent in view of the entire content of the patent application). *Contra* BGH, 17 October 2000, X ZR 223/98 (*Rollenantriebseinheit*), § 8 (suggesting that the contribution of a co-inventor needs to be inventive itself). See also, in the literature, HAEDICKE, cit., § 27; LAUBER-RÖNSBERG, HETMANK, cit., 571; STIERLE, *A De Lege Ferenda Perspective*, cit., 117; A. ENGEL, *Can a Patent Be Granted for an AI-Generated Invention?*, cit., 1128; BALLARDINI, HE, ROOS, cit., § 3.2.1.

([109]) EMMERICH, cit., § 4.VI.4.

([110]) BGH, 18 June 2013, X ZR 103/11 (*Zuerkennung des Miterfinderstatus*), passage translated by KIM, *The Paradox of the DABUS Judgment of the German Federal Patent Court*, in *GRUR International*, 2022, vol. 71(12), 2022, 1164.

generally lower than the standard for inventorship ([111]).

1.2.4 *Other jurisdictions*

Further to a multi-jurisdictional analysis on the figure of the inventor, *Shemtov* concluded that the core principle of inventorship consists in a natural person's "*engagement in the conception phase* [of an invention] that goes beyond the provision of abstract ideas on the one hand, and mere execution of those provided by others on the other hand, while at the same time having such engagement made on an *intelligent and creative level* rather than financial, material or mere administrative level" ([112]). Along the same lines, the 2015 AIPPI resolution on inventorship in multinational inventions concluded that "[a] *person* should be considered a (co-)inventor if they have made an *intellectual contribution to the inventive concept*" ([113]).

([111]) STIERLE, *A De Lege Ferenda Perspective*, cit., 129.

([112]) SHEMTOV, cit., 19. Cf. also 35 U.S.C. § 116(a) providing that "[w]hen an invention is made by *two or more persons* jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of *contribution*, or (3) each did not make a *contribution* to the subject matter of every claim of the patent".

As cited in JONES DAY, *Generative AI-Assisted Patent Inventorship Questions Remain*, June 2023, https://www.jonesday.com/en/insights/2023/06/generative-aiassisted-patent-inventorship-questions-remain, according to U.S. case law, there is "no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor" *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1358 (Fed. Cir. 2004) (citing *Fina Oil Chem. Co. v. Ewen*, 123 F.3d 1466, 1473). "All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998) (quoted by *Plastipak Packaging, Inc. v. Premium Waters, Inc.*, 55 F.4th 1332, 1340 (Fed. Cir. 2022). For detailed examples on what qualifies for inventorship in the U.S., see e.g., GATTARI, *Determining Inventorship for US Patent Applications*, in *Intellectual Property & Technology Law Journal* 2005, 17(5), 16.

([113]) AIPPI, Resolution Question Q244, *Inventorship of Multinational Inventions*, 14 October 2015.

1.3 The recognition principle

To conclude the overview of the notion of "inventor" it is important to stress, once again, that the way that the invention concretely came about is considered irrelevant in European patent law – as well as in most jurisdictions ([114]). Whether the invention is the result of years of research by a team of professors rather that "dumb luck", or even a dream makes no difference ([115]). What matters is the result ([116]).

([114]) See § III.A.2 above. SHEMTOV, cit., 21 (pointing out that this is "trite law"). See also 35 U.S.C. § 103, "Patentability shall not be negated by the manner in which the invention was made". The historical notes to this provision specifically add that "it is immaterial whether [the invention] resulted from long toil and experimentation or from a flash of genius".

([115]) KROHER, cit., § 7; MUSSO, cit., 746 ("L'invenzione può essere anche ottenuta per combinazione fortuita o per pur caso, non necessitando eziologicamente di una volontà causale"); ZOBOLI, cit., 85; LAUBER-RÖNSBERG, HETMANK, cit., 570; BANTERLE, cit., 69; MAAMAR, cit., 212-213; CORNISH, LLEWELYN, APLIN, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 8th ed., Sweet & Maxwell, London, 2013, para. 5-31; ABBOTT, *Everything is obvious*, in B.C.L. Rev. 1079 (1110) (2016); STIERLE, *A De Lege Ferenda Perspective*, cit., 121; DORNIS, *Muddy Waters*, cit., 13 (the author, however, stresses the conflict between the anthropocentric vision of inventor and the progressive dilution of the *de minimis* requirement of human contribution); GRECO, VERCELLONE, *Le invenzioni e i modelli industriali*, UTET, Turin, 1968, 98 ("peraltro, come generalmente e giustamente si ritiene, l'invenzione può anche essere dovuta al caso"); KRAßER, ANN, *Patentrecht*, 8th ed., C. H. Beck, Munich, 2022, § 11(9) (arguing that the question of the "creative character" of the invention does not have direct legal significance). BURK, cit., 307; SEYMORE, *Serendipity*, in *N.C. L. Rev.* 88(185), 2009, http://scholarship.law.unc.edu/nclr/vol88/iss1/6 (suggesting that the invention becomes such at the moment of the serendipitous event, not when it is conceived); SEYMORE, *Atypical inventions*, in *Notre Dame L. Rev.*, 2011, vol. 86, 2057; SAMUELSON, *Allocating Ownership Rights in Computer-Generated Works*, in *U. Pitt. L. Rev*. 1985, vol. 47, 1185, fn 85. In the scientific literature, see GARCIA*, Discovery by Serendipity: a new context for an old riddle*, in *Foundations of Chemistry*, 2009, 11, 33; BAN, *The role of serendipity in drug discovery*, in *Dialogues Clin Neurosci*, 2006, 8(3), 33. In the U.S. case law see e.g., *Radiator Specialty Co. v. Buhot*, 39 F.2d 373, 376 (3d Cir. 1930) ("[i]nvention is not always the offspring of genius; more frequently it is the product of plain hard work; not infrequently it arises from accident or carelessness; occasionally it is a happy thought of an ordinary mind; and there have been instances where it is the result of sheer stupidity"); *Earle v. Sawyer*, 8 F. Cas. 254, 256 (C.C.D. Mass. 1825) (No. 4247) ("It is of no consequence, whether the thing be simple or complicated; whether it be by accident, or by long, laborious thought […] that it is first done [because the] law looks to the fact, and not to the process by which it is accomplished").

([116]) BLOK, *The inventor's new tool: artificial intelligence - how does it fit in the*

In particular, it is an established principle that the intellectual contribution to the inventive concept can consist in the mere recognition of the significance and usefulness of the invention, regardless of the manner in which it was made ([117]). Hereafter, this notion will be referred to as the "recognition principle".

The fact that an invention may be come about by happenstance is not theoretical. Famous cases abound, especially in unpredictable fields such as chemistry and life sciences ([118]). Prior to becoming the blockbuster drug for erectile disfunction par excellence, Viagra (sildenafil) was being researched for cardiovascular diseases ([119]).

Penicillin was discovered by Alexander Fleming in 1928 thanks to a petri dish becoming accidentally contaminated by mould ([120]) as he was on holiday ([121]). Looking at the sample, Fleming noticed that the staphylococcus colonies he growing had started to break down around the mould, later identified as a rare strain of *Penicillium notatum* ([122]).

European patent system?, in *EIPR*, 2017, 39(2), 73. See also PAGENBERG, *The Concept of the "Inventive Step" in the European Patent Convention*, in IIC 1974, 160 ("there is today general agreement that only the result of the invention is important, and judicial decisions do not deny patentability either to accidental or to research based inventions").

([117]) DORNIS, *Muddy Waters*, cit., 13; SUMMERFIELD, *Machine-Assisted Inventing*, cit.; BURK, cit., 307; ABBOTT, *I Think*, cit., 57.

([118]) SEYMORE, *Serendipity*, cit., 187

([119]) OSTERLOH, *The discovery and development of Viagra® (sildenafil citrate)*, in DUNZENDORFER (ed.), *Sildenafil*, Springer, Basel, 1.

([120]) FLEMING, *The Discovery of Penicillin*, in *British Medical Bull.*, 2(1), 1944, 4.

([121]) AMERICAN CHEMICAL SOCIETY, *Discovery and Development of Penicillin* (undated), http://www.acs.org/content/acs/en/education/whatischemistry/landmarks/flemingpenicillin.html.

([122]) AMERICAN CHEMICAL SOCIETY, cit.

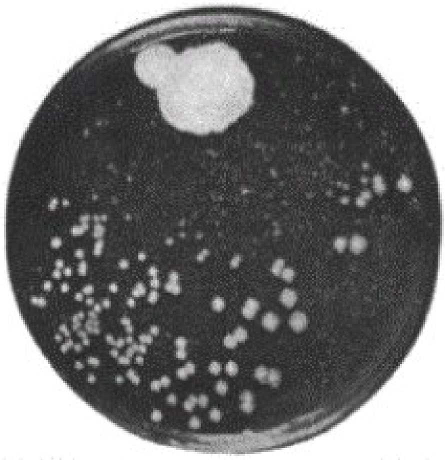

Fig. 16 – The original culture contaminated by penicillin (Source: A. FLEMING)

In neither case the inventors were trying to solve the specific technical problem finally addressed by the invention ([123]). Nevertheless, they were capable to recognize the potential significance and utility of their discoveries, turning them into inventions ([124]). This is more than enough to qualify them as inventors ([125]). Other well-known examples of inventions in which serendipity and intuition played an important role ([126]) include hair-loss drug minoxidil ([127]), antidepressants iproniazid and imipramine ([128]), Nylon ([129]),

([123]) FLEMING, cit., 4. Fleming was working on the variation of staphylococcus colonies but he was "always on the lookout for new bacterial inhibitors" given his previous research background. Upon his own account, that experience allowed him notice the fading of the staphylococcus colonies and pursue the subject further.

([124]) Yet Lemley points out that it took another decade before anyone exploited that idea, and it was not Fleming: LEMLEY, *The myth of the sole inventor*, cit., 742.

([125]) SEYMORE, *Serendipity*, cit., 188.

([126]) For additional examples of accidental inventions see also LEMLEY, *The Myth of the Sole Inventor*, cit., 733-734, and further references therein (including vulcanized rubber, the peacemaker, film); AFSHAR, *Artificial Intelligence and Inventorship - Does the Patent Inventor Have to Be Human?*, in *Hastings Sci. & Tech. L.J.*, 2022, vol. 13, 69 (adding also saccharin).

([127]) BRYAN, *How minoxidil was transformed from an antihypertensive to hair-loss drug*, in *The Pharmaceutical Journal*, 2011.

([128]) LÓPEZ-MUÑOZ ET AL., *Role of serendipity in the discovery of classical antidepressant drugs: Applying operational criteria and patterns of discovery*, in *World J Psychiatry* 2022, 12(4), 588; BAN, cit., 33.

([129]) SEYMORE, *Serendipity*, cit., 189 and fn. 15.

Teflon ([130]), Post-It notes ([131]), SuperGlue ([132]) and toys like Silly Putty ([133]), Play-Doh ([134]) and the Slinky ([135]).

A relatively recent Italian case addressed, and fully endorsed, (co-)inventorship in an happenstance invention. A college student was assigned a research task by her tutor for her thesis. Within her thesis' project, the student also prepared a new "scramble" polypeptide by randomly choosing the amino acids' positions. Surprisingly, the scramble polypeptide allowed the identification of MS antibodies at much higher rates that previously known substances: it was thus apparent that it could have been used to produce diagnostic kits for MS. The student's tutor and other professors from the research lab thus filed a patent application which

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([130]) SEYMORE, *Serendipity*, cit., 188 and fn. 14.

([131]) SANDOMIR, *Spencer Silver, an Inventor of Post-it Notes, Is Dead at 80*, in *New York Times*, 13 May 2021, https://www.nytimes.com/2021/05/13/business/spencer-silver-dead.html. The adhesive was discovered by Spencer Silver at 3M in 1968 while he was looking for a super-strong glue to be used in aircraft construction. A couple years later, 3M filed a patent designating Dr Silver as the inventor: US Patent No. 3,691,140, filed on 9 March 1970, titled "Acrylate copolymer microspheres". The idea of using the microsphere's adhesive on paper came more than 20 years later to another engineer at 3M, Art Fry, while he was attending mass. 3M filed another patent in 1990: U.S. Patent No. 5,194,299, filed on 31 December 1990, titled "Repositionable pressure-sensitive adhesive sheet material".

([132]) LEMELSON MIT, *Harry Coover, Super Glue*, https://lemelson.mit.edu/resources/harry-coover. See U.S. Patent No. 2,768,109 titled "Alcohol-Catalyzed Cyanoacrylate Adhesive Compositions/Superglue".

([133]) There are overlapping "happenstance invention" claims over Silly Putty by Earl Warrick at Dow Corning and James Wright at General Electric. ROBERTS, *A Successful Failure, Silly Putty's serious past*, in *Distillations Magazine*, 3 August 2015, https://sciencehistory.org/stories/magazine/a-successful-failure/. Two patents have thus been filed and granted: U.S. Patent No. 2,431,878, filed on 30 March 1943, titled "Treating dimethyl silicone polymer with boric oxide" (inventors: Rob Roy McGregor and Earl Warrick); U.S. Patent No. 2,541,851, filed on 23 December 1944, titled "Process for making puttylike elastic plastic, siloxane derivative composition containing zinc hydroxide" (inventor: James Wright).

([134]) KINDY, *The Accidental Invention on Play-Doh*, in *Smithsonian Magazine*, 12 November 2019, https://www.smithsonianmag.com/innovation/accidental-invention-play-doh-180973527/. See U.S. Patent No. 3,167,440 filed on 17 May 1960, titled "Plastic modeling composition of a soft, pliable working consistency".

([135]) LALLENSACK, *The Accidental Invention of the Slinky*, in *Smithsonian Magazine*, 29 August 2019, https://www.smithsonianmag.com/innovation/accidental-invention-slinky-180973016/. See U.S. Patent No. 2,415,012, filed on 21 August 1946, titled "Toy and process of use".

encompassed the "lucky" polypeptide, without assigning inventorship to the student. The student filed a lawsuit to be recognized as an inventor. The Appeal Court of Milan, approving the below judgement, held that "the accidental nature of the discovery does not hinder […] that [the invention] might be traced back to [the student] as a joint-inventor, thanks to her research work, her commitment and her knowledge as a graduating student" ([136]).

2. AI and the inventor's designation

As discussed in Chapter I ([137]), the impressive skills demonstrated by AI systems in research and development have led many experts to claim that AI will soon be capable of inventing "autonomously" ([138]). In turn, researchers

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([136]) Appeal Court of Milan, 31 December 2014, n. 4612, in *DeJure*. See also e.g., (*i*) in the German case law: BGH, 19 January 2016, X ZR 141/13 (*Rezeptortyrosinkinase*); (*ii*) in the UK case law: *In Guy Jackson-Ebben v James Nash and Wine Innovations Ltd BL* O/465/14 (the claimant was denied the claim to be substituted or included as an inventor on the grounds that his refinements had improved efficiency of manufacture, but had not comprised any contribution to the inventive concept itself; while his research had helped reveal where the inventive concept lay, the machine had already operated according to the claims of the patent prior to his involvement. The defendant was instead entitled to be designated as the inventor because, while he may not have fully understood how the invention worked prior to the claimant's involvement, had serendipitously arrived at it), cited in COLE, DAVIS, *CIPA Guide to the Patents Acts*, 9th ed., Sweet & Maxwell, London, 2022, § 7.10.

([137]) See § I.C.1 above.

([138]) ABBOTT, *Artificial Intelligence*, cit.; ABBOTT, *I Think*, cit., 1079 ff.; ABBOTT, *Everything is obvious*, in *U.C.L.A. L. Rev.*, 2018, 66(2), 66(1), 4 ("[f]or at least two decades, machines have been autonomously generating patentable inventions"); ABBOTT, *Hal the Inventor: Big Data and its use by Artificial Intelligence*, in SUGIMOTO, EKBIA, MATTIOLI (eds.), *Big Data is Not a Monolith*, MIT Press, Cambridge, 2016, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2565950; ABBOTT, *Inventive Algorithms*, cit., 339 ff. The same argument was also made, inter alia, in: VERTINSKY, RICE, *Thinking about thinking machines: implication of machine inventors for Patent Law*, in *B.U. Sci. & Tech. L.*, 2002, 574; HATTENBACH, GLUCOFT, *Patents In An Era Of Infinite Monkeys and Artificial Intelligence*, in *Stanford Tech. L. Rev.*, 2015, 19, 33; YANISKY-RAVID, LIU, *When Artificial Intelligence Systems Produce Inventions: The 3A Era and an Alternative Model for Patent Law*, in *Card. L. Rev.*, 2018, 39, 2215; VERTINSKY, cit., 489; SCHUSTER, *Artificial Intelligence and Patent Ownership*, in *Wash. Lee L. Rev.*, 2019, 75(4), 1945; MCLAUGHLIN, *Computer-Generated Inventions*, in *J. Pat. & Trad. Off. Soc.*, 2019, 101, 224 (no grant of AI inventions and focus on which activities constitute sufficient inventiveness); DORNIS, *Artificial Intelligence and Innovation*, cit., 12; DORNIS, *Muddy waters*, cit., 572; FABRIS, *From the PHOSITA to the MOSITA: Will "Secondary* and institutions began to question whether AI could or should be recognized as an inventor either now or *de lege ferenda* ([139]).

Based on the conclusions reached on the notion of the inventor, this section discusses the reasons why AI is not and cannot be an inventor on three different levels: (*i*) based on formal requirements; (*ii*) due to substantial legal provisions; and (*iii*) as a matter of fact.

2.1 Formal obstacles

The first obstacle to AI-inventorship is a formal one. While the subsistence of an "invention" is based on objective parameters ([140]), the designation of a natural person as the inventor remains a fundamental formal requirement for patent applications ([141]). Both at the EPO and at the national level the applicant must designate an inventor who is a natural person in the patent application ([142]). Hence, an inanimate object such as an AI system cannot be designated as the inventor.

Focusing on the EPO application process – which is arguably the most relevant one in Europe – if the designation of the inventor is absent or not made in accordance with Article 81 and Rule 19 EPC, the office will refuse

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Considerations" Save Pharmaceutical Patents from Artificial Intelligence?, in *IIC*, 2020, 51, 685; LI, KOAY, *Artificial intelligence and inventorship: an Australian perspective*, in *JIPLP*, 2020, 15(5), 400; AFSHAR, cit., 55; EBRAHIM, *Artificial Intelligence Inventions*, cit., 149 ("I define 'artificial' broadly to mean that inventors use AI-based tools in the inventive process or AI-based tools invent autonomously to produce AI generated output without human intervention"). See also for a comprehensive literature overview: IGLESIAS PORTELA, SHAMUILIA, ANDERBERG, *Intellectual Property and Artificial Intelligence - A literature review*, EUR 30017 EN, Publications Office of the EU, 2021, https://publications.jrc.ec.europa.eu/repository/handle/ JRC119102.

([139]) WIPO, *Conversation on Intellectual Property (IP) and Artificial Intelligence (AI),* Second Session, Revised Issues Paper, WIPO/IP/AI/2/GE/20/1 REV., 21 May 2020, www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_ai_2_ge_20/wipo_ip_ai_2_ ge_20_1_rev.pdf; FIRTH-BUTTERFIELD, CHAE, cit., 9-10; see also PICHT, THOUVENIN, cit., 919-921 (arguing in favour of introducing AI-inventorship); SUN, *Artificial Intelligence Inventions*, in *Florida State University Law Review*, 2022, vol. 50, 61 (also arguing in favour of recognizing AI inventorship).

([140]) LAUBER-RÖNSBERG, HETMANK, cit., 570; BANTERLE, cit., 69.

([141]) HUGENHOLTZ ET AL., cit., 100 (stressing the purely formal nature of the inventorship designation).

([142]) See § III.B.1.1 above.

the European patent application unless the issue is fixed within sixteen months of the filing date ([143]). To be sure, not all patent applications do indicate an inventor. According to Rule 20(1) EPC the inventor can waive the right to be named in the application in writing ([144]). Yet an AI system would not be capable of waiving such right. It follows that, under the current law, the AI system could not be designated as the inventor before the EPO even in case of an allegedly AI-generated invention ([145]).

To the contrary, without changing the law, there is no room for a "dynamic" interpretation of the notion of inventor that might encompass also AI systems ([146]). The patent offices' and courts' reactions to the DABUS designations, which are discussed below, are instructive in this respect ([147]).

To counterbalance these conclusions, *Banterle* suggests that in the unlikely case that the EPO examiner would not notice that a proper inventor's designation is missing in the application – either because the applicant did not indicate one or because an AI system is mentioned – technically that will not be a ground of invalidity of the European patent ([148]). The author correctly points out that list of invalidity grounds is exhaustive and does not include a missing/incorrect inventor designation ([149]). Besides, the inventor designation

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([143]) Rules 90(3), 90(5) and 60(1) EPC.

([144]) See also Rules 143(1)(g) EPC, 144(1)(c) and Article 129(1) EPC.

([145]) STIERLE, *Artificial Intelligence Designated as Inventor*, cit., 920 ("this […] argument of the Receiving Section is utterly convincing").

([146]) LIBERTINI, *I prodotti inventivi dell'intelligenza artificiale*, in PAINO, DONATI, PERRUCCI (eds.), *Intelligenza artificiale e diritto: una rivoluzione?*, vol. III, *Proprietà intellettuale, società e finanza*, il Mulino, Bologna, 2022, 89 (arguing that the inventor's designation is a pure formality and can be overcome by a dynamic interpretation of the notion of inventor). See also SENA, *Invenzioni brevettabili e intelligenza artificiale*, cit., 157 (arguing that when an invention is made "by a computer" the right to the patent belongs to the "research entrepreneur" that can use such tool; however, the Author concludes that, lacking the designation of a human inventor, the patent would rightly be refused under the current law).

([147]) See § III.C below.

([148]) BANTERLE, cit., 86; SENA, *I diritti sulle invenzioni*, cit., 410; SENA, *Invenzioni brevettabili e intelligenza artificiale*, cit., 157.

([149]) Article 138 EPC: "[s]ubject to Article 139, a European patent may be revoked with effect for a Contracting State *only* on the grounds that …", emphasis added.

can be correctly even after the grant further to Rule 21(1) EPC ([150]).

This argument is not entirely convincing. While a missing or incorrect designation, as such, might not determine the patent invalidity, the fact remains that – as discussed below in more detail ([151]) – either a natural person can be identified as the inventor, or the right to the patent on the invention would not arise at all. Therefore, it is possible that the patent could still be revoked in case of a missing/incorrect designation that is not derived from a clerical error, e.g., an alleged AI-inventorship. In Italy, for instance, Article 76(1)(d) c.p.i. provides that the patent is invalid if the patent holder had no right to obtain it and the rightful owner did not make use of the *rei vindication* actions. Article 118(4) c.p.i. adds that after two years from the publication of the patent grant, this ground of invalidity can be raised by any party that has a legitimate interest to it. While the assumption under Article 118(2) and (4) c.p.i. is that *there is* a party who is entitled to the patent application, it is arguable that this rule can also be applied by analogy where the applicant had no right to file the patent application in the first place, because there was actually *no entitled party* at all to do so, lacking a human inventor.

2.2 The human inventor(s) "behind" the AI

Moreover, the identification and designation of a human inventor is not a mere formality ([152]). A human inventor generally can and should be identified by looking "behind" the AI ([153]).

2.2.1 *The person that recognizes the merits of the AI output*

We have seen that a fundamental principle in patent law is that "an invention may be the result of long, laborious effort," but also a brief "spark of genius" or even "sheer luck" ([154]). Hence, even in the hypothetical case of an

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([150]) BANTERLE, cit., 86; SENA, *I diritti sulle invenzioni*, cit., 410. See also, more recently, SENA, *Invenzioni brevettabili e intelligenza artificiale*, cit., 157.

([151]) See § III.B.2.3 below.

([152]) *Contra*, HUGENHOLTZ et al., cit., 145.

([153]) BANTERLE cit., 87 ff.; YANISKY-RAVID, LIU, cit., 2215 ff.

([154]) SHEMTOV, cit., 21. See also § III.B.1.3 above.

AI-generated invention – where a natural person would do nothing more than "pushing a button" and the AI would "spit out" a fully formed invention – the inventor should be, first and foremost, the person who recognizes the importance and utility of the AI output and, if necessary, converts it into a proper technical teaching ([155]).

The act of recognizing the importance and potential value of a "lucky" invention generated by the AI system undoubtedly qualifies as an intellectual contribution to the inventive concept before the EPO and in all major European jurisdictions ([156]). The same principle is established also in U.S. patent law, where the fundamental step in the inventive activity is the "conception", i.e., "formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention" ([157]). For instance, in *Silvestri v. Grant* decision affirmed that "accidental and unappreciated duplication of an invention does not defeat the patent right of one who […] was the first to recognise that which constitutes the inventive subject matter" ([158]).

Within this framework, the fact that AI was used should not affect the identification of an invention and its inventor. There is no legally meaningful difference between recognizing the potential technical merits of an unforeseen molecule depending on whether it was designed by an AI system or, for instance, secreted by an hybridoma ([159]).

([155]) Also recognized by ABBOTT, *I Think*, cit., 1098. *Contra*, DORNIS, *Muddy waters*, cit., 580 (arguing that "a human actor pushing the on/off button [would] not even contribute to the conception of the creative process or its output" and that applying the recognition principle here suggested would be "distortive" and lead the assignment of patent rights to "happenstance and manipulation").

([156]) See § III.B.1.3.

([157]) *Townsend v Smith*, 36 F.2d 292 (C.C.P.A. 1929) at 295.

([158]) *Silvestri v Grant* 496 F.2d 593 (C.C.P.A. 1974); *Invitrogen Corp v Clontech Lab, Inc* 429 F.3d 1052, 1064 (Fed. Cir. 2005). See also BURK, cit., 307;

([159]) BURK, cit., 307; See also SHERMAN, *AI machines as inventors: The role of human agency in patent law*, in FRANKEL ET AL. (eds.), *Improving Intellectual Property. A Global Project*, Edward Elgar, Cheltenham, 2023, 222-223 (drawing a parallelism between chemical inventions as a testament that patent law has been willing to accept that non-human agency, such as that of nature, plays a role in the creations of inventions; and that "[i]nstead of rushing to look for policy solutions to deal with the perceived problems created by AI technologies, Besides, as a matter of fact, recognizing that the AI system stumbled upon a potentially worthy invention might not be as easy as it seems at first sight. For every scientific article on serendipitous inventions, another stresses that the "necessary factors common to these discoveries were creative minds" and the "availability of crucial basic knowledge of many related sciences" ([160]). And even if recognizing the potential subsistence of an invention based on the AI-output were to require no special mental effort on behalf of a person, that does not affect the fact they are an inventor, but is at most a factor in the assessment of inventive step ([161]).

2.2.2 *Other potential inventors or co-inventors*

On top of the person that recognized the AI output as an invention, other natural persons might qualify as inventors or co-inventors when they have made an intellectual contribution to the inventive concept. For instance, the

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it might be more beneficial to pause and consider what is at stake in these debates. A useful starting point might be to acknowledge that what is in issue is how we represent and think about patent law").

([160]) JESTE, GILLIN, WYATT, *Serendipity in Biological Psychiatry—A Myth?*, in *Arch Gen Psychiatry* 1979, 36(11), 1173 (adding that "[i]t is often stated that major biological treatments in psychiatry were discovered by accident or serendipity. […] According to the current usage, [serendipity..] is a discovery in which chance was a necessary and/or sufficient condition. With this definition, none of the discoveries of major biological treatments in psychiatry can be labeled serendipitous. […] We conclude that chance cannot substitute for long-term research and that the latter is the most likely way to lead to valuable discoveries"); HINDER, HARTL, *Translational Medicine – The Bridging Discipline. Role and Tools in the Drug Development Process* in HINDER ET AL., *Principles of Biomedical Sciences and Industry: Translating Ideas into Treatments*, Wiley, Hoboken, 2022, 132-133 ("[a] number of authors have emphasized the importance of the preparedness of mind, attitude, and mindset towards unexpected observations" and, in particular, as to sildenafil, that its discovery was made possible by "the meticulous observation and analysis of clinical trial data to identify populations and diseases which respond to a certain treatment played a key role"). See also LÓPEZ-MUÑOZ ET AL., cit., 588, citing an aphorism that is often attributed to Goethe ("Discovery needs luck, invention, intellect – none can do without the other"), and Pasteur (Dans les champs de l'observation le hasard ne favorise que les esprits préparés. In the field of observation, chance favours only the prepared mind: PASTEUR, *Inaugural Address as newly appointed Professor and Dean (Sep 1854) at the opening of the new Faculté des Sciences at Lille*, 7 Dec. 1854, in VALLERY-RADOT, *The Life of Pasteur*, 1919, 76 (as cited in JESTE, GILLIN, WYATT, cit., *supra*).

([161]) MAAMAR, cit., 254.

2020 AIPPI resolution on inventorship of inventions made using AI suggests that, depending on the circumstances, inventorship (or co-inventorship) could also bestow upon:

(i) A natural person who *uses an AI algorithm* to design a particular type of product or process provided that the resulting invention is of the *type of product or process intended* by the natural person;

(ii) A natural person who *designs an AI algorithm* used in the making of an invention provided that they designed the AI algorithm to solve a *predetermined problem which is effectively solved by the invention* ([162]). Conversely, if the AI algorithm is a generic AI algorithm designed without a specific problem in mind, the natural person who designed the AI algorithm should *not* be considered an inventor ([163]);

(iii) A natural person *who selects data or a data source for training an AI algorithm* provided that the data or data source are *selected with the purpose of solving a predetermined problem which is effectively solved* by the invention;

(iv) A natural person *who selects or generates data or selects a data source for input to a trained AI algorithm* provided that the data or data source are *generated or selected with the purpose of solving a predetermined problem and the invention effectively solves the problem* ([164]).

Furthermore, one might add that even the natural person that *identifies the*

([162]) See also: ABBOTT, *Artificial Intelligence and Intellectual Property: An introduction*, in ABBOTT (ed.), *Research Handbook on Intellectual Property and Artificial Intelligence*, Edward Elgar, Cheltenham, 2022, 11, https://ssrn.com/abstract=4065150.

([163]) SHEMTOV, cit., 30.

([164]) AIPPI, *Inventorship of inventions made using Artificial Intelligence*, Q272-RES-2020, 14 October 2020. In any case, according to AIPPI, with a view of fostering innovation, "inventions made using AI should not be excluded from patent protection *per se* regardless of whether or not there is sufficient contribution by a natural person […] provided that there is a natural or legal person named as an applicant". This position is not necessarily correct. As I discuss below, lacking a human inventor it is arguable that the right to the patent does not arise at all (see § III.B.2.3). Along the same lines, see LIM, LI, *Artificial intelligence and inventorship: patently much ado in the computer program*, in *JIPLP*, 2022, vol. 17(4), 376 (concluding that "[i]nventorship could rest with persons such as the programmer or operator of the AI (and those selecting input or training data) subject to the test for inventive contribution. This would align with most international practice in naming a human inventor while full automation of AI inventions is still a myth").

technical problem to be solved using the AI system, which is *then solved*, might qualify as an inventor ([165]). While merely stating a problem or an abstract goal generally does not qualify as a contribution to the inventive concept, that principle does not apply in cases where the problem itself was unrecognised, even if the claimed solution is, in retrospect, obvious. These are commonly known as "problem inventions" ([166]). Possibly, even simply *formulating* the problem in a way that the machine can understand it – i.e., in mathematical terms – might suffice ([167]).

The examples drawn so far can serve as a general guideline for the appraisal of inventorship of inventions made using AI. In each case, the natural person provided an intellectual contribution to the inventive concept: whether by using AI in to design a *particular* product or process, designing an AI system to solve a *particular* problem, or by selecting *particular* training or input data with a specific purpose in mind, and so forth. The proviso always being that the AI system's output then *actually solves* the *particular problem* the AI designer or trainer had in mind, or the invention is of the *specific type* the user *intended*. In other words, a causal link between the natural person's activity and the invention should be identified. Otherwise, there would be no intellectual contribution to the inventive concept. For instance, a person who develops a general-purpose AI system (e.g., ChatGPT), but is not involved in setting it up and applying it to a particular task, should not be regarded as an inventor of the system's output ([168]).

Furthermore, it must be stressed that in the examples made herein, the invention can be considered be the result (also) of the specific intellectual contribution of those coinventors even when – taken singularly – these activities would be neither considered *per se* inventive or materially sufficient to reach the invention ([169]). For example, the person who selects data

([165]) ABBOTT, *Artificial Intelligence and Intellectual Property: An introduction*, cit., 11.

([166]) See § IV.C.3.1 below.

([167]) ABBOTT, *Artificial Intelligence and Intellectual Property: An introduction*, cit., 11.

([168]) KIM ET AL., *Clarifying assumptions*, cit., 300.

([169]) *Contra*, DORNIS, *Muddy waters*, cit., 582, arguing instead that "the programmer and data trainer does no more than provide the AI application with access to the state of the art". See also, U.S. case law cited in fn specifically for the purpose of training an AI system to solve a predetermined problem, which is then solved, might not be the same person who then recognizes that the AI output is an invention. However, as discussed above, in case of co-inventorship it is generally accepted that, to qualify as a co-inventor, the intellectual contribution to the inventive concept does not need to be fully inventive as such. Simply *contributing* to the inventive concept is enough ([170]).

It follows that, in many cases, AI-generated and AI-assisted inventions will be *joint inventions*, owing their existence to the intellectual contribution of: (*i*) the natural person(s) setting up and using the AI system to solve a specific technical problem, which is then solved; and (*ii*) the natural person(s) recognizing that the AI output actually solves said problem. Potentially patent applications for AI-generated and AI-assisted inventions might need to list dozens of inventors ([171]). However, this is not necessarily the case, both because the full scope of the inventive activity (from setting up the AI system, to recognizing the invention) might be undertaken by a single person and because, at a minimum, there will be one inventor, i.e., the person recognizing (i.e., conceiving the existence of) the invention, even if they have done no prior work towards that goal.

Of course, recognizing (co-)inventorship to natural persons such as the AI users, trainers and developers requires a fact-specific assessment on a case-by-case basis to ascertain whether their activities might qualify as intellectual contributions to the inventive concept. But the potential complexities of a similar assessment in fact, as such, do not undermine the soundness of the principles outlined.

Conversely, neither the people responsible for funding the AI system's development, nor the owners of the machines that run the AI system or those that provide equipment can be considered *per se* inventors of the AI-assisted or AI-generated inventions obtained by using those systems, unless they have

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([170]) See § III.B.1.2 above.

([171]) For instance, the halicin patent application lists five inventors, all except one drawn from list of twenty researchers cited in STOKES ET AL., cit.: see § I.C.3.2.1.

made an intellectual contribution to the inventive concept ([172]). Likewise, persons involved in setting up the AI with purely executive tasks – e.g., cleaning up training or input data upon specific instructions – will not have a credible claim to inventorship.

2.2.3 *Critical aspects*

The interpretation of inventorship that here proposed, which focuses mainly on the acts of "recognition", has been met with a number of critical comments. The most relevant criticisms are discussed here below.

(a) Arbitrary selection of the inventor

First, some scholars suggest that attributing inventorship to a natural person that has recognized the invention made by the AI might result in potentially arbitrary claims ([173]). The underlying idea is that a passer-by that walks through a research laboratory might inadvertently read an AI output and then advance inventorship claims.

It is submitted that this is both an unlikely and irrelevant problem. On the one side, it is quite hard to imagine a real-world example in todays' increasingly sophisticated R&D ecosystem where a mere glance to an AI output by a person that is not involved in a research project would ever suffice to grasp an underlying inventive concept. For once, research laboratories tend to work under confidentiality agreements and at least some form of information management ([174]). On the other side, from a legal standpoint, the fact that an invention is first understood by a person that is not involved in the research project is fundamentally irrelevant, as long as it is that person (or group of persons) to recognize the technical merits of the invention. Such a contribution might even be fundamental (e.g., because nobody else working

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([172]) BLOK, cit., 72; ZOBOLI, cit., 84.

([173]) BANTERLE, cit., 88; ZOBOLI, cit., 85. See also MEITINGER, *Künstliche Intelligenz als Erfinder?*, cit., 50 (arguing that attributing inventorship to the person that recognized the invention would be a "desperate" solution).

([174]) G. SLOWINSKI, HUMMEL, KUMPF, *Protecting Know-How And Trade Secrets In Collaborative R&D Relationships*, in *Research-Technology Management*, 2006, 49:4, 30.

on the project had recognized the invention) and thus fully deserve an (exclusive or joint) inventorship claim.

Dornis raises a similar issue from a different angle. The author argues that "allowing mere recognition of a solution to suffice would be […] distortive" because "any subsequent recognizer of a human-found solution would have to be considered a co-inventor alongside the 'normal inventor'" ([175]). Again this is a theoretical problem. One would need to imagine that a first inventor (or group of inventors), by looking at the AI output, had fully recognized the invention and that a second person (or group of persons) looking at the same output *independently* recognized the same invention. Indeed, the second onlooker could be deemed to have made an intellectual contribution to the inventive concept only if his/her recognition of the invention was not prompted or informed in any way by the first inventor. It is well-known that many inventions appear self-evident in hindsight, once they are explained ([176])—an idea often conveyed as the "egg of Columbus" story ([177]).

Rather, it is submitted that, in this example, the second "recognizer" would actually be an *inventor*, not a co-inventor ([178]). And patent law has known and addressed the possibility of independent identical inventions (in Italian: "*incontri fortuiti*") since immemorable time ([179]). The conflict among

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([175]) DORNIS, *Muddy waters*, cit., 583.

([176]) EPO Guidelines, "*Ex post facto" analysis*, cit., G.VII.8 ("[o]nce a new idea has been formulated, it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps").

([177]) See e.g., the "Egg of Columbus" page on Wikipedia: https://en.wikipedia.org/wiki/Egg_of_Columbus.

([178]) Besides, as mentioned above, in Germany co-inventorship specifically requires collaboration: HEADICKE, *Ownerhisp*, cit., 251, §§ 33-34. In the UK, instead, strictly speaking there is no requirement for the inventors to actively collaborate, but if they do not there are chances that both would qualify as an inventor: BENTLY ET AL., cit., 628-629. A similar liberal attitude is found also in the U.S., where 35 U.S.C. § 116(a), titled "Joint inventions", reads in the relevant part: "[i]nventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent".

([179]) L. C. UBERTAZZI, *Profili soggettivi*, cit., 48 ff.

inventors of identical inventions is solved by first-to-file rules ([180]). The inventor that does not file first will at most benefit from *ad personam* defences such as prior use ([181]).

Besides, one might also wonder whether the fact that a "passer-by" could freely read and apprehend the invention implies that it was made available to the public before the patent application was filed, thereby potentially becoming part of the state of the art and anticipating any future application in terms of lack of novelty.

Finally, *Abbott* suggests that where an AI system can generate solutions and validate its own outputs, for instance by ranking them, then "attributing inventorship to the natural person who says, 'right, let's go with the option the AI like'" only because they recognized the value thereof "does not seem right" ([182]). The same arguments developed above apply, *mutatis mutandis*. In particular, it is hard to perceive a legally meaningful difference between the example suggested by *Abbott* and a "dumb luck" invention. In both cases, one might argue that the inventor did nothing else than being in the right place at the right time (e.g., to notice an unexpected chemical reaction first-hand or to read the "print out" of an AI system). However, the patent system is immune from similar arguments, since the origins of the invention are irrelevant. That said, in a similar case the patent application might face a (lack of) inventive step objection ([183]).

(b) Post-mortem invention paradox

Dornis draws a second criticism to the "recognition" principle suggesting that it would give rise to a "*post-mortem* invention paradox" whereby "an inventive AI application might continue inventing after the death of the programmer or data trainer" and, in turn, this would require "the fiction of a

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([180]) See Article 60(2) EPC: "If two or more persons have made an invention independently of each other, the right to a European patent therefor shall belong to the person whose European patent application has the earliest date of filing, provided that this first application has been published".

([181]) BENTLY ET AL., cit., 629;

([182]) ABBOTT, *Artificial Intelligence and Intellectual Property: An introduction*, cit., 11.

([183]) See § IV.C.3.3 below.

programmer's or developer's complete and perfect 'conception' of all thinkable future inventions that the application would ever make" ([184]). This criticism is based on a conceptual misunderstanding.

A person can be identified as an inventor (or co-inventor) only insofar as they make an intellectual contribution to the inventive concept. That is both a necessary and sufficient condition. Therefore, as discussed above, the development of a general-purpose AI system does not confer *per se* inventorship on the inventions developed by using said system. Conversely, an intellectual contribution can be identified if the person used, developed, selected training or input data for a particular purpose, which is then obtained.

Then, as long as the AI programmer or developer who passed-away made an intellectual contribution to the inventive concept, nothing prevents that the right to the patent is exercised by their successors. Patent laws explicitly provide that the inventor's moral rights survive the death of the inventor and can be enforced by their spouse, descendants and ascendants ([185]). As to the inventor's economic rights – and especially the inventor's right to obtain the patent ([186]) – they would be transmitted following the traditional rules of inheritance to their successors in title.

(c) Recognition vs. verification

A more subtle objection against the "recognition" principle is raised by the Authors who suggested that "[m]erely verifying a prediction of an AI, for example that a compound will be an effective medicament, may not suffice" ([187]). The implication of this argument is that the natural persons verifying the correctness of the AI output are carrying out purely manual or executive tasks, which would not qualify as intellectual contributions to the

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([184]) DORNIS. *Muddy waters*, cit., 582-583. See also MEITINGER, *Künstliche Intelligenz als Erfinder?*, cit., 50.

([185]) See Article 62 c.p.i.

([186]) L. C. UBERTAZZI, *Profili soggettivi*, cit., 43-44 ("l'interesse dell'inventore al cd. rilascio del brevetto non è protetto come un mero interesse legittimo, ma come un diritto soggettivo).

([187]) HERVEY, DRIVER, WOODHOUSE, cit., 277. See also, CAMERON, *Cameron's Canadian Patent and Trade Secrets Law*, 1996-2022, Chapter III, § 3.1.1.2. http://jurisdiction.com/campat.htm.

inventive concept.

The authors rely on two cases to run this argument. The first is *May & Baker Ltd. And Ciba Ltd.*, a 1948 case decided by the High Court of Justice in the UK. There Jenkins J. noted that in the chemical field:

> "an invention may […] be held to *possess subject-matter* provided that the substances produced are not only *new but useful* […] and that their useful qualities must be the inventor's own discovery as opposed to *mere verification by him of previous predictions*" ([188]).

At a closer look, however, this case is incorrectly cited. Keeping in mind that patent law was quite different back then, in that passage the Court was actually discussing the Court's proposed test for establishing patentability, not the figure of the inventor as such. A few paragraphs below the cited passage, the Court reformulated those principles as follows:

> "[t]he invention as claimed […] can be held to possess subject-matter if […] (a) the products of the invention are useful, and (b) the utility of the product can (*having regard to the state* of chemical and chemo-therapeutic knowledge on the relevant date […]) fairly be described as the inventor's own discovery as opposed to a *mere verification* of, or *obvious corollary to, something previously known*" (p. 282).

This passages shows, with greater clarity, that Jenkins J. was actually discussing what modern patent law would call inventive step or non-obviousness ([189]). The parenthetical "*obvious* corollary to" is a direct reference to the state of the art (or "something previously known"). Besides, in *May & Baker* the Court found that the products claimed lacked utility (at least not for the full breadth of the claim) and thus never even got to answer the second part of the question. It follows that *May & Baker* cannot be relied on as a precedent suggesting that the mere verification of AI predictions does not qualify as an invention.

The second is a Canadian case: *Apotex Inc. v. Wellcome Foundation Ltd.* ([190]). In that case, Glaxo/Wellcome had identified a new use for an old

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([188]) *Re May & Baker Ltd. and Ciba Ltd.* (1948), 65 R.P.C. 255, at 281.

([189]) ibid., 288.

([190]) *Apotex Inc. v. Wellcome Foundation Ltd*. (2000) 10 C.P.R. (4th) 65 (F.C.A. per Sexton J.A., Rothstein and Malone JJ.A.). The Court in § 33 cites *May & Baker*, but as compound, azidothymidine ("AZT"). In particular, they conceived the idea that AZT would work in humans against the HIV retrovirus in the mid-80s, a critical time in the AIDS epidemic. Because Glaxo/Wellcome was not equipped to do the necessary testing on AZT, they turned to a number of outside laboratories, including the National Institutes of Health (NIH). At the NIH two scientists performed blind tests on AZT and other compounds (none of which were identified) supplied by Glaxo/Wellcome. Ultimately, the NIH scientists found that AZT did indeed inhibit HIV replication in their in vitro HIV test system and so informed the defendants. A few days later, Glaxo/Wellcome filed the patent application in the United Kingdom from which the Canadian patent claimed priority. Apotex, a generic manufacturer, claimed that the patent at stake was invalid also on the ground that the NIH scientists were not indicated as co-inventors and, therefore, Glaxo/Wellcome had wilfully made a "material" misstatement to the patent office "for the purpose of misleading" it. In rejecting Apotex's claims, the Court of Appeal found that:

> "[w]here a person is directed to engage in a *purely mechanical act for the purpose of testing whether an invention will work*, in circumstances where 'the whole train of ideas put into motion […] were those of others,' […] the person is not to be treated as an inventor".

The Canadian Supreme Court fully confirmed the lower court decision stating that:

> "[i]t is clear that [the NIH scientists] were instrumental in providing crucial evidence on which the "sound prediction" of AZT's utility depended, but they were not responsible for the inventive concept. They carried out their investigation using extraordinary skill and expertise but […] their blind test of a chemical compound whose existence they had not identified, and with which (unlike Glaxo/Wellcome) they apparently had no prior experience, did not require them to be listed as co-inventors".

The principles expressed by *Apotex* in Canada are fully coherent with the notion of inventor outlined above. *Apotex* clearly distinguishes those who

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explained above, it is submitted that said reference is actually misplaced. Similarly see also *IDA v University of Southampton*, cit., §7.08 (according to which the University employees had merely to find out "whether or not [the] idea worked" and "that was a matter of simple and routine experimentation—mere verification". Therefore, they did not qualify as inventors. Their contribution had simply added the common general knowledge in the art).

provided an intellectual contribution to the inventive concept from those asked to only perform certain executive tasks (such as manually verifying that an invention works) ([191]).

However, those facts cannot be superimposed to a case of AI-assisted invention, where an AI system is making "predictions". Indeed, AI, as an inanimate object, is incapable of providing an intellectual contribution to the inventive concept as the researchers at Glaxo/Wellcome did. Instead, it is always the natural person who reviews the AI output (e.g., potential correlations between two molecules) to mentally recognize a potential invention and, only thereafter, verify that the invention actually works. Once again, it is the act of *recognition* that qualifies as an inventive activity, not the *verification* itself. For the same reasons, the researchers that first understood the potential effectiveness of *halicin* would probably qualify as inventors ([192]). Whether those inventions actually deserves patent protection is then a question of (novelty and/or) inventive step ([193]).

(d) Inventor's ancillary rights

Other critical aspects of the "recognition" approach concern the ancillary rights ([194]) that the law bestows upon the inventor, including moral rights and fair compensation rights for employee-inventions ([195]).

As to moral rights the answer is quite straightforward. Many studies have demonstrated how attribution rights provide an important incentive for inventors to invent ([196]). Therefore, as long as a natural person qualifies as an

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([191]) See also *Kellogg Company v. Helen L. Kellogg* [1942] Ex. C.R. 87, 97.

([192]) See § I.C.3.2 above.

([193]) See § IV.C.3.5 below.

([194]) STIERLE, *A de lege ferenda perspective*, cit., 119 (arguing that inventor's rights, moral rights and inventorship-based employee remuneration are "just an add-on to the core structure of the patent law functions, not a part essential to its operation in general").

([195]) See e.g., LUGINBÜHL, *Patent Protection of Inventions Involving Artificial Intelligence*, in BRUUN ET AL. (eds.), *Transition and Coherence in Intellectual Property Law: Essays in Honour of Annette Kur*, CUP, Cambridge, 2021, 197.

([196]) See SHEMTOV, cit., 23 and the literature cited therein, including: FROMER, *Expressive Incentives*, cit., 311; SAUERMANN, COHEN, *What Makes Them Tick? Employee* inventor for an AI-assisted or AI-generated invention, they are also automatically granted the right to be recognized as such (paternity right) and mentioned in the patent application (designation right) ([197]). In this respect, the fact that inventors might have obtained the AI-assisted or AI-generated invention with only minimal effort is irrelevant ([198]). Besides, the scope of the moral rights of the inventor is also minimal. In contrast to the broad moral rights that copyright law bestows upon the author in many *droit d'auteur* jurisdictions, the inventor cannot, for instance, "oppose any deformation, mutilation or other modification, and any act to the detriment of the work itself" ([199]) after they have assigned the economic rights on the invention.

As to employee's rights, it should be recalled that in many European states the economic rights arising from the invention and, in particular, the right to file the respective patent application belong to the employer ([200]).

However, employees-inventors might be entitled to additional compensation. For instance, Article 64(2) c.p.i. provides that an employee who develops an invention under his/her employment agreement, but wherein the inventive activity is *not a specific object* of the agreement and *no specific* remuneration is provided (so-called, in Italian, "*invenzioni d'azienda*" or "company inventions") ([201]) might be entitled to receive an additional compensation from the employer, the so-called "*equo premio*" ("fair

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Motives and Firm Innovation, in *Mgmt. Sci.* 2010, 56; WALSH, NAGAOKA, *Who Invents?: Evidence from the Japan-U.S. Inventor Survey*, Research Inst. of Econ., Trade & Indus., Working Paper No. 09-E-034, 2009, 22; LISSONI, MONTOBBIO, ZIRULIA, *Inventorship and authorship as attribution rights: An enquiry into the economics of scientific credit*, in *Journal of Economic Behavior & Organization*, 2013, vol. 95, 49-69.

([197]) L.C. UBERTAZZI, *Profili soggettivi*, 217 ss., arguing that, for instance, the inventor has no right to demand that the employer files the patent application. The employer is free to decide whether to patent or to use the invention in secret.

([198]) Cf. MEITINGER, *Künstliche Intelligenz als Erfinder?*, cit., 50 (arguing that the AI should then be attributed moral rights).

([199]) Article 20 l.d.a.

([200]) See e.g., ENGLAND, *A practitioner's guide to European Patent Law*, Hart, Oxford, 2022, Chapter 15, 443-447.

([201]) Note that by "company inventions" we are not referring to the German concept of *Betriebserfindungen* discussed above (§ III.B.1.1, fn 77).

compensation") ([202]). The fair compensation due to the employee is calculated *ex post* taking into account (a) the value of the invention, (b) the duties carried out by the employee, (c) the employee's overall wage, and finally (d) the *contribution* that they received *from the employer's organization* in developing the invention ([203]).

([202]) VANZETTI-DI CATALDO-SPOLIDORO, cit., 431 ff.; MANSANI, *Article 64 c.p.i.*, in VANZETTI (ed.), *Codice della proprietà industriale*, Giuffrè, Milan, 2013, 785 ff.; SARACENO, *La disciplina delle invenzioni dei dipendenti*, in GALLI, GAMBINO (eds.), *Codice commentato della proprietà industriale e intellettuale*, UTET, Padua, 2011, 691 ff..

Article 64 IPC provides two additional types of employee-inventions: (*i*) *Service inventions* ("invenzioni di servizio"), as per Article 64(1) c.p.i., namely the inventions reached by the employee in the performance of an employment agreement in which the inventive activity is a *specific object* of the agreement and is consequently *specifically remunerated*. In this case, when the invention is reached, the right to file the patent belongs automatically to the employer. The inventor, which is specifically remunerated *ex ante* for its inventive activity, has no right to a further remuneration. This nonetheless, the inventor has the moral right to be acknowledged as author of the invention; and (*ii*) *Occasional inventions* ("invenzioni occasionali"), as per Article 64(3) c.p.i., namely the inventions reached by the employee that fall within the employer's field of activity, when there is no practical connection between the employee's tasks and the invention. In the latter case, the right to the patent belongs to the employee-inventor, but the employer has a right of pre-emption to purchase the patent or to obtain a license on it.

Leaving aside occasional inventions, which are obviously a rare occurrence, the two main differences between service and company inventions are: (*a*) whether or not the inventive activity is a specific object of the employment agreement; and (*b*) whether or not a specific retribution is provided for the inventive activity. Italian case law is generally strict in the assessment of the employment agreement within the framework of service inventions, rather than that of factory inventions. Indeed, there is a clear tendency to construe the employee/employer relationship within the second hypothesis, as this allows for an additional remuneration of the employee, which takes into account the value of the invention. The cases in which the employee is specifically tasked with, and preventively remunerated for, developing inventions are thus essentially limited to few "pure" research agreements, in which a precise and usually high monetary compensation is provided to the employee, as a professional "inventor". It follows that also service inventions are essentially a marginal hypothesis, whereas factory inventions are the most common case (VANZETTI, DI CATALDO, SPOLIDORO, cit., 436). Notably, German patent law does not include a provision such as "company inventions", in the sense above, and always recognizes a bonus to the employee-inventor: see e.g., BARDEHLE PAGENBERG, *Employee Inventions Law*, http://www.bardehle.com/uploads/ files/Employee_Inventions_en.pdf.

([203]) The most common method used in Italy to determine the fair compensation is the so-called German formula. MANSANI, cit., 791-796. The German formula follows the principles provided by the Guidelines issued in 1959 by the German Ministry of Labour:

It follows that, in case an employee were to invent using an AI system that was developed (or at least paid for) by the employer, that would be a factor to be duly taken into due account in the determination of the fair compensation they might be entitled to. The investment in the AI technology could be considered a material (not intellectual) "contribution" that the inventor received from the employer. Provided that the actual effort of the employee-inventor was minimal as opposed to the investment made by the employer, the employee would be entitled to an equally minimal fair compensation. Furthermore, as regards to the Italian system, the fair compensation rule apply only for "company inventions", but not for "service inventions", where the employee is specifically hired to invent. Therefore, also *de lege ferenda*, there is no room to argue that the employees' fair compensations rights can tip the scale of the arguments towards recognizing inventorship to AI ([204]).

Richtlinien für die Vergütung von Arbeitnehmererfindungen im privaten Dienst, 20 July 1959 (Bundesanzeiger Nr. 169, S. 9994), last updated in March 2006, https://dpma.de/docs/dpma/richtlinienfuerdieverguetungvonarbeitnehmererfindungen.pdf.

The German formula is as follows: C = V * P. Where C is the fair compensation, V is the value of the invention and P is a proportional factor. V corresponds to the economic advantage the employer derives from the exclusive right to benefit from the invention. In simple terms, V corresponds to the hypothetical royalty the employer would need to pay to third parties to implement the invention. If the employer actually licensed or sold the invention, V would correspond to the actual profit made. P is calculated on the basis of three indexes, namely: (*i*) position of the problem, which measures the employee's initiative in identifying the technical problem (with a score of 1 to 6 as the degree of autonomy increases); (*ii*) solution of the problem, which measures the employee's initiative in solving the technical problem (a score of 1 to 6 as the degree of autonomy increases); and (*iii*) tasks performed and position occupied by the employee (an index that gives a score of 1 to 8, as the importance of the position occupied by the inventor employee decreases: the lower the position, the higher the prize). The result is a sum between 3 to 20. A conversion table shall be applied to the sum obtained, where at a factor of 20 the 100% of the value of the invention would be attributed to the employee.

([204]) Perhaps, however, clearer and harmonized rules as to employees inventions across Europe would be preferred: see e.g., STRAUS, *Sulla necessità di un'armonizzazione della normativa delle invenzioni dei dipendenti nell'ambito della comunità economica europea*, in *Dir. comm. e scambi int.*, 1981, 189.

2.3 The absence of a human inventor

Looking at the future, one might imagine cases where it is not possible to identify a natural person that provides an intellectual contribution to the inventive concept. That would be the case, for instance, where: (*i*) a general-purpose AI system is given a general task (e.g., "design a new product"); (*ii*) the AI system generates an output (e.g., a new product idea described in text or image); (*iii*) the AI output is drafted in the form of a patent application (either by the AI system or by a person having absolutely no technical understanding of the subject-matter); and (*iv*) the patent application is then filed before a patent office without any human review ([205]).

2.3.1 *Consequences of the absence of a human inventor*

In turn, the absence of an "inventor" – that is, a human inventor – would have relevant consequences in terms of substantive patent law ([206]). Inventorship is strictly linked to the right to the patent. We saw that, according to Article 60(1) EPC, the right to a European patent belongs to the inventor or their successor in title. The same provision adds that, if the inventor is an employee, the allocation of the right to a European patent is determined by the national law of the State where the employee is mainly employed ([207]).

There are thus essentially three options. The right to the patent might: (*i*) belong to the inventor; (*ii*) belong to a successor in title of the inventor (e.g., further to an assignment or inheritance); or (*iii*) belong to the employer of an employee-inventor, if the national law so provides.

It should be pointed out that, when national courts decide on entitlement of a European patent under the Protocol on Recognition, they must apply Article 60(1) EPC ([208]). Therefore, even if the national law of those countries

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([205]) Cf. the Jurassic experiment discussed in § I.D above.

([206]) Apparently *contra*, HUGENHOLTZ ET AL., cit., 99 (suggesting that the inventor's designation is a pure formality).

([207]) The provision continues by stating "if the State in which the employee is mainly employed cannot be determined, the law to be applied shall be that of the State in which the employer has the place of business to which the employee is attached."

([208]) Article 5 of the Protocol on Recognition ("if the subject-matter of a European patent provided for forms for acquiring the right to the patent that are not posited b Article 60(1) (e.g., usucapion) these rules would not be applicable to European patents ([209]). And, from a formal point of view, Article 81 EPC provides that where the applicant is not the inventor (or the sole inventor) "the designation shall contain a statement indicating the origin of the right to the European patent".

Within this framework, we also saw that when an invention is made in performance an employment agreement, the right to the patent vests directly in the employer in many EPC member states. German patent law is a well-known exception: the right to the patent originally belongs to the inventor and then passes to the employer by operation of law ([210]). In Italy the right to the patent arises directly onto the employer, but there is a longstanding doctrinal debate as to whether that happens originally (*a titolo originario*) ([211]) or rather derivatively (*a titolo derivativo*) ([212]).

In any case, irrespective of whether the right to the patent vests directly in the employer or is transferred thereto (by operation of law or by agreement), the existence of an underlying employment agreement is a

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application is the invention of an employee, the courts of the Contracting State, if any, whose law *determines the right to the European patent pursuant to Article 60, paragraph 1*, second sentence, of the Convention, shall have exclusive jurisdiction over proceedings between the employee and the employer", emphasis added).

([209]) J 8/20, 21 December 2021 (*Designation of inventor/DABUS*), § 4.2.2.

([210]) *ibid*. See §§ 6-9 ArbnErfG (either because the employer expressly claimed the invention or automatically if the employer does not release the invention to the employee within four months from the moment they received the communication that an invention was reached). SHEMTOV, cit., 31. The Author mentions that the same rules apply also to Nordic countries: Norwegian Employees Invention Act 2015, the Danish Consolidate Act on Employees Inventions (2012), the Finish Act on the Right in Employee Inventions (1967, as amended in 2006) and the Swedish Act on the Right to Inventions by Employees (1949).

([211]) MANSANI, cit. ("diritto di brevettare l'invenzione [di servizio e d'azienda] sorge in capo al datore di lavoro a titolo originario ed autonomo"); VERCELLONE, *Le invenzioni dei dipendenti*, Giuffrè, Milan, 75 ff.; DI CATALDO, *I brevetti per invenzione*, cit., 234 ("[i]l diritto al rilascio del brevetto nasce direttamente in capo al datore di lavoro").

([212]) L. C. UBERTAZZI, *Profili soggettivi*, cit., 28 ("l'imprenditore non acquista mai a titolo originario ma sempre a titolo derivativo"); L.C. UBERTAZZI, *L'appartenenza dei risultati creativi dei dipendenti* in *AIDA*, 2010, 516; OPPO, *Creazione ed esclusiva nel diritto industriale*, in *Riv. dir. comm.*, 1969, 9-10 ("[l'acquisto] dipende dal fatto creativo dell'autore e quindi dell'idoneità della creazione a fungere da titolo per l'autore [e] suppone un titolo nei fronti dell'autore").

conditio sine qua non for the right to arise in the first place ([213]).

However, AI systems can neither hold rights, nor be parties to an employment agreement, as they lack legal capacity in all EPC member states ([214]). It follows that, under the current legal framework, where there is no human inventor – and even if AI systems were to be accepted as "inventors" in the first place – there would be neither a subject that can transfer the right to the patent to the employer, nor a legal basis for the original or derivative acquisition of such right by third parties ([215]).

The same conclusions apply to a variety of similar situations – such as university researchers ([216]) or independent contractors ([217]) – regulated in the national laws of the EPC members. Again, there are only two options. The right to the patent can either: (*i*) arise onto the inventor, who can then assign or otherwise transfer said right; or (*ii*) arise directly onto another party (e.g., employer, university, client) based on an *underlying legal relationship* with the inventor. Neither option is applicable to an hypothetical "AI inventor", since AI can neither be originally vested the right to invent, nor it can be a party to a legal relationship. This means that, in principle, where there is no

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([213]) SHEMTOV, cit., 31.

([214]) In 2017, the European parliament issued a resolution the introduction of an "electric personality": EUROPEAN PARLIAMENT, *Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics* (2015/2103(INL)), which invited the Commission to consider "creating a specific legal status for robots in the long run, so that at least the most sophisticated autonomous robots could be established as having the status of electronic persons responsible for making good any damage they may cause, and possibly applying electronic personality to cases where robots make autonomous decisions or otherwise interact with third parties independently". Shortly thereafter, 285 experts in AI and robotics, law and ethics raised strong concerns against the European Parliament's resolution, stressing that the creation of a legal status of an "electronic person" demonstrated a "superficial understanding" of the capacities of AI and was unjustifiable (see *Open Letter on Robotics and AI to the European Commission*, http://www.robotics-openletter.eu/). See also ZOBOLI, cit., 77-78.

([215]) FRANCESCHELLI, *Sull'intelligenza artificiale (IA o AI)*, in *Riv. dir. ind.* (forthcoming), 17. *Contra* REKTORSCHEK, BAUS, *Protectability and Enforceability of AI-Generated Inventions*, in JACOB, SCHINDLER, STRATHAUSEN (eds.), *Liquid Legal, Towards a Common Legal Platform*, Springer, Cham, 2020, 475 (suggesting to attribute legal personality to the AI and then apply the employee-inventions framework).

([216]) Article 65 c.p.i.

([217]) See in general DI CATALDO, *I brevetti per invenzione*, cit., 243 ff.

human inventor, the right to the patent does not arise at all ([218]).

2.3.2 *Accession and property rules are not applicable to AI inventions*

As a final note, it is worth adding that the general civil law rules on property are equally not applicable to the case of an alleged AI inventorship. *Abbott* argues that, based on the common law rules on accession, the invention should be considered a "fruit" of the AI system and therefore belong to the AI system's owner ([219]).

The UK Court of Appeal, on majority opinion, firmly rejected this argument in deciding over DABUS' inventorship claims. The Court held that, on the one hand, an invention is a piece of information, which is not subject to property law and, on the other hand, that the rules on accession, developed in relation to tangible, rivalrous goods that can be materially possessed, such as a cow and its calf, do "not translate to the situation where an intangible – or at least an intangible of the kinds which are the subject-matter of intellectual property law – is produced by tangible property, because such intangibles are non-rivalrous goods" ([220]).

Similar outcomes would be expected also in other jurisdictions ([221]).

([218]) *Contra* STIERLE, *Artificial Intelligence Designated as Inventor*, cit., 920 ff.; STIERLE, *A De Lege Ferenda Perspective*, cit., 115.

([219]) ABBOTT, *Artificial Intelligence and Intellectual Property: An introduction*, cit., 15.

([220]) *Thaler v Comptroller General of Patents Trade Marks And Designs* [2021] EWCA Civ 1374 (21 September 2021).

([221]) In a 2017 communication, the European Commission envisaged the possibility of introducing a "data producer's right", i.e., a "right to use and authorise the use of non-personal data […granted] to the 'data producer', i.e. the owner or long-term user (i.e. the lessee) of [a…] device [that generates data]" (EUROPEAN COMMISSION, *Communication from the Commission to the European Parliament, the Council, the European economic and social committee and the Committee of the regions "Building a European data economy"*, COM(2017) 9 final, 10 January 2017, 13). The accompanying staff working document added that the "data producer's right" could be envisaged as a "right *in rem*", i.e., as a civil property right (EUROPEAN COMMISSION, *Commission Staff Working Document on the free flow of data and emerging issues of the European data economy, Accompanying the document Communication Building a European data economy*, 10 January 2017, SWD(2017) 2 final). A rich and mostly critical literature against the possibility to introduce forms of "data ownership" followed, see: HUGENHOLTZ, *Against 'Data Property'*, in ULLRICH, DRAHOS, GHIDINI, *Kritika: Essays on intellectual property*, vol. 3, Edward Elgar, For instance, in Italy the civil code explicitly defines "natural fruits" as those that originate directly from "things" and exemplifies them as "agricultural products, wood, animal parts, products from mines, quarries and peat bogs" ([222]). Fruits are thus necessarily tangible goods that belong to the proprietor of the "thing" that produces them ([223]).

2.4 De facto arguments against "AI-generated" inventions

Finally, it is submitted that, despite several bold statements in the literature ([224]), *de facto* there is no such thing as "AI-generated" inventions at

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Cheltenham, 2018, 48 ff.; DREXL ET AL., *Data ownership and access to data. Position statement of the Max Planck Institute for Innovation and Competition of 16 August 2016 on the current European debate*, Max Planck Institute for Innovation and Competition Research Paper No. 16-10, 2016, http://www.ip.mpg.de/en/link/positionpaper-data-2016-08-16.html; DREXL, *Data Access and Control in the Era of Connected Devices, Study on Behalf of the European Consumer Organisation BEUC*, 2018, https://www.beuc.eu/reports/data-access-and-control-era-connected-devices, 10-11 and 89-91 (arguing against a full recognition of civil law property in data); BANTERLE, *Data ownership in the data economy: a European dilemma*, in SYNODINOU ET AL. (eds.), *EU Internet Law in the Digital Era*, Springer, Cham, 2020, 213-214; DREXL, *Designing competitive markets for industrial data – between propertisation and access*, in *JIPITEC*, 2017, vol. 8(4), 271. Amongst those in favour of data onwership, see HOEREN, *Big Data and the Ownership in Data: Recent Developments in Europe*, in *EIPR*, 2014, No. 12, 751. The "data producer's right" was then abandoned: see GANGJEE, *The Data Producer's Right: An Instructive Obituary*, in LIM, MORGAN (eds.), *The Cambridge Handbook of Private Law and Artificial Intelligence*, Cambridge University Press, Cambridge, (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4051831. For a recent U.S. proposal on data property as a right *in rem* on data attributed to a person that has control over a copy of the data, and that would *not* imply an intellectual property right on the underlying information, see: GRIMMELMANN, MULLIGAN, *Data Property*, in *American University Law Review*, 2023, vol. 72, 829, https://ssrn.com/abstract=4251825.

([222]) Article 820 Italian Civil Code; See TORRENTE-SCHLESINGER, *Manuale di diritto privato* (ANELLI-GRANELLI eds.), 24th ed., Giuffrè, Milan, 2019, 190. See also VANZETTI, *Diritti reali e "proprietà" industriale (.. E mediazione obbligatoria)*, in *Riv. dir. ind.*, 2010, No. 3, 173 (arguing that in the Italian legal order, which is derived from Roman law, the rules for *in rem* property cannot be applied if not by careful analogy to *industrial* property rights, such as patents and trademarks; among other things, because property law concerns "goods" which are defined as "things" and "things" are tangibles: property as used in the IP code is to be understood as "absolute right" or "exclusive right" but not a "real" *in rem* right); VANZETTI, *Article 1 c.p.i.*, in VANZETTI (ed.), *Codice della proprietà industriale*, Giuffrè, Milan, 2013, 5-8 (raising similar arguments).

([223]) Article 821(1) cod. civ.

([224]) See above § III.B.1 and fn references.

the current state of technology. To the contrary, the growing consensus among scholars is that – for now and in the foreseeable future – AI does not invent "autonomously" but is, at most, a powerful computational tool in the hands of researchers ([225]).

([225]) GURGULA, *AI-assisted inventions in the field of drug discovery: readjusting the inventive step analysis*, in *Int. J. Soc. Sci. Pub. Pol.*, 2020, 2(8), https://doi.org/10.33642/ijsspp.v2n8p2; HILTY, HOFFMANN, SCHEUERER, cit., 7-8; HUGHES, *Is it time to move on from the AI inventor debate?*, in *IPKat*, 2 December 2020, https://ipkitten.blogspot.com/2020/12/is-it-time-to-move-on-from-ai-inventor.html; KIM, *AI-Generated Inventions*, cit., 443; DREXL ET AL., *Artificial Intelligence and Intellectual Property Law, Position Statement of the Max Planck Institute for Innovation and Competition of 9 April 2021 on the Current Debate*, MPI Research Paper No. 21-10, 2021, https://ssrn.com/abstract=3822924; BLOK, cit., 70; SHEMTOV, cit., 22 ("AI systems aimed at autonomously developing useful information […] do not appear to exist at present, nor are they likely to exist in the short to mid-term future"); GALLI, BOGNI, *Intelligenza artificiale, nuove dinamiche della ricerca e problem and solution approach*, in *Dir. ind.*, 2020, 2, 129; HUGENHOLTZ ET AL., cit., 116 ("fully autonomous creation or invention by AI does not exist and will not exist for the foreseeable future"); BURK, cit., 317 ("[a]sserting that AI tools are either inventors or infringers is […] absurd"); KIM ET AL., *Clarifying assumptions*, cit., 23 ff.; STRAUS, *Some lessons from "DABUS" patent applications*, in PENNISI ET AL. (eds.), *Studi di diritto commerciale in onore di Vincenzo di Cataldo*, Giappichelli, Turin, 2021, 630; KIM ET AL., *Artificial Intelligence Systems as Inventors? A Position Statement of 7 September 2021 in view of the evolving case-law worldwide*, MPI Research Paper No. 21-20, 2021, 5-7, https://ssrn.com/abstract=3919588 (arguing that it is not proven that AI systems can invent autonomously as a matter of fact); SUMMERFIELD, *Machine-Assisted Inventing*, cit.; SCHELLEKENS, *Artificial intelligence and the re-imagination of inventive step*, in *JIPITEC* 2022, 13, 91. IRELAND, *The skilled machines disrupting drug design*, in *Intellectual Property Magazine*, October 2018, 34. The same view was shared by most participants to the public consultation held by USPTO, *Public Views on Artificial Intelligence and Intellectual Property Policy*, cit., ii-iii ("the majority […] suggested that current AI could neither invent nor author without human intervention" and that "human beings remain integral to the operation of AI").

Even IBM, which boasts one of the largest portfolio of AI-patents in the world (WIPO, *Technology trends*, cit., 15), recently stated that "although AI has become essential to assisting and enhancing human endeavours and innovations in our everyday lives, we must not get ahead of ourselves. […] [A]utonomously generated AI inventions are […] far into the future" (SCHECTER ET AL., *IBM Letter to WIPO*, 30 June 2020, https://www.wipo.int/export/sites/www/about-ip/en/artificial_intelligence/conversation_ip_ai/pdf/corp_ibm.pdf). In contrast, a representative for Siemens argued that, in relation to a suspension system generated by using an AI system they "lack a natural person as an inventor" although the "AI system […] has created a novel, non-obvious device" (Weibel presenting at *Wipo Conversation on Intellectual Property and Artificial Intelligence* (WIPO/IP/AI/GE/19), 27 September 2019, 1:59 – 2:05, https://webcast.wipo.int/video/WIPO_IP_AI_GE_19_2019-09-27_AM_31245.

Indeed – from a technical point of view – it could be argued that AI would invent so-to-say "autonomously" ([226]) only where a natural person could simply tell the AI system a final goal, without any specific instructions, and the AI system would then deliver a perfected invention ([227]) – similarly to how "text-to-image" models work.

However – and perhaps unfortunately – there is no such thing as a "text-to-drug" model yet ([228]). As discussed above, humans play fundamental roles, including in formulating the problem to be solved by the AI system (e.g., setting the cost or fitness functions), picking and refining the model's architecture and the training algorithms, selecting the training and/or input data, training the algorithm, and/or assessing the outputs ([229]). More in general, in most cases ML models require special-purpose adjustments to be used in R&D , and cannot work "off the shelf" ([230]). Based on these findings, the MPI recently concluded that:

> "[a]s long as a human conceives the overall computational process and specifies instructions as to how it should be carried out, *computers are tools assisting human inventors*. Such assistance cannot be deemed more material for the allocation of inventor's rights to a human than in situations where other research tools or techniques are applied in the process of developing an invention" ([231]).

Along the same lines, *Kim et al.* added ([232]):

> "[a]ll tools are considered to share one attribute – they require human guidance. As long as AI systems are not self-organising systems capable of performing automated tasks without pre-programmed instructions or disobeying such instructions, they are, *technically*, *tools*".

This work therefore adopts the position that AI is simply a *computational tool*

([226]) On the subtle distinction between automation and autonomy, see: KIM, *AI-generated inventions*, cit., 446-447.

([227]) DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 23.

([228]) Although ChatGPT is starting to be used as a tool in drug discovery tasks, mainly as an interface to other AI systems (e.g., for data summaries and natural language explanations): SAVAGE, *Drug discovery companies are customizing ChatGPT: here's how*, in *Nat Biotechnol*. 2023, 41(5), 585-586.

([229]) See § I.B.4.1.2I.B.4.1.1 above.

([230]) KIM, *Clarifying assumptions*, 298.

([231]) DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 24.

([232]) KIM ET AL., *Clarifying assumptions*, cit., 319.

in the hands of researchers, which can "expedite and optimize the inventing process" ([233]), following human instructions. Therefore, going forward, the preferred term to refer to inventions made by using AI systems is "AI-assisted inventions", as opposed to "AI-generated inventions". Indeed, while not all AI systems are the same and the respective contributions of humans and AI vary widely on a spectrum ([234]), the expression "AI-assisted inventions" is flexible enough to accommodate different use cases.

Notably, finding that AI is *a tool* is not meant to undervalue the great advances in the AI field that we have witnessed in recent times or that may come in the near future. While many researchers doubt that we are anywhere near to AGI now, there is considerably less scepticism as to the possibility that AGI is reached in 50 years ([235]). However, it is submitted that if AI was truly capable of inventing autonomously, thus essentially "assuring technical success without risk", that should be "cause for celebration" for humankind ([236]) and at the same time prompt to reconsider not only the fundamental rules of patent law ([237]), but perhaps the need for the patent system altogether ([238]).

Indeed, as discussed above, the most accredited policy justification for patents' exclusivity is the utilitarian incentives theory and, more particularly, the investment protection approach ([239]). If and when generating inventions would import basically no investment on behalf of the inventor, the rationale for patent protection would seem to be lost.

Of course, before rushing to suggest the abolition patent system, a few isolated instances of AI-generated inventions would not be compelling.

([233]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 134. See also BLOK, cit., 70; BURK, cit., 310-311; GURGULA, cit., 14; DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 23-24.

([234]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., § 2.2.

([235]) See § I.B.2 above.

([236]) BURK, cit., 7.

([237]) GALLI, BOGNI, *Intelligenza artificiale*, cit., 130; P. SLOWINSKI, cit., 265. LUGINBÜHL, cit., 197 (suggesting to abolish for the inventive step requirement).

([238]) KIM ET AL., *Clarifying assumptions*, cit., 298; KIM ET AL., *Artificial Intelligence Systems as Inventors?*, cit., 11; see also HILTY, HOFFMANN, SCHEUERER, cit., 28.

([239]) See § II.C.2 above.

Strictly speaking, the possibility that AI would invent "autonomously" – from a technical point of view – does not affect the findings on the figure of the "inventor". As discussed at length in the previous section, even in case of a truly AI-generated invention, the natural person that recognizes its technical merits would probably qualify as an inventor for having made an intellectual contribution to the inventive concept. The serendipity (or "dumb luck") doctrine would apply.

However, if evidence of a widespread, cross-sectorial and fundamentally complete reliance on AI systems to invent were to emerge, so that the majority of inventions would not reflect meaningful investments on behalf of the applicants, that might suggest that the patent system ran its course. For industries where considerable investments are nevertheless expected *after* the invention ([240]) – typically in the pharmaceutical field, where the bulk of the costs are the preclinical and clinical trials – other mechanisms, such as *ad hoc* regulatory protections ([241]), might fill in the gap

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([240]) LEMLEY, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, in *U. Chicago L. Review*, vol. 71, 2004.

([241]) Pharmaceutical products are already beneficiaries of regulatory protection mechanisms: the so-called "data" and "marketing exclusivity" periods. In particular, Art. 10 of Directive 2001/83/EC (as amended in 2004), introduced additional layers of protection for pharmaceutical products that are independent from patent law, securing the results of pre-clinical tests and clinical trials conducted by originator companies and reserving the market for a minimum period. Because generic companies are allowed to lodge an abridged application for a marketing authorisation ("MA"), relying entirely on the regulatory dossier of the innovator, the European legislator established an appropriate timeframe for it to be possible, and to reward innovators at once. The current system is usually referred as the "8+2+1" formula, meaning that: (*i*) for eight (8) years from the date of the first MA a generic company cannot use (cross-refer) to the registration dossier of the originator product; this essentially means that the generic company cannot file an application for MA during this period (data exclusivity); (*ii*) thereafter, abridged applications can be made, but the generic product cannot be placed on the market for two additional years (8 + 2) (marketing exclusivity); (*iii*) the marketing exclusivity period can be extended for an extra year, to a maximum of 11 years (8 + 2 + 1) if, during the first 8 years, the holder of the MA obtains further authorisation for one or more new therapeutic indications. On the regulatory protection mechanisms see ERASMUS, *Abridged procedure*, in SHORTHOSE (ed.), *Guide to EU and UK Pharmaceutical Regulatory Law*, 8th ed., Wolters Kluwer, Alphen aan der Rijn, 2023, 469; KIM, *Access to non-summary clinical trial data for research purposes under EU law*, Springer, Cham, 2021, 96.

to prevent market failures ([242]). However, the majority of scholars suggest that this is a wildly premature discussion at this stage ([243]).

For the same reasons, it is arguable that the *de lege ferenda* proposals to introduce an AI-inventorship – either declaring machines as inventors ([244]), or introduction as a sort of "company" inventorship ([245]) – are fundamentally misguided. As long as there is a natural person that provides an intellectual contribution to the inventive concept – if only in the "recognition" phase – there is no need to introduce any type of AI-inventorship. Hence, the only place for AI-inventorship would be a case where the causal chain between human "efforts" and the invention is completely broken. However, when and if inventing becomes as easy as "pushing a button" – implying essentially *no* mental or organizational efforts and investments on behalf of the inventor – there is in principle no (deontological or utilitarian) justification for attributing a 20-year exclusive monopoly period to inventors. Until then, the patent system can most likely take on the challenge, and the role of weeding out undeserving patents can be fulfilled by the patentability requirement and, in particular, by inventive step ([246]).

C. THE DABUS CASES

The decisions issued by patent offices and courts around the world on the DABUS patent applications confirm, almost unanimously, the arguments

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([242]) P. SLOWINSKI, cit., 265. Similarly, also LEMLEY, *Expecting the Unexpected*, in *Notre Dame L. Rev.*, 2017, vol. 92, 1392 (arguing that regulatory exclusivity could provide a better incentive than patent law for developing predictable but unexpected results, that would otherwise be unpatentable according to the author).

([243]) HUGENHOLTZ ET AL., cit., 111 (arguing that widespread diffusion of AI tools in the inventive process capable of affecting the inventive step analysis is "a mere dot on the distant horizon policy radar").

([244]) PICHT, THOUVENIN, cit., 922-923.

([245]) See further in § III.B.1.2.3, fn 77, the discussion about the old German notion of company inventions (*Betriebserfindungen*). In the U.S. scholarship, discussing the possibility to introduce an "invention-for-hire" doctrine whereby inventorship is bestowed upon corporations that control inventive AI systems, see CROUCH, *Legal fictions and the corporation as an inventive artificial intelligence*, in ABBOTT (ed.), *Research Handbook on Intellectual Property and Artificial Intelligence*, Edward Elgar, Cheltenham, 2022, 370 ff.

([246]) See IV.C below.

developed up to this point ([247]). To conclude on the matter of "AI inventorship" it is therefore helpful to provide an overview of these judgements.

1. The DABUS European patent applications

1.1 The Receiving Section decision

In filing the European patent applications ([248]), Thaler had declared that the two alleged inventions had been generated by DABUS, which would have "identified the novelty of its own idea before a natural person did" ([249]). Thaler also argued that he had acquired the right to the European patent as the "employer" of the AI system or as its "successor in title" ([250]). In January 2020, the Receiving Section of the EPO refused both the DABUS European patent applications on two grounds ([251]).

First, the Receiving Section found that the inventor's designation proposed by Thaler did not meet the requirements of Article 81 and Rule 19 EPC since an inventor within the meaning of the EPC must be a natural person. The Receiving Section derived this principle from a variety of sources, including the *travaux préparatoires* ([252]) and the fact that AI systems cannot hold the rights granted to the inventor as they lack legal personality ([253]). Moreover, the Receiving Section pointed out that: (*i*) the understanding of the inventor as a natural person is an internationally applicable standard; (*ii*) the laws of some EPC member states explicitly provide that the designated inventor must be a natural person; and (*iii*) no national law recognizes the possibility of designating an AI system as an

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([247]) See § I.C.2.1.3 above.

([248]) See § fn 188 and 189 above.

([249]) Since the EPO issued two substantially identical decisions with respect to the two applications, we will refer only to the decision concerning the DABUS' food container patent application. See EPO (Receiving Section), 27 January 2020 on EP 18 275 163, RJ/N35111-EP, §§ 3-5.

([250]) ibid.

([251]) ibid.

([252]) ibid. § 24.

([253]) ibid. §§ 26-27.

inventor ([254]).

Second, the Receiving Section found that the statements by which Thaler claimed to have acquired the right to the patent as the "employer" or "successor in title" of DABUS did not comply with Articles 60(1) and 81 EPC ([255]). Since they lack legal personality, machines cannot be considered "employees" but, rather, they are owned. Since they do not have rights, machines also cannot transfer (by law or agreement) the right to the patent ([256]).

1.1.1 *The Boards of Appeal decision*

Thaler appealed both decisions before the Boards of Appeal raising both substantial and procedural objections ([257]). On 21 December 2021 (grounds published in June 2022), the appellate body confirmed in full the lower decisions ([258]).

Before addressing the merits of the case, the EPO wanted to clear the air as to the scope of its powers and duties during examination. In the appeal, Thaler contended that the EPO was not competent to verify the accuracy of the statement on the origin of the right to the patent or to assess entitlement ([259]). Admittedly, Rule 19(2) EPC leads in that direction, as it

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([254]) ibid. § 29.

([255]) ibid. § 30.

([256]) ibid. §§ 30-33. *Contra* STIERLE, *Artificial Intelligence Designated as Inventor*, cit., 922, who criticises this point because under Article 60(3) EPC, "the applicant shall be deemed to be entitled to exercise the right to a European patent" and the EPO actually has no authority to second-guess the applicant's declarations. The EPO also touched upon, and rejected, other ancillary arguments raised by Thaler, including the alleged right of the public to know who the inventor is: EPO Receiving Section Decision, §§ 34-41. See also A. ENGEL, *Can a Patent Be Granted for an AI-Generated Invention?*, cit., 1123; LUZZATI, *L'innovazione artificiale al vaglio dell'Ufficio Brevetti Europeo. Prime riflessioni sulla compatibilità del sistema brevettuale con le invenzioni dell'imminente futuro*, in *Riv. dir. ind.*, 2020, 262; CAPPARELLI, *Le invenzioni dell'Intelligenza Artificiale: questioni aperte di tutela autoriale e brevettabilità*, in RUFFOLO (ed.), *Intelligenza artificiale. Il diritto, i diritti, l'etica*, Giuffrè, Milan, 2020, 354 ss.

([257]) J 8/20, 21 December 2021 (*Designation of inventor/DABUS*).

([258]) See also J 8/20, 21 June 2021, Communication pursuant to Article 15(1) RPBA (*Designation of inventor/DABUS*).

([259]) J 8/20, 21 December 2021 (*Designation of inventor/DABUS*).

provides that "[t]he EPO shall not verify the accuracy of the designation of the inventor" ([260]). However, the Board pointed out that Article 90(3) EPC states that the EPO "*shall examine* […] whether the requirements in Articles 14, 78 and 81 […] are satisfied". It follows that, in the Board's view, "the EPO *must* check whether the [applicant…] identifies an inventor within the meaning of the EPC" and if the applicant and the inventor do not coincide "it must also examine whether the statement filed under [Article 81 EPC…] identifies an origin for the right to the patent which falls within the scope of [Article 60 EPC]". The Board conceded that the office shall not assess evidence or carry out a thorough analysis on the merits of the inventor's designation. Examiners shall simply undertake a formal *prima facie* assessment as to whether the basic requirements of the designation and indication of origin are met. The designation of an AI system as the inventor would therefore be necessarily examined by the office and rejected as *prima facie* inadmissible.

Coming to the merits, the Board's decision was very streamlined. The Board found that Article 60(1) EPC vest the rights to the European patent in the inventor and, therefore, "it postulates a person with legal capacity" ([261]). Article 60(1), together with Rule 19 EPC, leaves no room for "lexical or contextual ambiguity" ([262]). Therefore, there is no need to go back to the *travaux* for any further analysis ([263]).

The Board even conceded to Thaler that, when no human inventor can be identified, then the *ratio legis* of Article 81, first sentence, EPC – i.e., the mandatory designation of the inventor – would not apply. However, the Board pointed out that a statement on the origin of the right to the European patent is nevertheless necessary under Article 81, second sentence, EPC. Therefore, the applicant's argument that they would have derived the right to the patent as "owner and creator" of the machine "does not refer to a legal situation or transaction which would have made him successor in title of an inventor,

([260]) See also Article 60(3) "the applicant shall be deemed to be entitled to exercise the right to a European patent".

([261]) J 8/20, 21 December 2021 (*Designation of inventor/DABUS*), § 4.3.1.

([262]) ibid § 4.3.2.

([263]) ibid § 4.3.2.

within the meaning of the EPC" ([264]).

Finally, the Board tackled two outstanding arguments raised by Thaler. First, it recognized that any invention which is novel, industrially applicable and involves an inventive step would be patentable under Article 52(1) EPC and that "[h]ow the invention was made apparently plays no role in the European patent system" ([265]). Yet the Board concluded that while AI-generated inventions might be patentable as such, in relation to those inventions no right to a patent would be provided under Article 60(1) EPC: the two provisions are not coextensive. Second, the Board dismissed the applicant's argument that denying patent protection only on the account that a formal requirement such as the statement on the origin of the invention is missing would be disproportionate. On the one side, the Board refused to "fully ignore a formal requirement of the EPC" ([266]). On the other side, the Board stressed that the applicant was free to provide information in the application concerning the origin of the invention to "satisfy the fairness concerns raised" ([267]).

In the end, the Board dismissed Thaler's appeal in full. The decision is final and, therefore, the DABUS European patent applications are deemed to be withdrawn.

1.2 The DABUS European divisional application

The European patent saga of DABUS is not over yet. Thaler has also filed a divisional application to the food container patent application. The application was published in October 2022 ([268]). At first, no mention of the inventor was submitted. During prosecution, Thaler filed two inventor designations, reading, respectively:

> 1) Main Request: "The applicant is unable to identify a person as the inventor. The applicant has the right to be granted the patent as the applicant own the entirety of the AI system that devised the invention. Should a person claim any

([264]) ibid § 4.4.1.
([265]) ibid § 4.6.2.
([266]) ibid.
([267]) ibid.
([268]) European patent application No. EP 4 067 251.

> rights of inventorship, the applicant claims to have the rights to the invention and to the patent by way of succession in title" ([269]);
>
> 2) Auxiliary Request: "Stephen L. Thaler by virtue of being the owner of the AI system (DABUS) that created the invention disclosed in the application" ([270]).

On 14 March 2023, the Office issued a communication to the applicant arguing that neither inventor designation meets the requirements of Article 81 EPC ([271]). The first, because "it does not contain a statement of origin of the right to the patent" compliant with Article 81, second sentence, EPC and Article 60(1) EPC. The second, because the applicant's statement is unclear and ambiguous as to who (or what) the inventor is (either Thaler, DABUS or perhaps both). The fact that DABUS is described as having "created" the invention seems to suggest that it is the inventor. To this date, the applicant is yet to provide its replies to the office, having requested, and obtained, two consecutive extensions of its deadlines ([272]).

2. Other DABUS patent applications

The DABUS applications have been rejected also in many other jurisdictions as a testimony to the broad consensus on the notion of inventor as being necessarily a natural person on both formal and substantive law grounds ([273]).

([269]) Designation of invention, No. 21 216 024.6, Main request, 22 August 2022, https://register.epo.org/application?documentId=L76B4SXX1CNOR1O&number=EP21216024&lng=en&npl=false.

([270]) Designation of invention, No. 21 216 024.6, Auxiliary request, 22 August 2022, https://register.epo.org/application?documentId=L76B4TGH16K0X5S&number=EP21216024&lng=en&npl=false.

([271]) EPO, Communication pursuant to Art. 94(3) EPC, No. 21 216 024.6, 14 March 2023, https://register.epo.org/application?documentId=LF1C0ZJQ1GJI9XX&number=EP21216024&lng=en&npl=false.

([272]) EPO, Extension of time limit pursuant to Rule 132(2) EPC, 18 July 2023, https://register.epo.org/application?documentId=LK1FRZ9I1JWC4AT&number=EP21216024&lng=en&npl=false; EPO, Extension of time limit pursuant to Rule 132(2), 19 September 2023, https://register.epo.org/application?documentId=LMJGD2G91NOW4HZ&number=EP21216024&lng=en&npl=false.

([273]) For a complete summary as of December 2022 see ZOBOLI, cit., 91-103.

2.1 The UK case

The UKIPO rejected the DABUS patent applications in 2019 ([274]). While the examination of the DABUS applications was in progress, the UKIPO also amended its guidelines, stating that "[a]n 'AI Inventor' is not acceptable as this does not identify 'a person' which is required by law" ([275]). The UKIPO decision was squarely confirmed by the High Court ([276]) and by the Court of Appeal, although Birss J dissented in the latter decision ([277]). The applicant was then granted permission to appeal the case before the United Kingdom Supreme Court. The oral hearing before the Supreme Court took place on 2 March 2023 but, to this date, the case is still awaiting judgement ([278]).

2.2 The German cases

In Germany, the DPMA also rejected the food container patent application indicating DABUS as the inventor ([279]). The applicant appealed the decision and the DPMA referred the appeal before the Federal Patent Court (*Bundespatentgericht*) (11th Senate). Within those proceedings, the applicant filed auxiliary requests proposing several variations to the inventor designation. The Federal Patent Court rejected the appeal on the main request (i.e., DABUS as inventor) and the first auxiliary request (i.e., no inventor designation on the grounds that no natural person fulfils the

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([274]) UKIPO, 4 December 2019, BL O/741/1. The UKIPO also pointed out that, although AI cannot be an inventor, "times have changed and technology has moved on. It is right that this is debated more widely and that changes to the law be considered in the context of such debate".

([275]) UKIPO, *Formalities Manual*, § 3.05, www.gov.uk/guidance/formalities-manual-online-version/chapter-3-the-inventor.

([276]) *Thaler v The Comptroller-General of Patents, Designs And Trade Marks* [2020] EWHC 2412 (Pat). The decision was appealed: SIMMONS & SIMMONS, *Court of Appeal to Consider If AI System Can Be a Patent Inventor*, 18 January 2021, www.simmons-simmons.com/en/publications/ckk2ji0621aip0954oyl31re9/court-of-appeal-to-consider-if-ai-system-can-be-a-patent-inventor.

([277]) *Thaler v Comptroller General of Patents Trade Marks And Designs* [2021] EWCA Civ 1374 (21 September 2021).

([278]) UKSC, Case 2021/0201, https://www.supremecourt.uk/cases/uksc-2021-0201.html.

([279]) BPatG, 11 November 2021, Case 11 W (pat) 5/21 (*Food container*) (translation provided by Köllner & Partner). See German patent application No. DE 10 2019 128 1 202.

requirement of inventorship) ([280]), stressing that only natural persons can be designated as inventors.

Quite surprisingly, however, the Federal Patent Court allowed Thaler's appeal on a further auxiliary request whereby he had indicated himself as the inventor with the proviso that he had "prompted the artificial intelligence DABUS to create the invention" (as reproduced from the original form hereafter).

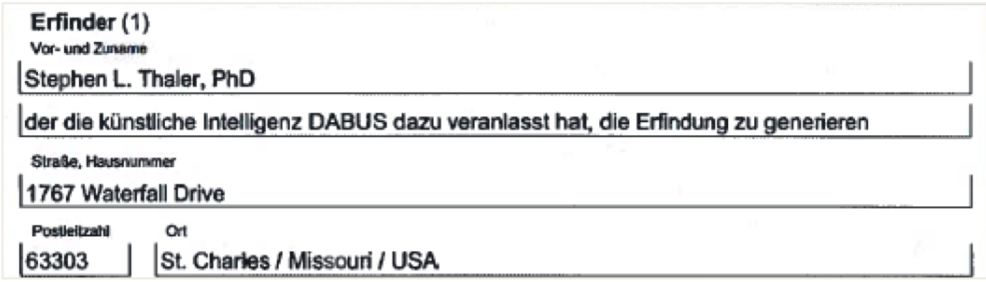
Erfinder (1)
Vor- und Zuname
Stephen L. Thaler, PhD
der die künstliche Intelligenz DABUS dazu veranlasst hat, die Erfindung zu generieren
Straße, Hausnummer
1767 Waterfall Drive
Postleitzahl | Ort
63303 | St. Charles / Missouri / USA

Fig. 17 -Excerpt from Federal Patent Court

Indeed, the Court found that, in this case, a natural person could be clearly identified as the inventor, the origin of the right to patent followed because the inventor was also the applicant, and there was no rule that prohibited adding contextual or even unnecessary information to the designation of the inventor ([281]). An appeal against the Federal Patent Court is currently pending before the German Federal Supreme Court (*Bundesgerichtshof*) ([282]).

Scholars quickly pointed out that the Federal Patent Court reasoning

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([280]) As to the first auxiliary request, the Court also pointed out that "from the legal fiction of § 7(1) of the Patent Act, it follows that the applicant must designate himself in case of doubt". § 7(1) PatG reads: "[i]n order to avoid the substantive examination of the patent application being delayed owing to the need to establish the identity of the inventor, the applicant is deemed, in the proceedings before the German Patent and Trade Mark Office, to be entitled to request the grant of the patent". The second auxiliary request, where Dr. Thaler was indicated as the inventor, but the description was amended to include the wording "the present invention (was) created by an artificial intelligence called DABUS" was also rejected for having made an "inadmissible extension of the disclosure of the application" further to §14(2) PatG.

([281]) BPatG, 11 November 2021, Case 11 W (pat) 5/21 (*Food container*).

([282]) SANDYS, *Germany's latest Dabus decision aligns with European approach*, 28 June 2023, in *Juve Patent*, https://www.juve-patent.com/cases/germanys-latest-dabus-decision-aligns-with-european-approach/.

incurred in a paradox ([283]). On the one side, it recognized the inventor's principle – whereby only a natural person can be deemed the inventor – and on the other side allowed Thaler to claim inventorship although he had repeatedly admitted, throughout prosecution that he had "no influence on the task and its solution" and that designating himself as the inventor "[would] not correspond to the actual facts". Furthermore, it should be noted that, although the wording used in Germany and in the divisional application before the EPO is slightly different ([284]), the Federal Patent Court could have also spotted the self-contradiction of Thaler's designation in that it was not clear as to who had "created" the invention according to the applicant, whether himself, the AI or perhaps both.

Finally, in a recent development, another division of the *Bundespatentgericht* (18th Senate) hearing the appeal filed by Thaler against the refusal of the parallel patent application on the device for attracting enhanced attention ([285]) came to different conclusions ([286]). As opposed to their colleagues at the 11th Senate of the Court, the 18th Senate did not accept any of the auxiliary requests filed by Thaler, bringing the decision in line with the broader European approach. It is still to be seen whether Thaler will appeal this latter decision before the *Bundesgerichtshof* and whether the Supreme court will align the German positions.

2.3 The German utility model

As a further peculiarity of the DABUS case in Germany, it should be pointed out that Thaler also filed a German utility model on the food container, which

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([283]) KIM, *The Paradox of the DABUS Judgment of the German Federal Patent Court*, in *GRUR International*, 2022, vol. 71, issue 12, 2022, 1162.

([284]) Before the EPO the auxiliary request read: "Stephen L. Thaler by virtue of being the owner of the AI system (DABUS) that created the invention disclosed in the application". Before the BPatG, the auxiliary request read: "Stephen L. Thaler PhD who prompted the artificial intelligence DABUS to create the invention". The two requests are different in that, at the EPO, Thaler figured as inventor through ownership of the system, whereas in Germany there was at least the suggestion that Thaler himself had done something towards the invention, i.e., prompting the AI.

([285]) See German patent application No. DE 10 2019 129 136 A1.

([286]) BPatG, 21 June 2023, Case 18 W (pat) 28/20.

was published in 2022 ([287]). In this respect, *Meitinger* stressed that, while the "inventor principle" applies also to utility models, German patent law does not require the designation of the inventor for these rights and suggests that this is an argument to get rid of the inventor designation, *de lege ferenda* ([288]).

However, little turns on the law of utility models. There is no previous examination of utility models in Germany, so that the absence of a formal requirement such as the inventor's designation is not surprising ([289]). More importantly, as discussed above, the formal designation of the inventor is quite a secondary matter as opposed to the substantive law finding that, absent a human inventor, no right to a patent arises. This principle also applies to utility models ([290]). Therefore, despite their publication, German utility models without an inventor might not hold up in Court ([291]).

2.4 The US case

On the other side of the Atlantic, the USPTO likewise rejected the parallel DABUS applications, by holding that the law requires an inventor to be a "natural person" ([292]). On 2 September 2021, Judge Brinkema of the U.S. District Court for the Eastern District of Virginia denied Thaler's motion for summary judgement against the USPTO decision, stating that the "clear answer" to the question "can an [AI] machine be an 'inventor' under the Patent Act" is "no" ([293]).

([287]) See German utility model No. DE 20 2019 005 767 U1.

([288]) MEITINGER, *Künstliche Intelligenz als Erfinder*, cit., § X.

([289]) Section 8(1), second sentence, GebrMG ("Eine Prüfung des Gegenstands der Anmeldung auf Neuheit, erfinderischen Schritt und gewerbliche Anwendbarkeit findet nicht statt").

([290]) MEITINGER, *Künstliche Intelligenz als Erfinder*, cit., § X. In this respect, see e.g., § 22(1) GebrMG, providing that the right to the utility model, the right to its registration and the right based on the registration pass *to the heirs (*"Das Recht auf das Gebrauchsmuster, der Anspruch auf seine Eintragung und das durch die Eintragung begründete Recht gehen auf die Erben über").

([291]) The same goes also for Italy: see Article 83 c.p.i. which is fully aligned with the inventor's principle ("il diritto al brevetto spetta all'autore del nuovo modello ed ai suoi aventi causa").

([292]) USPTO, *In Re Application No. 16/524,350*, 22 April 2020.

([293]) *Thaler v. Hirshfeld*, 558 F. Supp. 3d 238 (E.D. Va. 2021).

The case was then appealed before the Court of Appeals for the Federal Circuit. The appellate court fully endorsed the lower court decision as a matter of plain statutory interpretation. It found that statute provides no ambiguity: "the Patent Act requires that inventors must be natural persons; that is human beings" and the Court analysis need not to go any further ([294]). The Federal Circuit then denied a request filed for a panel rehearing and *en banc* rehearing ([295]).

Thaler lodged an appeal before the Supreme Court. Esteemed scholars such as Lawrence Lessig and Peter Georg Picht filed *amicus curiae* briefs in support of the applicant arguing that denying patent protection to AI-generated inventions would risk hampering the US economy and impair investments in R&D ([296]). Nevertheless, the case was denied certiorari ([297]) and the Federal Circuit decision became final.

2.5 Other cases

At some point in the summer of 2021 it looked like the wind was shifting in favour of Thaler. On 28 July 2021, the South African Companies and Intellectual Property Commission ("CIPC") granted a patent indicating DABUS as the inventor ([298]). Two days later, the Federal Court of Australia ("FCA"), held that "the name of the inventor can be a non-

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([294]) *Thaler v. Vidal*, 43 F.4th 1207 (Fed. Cir. 2022). In short, the Court found that 35 U.S.C. § 100(f), as amended further to the Leahy-Smith American Invents Act, provides that inventors are "individuals". In turn, established case law suggests that the word "individual" indicates natural persons.

([295]) ARTIFICIAL INVENTOR PROJECT, *Patents and Applications*, cit. (making available the unreported decision).

([296]) Brief of Amici Curiae Lawrence Lessig, Shlomit Yanisky-Ravid, Osman Güçlütürk, and Dr. Christopher Mason in support of Petitioner, *Thaler v. Vidal*, No. 22-919 (U.S. 12 April 2023); Brief of Amici Curiae Brooklyn Law Incubator & Policy (BLIP) Clinic and Prof. Dr. Peter Georg Picht in support of Petitioner, *Thaler v. Vidal*, No. 22-919 (U.S. 14 April 2023).

([297]) *Thaler v. Vidal*, 143 S.Ct. 1783 (Mem) (24 April 2023).

([298]) Patent No. ZA 2021/03242, filed on 17 July 2019 (PCT), titled "Food Container and Devices and Methods for Attracting Enhanced Attention". Apparently, this title incorporates the subject-matter of both EP 18 275 163 and EP 18 275 174. https://www.ipwatchdog.com/wp-content/uploads/2021/07/AP7471ZA00-Notice-of-Acceptance-1.pdf.

human" ([299]) and remitted the matter for consideration to the Australian Patent Office, which had previously rejected the DABUS application ([300]). However, these are marginal cases. On the one hand, the CIPC does not examine patent applications. Indeed, South Africa has implemented, essentially, a patent registration system ([301]). On the other hand, the FCA decision, which had been strongly criticized by scholars ([302]), was reversed in appeal, with a final decision ([303]). The DABUS applications in Canada, China, India, Israel, New Zealand and Taiwan, among others, have been rejected as well ([304]).

D. CONCLUSION

This chapter has examined the notions of "inventor" and "invention" in relation to the emerging use of AI in R&D. In particular, it has shown that the notion of invention in European patent law is strictly objective. In general terms, inventions consist of technical subject-matter – where "technical" implies the use of physical means or some sort of materiality – as opposed to purely abstract creations. Hence, the notion of invention is independent from the figure of the inventor. Thus, in principle, both AI-assisted and AI-generated inventions could constitute "inventions" under patent law.

Turning to the "inventor" reveals a more complex picture. The "inventor" was identified as a natural person who makes an *intellectual contribution* to an inventive concept. It is irrelevant whether said intellectual contribution was carefully planned and executed or the result of pure chance. Simply recognizing that subject-matter on which one stumbles upon accidentally is an invention would be enough to qualify as an inventor (*recognition principle*).

([299]) *Thaler v Commissioner of Patents* [2021] FCA 879 (30 July 2021).

([300]) *Stephen L. Thaler* [2021] APO 5, concerning AU 2019363177.

([301]) NAIDOO, MAMMEN, *DABUS Gains Traction: South Africa Becomes First Country to Recognize AI-Invented Patent*, in *PatentlyO*, 4 August 2021, https://patentlyo.com/patent/2021/08/traction-recognize-invented.html;

([302]) See e.g., KIM ET AL., *Artificial Intelligence Systems as Inventors?*, op. loc. cit.

([303]) *Commissioner of Patents v Thaler* [2022] FCAFC 62.

([304]) See ARTIFICIAL INVENTOR PROJECT, *Patents and Applications*, cit.. The page is regularly updated with the latest developments on the DABUS cases.

It follows that AI is not and cannot be an inventor on three different levels. *First*, because mandatory formal requirements common to the EPO and national jurisdictions require patent applicants to identify a natural person as the inventor. *Second*, because human inventor(s) can be identified in all but extreme and unrealistic cases. Indeed, based on the recognition principle, the inventor is first and foremost the person who recognizes the subsistence of an invention, irrespective of the role of AI in the inventive process. Moreover, other potential (co-)inventors are those who have made an intellectual contribution to the inventive concept, so that a causal link can be established between their contribution and the invention. These include, for example, a natural person that programmed an AI system for a specific goal (which is met) or selected the training data for specific ML purposes (which are achieved). *Third*, because in the unlikely case of a truly AI-generated invention, where it is not possible to identify a human inventor, the general rules on employee-inventions or succession in title cannot be applied by analogy. AI systems can neither hold rights, nor be parties to an employment agreement, since they obviously lack legal capacity. Simply put, lacking an inventor the right to the patent would not arise at all.

From a different point of view, it is also arguable that AI systems *de facto* do not invent in any meaningful sense of the word. At the current state of technology AI systems are tools in the hands of researchers, and they should be treated as such. Nevertheless, if we were to assume that AI is truly capable of "inventing", thus allowing technological progress without risks and uncertainties, the utilitarian justification of the patent system would be seriously tested, prompting to question whether patent law must give way. For the same reason, *de lege ferenda* proposals to introduce AI-inventorship make little sense. In the current scenario AI-inventorship is unnecessary since human inventors can generally be identified. Were AI-generated inventions to become the norm, it is the patent system that might become unnecessary.

The brief overview of the DABUS decisions that concludes the chapter shows how courts and patent offices have almost unanimously adopted the positions expressed in this work, rejecting claims of AI-inventorship on both formal and substantial grounds.

In the end, the comprehensive analysis carried out in this chapter has shown that the AI-inventorship discussion is not only based on many imprecise or flawed assumptions, but also mostly unnecessary. The patent system, as it stands, is perfectly capable of accommodating AI-assisted inventions. It is thus suggested that the debate on AI-inventorship has obfuscated the arguably more relevant questions concerning the need to re-calibrate the substantive patentability requirements – and in particular inventive step – to take into account the increasing role of AI in R&D. This issue is addressed hereafter, in Chapter IV.

IV.
THE SKILLED PERSON, INVENTIVE STEP AND AI

This chapter addresses the impact that the increasing use of AI in R&D might have on the notion of "person skilled in the art", with particular focus on the inventive step requirement. Section IV.A starts by addressing the central role played by the skilled person in European patent law, and its main features. Section IV.B discusses the fundamental principles of the inventive step requirement. Mirroring the structure of the first two parts of the chapter, Section IV.C then looks at the impact of AI tools on the constructions the person skilled in the art and on the obviousness analysis. Finally, Section IV.D discusses, and rejects, the proposals to introduce a disclosure obligation covering the use of AI in the inventive process.

A. The skilled person

1. The notion of the skilled person

Technical teachings are not addressed to the layman but to a person that might actually understand them ([1]). In patent law, that person is known as "the person skilled in the art" (also referred to as "skilled person" or "PSITA"). In simple terms, the skilled person represents the average expert in the technical field of the invention. The are the yardstick against which the core patentability requirements – novelty, inventive step and sufficiency of disclosure – are assessed and, more in general, technical teachings are interpreted ([2]). Yet the skilled person does not correspond to any real person ([3]). It is a legal fiction that patent examiners and courts must construe in order to provide objective evaluations on the invention ([4]).

([1]) Nägerl, Walder-Hartmann, *Differentiation from the state of the art*, in Haedicke, Timmam (eds.), *Patent Law, A Handbook on European and German Patent Law*, Beck, Munich, 2014, 131, § 338.

([2]) ibid.

([3]) Ammendola, *La brevettabilità nella convenzione di Monaco*, cit., 135-136.

([4]) ibid. See also Ottolia, *Article 48 c.p.i.*, in L. C. Ubertazzi, *Commentario breve alle leggi su proprietà intellettuale e concorrenza*, Wolters Kluwer, 6th ed., 2016, 380. See

While there are few nuances as to the appropriate construction of the skilled person – both with respect to the specific aspects at stake and the different approaches adopted across Europe – the EPO Guidelines' definition is a useful starting point. The skilled person is identified as ([5]):

> "a skilled *practitioner* in the *relevant field* of technology who is possessed of *average knowledge* and *ability* […]. The person skilled in the art is aware of what was *common general knowledge* in the art at the relevant date […]. The skilled person is also presumed to have had access to *everything* in the 'state of the art' […] and to have been in possession of the *means and capacity for routine work and experimentation* which are normal for the field of technology in question".

To appreciate who the person skilled in the art is with respect to an invention it is thus necessary to determine: (*i*) what is the "relevant field of technology"; (*ii*) what is the "average knowledge" in that field (and, in particular, the "common general knowledge"); and (*iii*) what are the "normal means and capacity for routine work and experimentation". The following paragraphs will examine the features of the skilled person in detail drawing from the EPO, Italian, UK and German experiences, which are broadly speaking aligned. Before getting into this analysis, however, it is worth stressing that the determination of the skilled person is a very delicate moment in the patentability assessment. As Pumfrey J warned ([6]):

> "to an inappropriately defined skilled man, nothing may be obvious or everything may be obvious. The most difficult part of any obviousness case is the attribution of the relevant skill and knowledge to the notional addressee of the patent. When the common general knowledge is identified, the height of the bar is set".

The same reasoning can be applied, *mutatis mutandis*, to the definition of the

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also STIERLE, *A De Lege Ferenda Perspective*, cit., 120 (reporting that "[f]irst drafts of the EPC did not even refer to a 'person skilled in the art' but described an invention as involving an inventive step if it was not obvious in the light of the state of the art. […T]he concept of the 'person skilled in the art' was introduced for the sole reason that some EPC member states feared a very subjective application of the standard by patent examiners: *the 'person skilled in the art' was therefore included as an objective legal fiction*", emphasis added).

([5]) EPO GUIDELINES, cit., § G-VII.3.

([6]) *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc & Anor* [2006] EWHC 260 (Pat) (24 February 2006) at [35]; *Actavis UK Ltd v. Merck & CO Inc 2007* EWHC 1311 (pat.). See also: COLE, DAVIS, *CIPA Guide to the Patents Acts*, cit., § 3-07; GURGULA, cit., 9.

skilled person in relation to the other patentability criteria (e.g., novelty and sufficiency) and the scope of the patent claims.

1.1 The legislative sources

The person skilled in the art is not a creature of case law – at least not entirely ([7]). The skilled person is referred to in several EPC provisions and in the corresponding national norms. In particular, Article 56 EPC, first sentence, defines the inventive step requirement as follows: "[a]n invention shall be considered as involving an inventive step if, having regard to the state of the art, it is *not obvious to a person skilled in the art*" ([8]). Instead, Article 83 EPC introduces the requirement of sufficiency of disclosure and reads: "[t]he European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be *carried out by a person skilled in the art*" ([9]). Furthermore, the Protocol on the Interpretation of Article 69 EPC specifically refers to the "person skilled in the art" as the standard for construing the patent claims ([10]). Anchoring the inventive step and sufficiency assessment, as well as the infringement analysis, to the fictitious model of the skilled person is thus required by the law.

1.2 The potential multiplicity of the skilled person

Against this background, the skilled person is not necessarily the same for all purposes. In particular, the skilled person to assess inventive step and the one

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([7]) SORDELLI, *Il paradigma della "persona esperta del ramo" nella legge sulle invenzioni*, in *Studi in onore di Remo Franceschelli*, Giuffrè, Milan, 1983, 193 (amply discussing how the scholarship and the case law had introduced the "skilled person" model for the assessment of "originality" years before the notion of inventive step became law).

([8]) See Article 48 c.p.i.

([9]) See Article 51(2) and (3) c.p.i. Notably, the "skilled person" was part of the definition of the sufficiency requirement in Italian patent law long time prior to the introduction of the same notion together with the inventive step requirement: Article 28(2) Royal Decree, 29 June 1939, No. 1127 (*Legge invenzioni*) ("[l]'invenzione deve essere descritta in modo che ogni persona esperta possa attuarla e deve essere contraddistinta da un titolo corrispondente al suo oggetto").

([10]) See Protocol on the Interpretation of Article 69 EPC of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000.

for sufficiency might differ with respect to the same invention ([11]). When construing the skilled person that is tasked with solving the technical problem, one must assume that they are *not* aware of the solution. The test for inventive step is indeed precisely whether the skilled person would have arrived at the solution as a matter of course, based on the prior art and the common general knowledge in the field ([12]). Instead, the test for sufficiency of disclosure assumes that the skilled person is provided with the invention (i.e., they have read the patent application) in order to appreciate whether they would be able to carry it out or not. Therefore, while the EPO posits that the same level of skill has to be applied when inventive step and sufficiency are considered, the two starting points differ ([13]).

Furthermore, the skilled person might be construed based on different time references. For instance, the EPO Guidelines draw an important distinction between the relevant time for the novelty and inventive step assessment. When assessing whether an invention is novel – i.e., that is was not comprised in the state of the art – a prior art document ought to be read at its *publication date*. Assuming a paper was published on 1 January 1950, that document shall be interpreted as if the skilled person read it on that date ([14]). For the assessment of inventive step, instead, a prior art document ought to be read at the date of filing of the patent application under examination. In relation to a patent application filed in 2023, the same paper from 1950 would be read by the skilled person in 2023 ([15]). And it is quite evident that the skills, knowledge and understanding of the notional skilled person might have changed significantly from 1950 to 2023.

Finally, the case law has hinted at the possibility that there might be different skilled persons to the different claims within the same patent, e.g., a product and a process claim ([16]). Likewise, the EPO suggests that the figure

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([11]) ENGLAND, *A practitioner's guide*, cit., 10.

([12]) See further in § IV.B below.

([13]) EPO CASE LAW, *Skilled person – level of knowledge*, cit., § 8.3.

([14]) EPO GUIDELINES, *Relevant date of a prior-art document*, cit., § G.VI.3.

([15]) EPO GUIDELINES, *Obviousness*, cit., G.VII.4.

([16]) *Actavis UK Ltd & Ors v Eli Lilly & Company* [2015] EWCA Civ 555 (25 June of the skilled person might vary depending on the various aspects of an invention under consideration ([17]).

1.3 The relevant field of technology

Keeping in mind the above, the first step in defining the person skilled in the art is naturally to identify the "art", i.e., the relevant field of technology in which the skilled person operates ([18]).

In many cases determining the field of technology will be intuitive. For instance, an invention relating to a mechanical device will generally belong to the field of mechanical engineering, or to a branch thereof ([19]). Besides, the EPC implementing regulations ([20]) – and national rules alike ([21]) – impose on the applicant to include the technical field of the invention as part of the patent description, which might further simplify the task ([22]).

The determination of the relevant field of technology can get more complicated when multiple technical fields are potentially at stake ([23]). When construing the skilled person for the assessment of inventive step, the approach adopted by the EPO is to take into account the technical *problem* to

2015), § 32-34 (it was argued in the case that a second medical use and a product claim required two different skilled persons: i.e., only an oncologist for the first and a team composed by an oncologist and a chemist for the second; while the Judge was intrigued by this argument, he preferred not to express any concluded view, as he deemed that in the case at stake every claim was addressed to a team composed of an oncologist and a chemist).

([17]) EPO, T 412/93, 21 November 1994 (*Erythropoietin/KIRIN-AMGEN*).

([18]) See DI CATALDO, *L'originalità dell'invenzione*, cit., 63; BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 8-29; SUOMINEN, DE LANGE, RUDGE, cit., 184 ("[t]he reference to 'art' in Art. 56 should not be construed to technology in general but to the specific field of technology with which the invention is concerned").

([19]) See e.g., EPO, T 1915/14, 14 March 2018 (*Koninklijke Philips N.V./Rotary shaver*), wherein the invention related to a "shaving device […] configured to support at least two rotating heads" and the skilled person was identified as some with knowledge in mechanical engineering.

([20]) Rule 42(1)(a) EPC

([21]) See e.g., Article 2(3), Decree (Italian Ministry of Economic Development) 27 June 2008, OJ No. 153 of 2 July 2008.

([22]) BENTLY ET AL., cit., 583.

([23]) VANZETTI, DI CATALDO, SPOLIDORO, cit., 409.

be solved ([24]). If the problem *prompts* the skilled person to seek the solution in another technical field, then the skilled person is the specialist in *that* (second) field ([25]). A classic example in the literature is that – in relation to an invention concerning a particular metallic clasp for a beehive – the person skilled in the art should not be sought among beekeepers, but among blacksmiths ([26]). Similarly, in relation to an invention that addressed the need to replace a metallic element used in conveyor belts that often broke down, the Boards concluded that, while the problem confronted conveying equipment specialists, it also prompted them to seek a solution in the field of material science: hence, the skilled person qualified to solve the problem had to be a materials specialist ([27]).

However, the technical problem shall *not* be formulated so as to *anticipate* the solution ([28]). If the technical field to which the solution belongs is different to the one considered when formulating the technical problem, the construction of the skilled person shall *not* include the skills and knowledge of that (second) field ([29]). Rather, the fact that the inventor was able to bridge

([24]) EPO, T 1450/16, 17 January 2020 (*Acoustic port of a hearing device/SHURE)*. Appeal Court of Turin, 18 December 2018, *E.S.P. International v. EP Company S.A.S. et al.*, in *Darts-ip* (applying the same principles). See also BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 8-32 (“The appropriate test in case of obviousness is to consider the relevant art in which the problem in fact lay”); NÄGERL, WALDER-HARTMANN, cit., 133; HERVEY, DRIVER, WOODHOUSE, cit., 8-091.

([25]) EPO, T 26/98, 30 April 2002 (*Iontophoretic delivery device/ALZA CORPORATION*).

([26]) DI CATALDO, *L’originalità dell’invenzione*, cit., 64. The A. marks a distinction between the “problem solving” approach (i.e., looking at the field where the solution is found, not to be confused with the problem-solution approach) and the “problem function” approach (i.e., looking at the field where the solution would be used), but in the ends suggests that, in this example, the person skilled in the art should have knowledge of both technical fields (i.e., beekeeping and forging), since both fields are part of the problem to be addressed (i.e., finding a better metallic clasp for a beehive). The Author’s suggestion is workable, since the person skilled in the art might as well be a team (see § IV.A.1.7 below).

([27]) EPO, T 32/81, 5 March 1982 (*Cleaning apparatus for conveyor belt*), § 4.

([28]) EPO, T 641/00, 26 September 2002 (*Two identities/COMVIK*).

([29]) EPO, T 422/93, 21 September 1995 (*Luminescent security fibres/ JALON*). In this case, the Board was asked to assess the inventive step of an invention concerning the production of security fibres that are made luminescent by dyeing them with luminescent chelates after they are produced (e.g., by extrusion). The prior art illustrated a process the gap between two different technical fields might show that the invention is non-obvious ([30]).

This rule, however, does not necessarily apply to the construction of the skilled person to assess sufficiency of disclosure. As discussed above ([31]), the skilled person against which to evaluate sufficiency is by definition acquainted with the solution to the technical problem (i.e., they have the patent application in their hands). Therefore, they might combine the knowledge of the average experts in both fields (i.e., the field of the problem and the field of the solution) in order to carry out the invention ([32]).

1.4 The identity of the skilled person

Coming to the identity of the skilled person, they are, first of all, natural persons ([33]). This is implicit both in the law – literally they are "person[s]", albeit fictitious ones – and in the case law ([34]). Besides, it is submitted that,

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whereby luminescent chelates were added to the mass of the product (e.g., plastic) before the extrusion. This process was subject to severe constraints since it was not suitable for the production of small quantities of security fibres. The technical problem was therefore that of developing a different process for incorporating luminescent chelates in small quantities. In the opposition proceedings, the opposition division found that the skilled person was an expert in dyeing of fibres and that they would have found it obvious to add luminescence by dyeing the fibres instead of adding the luminescent chelates to the mass. The Board took a different view. It held that the principle of introducing luminescent chelates by a dyeing process was part of the solution of the technical problem and was added to the problem with hindsight. Therefore the skilled person was not a dyeing expert, but rather an expert in security materials. And to that person skilled in the art, introducing a dyeing step would not have been obvious.

([30]) See e.g., *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819 ("[i[f a patentee says 'marry the skills of two different arts to solve a problem,' marrying may be obvious or it may not. If it is not, and doing so results in a real technical advance then the patentee deserves and ought to have, a patent. His vision is out of the ordinary").

([31]) See § IV.A.1.2 above.

([32]) See BIRSS ET AL., *Terrell on the Law of Patents*, cit., 222-225; ENGLAND, *A practitioner's guide*, cit., 10-13, both citing *Schlumberger Holdings Ltd v Electromagnetic Geoservices AS* [2010] EWCA Civ 819. See also EPO, T 422/93, 21 September 1995 (*Luminescent security fibres/JALON*).

([33]) BLOK, cit., 70. GUARDA, TREVISANELLO, *Robots as artists, robots as inventors, is the intellectual property rights world ready?*, in *EIPR* 2021, 43(11), 744.

([34]) As discussed in the following paragraphs, the reference drawn to build the skilled person are unfailingly people: practitioners, researchers, experts and so forth.

since the inventor is necessarily a human being, the same must apply also for the skilled person ([35]). Otherwise, the skilled person would not constitute a proper benchmark for the patentability assessment ([36]).

Moreover, the skilled person is generally construed as a practitioner ([37]). More precisely, the skilled person is an *average* practitioner. While the relevant provisions do not include the term "average", the case law and literature have consistently found that, as the standard reference for patentability requirements, the skilled person should be construed neither as an "excellent" nor as a "depressed" figure, but somewhere in the middle ([38]).

In certain fields characterized by high technical complexity, the skilled person might nevertheless be a researcher ([39]). For instance, according to the Boards, the skilled person in the biotechnology field in the 1980s was neither a Nobel graduate – although many of the people working in the field were

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([35]) See § III.B.1.1 above.

([36]) See § IV.C.1.1 below.

([37]) AMMENDOLA, cit., 159; DI CATALDO, *L'originalità dell'invenzione*, cit., 69; OTTOLIA, *Article 48 c.p.i.*, cit., 380. In the case law, see e.g., Appeal Court of Milan, 10 February 2010, in *Giur. ann. dir. ind.*, 2010, 428 ("[l]'esperto del ramo [è una] figura che sintetizza le caratteristiche intellettuali e professionali dell'operatore pratico attivo in un dato settore e di [questo] mediamente esperto"); Court of Milan, 30 June 2017, in *Sprint* ("[p]er esperto del ramo va inteso il tecnico interessato ad utilizzare l'invenzione brevettata e non un addetto alla ricerca o all'ideazione").

([38]) DI CATALDO, *L'originalità dell'invenzione*, cit., 68. See also *Gillette Safety Razor v American Trading* (1913), RPC, vol. 30(18), where Lord Moulton famously said "I recognise that it would be most unfair to subsequent patentees if we tested this by what it would conveyor suggest to a mechanical genius: but, on the other hand, it would be equally unjust to the public to take it as though it were read only by mechanical idiots"; EPO, T 39/93, 14 February 1996 (*Polymer powders/ALLIED COLLOIDS*) ("he is the expert in the relevant field, who is possessed of average knowledge and ability, i.e. not an exceptional, outstanding or brilliant expert"). In the Italian case law the reference to the "average technician" is common as well, see e.g., Appeal Court of Turin, 18 December 2018, *E.S.P. International v. EP Company S.A.S. et al.*, in *DeJure*; Court of Milan, 25 January 2016, in *Sprint* ("[l]'esperto del ramo deve essere individuato nella figura di un generico professionista, operante nel settore tecnico di riferimento, che abbia conoscenze ed abilità medie, ovvero che sia in grado di eseguire solo immediate associazioni logiche tra soluzioni note alla tecnica, oltre ad essere capace di eseguire lavori di routine e semplici esperimenti noti nel settore tecnico di pertinenza, senza che gli sia richiesto di essere dotato di attività creativa").

([39]) A similar evolution has been witnessed in U.S. patent law: DARROW, *The neglected dimension of patent law's PHOSITA standard*, in *Harvard Journal of Law and Technology*, 2009, vol. 23(1), 227.

awarded the prize – nor a mere laboratory technician. Rather, they should be assumed to be scientists working as teachers or researchers in the laboratories that made the transition from molecular genetics to genetic engineering at that time ([40]). However, if at the priority date there were only few highly qualified experts in a field that was largely unexplored, they do not provide proper guidance to assess the skills of the skilled person ([41]).

In any case, the skilled person certainly does *not* correspond to the inventor, the patent holder, the opponent, the patent examiner or the judge ([42]). Italian scholars also stress that the skilled person does not correspond to the court-appointed expert ([43]). That said, while the person skilled in the art does not correspond to an existing person – it is a legal fiction – they must be construed based on an assessment of the relevant technical field that is grounded to reality ([44]).

1.5 The knowledge of the skilled person

The skilled person is particularly knowledgeable. They know the prior art in their field – and potentially other fields of technology – and display "common general knowledge", i.e., the "mental equipment" that every practitioner is

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([40]) EPO CASE LAW, cit., § I.D.8.1.3; In particular see: EPO, T 60/89, 31 August 1990 (*Fusion Proteins*); EPO, T 412/93 21 November 1994 (*Erythropoietin/KIRIN-AMGEN*). In the latter case, the patent related to the production of erythropoietin. The parties agreed that in this particular case the skilled person should be treated as a team of three, composed of one PhD researcher with several years' experience in the aspect of gene technology or biochemistry under consideration, assisted by two laboratory technicians fully acquainted with the known techniques relevant to that aspect. See also MINSSEN, *Meanwhile on the Other Side of the Pond: Why Biopharmaceutical Inventions That Were Obvious to Try Still Might Be Non-Obvious - Part I*, in *Chicago-Kent J. of Int. Pr.*, 2010, 9(2), 84.

([41]) NÄGERL, WALDER-HARTMANN, cit., § 349.

([42]) EPO, T 1462/14, 1 January 2019 (*Contactless circuit/WISeKey Semiconductors*), § 15.

([43]) DI CATALDO, *L'originalità dell'invenzione*, cit., 69 (among other things, because they are generally drawn from a selected group of well-known practicing patent attorneys, who should not be considered the "average" practitioner); AMMENDOLA, cit., 168. Apparently *contra*, ACQUAFREDDA, *L'altezza inventiva tra il giudizio di non evidenza e la C.T.U.*, in *Dir. ind.*, 2003, 5, 415 (arguing that, given the CTE's experience, they are best placed to assess the technical capabilities of the skilled person).

([44]) ENGLAND, *A practitioner's guide*, cit., 11; DI CATALDO, *L'originalità dell'invenzione*, cit., 67-68; SORDELLI, cit., 226.

expected to have in the field. Whether a piece of information is (only) prior art or common general knowledge can have a significant impact on the inventive step assessment.

1.5.1 *Specific, neighbouring and remote technical fields*

The skilled person in the art is assumed to have had access to *everything* in the "state of the art" ([45]) – including published documents and prior uses – but only in their technical field(s) ([46]). This follows directly from Article 56(1) EPC which refers to a person skilled "in the art" and not in "all fields of technology" as provided for instance by Article 52 EPC ([47]).

The breadth of the technical field depends on its characteristics. Engineering is hardly a single field. Most likely the skilled person's field is a specific branch of engineering (e.g., chemical engineering). Within their field, the skilled person is updated and involved in the constant development of the technology ([48]).

Moreover, the skilled person can be expected to look for suggestions also in *neighbouring technical fields*, provided that the same or a similar problem arises in such fields ([49]). Also, the skilled person might look for suggestions in a *general technical field*, as long as they are aware of such field ([50]). The Italian literature suggests that, as a general rule, the familiarity of the skilled person in fields other than their own decreases progressively in relation to the distance from their core field ([51]).

([45]) See § IV.A.2 below.

([46]) Recall that an invention might cover multiple technical fields: see § IV.A.1.3 above.

([47]) See also DI CATALDO, *L'originalità dell'invenzione*, cit., 71.

([48]) EPO GUIDELINES, *Person skilled in the art*, cit., G.VII.3.

([49]) EPO, T 454/87, 21 July 1988 (*Perkins Engines Group Limited*) (the Board found that a skilled person specialising in gas chromatography equipment would also observe developments in equipment used in another analytical field such as adsorption spectral analysis). See also EPO, T 26/98, cit. § 6.3; EPO, T 176/84, 22 November 1985 (*Erfinderische Tätigkeit, relevanter Stand der Technik*).

([50]) EPO, T 26/98, cit. § 6.3.

([51]) VANZETTI-DI CATALDO-SPOLIDORO, cit., 409. *Contra* see GALLI, BOGNI, *Intelligenza artificiale*, cit., 130 (stressing that the "progressive decrease" rule is too abstract because there are technical problems that are inherently cross-field and insisting for an application of the technical field that corresponds to the problem addressed).

The skilled person might even look at *remote technical fields*, but only when prompted to do so ([52]). For instance, in a case where the problem to be solved was to find a substitute for asbestos fibres as a reinforcing material for an acetylene storage vessel (i.e., a gas tank), the Board found that the risks that asbestos posed as a material were well-know at the priority date, even among the general public ([53]). The person skilled in the art would have thus looked also at the solutions found in the building industry – which is quite distant from that of storage vessels – for reinforcing cement products with non-asbestos fibres ([54]).

1.5.2 *Common general knowledge*

On top of specialized knowledge, the skilled person is endowed also with the "common general knowledge" (often abbreviated as "CGK").

The common general knowledge is special class of prior art. Laddie J defined it broadly as "the *technical background* of the notional man in the art against which the prior art must be considered" ([55]). The common general knowledge permeates everything that is required to the skilled person, including reading and understanding the patent, as well as the prior art ([56]). In other words, the common general knowledge represents the "intellectual toolbox" of the skilled person ([57]) and it includes both the knowledge acquired in the course of training and the knowledge that any technician possesses, regardless of their area ([58]) (e.g., basic mathematical skills) ([59]). According to

([52]) EPO, T 676/89, 10 September 1991 (*Washing Composition/UNILEVER*) (carpets and wigs are not a related technical fields).

([53]) EPO, T 560/89, 21 April 1991 (*Filler mass/ N.I. Industries*).

([54]) ibid.

([55]) *Raychem Corp's Patents* [1998] RPC 31, 40, emphasis added.

([56]) BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 8-62.

([57]) BPatG, 13 February 2008 (*Scharnierkonstruktion*) in *GRUR*, 2008, 689. See also NÄGERL, WALDER-HARTMANN, cit., 132.

([58]) NÄGERL, WALDER-HARTMANN, cit., 132 (adding that if there is no training specific for that area, it is possible to piece together from other fields). See also BGH, 4 October 1988, X ZB 25/87 (*Gurtumlenkung*).

([59]) AMMENDOLA, cit., 140.

the EPO Boards of Appeal, three important aspects for assessing the common general knowledge of the skilled person are:

> "(a) Firstly, the skills of such a person include not only *basic general knowledge* of a particular field of technology, but also the *ability to look up such knowledge* in encyclopaedias and handbooks […].
>
> (b) Secondly, […] in order to identify this common general knowledge, the skilled person *will* [not] *carry out a comprehensive search* of the literature covering virtually the whole state of the art. […].
>
> (c) Thirdly, the information found *must be unambiguous and usable in a direct and straightforward manner* without doubts or further research work […].
>
> These three aspects actually correspond to the classical steps of (a) picking an adequate reference book (handbook, encyclopaedia, etc.) from the bookshelf in the library, (b) identifying the appropriate section(s) without this requiring any significant effort and (c) getting the correct information or unambiguous data that can be used without further research work" ([60]).

While common general knowledge "is to be found in basic handbooks, monographs, encyclopaedias, textbooks and reference books" ([61]), this notion is not limited to written disclosures but can include also the unwritten "mental furniture" of the skilled person ([62]). On the other hand, not "every word" that can be read in a manual is *per se* common general knowledge ([63]). Information does not become general knowledge because it has been published in a particular textbook. Rather, information appears in "handbooks or textbooks because it was *already* common knowledge" ([64]).

The common general knowledge normally does not include patents and scientific publications. While both categories belong to the state of the art, they are *prima facie* specialists' information ([65]). By way of exception, however, information contained in patent specifications and scientific articles may be considered part of the common general knowledge, for instance: (*i*) "when a field of research is so new that [it] has not yet found its way into

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([60]) EPO, T 890/02, 14 October 2004 (*Chimeric gene/BAYER*) § 3, emphasis added. See also EPO, T 149/07, 20 November 2009.

([61]) EPO CASE LAW, *Definition of "common general knowledge"*, cit., § I.C.2.8.1.

([62]) EPO, T 939/92, 12 September 1995 (*Triazoles/AGREVO*).

([63]) *Raychem Corp's Patents*, cit. 40.

([64]) EPO, T 766/91, 29 September 1993 (*Decorative laminates/BOEING*), § 8.2, emphasis added.

([65]) EPO, T 475/88, 23 November 1989.

textbooks” ([66]); (*ii*) “when […] a series of publications provides a consistent picture that a particular technical procedure was generally known” ([67]); (*iii*) when a specialized document provides a “broad review or survey on a topic” ([68]); or (*iv*) when the information appeared in scientific periodicals addressed to qualified professionals and enjoying a worldwide repute ([69]).

Within these loose boundaries, the assessment of what constitutes common general knowledge is a question of fact ([70]), which needs to backed up by evidence, if challenged ([71]). The guiding principle is that, to qualify as common general knowledge, the information must be commonly accepted on the merits — in the words of T-890/02 the information “must be unambiguous and usable in a direct and straightforward manner without doubts or further research work”. Therefore, information that has drawn scepticism from workers in the field is not common general knowledge even if widely published. Likewise, ideas that have never been put into practice (“paper proposals”) might not become part of the common general knowledge ([72]). These principles have been summarised in T 383/88 as follows ([73]):

> “common general knowledge is notoriously difficult to prove, even when all the various types of evidence permitted […] are taken into consideration […]. The difficulty lies mostly in gauging the degree of commonality, for whilst information may be *generally disseminated*, and therefore known within the community of skilled addressees, it may well, at the same time, not be *commonly accepted*. In other words, there may be differing views on the truth or falsity of the information and no less so if these views are expressed in standard textbooks. Nor can too much reliance be placed on affidavit evidence from over-qualified persons, for the relevant knowledge is that of the notional, i.e. average skilled addressee, and not that commanded by leaders in the

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([66]) EPO, T 1634/15, 14 October 2016 (*CODIS core STR loci forensic human identification/PROMEGA*), § 12.

([67]) ibid.; see also EPO, T 537/90, 20 April 1993 (*Walzdraht*) (numerous publications in the specialist press over a fairly short time reporting on meetings and research in a particularly active field of technology).

([68]) EPO GUIDELINES, *Common general knowledge of the skilled person*, cit., § G-VII.3.1. See also EPO, T 309/88, 31 October 1990 (-).

([69]) EPO, T 378/93, 6 December 1995 (*TOSHIBA/Self-aligned*).

([70]) EPO, T 890/02, 14 October 2004 (*Chimeric gene/BAYER*), cit., § 3.

([71]) EPO GUIDELINES, *Common general knowledge of the skilled person*, cit., § G-VII.3.1. EPO, T 939/92, 12 September 1995 (*Triazoles/AGREVO*).

([72]) COLE, DAVIS, *CIPA Guide to the Patents Acts*, cit., § 3.12.

([73]) EPO, T 383/88, 1 December 1992 (*Pyrimidinones/BIOMEASURE*).

> relevant scientific discipline or field".

UK courts – which have dedicated unparalleled attention to the definition of common general knowledge ([74]) – have adopted a similar, but perhaps broader approach to the definition common general knowledge. As put in the *General Tire* decision ([75]), quoting a passage from Luxmoore J in *British Acoustic Films* ([76]):

> "[a] piece of particular knowledge […] does not become [CGK] merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and [*generally regarded as a good basis for further action*] by the bulk of those who are engaged in the particular art" ([77]).

Based on *General Tire*, the threshold for CGK in the UK might appear lower than the EPO one at first sight, since information that is "generally regarded as good basis for further action" might not be "unambiguous". The Court in *General Tire* specifically stressed that while the Luxmoore J held that information is CGK when it is "accepted without question", that would risk "putting the position rather high" ([78]). Hence "without wishing to put forward any full definition", the Court suggested to set the bar of CGK as information that is "generally regarded as a good basis for further action" ([79]).

Therefore, UK scholars suggest that a scientific theory does *not* need to have been "*generally accepted* as correct" to qualify as common general knowledge, provided that "it is regarded as a *reasonable working hypothesis* by the bulk of those skilled in the art" ([80]). Recently, Birss J also suggested

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([74]) This is in part because the UK approach to inventive step is more reluctant to combine different documents, so CGK assumes a higher relevance, as discussed in § IV.B.4.2.2 below.

([75]) *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] R.P.C.

([76]) British Acoustic Films (53 R.P.C., 221, at 250).

([77]) *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] R.P.C. 457 at 482-483 (referring to scientific papers, but the argument can be extended also outside this category). See also *Cipla Ltd. & Ors v Glaxo Group Ltd.* [2004] EWHC 477 (Pat) at 25. FRANZOSI, *Non ovvietà*, cit., 573; FRANZOSI, *I requisiti*, cit., 579.

([78]) *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd*, cit., 483.

([79]) ibid. See also BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 8.64; FRANZOSI, *Non ovvietà*, cit., 573; FRANZOSI, *I requisiti di brevettabilità*, in FRANZOSI, SCUFFI (eds.), *Diritto industriale italiano*, CEDAM, Padova, 2014, 579.

([80]) BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 8-66, emphasis added.

that "the existence of a defined area of doubt and uncertainty does not mean that, in principle, such knowledge is not part of the common general knowledge" ([81]). Whether the EPO and UK approaches to common general knowledge actually differ on the merits is an open question ([82]). In both cases, however, the key to the CGK assessment is that "requirements of *quality* and *reliability* must be satisfied" ([83]).

In recent years, it was questioned whether information that can be retrieved in a widely used electronic database would qualify as common general knowledge. In T 890/02 the Board found that the nucleotide sequences included in the EMBL and ENZYME databases were common general knowledge since the skilled person looking for that information would have been able to find it easily, without any further research work, by simply by typing the enzyme name ([84]). Therefore, those databases were functionally equivalent to an encyclopaedia.

Once again the point was not that said information was available as

([81]) *Merck Sharp & Dohme Ltd v Ono Pharmaceutical Co Ltd & Anor* [2015] EWHC 2973 (Pat) (22 October 2015) at [24].

([82]) *Rockwater Ltd v Technip France SA & Anor* [2004] EWCA Civ 381 (01 April 2004) at 9 ("other countries within the European Patent Convention apply, so far as I understand matters, essentially the same standard").

([83]) *Omnipharm Ltd v Merial* [2011] EWHC 3393 (Pat) (21 December 2011) at [42], emphasis added. See also ENGLAND, *A practitioner's guide*, cit., 16.

([84]) EPO, T 890/02, 14 October 2004, cit. To the contrary, indexes of chemical abstracts cannot serve this function as it would imply to ask the skilled person to look up in the entire state of the art: EPO, T 206/83, 26 March 1986 (*Herbicides*). See also ENGLAND, *A practitioner's guide*, cit., 16. The Author suggests that the EPO adopts a more generous approach to databases as part of the CGK as opposed to English courts which tend to disagree that the information the skilled person knows they can look up as a matter of routine is part of the CGK. See in particular, *KCI Licensing Inc & Ors v Smith & nephew Plc* 2010 EWHC. See also *Beloit Technologies v Valmet Paper Machinery* ("employees of some companies with the use of libraries and patent departments, will become aware of information soon after it is published in a whole variety of documents; whereas others, without such advantages may never do so until that information is accepted generally an put into practice. The notional skilled addressee is the ordinary man who may not have the advantages that some employees of large companies have"). However, this position seems at odd with the generally quoted statement in Raychem's Patents, according to which the CGK is "not limited to material which he has memorized and has in the front of his mind. It includes all the material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work".

such, but rather that the skilled person deemed the EMBL and ENZYME databases as an "adequate source" of information, which was available "in a straightforward and unambiguous manner without any need for supplementary searches" ([85]). If that assumption is correct, the Board's approach seems sensible. It should be noted, however, that the patent holder had argued that information in those databases, although harvested from scientific papers, was added as "unverified, raw or crude information prone to contain numerous and major errors" ([86]). If that were the case, the content of those databases ma not qualify, as a matter of fact, as CGK.

Finally, the geographic latitude of the common general knowledge is somewhat uncertain. For instance, English courts have suggested that, while the "state of the art" is by definition universal ([87]), the CGK is that held by a skilled person working in the UK ([88]). Italian scholars have maintained similar positions ([89]). In contrast, the EPO has rather clearly affirmed that "a differentiation between skilled persons according to their nationality as regards their knowledge" would run "against the objective assessment of inventive step" ([90]). The matter has not been settled conclusively.

1.6 The means and capacities available to the skilled person

On top of abundant knowledge, the skilled person has "the means and capacity for routine work and experimentation which are normal for the field of technology in question" ([91]). The "normal" means comprise the intellectual capabilities, the techniques, as well as the equipment/tools available to the

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([85]) ibid.

([86]) ibid.

([87]) See § IV.A.2.

([88]) *Regen Lab v, Estar Medical*, cit. 48; *Generics UK Ltd vs Warne Lambert*, cit., 123-124.

([89]) DI CATALDO, *L'originalità dell'invenzione*, cit., 73 ss (more broadly referring to the skills of the person skilled in the art); DI CATALDO, *I brevetti per invenzione*, cit., 144.

([90]) EPO, T 426/88, 9 Novemebr 1990 (*Combustion engine*); EPO, T 124/85, 14 December 1987; See also KROHER, cit., § 25; SUOMINEN, DE LANGE, RUDGE, cit., 183 (arguing that "nationality makes no difference […] there is no difference between a European and an American skilled person; knowledge is accessible everywhere").

([91]) EPO GUIDELINES, cit. § G-VII. See also BLOK cit. 70-71, and further references therein.

skilled person ([92]).

From an intellectual point of view, despite being quite knowledgeable, the skilled person is, by definition, unimaginative ([93]) and non inventive ([94]). Otherwise, the skilled person would be an inventor ([95]). The skilled person is nevertheless fully rational, having the "capacity to draw conclusions from information obtained" from the prior art ([96]) and thus to make obvious combinations thereof ([97]). The skilled person is also constantly occupied with the elimination of deficiencies, the overcoming of drawbacks and the

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([92]) STANKOVÁ, cit. 21 (stating that the PSITA "is a notional expert (or a team of experts) in the technical field of the invention who […] possesses the necessary equipment and *technical tools* which vary according to the technical field", emphasis added); P. SLOWINSKI cit., 265 (using a microscope as the example of the typical tool in the hands of the PSITA).

([93]) EPO, T 1761/12, 19 December 2017. See also BENGI, HEATH, *Patents and Artificial Intelligence Inventions*, in HEATH, SANDERS, MOERLAND (eds.), *Intellectual Property Law and the Fourth Industrial Revolution*, Wolters Kluwer, Alphen aan den Rijn, 2020, 141 (the skilled person is "one who knows everything, yet imagines nothing"). See also BGH, 7 September 2004, X ZR 255/01 (*Bodenseitige Vereinzelungseinrichtung*).

([94]) EPO, T 39/39, 14 February 1994 (*Polymer powders*), § 7.8.4. SUOMINEN, DE LANGE, RUDGE, cit., 183 (stressing that defining the skilled person as "uninventive" is not "useful, as it will probably result in a circle reasoning").

([95]) EPO, T 39/39, 14 February 1994 (*Polymer powders*), § 7.8.4. *Contra* DI CATALDO, *L'originalità dell'invenzione*, cit., 74; CERULLA, *La brevettabilità delle invenzioni realizzate dall'intelligenza artificiale*, Ph.D. Thesis at the University of Pavia, 2021, 100-101. Also VANZETTI, DI CATALDO, SPOLIDORO, CIT., 410 ("sicuramente deve essere riconosciuta al tecnico medio la capacità di combinare le anteriorità in un mosaico coerente"). *Contra*, GALLI, *Per un approccio realistico al diritto dei brevetti*, in *Dir. ind.*, 2010, 2, 136 (stressing that such a broad reference to the skilled person's capability to combine prior art, in general, might go beyond the threshold for non-obviousness which is more conservative). In the case law, see e.g., Court of Venice, 30 September 2009, in *Giur. ann. dir. ind.*, 2009, *5458* ("la persona esperta del ramo è un soggetto dotato di elevata esperienza nel settore di riferimento ma non è un 'inventore'"); Court of Venice, 13 October 2009, in *Giur. ann. dir. ind.*, 2009, *5460* (identical wording).

([96]) EPO, T 1761/12, cit. See also, Appeal Court of Milan, 29 December 1992, in *OneLegale* ("[l]'esperto del settore dispone non solo di mere capacità applicative, ma altresì di capacità di rielaborazione del patrimonio tecnico, limitatamente a collegamenti ovvi che potrà essere in grado di stabilire fra le varie anteriorità rilevanti"); Court of Milan, 12 February 2014, in *OneLegale* ("[l'esperto è dotato di] capacità di rielaborazione che gli consente di combinare la tecnica anteriore più vicina con altre anteriorità purché alla data di deposito della privativa esistesse uno stimolo univoco e non una mera possibilità di compiere tale operazione").

([97]) Court of Milan, 25 January 2016, cit.

achievement of improvements of known devices and/or products ([98]) and can spot and correct obvious mistakes ([99]). Furthermore, the skilled person is affected by the prejudices and limitations that are common in the field ([100]). Jacob LJ thus famously defined the skilled person as "a nerd […] but not a complete android" ([101]).

More in general, the skills and attitude of the skilled person strongly depend on their area of expertise. In certain technical fields the average skilled person is assumed to be sophisticated (e.g., genetic engineering), whereas in others less so ([102]). In the biotechnology field, for instance, the skilled person was deemed generally cautious and conservative, not a risk taker ([103]).

On a practical level, the skilled person is capable of carrying out routine experiments which do not cause a great difficulty or a full scientific research in un-investigated or technically complex fields ([104]). The skilled person will carry out experiments and deploy techniques when there is a reasonable expectation of improvement ([105]) or an urgent need for a solution to a technical problem ([106]). They will not carry out experiments out of pure curiosity ([107]).

According to the Boards of Appeal, nothing more can be expected from the skilled person than the carrying out of experimental work by *routine means* within the framework of the normal practice of filling gaps in

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([98]) EPO, T 455/91, 20 June 1994 (*Expression in yeast/GENENTEHC*).

([99]) *Valensi v BTC* [1973] PC 337 at [377].

([100]) See also DI CATALDO, *L'originalità dell'invenzione*, cit., 69.

([101]) *Rockwater Ltd v Technip France SA & Anor* [2004] EWCA Civ 381 (01 April 2004). In the same decision, Pill LJ questions the wording by Jacob J, stating: "[a] 'nerd' is defined in the Concise Oxford Dictionary […] as 'a person who lacks social skills or is boringly studious' and an 'android', in the same work, as '[…] a robot with a human appearance'. I hope that those working in this field will not regard 'men skilled in the art' as figures from science fiction who lack social skills".

([102]) *Cipla Ltd. & Ors v Glaxo Group Ltd.* [2004] EWHC 477 (Pat) at 24.

([103]) EPO, T 455/91, 20 June 1994 (*Expression in yeast/GENENTEHC*). ENGLAND, *A practitioner's approach*, cit., 16 and 18-19.

([104]) NÄGERL, WALDER-HARTMANN, cit., 348.

([105]) EPO, T 2/83, 15 March 1984 (*Simethicone Tablet / Rider*).

([106]) BGH, 19 December 1985, X ZR 53/83 (*Thrombozyten-Zählung*).

([107]) EPO, T 939/92, 12 September 1995 (*Triazoles/AGREVO*).

knowledge by the application of existing knowledge ([108]). In a case where the technical problem consisted in the exact identification and characterization of certain DNA sequences of the Hepatitis B virus ("HBV"), the Board found that there was no inventive step because (*i*) the prior art contained a good amount of knowledge on the HBV and its genome, and (*ii*) the missing information could be found by relying on the "*methods and means* (e.g. [specific] antisera […]) as well as *techniques for the location and DNA* sequence analysis [which] were known in the art" ([109]).

The Italian scholarship further stresses that the skilled person shall also be deemed to have an average financial availability and equipment ([110]). In contrast, there is at least one precedent in UK case law that suggests that the person skilled in the art should be credited with the "best available equipment" ([111]). The case was a gene sequencing one, which was a quite advanced technical field at the time, and the Court's conclusion might make sense in that specific context. However, as a general principle, giving the skilled person the "best equipment" seems at odds with the construction of the skilled person as being the average one. Depending on the circumstances, having and knowing how to operate the "best" equipment might indeed fall outside the common general knowledge of the average skilled person ([112]).

([108]) EPO, T 886/91, 16 June 1994 (*Hepatitis B virus/BIOGEN INC*).

([109]) EPO, T 886/91, 16 June 1994 (*Hepatitis B virus/BIOGEN INC.*), § 8.24.

([110]) DI CATALDO, *I brevetti per invenzione*, cit., 144-145; VANZETTI-DI CATALDO-SPOLIDORO, cit., 409-410. The authors, however, also suggest that a research path that implies a considerable investment in time, money and equipment – e.g., pharmaceutical screenings – might therefore be out of the reach of the skilled person even if it only implies routinary techniques. *Contra*, however, GALLI, BOGNI, *Il requisito di brevettabilità dell'attività inventiva*, cit., 613, who convincingly stress that the latter interpretation proposed by Vanzetti and Di Cataldo, which is exclusively focused on the research efforts, rather than the non-obviousness thereof, must be rejected.

([111]) *Genentech Inc's Patent* [1989] R.P.C. 147, 261–266. Hints in the same direction can be seen also in EPO, T 192/82 ("[t]he skilled man must be free to employ the best means already available for his purposes").

([112]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 136. (also suggesting that the "best available equipment" is not in line with the EPO standard, but pointing out that if that means "best available equipment" in the particular field, that can still be the normal one).

1.7 The skilled team

Finally, it is broadly accepted that the skilled person can be represented by a skilled *team* ([113]). The EPO considers this approach helpful where "an expert in one particular field was appropriate for solving one part of the problem, while for another part one would need to look to another expert in a different area" ([114]).

This is often the case in complex fields, such as in pharmaceutical research, where multidisciplinary teams in R&D are the norm ([115]). For instance, in *Actavis v. Lilly* the invention ([116]) concerned a combination therapy of an antifolate (pemetrexed) with vitamin B_{12} and optionally folic acid, in the form of a "Swiss-type" claim ([117]). There, the UKSC found that the skilled person was a team made up by an oncologist and a chemist. Both figures would have contributed to the invention, respectively for the therapeutic aspects and the chemical form of the drug ([118]).

In another well-known case, the EPO Boards of Appeal held that "where a new technology [is] about to spread into a traditional field, it [is] common practice to group people from both technical fields into a development team" ([119]). In particular, the Board found that the skilled person for solving the problem of improving the fabrication of dental appliances consisted of a team of an orthodontist and an expert in computer-assisted design/manufacturing ("CAD/CAM") technology, based on an overall

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([113]) EPO CASE LAW, cit., § I.D.8.1.2. See also BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 8-36. *Contra*, but isolated, AMMENDOLA, *La brevettabilità nella convenzione di Monaco*, cit., 136.

([114]) EPO, T 986/96, 10 August 2000.

([115]) GURGULA, cit., 16.

([116]) More precisely, claim 1 of the patent at stake (EP 1 313 508).

([117]) Swiss-type claim refers to the wording of a claim such as "use of a substance or composition X for the manufacture of a medicament for the therapeutic application Z". This wording was used before the EPC 2000 amendment to Article 54(4) and (5) EPC which explicitly allowed claims directed to a first or further medical use of a known product. See EPO GUIDELINES, *First or further medical use of known products*, cit., § G.VI.7.

([118]) *Actavis v Eli Lilly* [2017] UKSC 48, § 22. See also *Actavis v. ICOS* [2019] UKSC 15, § 17 ("the notional skilled team […] would include a clinical pharmacologist with experience in pharmacokinetics and a clinician specialising in urology").

([119]) EPO, T 15/15, 16 March 2017, § 4.4.

assessment of the field as derived from the prior art ([120]).

In some circumstances, the case law implies that rather than a skilled *team* proper, the skilled person should be construed as an individual which, in relation to specific aspects of the invention, would consult the average expert in another technical field ([121]). This different construction of the team might import some differences as to the amount of knowledge that the "consulted" skilled person would bring. Indeed, while it is reasonable to assume that, within a skilled *team*, each member would bring their own competency and common general knowledge in full, this is not necessarily the case in all circumstances. In other words, one might assume that the skilled person, reaching out to another person for a particular aspect of the invention, would have derived only certain technical information, but would not have automatically "absorbed" the full common general knowledge in that field. For instance, a mechanical engineer might necessitate some technical knowledge in lubricants chemistry and, for that reason, they would call up a chemist on certain aspects. That does not mean – at least, automatically – that the mechanical engineer would then dispose of the chemist's full CGK.

Within the team, depending on the circumstances, the skilled members might have different roles and work under the supervision of a leader ([122]). The composition of the team can vary depending on the knowledge and skills required for a particular aspect ([123]). The team does not necessarily work as a single unit and sub-contractors can also be part of the skilled team ([124]).

([120]) ibid. ("[i]n the early nineties, use of computers in planning and manufacturing was spreading into basically every industry and field of technology. As evidenced by e.g., E30, […] the field of dentistry and orthodontics was no exception"; document E30, i.e., U.S. Patent No. 5,338,198, read: "[CAD/CAM] have significant potential for improved quality and cost efficiency when applied to dentistry").

([121]) EPO, T 164/92, 29 April 1993 (*Electronic computer components*). In the German case law: BGH, 29 September 2009, X ZR 169/07 (*Diodenbeleuchtung*).

([122]) *Actavis vs. ICOS Corp*, cit. (the clinician takes the lead when assessing the clinical significance of an effect); OTTOLIA, cit., 377 ("caratteristiche ulteriori quale il livello di organizzazione del gruppo di ricerca medio").

([123]) EPO, T 412/93 21 November 1994 (*Erythropoietin/KIRIN-AMGEN*).

([124]) *Genentech Inc's Patent* [1989] R.P.C. 147 at 261–266.

2. The state of the art

Finally, a few words must be devoted to the notion of "state of the art". The state of the art (also referred to as "prior art") is defined in Article 54 EPC as "everything made available to the public by means of a written or oral description, by use, or in any other way" before the date of filing of the European patent application, or its priority date ([125]). The Italian corresponding provision is essentially identical, but for the clarification that it is indifferent whether the prior art has been made available in the "territory of the State or abroad" ([126]). The state of the art is thus absolute and universal in nature ([127]). It comprises *everything* made available in way, in *any* country, in *any* language, at *any* time ([128]).

For the purposes of the present work, the most important feature of the prior art is its availability to the public ([129]). The standard adopted on availability by the EPO is rather broad. The longstanding approach was that the "theoretical possibility" of having access to information was sufficient to make it available to the public ([130]). That case law, however, mostly concerned printed disclosures. As Internet disclosures became the norm, the Boards found it necessary to add that what is required is the "practical possibility of having access" for at least one member of the public. That means, for instance, that the online content is prior art when it was indexed (i.e., it could be found via a search engine and keywords) and it remained accessible long enough to make access realistic ([131]).

In any case, as a matter of law, it is irrelevant whether on the priority or

([125]) Article 47(3) c.p.i.

([126]) Article 46(2) c.p.i.

([127]) VANZETTI-DI CATALDO-SPOLIDORO, cit., 404.

([128]) See e.g., *Unilin Beheer BV v Berry Floor NV* [2007] F.S.R. 25 at [46] (Jacob J: "my favourite pretend example is an anticipation written in Sanskrit wrongly placed in the children's section of Alice Springs public library").

([129]) Court of Milan, 23 January 2017, in *Giur. ann. dir. ind.* 2017, 6504; Court of Milan, 14 May 2020, in *Giur. ann. dir. ind.* 2020, 6916 ("[una divulgazione] deve consistere in una comunicazione o diffusione che porti il trovato a conoscenza di un numero indeterminato di persone").

([130]) EPO, T 444/88, 9 May 1990.

([131]) EPO, T 1553/06, 12 March 2012 (Public availability of documents on the World Wide Web/PHILIPS).

application date a member of the public actually *saw* the document or *knew* it was available ([132]). Also, a document is considered "made available" even if it is in practice accessible only by one single member of the public ([133]).

In contrast, information is not "made available" to the public when it is disclosed under confidentiality rules – either explicitly or, in certain cases, even implicitly ([134]). Typical cases of confidential disclosures are those made under a non-disclosure agreement (NDA) or the internal company information (e.g., test results or trials), based on the employees' duty of loyalty ([135]).

Moreover, the case law stresses that information is *not* made available if the people receiving it are not able to understand it and, therefore, are not in a position to use it or to disseminate it ([136]). A complex chemical formula is not made available to the public if shown to a child ([137]). More precisely, a disclosure that is relevant for the state of the art implies that there is a technical teaching that a skilled person would be in the position to appreciate and have access to ([138]).

Finally, Article 54(3) EPC adds to the state of the art also the European patent applications that had been already filed at the priority date (or application date) of a second European patent application, provided that they are then published. These applications are, by definition, not made available

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([132]) EPO, T 381/87, 10 November 1987 (*Publication*).

([133]) EPO, T 1081/01, 27 September 2004 (*Acetals/NEW JAPAN CHEMICAL*).

([134]) Court of Turin, 22 February 2007, *Giur. ann. dir. ind.* 2007, 5140; Court of Milan, 14 May 2020, cit. (no disclosure when third parties are bound by confidentiality obligations).

([135]) E.g., in Italy, Article 2105 c.c. ("[i]l prestatore di lavoro non deve […] divulgare notizie attinenti all'organizzazione e ai metodi di produzione dell'impresa, o farne uso in modo da poter recare ad essa pregiudizio").

([136]) BIRSS ET AL., *Terrell on the Law of Patents*, cit., 313.

([137]) *Folding Attic Stairs Ltd v The Loft Stairs Company Ltd & Anor* (Rev 1) [2009] EWHC 1221 (Pat) (09 June 2009) ("[w]ould an abstruse chemical formula displayed on private premises be 'made available to the public' if none were present except a child who could not understand it; or a lady who was not wearing her glasses; or a man who was focusing his attention on the Cup Final on TV?", the answer being no since "there is no irrebuttable presumption of law that information that is capable of being perceived by persons who are on private premises is in fact perceived by them, if the circumstances are such as to make it unlikely that those persons were interested in the subject-matter").

([138]) NÄGERL, WALDER-HARTMANN, cit., § 378.

to the public because they are published 18 months after the filing date ([139]). However, as a policy choice, secret applications are considered part of the state of the art only for the assessment of novelty in order to avoid the possibility of identical inventions being filed by different applicants at different times. Notably, the state of the art for the assessment of inventive step does *not* include secret applications, but only published ones ([140]). Secret applications cannot be accounted against the inventor of the subsequent patent application for inventive step also when they were filed by the same person which, by definition, was aware of them ([141]).

B. INVENTIVE STEP

1. The notion of inventive step

Inventive step is arguably the most important ([142]) and most problematic ([143]) requirement for patentability. In simple terms, its goal is to ensure that only inventions that do not "lie at the fingertips" of the skilled person are protected by exclusive rights ([144]). This is because it is assumed that the skilled person

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([139]) Article 93(1)(a) EPC.

([140]) Article 56, second sentence, EPC.

([141]) GALLI, BOGNI, *Intelligenza artificiale*, cit., 131.

([142]) BEIER, *The inventive step in its historical development*, in IIC 1986, 301-303 (arguing that inventive step is the "crucial condition of patentability" that "dominat[es] all other requirements"). See also CASALONGA, *The Concept of Inventive Step in the European Patent Convention*, in *IIC*, 1979, 412. In the U.S. scholarship: WITHERSPOON (ed.), *Non-Obviousness: The ultimate condition of patentability: papers compiled in commemoration of the silver anniversary of 35 USC 103*, Bureau of National Affairs, Washington, 1979.

([143]) BENTLY ET AL., cit., 577, quoting Learned Hand famous statement that "invention" – in the pregnant sense thereof that comprises also the modern notion of "nonobviousness" – is "as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts" (in *Harries v. Air King Products Co*., 183 F.2d 158). Unsurprisingly, inventive step is also the patentability requirement that is most often litigated: LUGINBÜHL, cit., 194; FABRIS, cit., 688; See also CHISUM, *Chisum on patents: a treatise on the law of patentability, validity, and infringement*, LexisNexis, 1978-2021, II, § 5.02.6; ROMM, cit., 1422.

([144]) P. SLOWINSKI, cit., 263. See also BENGI, HEATH, cit., 141. Court of Rome, 12 September 2001, in *Giur. ann. dir. ind.*, 2002, *4362*, 291 ("[l'attività inventiva] segna la linea di confine fra ciò che appartiene al divenire normale di ciascun settore, che potrebbe essere would carry out obvious and routine developments in the relevant field in any case without needing a separate incentive through patent protection ([145]).

Article 56 EPC thus provides that an invention involves an inventive step if it is *not obvious to a skilled person*, having regard to the state of the art. The EPO Guidelines generally define the term "obvious" as something that "does not go beyond the *normal progress* of technology", following logically from the prior art, and does not imply the exercise of any "ability beyond that to be expected of the person skilled in the art" ([146]). However, there is no useful paraphrase or definition of what "obvious" means ([147]). Obviousness inevitably requires a factual inquiry that touches upon several

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realizzato da qualunque operatore e che, quindi, non merita la protezione, e ciò che invece è frutto di un'idea che supera le normali prospettive di evoluzione del settore, che non è alla portata dei tanti che in esso operano e che, quindi, merita la tutela esclusiva"); reaffirned in Court of Bologna, 28 April 2010, *Gruppo Barbieri & Tarozzi s.p.a. c. Sima s.r.l.*, in *Giur. ann. dir. ind.* 2010, *5552*. This principle was formulated in the scholarship, see: VANZETTI, DI CATALDO, SPOLIDORO, cit., 408; DI CATALDO, *Le invenzioni*, cit., 139; ACQUAFREDDA, cit., 415.

([145]) RAMALHO, cit., 87 (arguing that "inventive step […] "selects" the inventions that would not be created if a patent system did not exist. Conversely, if the invention would be created anyways – because within the reach of the skilled person – granting a patent over it would be counter-intuitive"). See also EMMERICH, *Die Auswirkungen künstlicher Intelligenz auf die erfinderische Tätigkeit und das Erfinderprinzip*, LIT, Berlin, 2021, 45. This principle was clearly expressed in the seminal U.S. Supreme Court decision *Graham v. John Deere Co.*, 383 U.S. 1 (1966), 11, which held that the non-obviousness requirement is a "means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent". See also ABRAMOVICZ, DUFFY, *Inducement Standard of Patentability*, in *Yale Law Journal*, 2011, 120(7), 1590 (arguing that inducement should be the doctrinal polestar in the understanding of non-obviousness); NAKAYAMA, *Patentability and PHOSITA in the AI Era – A Japanese Perspective*, in LEE, HILTY, LIU (eds.), *Artificial Intelligence and Intellectual Property*, Oxford University Press, Oxford, 2021, 109 (also making reference to the inducement standard). *Contra* MANDEL, *The non-obvious problem: how the indeterminate nonobviousness standard produces excessive patent grants*, in *U.C. Davis Law Review*, vol. 42, 86-87 (suggesting that an inducement standard, if strictly applied, would be problematic as it might allow patents on trivial inventions that would not have occurred if not of the possibility of a patent).

([146]) EPO GUIDELINES , cit., § G-VII.4.

([147]) *Johns-Manville Corporation's Patent* [1967] RPC 479 (Lord Diplock held: "I doubt whether there is any verbal formula [of obviousness] which is appropriate to all classes of claims").

different factors ([148]). Given the fact-specific nature of the inquiry, scholars also warn that precedents should always be "treated with caution" ([149]).

The EPO and national courts have developed different tests and approaches to the question of obviousness. However, in the end, inventive step boils down to the one question: "is it obvious?" ([150]). It is important never to lose sight of the overall question ([151]).

In a short paper published in 2008, *Franzosi* suggested that since inventions are "an act of intuition", the inventive step assessment also requires "an intuition", i.e., a *common sense* evaluation, whereas excessively rigid formulas that attempt to demonstrate non-obviousness deductively are neither possible, nor correct ([152]). As such, this view is perhaps extreme ([153]) as the study of inventive step in Europe can benefit from at least 50 years of uninterrupted case law and scholarship since the Munich convention in 1973. Nevertheless, drawing the line in the sand between what is obvious and what

([148]) DAVIS, QUINTIN, TRITTON, *Tritton on Intellectual Property Law*, 5th ed., Sweet & Maxwell, London, 2018, 2-176; PILA, TORREMANS, *European Intellectual Property Law*, 2nd ed., 2019, 172 (stressing how the multifactorial nature of the inventive step requirement was appreciated since its very adoption by the contracting states).

([149]) BENTLY ET AL., cit., 578.

([150]) As a side note, it should be noted that the term "obvious" is used to mean different things in patent law. For instance, Rule 139 EPC provides that "[l]inguistic errors, errors of transcription and mistakes in any document filed with the European Patent Office may be corrected on request. However, if the request for such correction concerns the description, claims or drawings, the correction must be obvious *in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction*" (emphasis added). Obviousness under Rule 139 EPC clearly does not correspond to that of Article 56 EPC.

([151]) JOHNSON, *Article 56 EPC*, in HACON, PAGENBERG (eds.), *Concise European Patent Law*, 2nd ed., Wolters Kluwer, Alphen aan den Rijn, 2008, 56.

([152]) FRANZOSI, *Definizione di invenzione brevettabile*, cit., 33. The reference to common sense is drawn from the seminal U.S. Supreme Court decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) ("[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. […] Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it").

([153]) However, later contributions of the Author, provide a more comprehensive analysis, see e.g., FRANZOSI, *I requisiti di brevettabilità*, cit., 568-573.

is not is still quite complicated ([154]) and some degree of subjectivity is perhaps inevitable ([155]).

The following paragraphs briefly address the evolution of the inventive step requirement (§ IV.B.2), its objective nature (§ IV.B.3) and the different approaches adopted by the EPO, as well as in Italy, the UK and Germany to structure the analysis (§ IV.B.4). The purpose is not to put forward a full-fledged comparative study, but rather to derive the shared traits of the inventive step examination across these jurisdictions. The analysis then turns to the specific issue of "obvious to try" inventions, both at the EPO and before national courts (§ IV.B.5). Finally, this section touches upon the so-called secondary indicia of inventive step (§ IV.B.6) and concludes stressing the need to adopt a nuanced approach to the assessment of inventive step (§ IV.B.7)

2. Origins of the inventive step

The inventive step requirement is a relatively modern notion in patent law ([156]). While the Venetian Inventor's Statute of 1474 ([157]) already provided for a protection against imitation for "new and ingenious devices" ([158]) it was

([154]) VANZETTI, DI CATALDO, SPOLIDORO, cit., 409.

([155]) DI CATALDO, *L'originalità dell'inenzione*, cit., 81.

([156]) For a complete account on the history of "inventive step" or "nonobviousness" see: DUFFY, *Inventing Invention: A Case Study of Legal Innovation*, in *Texas Law Review*, 2007, vol. 86, No. 1, 1; PESSERS, *The inventiveness requirement in patent law: An exploration of its foundations and functioning*, Kluwer Law, Alphen aan der Rijn, 2016.

([157]) The Venetian Inventor's Statute is presumably the oldest patent legislation in the world and it was strikingly discovered only in the mid-twentieth century by the Italian researcher Giulio Mandich: see MANDICH, *Le privative industriali veneziane*, in *Riv. dir. comm.*, 1936, 511. See also SCHIPPEL, *La storia delle privative industriali nella Venezia del '400*, Centro tedesco di studi veneziani, Venezia, vol. 38, 1989.

([158]) Cfr. *La legge veneziana sulle invenzioni. Scritti di diritto industriale per il suo 500° anniversario*, Giuffrè, Milan, 1974. See also the contribution from Sordelli in the same volume: SORDELLI, *Intérêt social et progrès technique dans la "parte" vénitienne du 19 mars 1474 sur les privilèges aux inventeurs*, cit., 265 (arguing that the reference to « ingenious » devices suggested that, at least in principle, a certain originality and inventive level were expected). *Contra*, BEIER, cit., 305 (suggesting that the reference to an "ingenious" device is "nothing more than an additional argument to justify the issuance of the privilege rather than a condition of protection […] in today's sense"). Similarly also PESSERS, cit., 49 (arguing not until the mid-nineteenth century that the U.S. Supreme Court first suggested in *Hotchkiss v. Greenwood* that "unless more ingenuity and skill […] were required [….] than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that *degree of skill and ingenuity which constitute essential elements of every invention*" ([159]). Because the 1790 Patent Act only referred to the "novelty and utility" requirements, from then on in the U.S. case law the term "invention" was used also to imply a certain *quality* of the invention that was necessary for its patentability, i.e., its *inventive character* ([160]).

The U.S. case law – also inspired by the raging antitrust sentiment of Roosevelt's "New Deal" – progressively embraced a remarkably strict interpretation to that *quality* of the invention. This culminated in the equally famous case *Cuno Engineering* of 1941, where the Supreme Court held that an invention could be patented only as long as it revealed a "flash of creative genius" ([161]). In the following years, the courts' positions on patentability grew extreme – barely conceding that an invention "need not to be as startling as an atomic bomb to be patentable" ([162]). The U.S. Congress then attempted to abolish the "flash of genius" test by enacting a new patent statute in 1952 which introduced the well-known modern definition of non-obviousness in 35 U.S.C. § 103 (later amended) as a separate patentability requirement as follows:

> "[a] patent may not be obtained […] if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter

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that "a certain amount of prudence is warranted" as to the relevance of the Venetian Law for the inventiveness standard; according to the author "the concept of inventiveness was given some weight [in the Venetian Law] within contemporary patentability assessments, though without being transformed into a sharply defined legal standard").

([159]) *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850).

([160]) BEIER, cit., 305. See e.g., the detailed analysis of the "invention" requirement in DELLER, *Walker on Patents, Deller's Edition*, Baker, Voorhis & Co., New York, 1937, 109-253.

([161]) *Cuno Engineering Corp. v. Automatic Devices Corp.,* 314 U.S. 84, (1941).

([162]) See concurring opinion by Mr. Justice Douglas (to whom Mr Justice Black agreed) in *A. & P. Tea Co. v. Supermarket Equipment Corp.,* 340 U.S. 147 (1950), as cited in BEIER, cit., 305.

pertains" ([163])

Nevertheless, the case law did not give in easily. In *Graham v. John Deere*, the U.S. Supreme Court held that the newly minted § 103 had actually codified its previous jurisprudence ([164]). At the same time, *Graham* also laid out the modern doctrinal framework for obviousness ([165]), stating that:

> "[u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined" ([166]).

The current leading case on non-obviousness in the U.S. is *KSR Intern. Co. v. Teleflex Inc.*, which essentially confirmed the *Graham* framework ([167]).

The emergence of the inventive step criterion followed essentially the same path also in Germany, England, Italy and France. Until the mid-twentieth century, national patent statutes generally recognized only novelty and industrial applicability as patentability criteria, but the case law had progressively imbued the notion of "invention" so to imply also a certain distance from (or quality related to) the prior art ([168]). The dogmatic notion of

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([163]) The current wording of 35 U.S.C. § 103 is: "[a] patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made".

([164]) *Graham v. John Deere Co.*, 383 U.S. 1 (1966), 3.

([165]) GRIMMELMANN, *Patterns of Information Law*, 2016-2022, Chapter 3, 56, http://james.grimmelmann.net/courses/ip2022F/.

([166]) *Graham v. John Deere Co.*, 383 U.S. 1 (1966) (the Court added that "Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented").

([167]) *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007). Famously, in *KSR* the Court stressed that "the person of ordinary skill is also a person of ordinary creativity, not an automaton".

([168]) DI CATALDO, *L'originalità dell'invenzione*, cit., 13 ff and 37 ff. See e.g., HOPKINS, *Handbook of the German Patent Law*, Hopkins & Lenz, Berlin, 1894, 4 (holding that "the novel means forming the alleged invention must not merely consist of an exchange of parts inventive step – as relating to subject-matter that would not be obvious to a person skilled in the art – was only first introduced (although not in these precise terms) by Germany in the proposal to the Council of Europe's Committee of Experts in Patents in the 1950s as a notion modelled of the U.S. legislation and supported by the case law of several European states ([169]).

The inventive step requirement was then formally adopted in the span of ten years in three international treaties counting many European contracting states: the Strasbourg Convention (1963), the PCT (1970) and the EPC (1973) ([170]). From there, it found its way in the national patent systems ([171]). Notably, the adoption of the modern notion of inventive step definitively removed the idea that, in order to be patentable, the invention must bring about a "technical progress", as in an objective advancement to the state of the art. Providing an *alternative* (not necessarily *better*) solution to a known problem is enough. Nowadays, it is established that progress *per se* is not a prerequisite for patentability, but at most a secondary indicia of non-obviousness ([172]).

[…], such as might reasonably be devised b any skilled workman but such combination must have as its basis one or more original or generic idea or ideas so as to remove the invention from the region of mere constructiveness").

([169]) PILA, TORREMANS, cit., 172.

([170]) Respectively in: Article 5 SC (notably, this provision did not mention the skilled person, but merely that "[a]n invention shall be considered as involving an inventive step if it is not obvious having regard to the state of the art") Article 33 PCT, Article 56 EPC.

([171]) See e.g., fn. 47 above (discussing the introduction of the inventive step requirement in the Italian patent law).

([172]) AMMENDOLA, cit., 198 ("si è così ricondotti verso la ben nota relazione tra 'progresso tecnico' e 'attività inventiva', secondo la quale la presenza del primo di tali fattori costituisce un indizio sull'esistenza del secondo"). DI CATALDO, *I brevetti per invenzione*, cit., 140, fn 95 and 147; DI CATALDO, *L'originalità dell'invenzione*, cit., 30 ff. and 87 ff. (detailing the old approach in the case law, whereby originality was interpreted as requiring both (*i*) technical progress and (*ii*) a creative contribution; and then the current understanding of the law); GALLI, BOGNI, *Il requisito di brevettabilità dell'attività inventiva*, cit., 583-584; BOSSHARD, cit., 154. See also BERGIA, *Article 48 c.p.i.*, in VANZETTI (ed.), *Codice della Proprietà Industriale*, Giuffrè, Milan, 2013, 664 ff. (discussing the role of "technical progress" in the Italian case law before the introduction of the "inventive step" concept and then confirming that, the modern notion of inventive step does an objective progress). BERGIA, cit., 667, also stresses that the provision under Article 71 c.p.i. which provides for a compulsory license of a "dominant" patent with respect to a "dependent" one

3. Inventive step as an objective notion

At the outset it is important to stress once again that inventive step, like the invention, is an objective concept both at the EPO and in the jurisdictions here considered (and, more broadly, in most modern patent laws) ([173]). The subjective state of the inventor is thus entirely irrelevant for the inventive step assessment. What matters is only whether at the application (or priority) date the notional skilled person would have found the invention obvious or not having regard to the state of the art ([174]). Briss J put it quite plainly in *Thaler*:

> "[w]hether there has been an inventive step is a question answered by considering how a notional person skilled in the art would behave. The notional person skilled in the art has attributes which no real human being does or could have. The test involves the application of an objective legal standard […]. Real inventors do not have to make subjective inventive steps when they devise their inventions. Many inventors think that the inventions they have made were obvious to them. Whether they thought that or not is irrelevant because the

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depends on the fact that the second shows an "important technical progress". Indirectly this provision confirms that there can be valid patents that do *not* imply such an "important technical progress".

It is thus quite surprising that even contemporary decisions from the Italian Supreme Court still mention "technical progress" (and, oddly enough, in relation to the novelty requirement): see e.g., Cass., 23 March 2012, No. 4739, in *Giur. ann. dir. ind.* 2012, 1, 49 ("ai fini del riconoscimento del brevetto per invenzione industriale si richiede, sotto il profilo sostanziale, che l'invenzione si fondi sulla soluzione di un problema tecnico non ancora risolto e sia idonea ad avere concrete realizzazioni nel campo industriale, tali da apportare un *progresso rispetto alla tecnica* ed alle cognizioni preesistenti […] e da esprimere un'attività creativa dell'inventore, che non sia semplice esecuzione di idee già note e rientranti nella normale applicazione dei principi conosciuti […]", emphasis added). Likewise, see Cass., 22 November 2010, No. 23592, in *Giur. ann. dir. ind.*, 2010, *5493*; Cass., 4 November 2009, No. 23414, in *Giur. ann. dir. ind.* 2010, 31. However, it is suggested that the reference to "technical progress" is merely paying lip service to the concept, without deriving from it relevant consequences, and also fundamentally wrong (see e.g., the anonymous note to Cass. 23 March 2012, in *Giur. ann. dir. ind.*, cit.). Contemporary decisions confirm this interpretation: Cass., 11 December 1999, No. 13863; Cass. 9 September 2005, No. 17993, in *Foro it.*, 2006, 129(1), 113, with comments from CASABURI.

([173]) KROHER, cit., §§ 6-9. See also in the U.S. scholarship, CHISUM, *Chisum on patents: a treatise on the law of patentability, validity, and infringement*, LexisNexis, 1978-2021, § 5.04[2] ("[t]he proper inquiry is not what the particular inventor in fact did to develop the invention but rather what a [PHOSITA] would have been required to do to develop the invention").

([174]) DAVIS, QUINTIN, TRITTON, cit., 2-178; KROHER, cit., § 6.

legal standard is an objective one" ([175]).

Likewise, eminent scholars have stressed that:

> "[t]he comparison called for [in the inventive step analysis] is between two *objective* conditions: the state of the art and what the patentee claims to have invented. It is not an inquiry into how easy or difficult it was for him *personally* to take the step. The patent system makes no attempt to exclude protection for accidental, lucky or sudden inventions. […] Equally it is of no relevance to consider whether the person responsible thought that he had made an invention" ([176]).

The EPO has often repeated the principle as well ([177]).

4. Structured approaches to the inventive step assessment

The EPO – and national courts alike – have developed and progressively refined a number of structured approaches to the question of obviousness in order to increase predictability and reduce the room for subjectivity and hindsight bias. None of these methods are provided by the law or set in stone. They are all instruments to orient the interpreter in asking the right questions ([178]). The following paragraphs briefly explore these methods, in turn.

4.1 The EPO problem-solution approach

The EPO adopts the so-called "problem-solution approach" to the determination of inventive step ([179]). While the EPO recognizes that the problem-solution approach is not mandatory, it is applied in all but

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([175]) *Thaler v Comptroller General of Patents Trade Marks And Designs* [2021] EWCA Civ 1374, cit.. The court also added that "if there is now a class of potentially patentable inventions which can be created without a human inventor then this does not mean that objective standard could not be applied to consider whether the invention satisfies the test".

([176]) CORNISH, LLEWELYN, APLIN, *Intellectual property: patents, copyright, trade marks and allied rights*, 9th ed., Sweet & Maxwell, London, 2013, § 5-31, emphasis added.

([177]) EPO, T 24/81, 13 October 1982, (*Metal refining/Basf AG*), § 4.

([178]) *Actavis v. ICOS* [2019] UKSC 15.

([179]) The problem-solution approach finds support *inter alia* in Rule 42(1)(c) EPC, which provides that the description shall "disclose the invention, as claimed, in such terms that the *technical problem*, even if not expressly stated as such, *and its solution* can be understood, and state *any advantageous effects* of the invention with reference to the background art". FABRIS, cit., 689 and further references therein. In general, on the problem-solution approach see KNESH, *Assessing inventive step in examination and opposition proceedings in the EPO*, in *epi Information* 1994, 3, 95.

exceptional cases ([180]). The problem-solution approach comprises three main steps: (*i*) determining the *closest prior art*; (*ii*) establishing the *objective technical problem* to be solved; and (*iii*) considering if the claimed invention, starting from the identified closest prior art and the objective technical problem, *would have been obvious* to the skilled person ([181]).

4.1.1 *Determining the closest prior art*

The first step in the problem-solution approach is to identify the closest prior art. The Guidelines define the closest prior art as the "single reference [that] discloses the combination of features which constitutes the most promising starting point for a development leading to the [claimed] invention" ([182]).

To select the closest prior art one must look at whether the document is directed to a similar purpose or effect as the invention or at least belongs to the same or a closely related technical field as the claimed invention. Generally, the closest prior art is that which corresponds to a similar use and requires the minimum of modifications ([183]). If there are several equally valid starting points, the problem solution approach must be applied to each of them in turn. The closest prior art is assessed from the skilled person's point of view on the day before the filing or priority date for the claimed invention ([184]).

([180]) SUOMINEN, DE LANGE, RUDGE, *Visser's Annotated European Patent Convention*, Wolters Kluwer, Alphen aan den Rijn, 2022, 197 ("although this means of analysing inventive step is not mandatory, it is very unusual for the EPO to take any other approach").

([181]) EPO GUIDELINES, cit., § G-VII.5. It should be noted that the terms "obvious" (English version), "évidente" (French version) and "naheliegend" (German version) are not entirely corresponding. In particular, the word "évidente" (evident) as opposed to "obvious" might seem to imply a lower threshold (the difference being that "évidente" implies something that can be plainly seen). However they are treated as uniform in the interpretation developed by the EPO and the contracting states: KROHER, cit., § 41.

([182]) EPO GUIDELINES, cit., § G-VII.5. However, see also EPO, T 855/15, 10 January 2018 (*Security architecture/WONDERWARE*) (arguing that if a piece of prior art is "too remote" from an invention, it should be possible to show that the invention is not obvious to a skilled person having regard to this piece of prior art).

([183]) EPO, T 606/89, 18 September 1990 (*closest prior art/Unilever*).

([184]) EPO GUIDELINES, cit., § G-VII.5.

4.1.2 *Establishing the objective technical problem*

The *objective* technical problem of the invention is then established essentially by subtraction. In particular, one studies the patent (or the patent application) to spot the differences in terms of features (also known as "distinguishing features") between the invention as claimed and the closest prior art ([185]).

The *technical effect* that these differences give rise to is then identified and the objective technical problem is determined accordingly to those differences. Features that do not make any contribution to the technical character of the invention cannot support the presence of the inventive step ([186]). The term "objective" is used to distinguish this notion from any generic technical problem that the patent application may have described in the specification. In the EPO's view, only the *objective* technical problem properly takes into account the real distance between the (closest) prior art and the invention, while the inventor might perceive the distance as wider (for instance, because they are not subjectively aware of the closest prior art) ([187]).

However, it is important that the objective technical problem is not formulated so as to contain *pointers* to the technical solution, since including part of the technical solution within the problem would necessarily lead to an *ex post facto* approach to the inventive step question ([188]).

4.1.3 *Obviousness* (*could-would approach)*

The third step of the problem-solution approach is where the obviousness question is specifically asked and answered. To do so the EPO introduced a sub-test, known as "could-would approach". The question to be asked is whether there is any teaching in the prior art that *would* – not simply *could* – have prompted the skilled person, being faced with the objective technical problem, to modify or adapt the closest prior art and achieve what the

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([185]) EPO GUIDELINES, Formulation of the objective technical problem, cit., § G-VII.5.2.

([186]) Typically, this is the case of computer-implemented inventions. See EPO, T 641/00 26 September 2002 (*Two identities/COMVIK*).

([187]) EPO GUIDELINES, Formulation of the objective technical problem, cit., § G-VII.5.2.

([188]) EPO, T 229/85, 27 October 1986 (*Etching process*).

invention achieves, for instance because the prior art provided motivation to do so in the expectation of some improvement or advantage ([189]). The motivation or incentive can also be implicit ([190]).

In this respect, it is worth noting that obviousness is not only at hand when the results are clearly predictable ([191]), or a "one-way-street" necessarily leads to the invention ([192]), but also when the skilled person has a reasonable expectation of success ([193]). Furthermore, an invention can be found obvious also when it requires a series of steps starting from the closest prior art, provided that the technical problem leads the skilled person to the solution step-by-step and each individual step is obvious in the light of the previous one(s) and the residual problem to be solved ([194]). To the contrary, the simple fact that a solution would have been *technically possible* does not imply that is was obvious for the person skilled in the art ([195]).

4.1.4 *Combining pieces of prior art*

In everyday practice, the EPO generally considers (lack of) inventive step arguments construed as combinations of prior art documents (also known as "mosaicing"). Typically, an examiner or an opponent would argue that, starting from the closest prior art, the distinguishing features are obvious in light of the disclosure found in another piece of prior art (e.g., a document, a public prior use, etc.) ([196]). That is: Document 1 (D1) + Document 2 (D2) = Invention.

([189]) EPO, T 2/83, 15 March 1984 (*Simethicone Tablet / Rider*), § 7.

([190]) EPO, T 257/98, 3 September 2002 (*Lipase-containing detergent composition/ UNILEVER*); EPO, T 35/04, 18 January 2006 (*Paper surface sizing/AVEBE*).

([191]) EPO, T 149/93, 23 March 1995 (*RETINOIDS/Kligman II*).

([192]) EPO, T 231/97, 21 March 2000 (*Emissionsarme Dispersionsfarben/ CLARIANT*).

([193]) EPO, T 149/93, 23 March 1995 (*RETINOIDS/Kligman II*); GALLI, *Per un approccio realistico al diritto dei brevetti*, in *Dir. ind.*, 2010, 2, 136 ("le brevettabilità dell'invenzione [non va] esclusa solo nel caso in cui l'esperto si trovasse di fronte una strada obbligata, dovendosi invece valutare ogni volta, e caso per caso, se l'impiego di determinati accorgimenti fosse suggerito dai documenti che il tecnico avrebbe considerato nell'esaminare il problema").

([194]) EPO, T 558/00, 18 February 2004 (*Developer/CANON*), § 4.

([195]) KROHER, cit., § 77.

([196]) JOHNSON, cit., 55.

The EPO is considerably more sceptical of lack of inventive step arguments that combine more than two disclosures ([197]). Rather, the fact that the skilled person needs to combine three or more disclosures might indicate the presence of an inventive step ([198]). However, information pertaining to the common general knowledge can generally be combined with the disclosure(s) of the prior art, even when the CGK is not referred to in the prior art ([199]). Therefore, it is generally permissible to build an inventive step argument such as: D1 + D2 + CGK = Invention.

In the EPO practice it is not strictly necessary that one of the two documents to combine points out to the other, but a similar pointer would suggest that the combination is obvious ([200]). To the contrary, when two disclosures are inherently incompatible with respect to disclosed features which are essential to the invention, their combination is normally regarded as non-obvious ([201]).

Finally, an important factor to consider as to the combination of prior art disclosures is whether they come from similar, neighbouring or remote technical fields: the farthest away, the less obvious the combination ([202]).

4.1.5 *Critical aspects of the problem-solution approach*

Over the years, the problem-solution approach has proved to be a workable

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([197]) JOHNSON, cit., 56.

([198]) EPO GUIDELINES, *Combining pieces of prior art*, G.VII.6. See also BENGI, HEATH, cit, 141; JOHNSON, cit., 56.

([199]) JOHNSON, cit., 56-57.

([200]) See e.g., EPO, T 905/17, 16 September 2019. As reported in the EPO CASE LAW, cit., "the board did not find persuasive the opposition division's dismissal of a line of argument on the basis that there was no 'hint[']' [in the prior art]. The skilled person starting from one element of the state of the art and faced with the need to solve a given problem did not necessarily need a 'hint' associated with that element. Otherwise, it would never be possible to establish a lack of inventive step based on the object of a prior public use, which usually does not come with any hints. In the absence of a hint, the skilled person might still take the steps leading to the claimed subject-matter on the basis of their common general knowledge or documents belonging to the state of the art that explicitly teach a solution to the problem to be solved".

([201]) EPO GUIDELINES, *Combining pieces of prior art*, G.VII.6.

([202]) EPO GUIDELINES, *Combining pieces of prior art*, G.VII.6.

and efficient method for assessing inventive step at the EPO ([203]). Focusing on a single piece of prior art as the closest is particularly convenient for EPO's administrative functions ([204]). Yet the problem-solution approach has drawn a fair share of criticism.

In particular, already in the 90s, in ALCAN/*Aluminium alloys*, the Boards highlighted that the problem-solution approach should be considered as one amongst other possible approaches, each with its own advantages and drawbacks ([205]). An opponent should not be tied down to selecting *one* piece of prior art as the closest and run the risk of failing in his opposition if the Board disagrees with that selection. The main issue highlighted by ALCAN with the problem-solution approach is that "it is inherently based on hindsight" as it "relies on the results on a search" of the closest prior art and the objective technical problem that is "made with actual knowledge of the invention" ([206]). Furthermore, the Board stressed that the problem-solution approach led to "a complicated multi-step reasoning" even when the facts are simple. For instance, if the invention "breaks entirely new ground, it might suffice to say that there is no close prior art" rather than going through the three steps ([207]).

On top of the inherent hindsight issues highlighted also by the Boards ([208]), the problem-solution approach has been criticized by European courts and scholars for being "unnecessarily artificial", since many inventions are not developed having a specific problem in mind ([209]). The problem-

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([203]) BENTLY ET AL., cit., 579; PILA, TORREMANS, cit., 174-175 ; DAVIS, QUINTIN, TRITTON, cit., § 2-197 (according to the authors, this is to be applauded because, in the majority of cases, the problem-solution approach works well).

([204]) PILA, TORREMANS, cit., 174-175.

([205]) EPO, T 465/92, 14 October 1994 (*Alcan/Aluminium alloys*).

([206]) ibid, § 9.5.

([207]) ibid. See also *contra*, SZABO, *Clarifying addendum to the problem-solution approach*, in *epi Information*, 1995, 1, 13.

([208]) ENGLAND, *A practitioner's guide*, cit., 331. See also DAVIS, QUINTIN, TRITTON, cit., § 2-183 – 2-185 (arguing that the identification of the problem too narrowly and too close to the invention is flawed: a better approach would be to define the problem in reference to the disadvantage in the prior art).

([209]) BENTLY ET AL., cit., 581. HAGEL, MENES, *Making proper use of the problem-solution approach*, in *epi Information*, 1995, 1, 14. See also PILA, TORREMANS, cit., 175.

solution approach is also hardly applicable in the case of "problem inventions" ([210]) in which the invention lies in posing the problem, whereas the solution becomes obvious once the problem is formulated ([211]).

4.2 National approaches to the inventive step assessment

4.2.1 *The Italian approach*

The Italian provision on inventive step is encompassed in Article 48 c.p.i., which is essentially identical to Article 56 EPC save for the fact that – in line with the French version of the EPC – rather than "obvious" the term "evident" appears ([212]). However, the prevailing opinion is that there is no material difference between "obviousness" and "evidence" in the context of the inventive step assessment ([213]).

Despite some initial resistance in the scholarship ([214]), Italian courts

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([210]) See § IV.C.3.1 below.

([211]) See e.g., *Actavis UK Ltd v Novartis AG* [2010] EWCA Civ 82 (17 February 2010). Likewise, see VANZETTI, DI CATALDO, SPOLIDORO, cit., 414. *Contra*, PEARCE, *Problem-Solution Approach: ur doin it wrong*, in *IPKat*, 17 February 2010, https://ipkitten.blogspot.com/2010/02/problem-solution-approach-ur-doin-it.html (arguing that these perceived hindrances "are well known and fit into the problem-solution approach without too much difficulty"; as to problem inventions, in particular, this is because "the problem may not even have been recognised as being a problem, but instead merely a fact of life, so the recognition of it being one with a potential solution could form part of the inventive step").

([212]) Article 48 c.p.i., first sentence, reads: "[u]n'invenzione è considerata come implicante un'attività inventiva se, per una persona esperta del ramo, essa non risulta in modo evidente dallo stato della tecnica".

([213]) SORDELLI, cit., 227. *Contra* GIAN. GUGLIELMETTI, *Le invenzioni e i modelli industriali dopo la riforma del 1979*, cit., 43.

([214]) In particular, Cesare Galli highlighted how authors such as Adriano Vanzetti, Vincenzo Di Cataldo e Giuseppe Sena relied, until recently, on vague formulations of the inventive step requirement: GALLI, BOGNI, *Il requisito di brevettabilità dell'attività inventiva*, cit., 585; GALLI, *Per un approccio realistico*, cit., 140, referring to VANZETTI, DI CATALDO, SPOLIDORO, cit., 408 (the current editions, however, also includes a dicussion of the problem-solution approach: ibid., 411-414); SENA, *I diritti sulle invenzioni*, cit., 125 and 148. Instead, Mario Franzosi embraced the problem-solution early on: FRANZOSI, *Non ovvietà*, cit., 560 ff; FRANZOSI, *I requisiti di brevettabilità*, cit., 572 (rephrasing the problem-solution approach as a 10-steps test). For a broader study on the inventive step interpretation under Italian (and EPO) law, see SANSEVERINO, *Il passo inventivo*, Giuffrè, Milano, 2012.

have broadly adopted EPO's problem-solution approach for the determination of inventive step ([215]). Recently, the Italian Supreme Court endorsed the lower court's reliance on the problem-solution approach as elaborated in the EPO Guidelines ([216]). At the same time, however, the Court stressed that any alleged violation or wrongful application of the EPO Guidelines is only relevant for an Italian court insofar it also determines a violation or wrongful application of Article 48 c.p.i. and Article 56 EPC. Along the same lines, scholars have stressed that the problem-solution approach, while a helpful method, shall not be applied mechanistically ([217]).

4.2.2 *The UK approach*

Inventive step in the UK is regulated under Section 3 Patent Acts 1977, which is essentially identical to Article 56 EPC ([218]). The structured approach to the assessment of obviousness currently used in the UK was first set out in 1985

([215]) Cass., 26 February 2016, No. 3805. See also *ex multis*: Court of Milan, 17 January 2017, in *DeJure*; Court of Milan, 24 January 2017, in *DeJure*; Court of Bologna, 21 April 2016, in *DeJure*; Court of Milan, 17 September 2014, in *Giur. ann. dir. ind.*, 2014, *6173*; Court of Milan, 17 May 2012, in *Giur. ann. dir. ind.*, 2012, *5881*; Court of Turin, 11 April 2011, in *Giur. ann. dir. ind.*, 2011, *5714*; Court of Turin, 2 March 2011, in *Giur. ann. dir. ind.*, 2011, *5702*. It is submitted that the adoption of the problem-solution approach by Italian courts is in part due to the relevant influence that European patent attorneys have on Italian proceedings. In patent cases, merits courts generally appoint an independent patent attorney (as a "*consulente tecnico d'ufficio*" or C.T.U.) with experience in the field of the invention to carry out a technical assessment to support the judge's decision. Each party then appoints its own patent attorney and this gives rise to a sort of "technical" sub-proceedings. At the end of this "technical phase", the Court-appointed technical expert delivers a "technical opinion" ("*relazione di CTU*"). Since those appointed are usually European patent attorneys, they have brought their experience in dealing with EPO, which in turn ended up forming the basis of the Court's reasoning and brought to the progressive adoption of the problem-solution approach within Italian case law (see FRANZOSI, *I requisiti di brevettabilità*, cit., 567). See, in general on the role of the C.T.U. in Italian proceedings, ACQUAFREDDA, cit., 415 (arguing that the court's reliance of the expert's opinion is sometimes acritical); MANSANI, *La consulenza d'ufficio nelle cause di proprietà intellettuale: profili giuridici*, in *Dir. ind.*, 2013, 3, 281 (raising similar concerns).

([216]) Cass. 16 March 2022, No. 8584.

([217]) VANZETTI, DI CATALDO, SPOLIDORO, cit., 413-414.

([218]) This provision reads: "[a]n invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art […]". Like Article 56 EPC, the state of the art for inventive step under Section 2 Patents Act 1977 does not include unpublished patent applications.

in the *Windsurfing* case ([219]) and was later adjusted by Jacob LJ in *Pozzoli* ([220]). The test is thus commonly referred to as the "Windsurfing/Pozzoli" approach. The steps are the following:

> "(1) (a) Identify the notional person skilled in the art; (b) Identify the relevant common general knowledge of that person;
>
> (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
>
> (3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
>
> (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"

Notably, the Windsurfing/Pozzoli test does not presuppose the identification of the closest prior art, nor the determination of the objective technical problem addressed by the invention (at least expressly).

Furthermore, in contrast with the EPO practice, combining different prior art citations ("mosaicing") is generally *not* permissible in the UK – a "heresy" according to some ([221]) – unless it can be shown that, confronted with a particular piece of prior art, the skilled person would have turned to some other citation ([222]). This is the case, for instance, when the first document *cross-references* the second ([223]). Hence, lack of inventive step arguments are usually construed either as the combination of *a* prior art document with CGK (D1 + CGK) or, more rarely, based on common general knowledge alone ([224]).

Despite the marked differences between the approaches, several voices in scholarship and among judicial ranks have stressed that the PSA and the Windsurfing/Pozzoli methods are unlikely to come to different results on the

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([219]) *Windsurfing International Inc v Tabur Marine* [1985] RPC 59.

([220]) *Pozzoli v BDMO* 89 [2007] EWCA Civ. 588, [2007] FSR 37.

([221]) DAVIS, QUINTIN, TRITTON, cit., § 2-207.

([222]) BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 12-149.

([223]) *Pfizer Ltd's Patent* [2001] F.S.R. 16 at [65]–[66] (adding that the presence of a cross-reference is not the only instance when documents can be combined).

([224]) BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 12-44 – 12-46.

merits in most cases and that UK Courts should attempt to approximate EPO Boards' decisions as much as possible ([225]).

4.2.3 *The German approach*

Inventive step in Germany is regulated by Section 4 PatG, which is essentially identical to Article 56 EPC ([226]). To assess inventive step, the *Bundesgerichtshof* generally asks the following questions (often to an expert) ([227]):

> "1) Which steps would the average person skilled in the art have to carry out to arrive at the teaching of the application or patent?
>
> 2) Would the average person skilled in the art have cause to direct his or her thinking in this direction?
>
> 3) What in the present case at hand argues for or against the average person skilled in the art carrying out these considerations and arriving at the solution claimed in the application or patent?".

Similarly to UK courts, also German courts have refrained from adopting the problem-solution approach and, in particular, the closest prior art standard, rather opting for a more holistic assessment ([228]). According to German courts, whether the skilled person would start from a certain piece of prior art does not hang upon it being the closest to the invention, since that is something that can be ascertained only with hindsight ([229]). Hence, German courts might take into consideration several pieces of prior art at a time. Prior art documents can also be combined ("mosaicing"), especially when there is a clear cross-reference ([230]).

([225]) BENTLY ET AL., cit., 464.

([226]) This provision reads: "An invention is deemed to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art". Like Article 56 EPC, the state of the art for inventive step under Section 4 PatG does not include unpublished patent applications.

([227]) ENGLAND, *Inventive step in Europe and the UPC*, in *JIPLP*, 13(7), 536. Cf. also NÄGERL, WALDER-HARTMANN, cit., § 566.

([228]) ROTH, *Office practice – Inventive step attacks in Europe and Germany*, in LEXOLOGY, 27 February 2018; ENGLAND, *Inventive step in Europe and the UPC*, cit., 566.

([229]) BGH, 16 December 2008, X ZR 89/07 (*Olanzapin*); BGH, 18 June 2009, X ZR 138/05 (*Fischbissanzeiger*).

([230]) NÄGERL, WALDER-HARTMANN, cit., § 566.

In the determination of obviousness, however, the approach adopted by German courts is somewhat similar to the could-would method ([231]). Additional incentives, suggestions, hints or other reasons which go beyond the recognizability of the technical problem are usually required to seek the solution of the technical problem by means of the invention ([232]).

4.3 Conclusion on the structured approaches

The structured approaches to the determination of inventive step at the EPO and those adopted by Italian, UK and German courts are not aligned with one another, and several differences as to how inventive step is assessed remain. In particular, the most contested aspects of EPO's problem-solution approach is the formalistic reliance on the "closest prior art" and formulation of the "objective technical problem" starting from it. Nevertheless, it also submitted that the different approaches share sufficient similarities to allow a broadly coherent discussion ([233]). As noted in a comparative study, indeed, whatever the structured approach adopted "they all ask the obviousness question itself in the last stage" ([234]). And, looking ahead, one hopes that the UPC will draw upon the EPO and national experiences commonalities to put forward an uniform notion of inventive step ([235]).

5. Reasonable expectations of success and "obvious to try"

Within this background, one way of looking at the obviousness question that has gained considerable traction, especially in the pharmaceutical and biotechnology fields, is the so-called "obvious to try" question. Recognizing that chemistry and biology are generally unpredictable sciences – meaning that, before trying something out, one cannot tell with certainty if it will work

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([231]) KROHER, cit., § 77.

([232]) BGH, 30 April 2009, X ZR 92/05 (*Betrieb einer Sicherheitseinrichtung*).

([233]) See e.g., FRANZOSI, *I requisiti di brevettabilità*, cit., 560-561 (arguing that the differences between the English and EPO approaches are "substantially formal" and that the German approach "is not different from the European one).

([234]) ENGLAND, *A practitioner's approach*, cit., 351.

([235]) ibid.

or not ([236]) – a number of decisions, both at the EPO and before national courts, have established that when a particular research path is (*i*) "obvious to try" and (*ii*) the skilled person would have had a "reasonable expectation of success" to find a solution to the technical problem, the invention will often lack inventive step ([237]).

5.1 The EPO approach

According to the EPO case law, a "reasonable expectation of success" must not be confused with a mere "hope to succeed": it implies "the ability of the skilled person to *predict rationally*, on the basis of the knowledge existing before a research project was started, the *successful conclusion* of the said project *within acceptable time limits*" ([238]). In other words, while a specific research path might be "obvious to try" the resulting invention might still be non obvious if the skilled person would have deemed its results completely unpredictable ([239]).

In this respect, "the more unexplored a technical field of research [is], the more difficult it [is] to make predictions about its successful conclusion and, consequently, the lower the expectation of success" ([240]). Likewise, the degree of expectation of success also depends on the complexity of the

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([236]) GURGULA, cit., 7.

([237]) GALLI, BOGNI, *Il requisito di brevettabilità dell'attività inventiva*, cit., 588; MINSSEN, cit., 75; BIRSS ET AL., *Terrell on the Law of Patents*, cit., § 12-74 ff.; ENGLAND, *Obvious to try, one year on*, in *JIPLP*, 2009, vol. 4(2), 114. See e.g., in the Italian case law, Court of Milan, 24 July 2019, *Actavis Group PCT EHF et al. v. AstraZeneca AB et al.*, in *Darts-ip* ("le […] rivendicazioni non superano il giudizio di non ovvietà secondo i criteri comunemente utilizzati dalla giurisprudenza comunitaria e nazionale. Vi era infatti una chiara spinta a percorrere la strada poi battuta da EP '573, con una ragionevole aspettativa di successo"). The "obvious to try" approach has been adopted also in the U.S., for instance in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). In the literature, see e.g.: LEMLEY, *Expecting the Unexpected*, in *Notre Dame L. Rev.*, 2017, vol. 92, 1369 (arguing that whenever the doctrine of "obvious to try" conflicts with the fact that an "unexpected result" was obtained, the latter doctrine must give way); TRASK, *"Obvious To Try": A Proper Patentability Standard in the Pharmaceutical Arts?*, in *Fordham L. Rev.*, vol. 76, 2008, 2625, https://ir.lawnet.fordham.edu/flr/vol76/iss5/9.

([238]) EPO, T 296/93, 28 July 1994 (*HBV antigen production*), § 7.4.4, emphasis added.

([239]) GURGULA, cit., 8.

([240]) ibid.

technical problem to be solved ([241]). Lower challenges are usually associated with a higher expectation of success, while for more complex problems, where important difficulties might arise, the expectation of success would also be lower ([242]).

Even when it is possible to conceive a straightforward approach in theory, the skilled person might be confronted with unexpected difficulties when putting that strategy into practice and might need to take a number of decisions along the way. In similar cases, it cannot be said that the skilled person had a reasonable expectation of success ([243]). On the other hand, the mere fact that a claimed invention was the result of a research path that required considerable amounts of time and money, *per se*, does not necessarily mean that the skilled person would not have arrived at the solution, in particular when the work was relatively uncomplicated and routine ([244]).

As a variant to the "obvious to try" approach, the EPO identified the so-called "try-and-see" situations. The Boards have found that when "the implementation and the testing of an approach suggested by the prior art does not involve any particular technical difficulties" there is no need to assess whether the skilled person would have had a reasonable expectation of success or not. In those situations, the skilled person would prefer to verify whether the potential solution works ("try-and-see"), rather than abandon the project because it is uncertain ([245]).

At first sight, the EPO case law on "try-and-see" seems to contradict the principle that a mere "hope to succeed" is not sufficient to establish a lack

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([241]) EPO, T 2168/11, 24 June 2015 (*Alzheimer's disease beta amyloid peptide mouse model/ELAN ELI LILLY*), § 11.3.

([242]) EPO, T 192/06, 6 March 2007, (*FokI endonuclease/JOHNS-HOPKINS*) § 11; EPO, T 782/07, 4 February 2009, (*Human Antibodies/WELLCOME*) § 35.

([243]) EPO, T 816/90, 7 September 1993 (), § 5.2.7; EPO, T 923/92, 8 November 1995 (*human t-PA*), § 51; See also ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 867 (stressing that in fields where there are uncertain prospects, the distance to the state of the art increases with every decision that the expert has to make about the course of the research).

([244]) EPO, T 333/97, 5 October 2000 (*Somatic changes/MONSANTO*). See also MINSSEN, cit., 77.

([245]) EPO, T 259/15, 25 July 2017 (*Buprenorphine patch/EURO CELTIQUE*).

of inventive step. However, the "try-and-see" approach can be reconciled with the "obvious to try" test simply noting that the foundational assumption of the first is that the skilled person does not expect *any* difficulties arising from the implementation and the testing: pure routine is at stake. In similar cases, the mere fact that the result would be unpredictable, and thus the skilled person would not materially known whether something would work before trying it out, is not enough to eschew a lack of inventive step finding. In these terms, a "try-and-see" situation would still be one where the skilled person would have had at least *some* expectation of success. In line with this reading, the Boards have recently added that a "try-and-see" attitude "does not equate with an absence of a reasonable expectation of success" ([246]). Floyd J reached the same conclusion in *Regeneron v Genentech*, as he declined to read the "try-and-see" language "as setting a standard inconsistent with the requirement for a fair expectation of success" stressing that "the degree of expectation depend[s] on the facts of the case" ([247]).

5.2 Examples

Within this broad framework, the assessment of whether an invention is "obvious to try" with a "reasonable expectation of success" requires a case-by-case assessment.

For instance, the Boards found that it was obvious to run comparative tests on twelve compounds indicated in a prior art document to find out the most effective one for an obvious purpose ([248]). In contrast, the English Court of Appeal, overturing the first instance decision ([249]), found that an ointment consisting of two known active ingredients (calcipotriol and betamethasone), a base and a commercially available solvent (Aramol E) was inventive ([250]). At the priority date, the common general knowledge was that the active

([246]) EPO, T 1396/06, 31 May 2007 (*HLA Binding Peptides/EPIMMUNE*).

([247]) *Regeneron Pharmacueticals Inc v Genentech Inc* [2012] EWHC 657 (Pat) (22 March 2012), § 128.

([248]) EPO, T 541/89, 21 March 1991 (*BEECHAM-WÜLFIND/PVD*)

([249]) *Teva UK Ltd & Anor v Leo Pharma A/S* [2014] EWHC 3096 (Pat).

([250]) *Teva UK Ltd & Anor v Leo Pharma A/S* [2015] EWCA Civ 779 (28 July 2015), cited also in ENGLAND, *A practitioner's approach*, cit., 325-326.

ingredients could not be used together, but that a non-aqueous solvent could have solved the problem. However, it was not clear whether there was any solvent that would produce a stable ointment. The skilled person would have had to undergo a research project to find out an appropriate one. While the use of non-aqueous solvents was "well worth investigating", that did not mean that any solvent had a reasonable expectation of success ([251]).

Also cases that are *prima facie* very similar can lead to different conclusions. In T 777/08, the Board found that a crystalline form of a known active ingredient (atorvastatin hydrate) was obvious ([252]). From the CGK, the skilled person would have known that (*i*) polymorphism is commonplace in molecules of interest in the pharmaceutical industry; (*ii*) screening for polymorphs can be done by routine methods; and that (*iii*) crystalline products are generally easier to isolate, purify, dry, handle and formulate. Having this in mind, the skilled person would have had a clear expectation that a crystalline form with the required characteristics (improved filterability and drying) could be obtained. It was therefore "obvious to try this avenue with a reasonable expectation of success without involving any inventive ingenuity" ([253]). As to the specific polymorph claimed, the Board found that it was a mere arbitrary selection from a group of equally suitable candidates, and that selection did not involve an inventive step ([254]).

To the contrary, in T 1684/16, the Board found that a specific crystalline form of an active ingredient (bosutinib monohydrate) was not obvious ([255]). The objective technical problem was identified as providing a more stable form of bosutinib. While the investigation into polymorphs to isolate the best crystalline form was indeed routine, the Board found that there was no clear pointer in the prior art that the specific identified crystalline form would solve the technical problem and it would have been completely unpredictable which form would be the most stable one (the prior art suggested that "solvate

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([251]) *Teva UK Ltd & Anor v Leo Pharma A/S* [2015] EWCA Civ 779 (28 July 2015).
([252]) EPO, T 777/08, 24 May 2011 (*Atorvastatin polymorphs/WARNER-LAMBERT*).
([253]) ibid., § 5.2.
([254]) ibid.
([255]) EPO, T 1684/16, 3 March 2020; cited also in GURGULA, cit., 8-9.

formation can be a nightmare") ([256]). The Board, prompted by the appellant, further compared this case to T 777/08 and found that, the present case was not "about the selection of any crystalline form but about the selection of one specific […] form" and that said selection was not arbitrary but rather due to the unexpected properties (improved stability) of the form.

5.3 The national approaches

The UK case law is particularly rich with precedents addressing "obvious to try" situations ([257]). Notably, however, in the UK the issue of "obvious to try" is not approached as a standard of obviousness, but rather as one of many factors to be considered, taking into account the circumstances of the particular case ([258]). For instance, in *Medimmune v Novartis*, Kitchin LJ held:

> "[o]ne of the matters […] to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious. On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.
>
> For these reasons, the judgments […] often reveal an enquiry […] into whether it was obvious to pursue a particular approach with a reasonable or fair expectation of success as opposed to a hope to succeed. Whether a route has a reasonable or fair prospect of success will depend upon all the circumstances including an ability rationally to predict a successful outcome, how long the project may take, the extent to which the field is unexplored, the complexity or otherwise of any necessary experiments, whether such experiments can be performed by routine means and whether the skilled person will have to make a series of correct decisions along the way" ([259]).

Therefore, similarly to the EPO, English courts have at times denied obviousness in cases where there was absolutely no likelihood of

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([256]) ibid., § 4.3.4.

([257]) See e.g., BIRSS ET AL., *Terrell on the Law of Patents*, cit., §§ 12-74 – 12-86; COLE, DAVIS, *CIPA Guide to the Patents Acts*, cit., 147-153.

([258]) *Pfizer's Patent* [2002] EWCA Civ 1, § 57.

([259]) *Medimmune Ltd v Novartis Pharmaceuticals UK Ltd* [2012] EWCA Civ 1234.

success ([260]), but held that the results of purely routine experiments which are undertaken without any particular expectation of success as to the result are likely obvious ([261]).

The passage cited from *Medimmune v Novartis* also shows that the UK case law has been – to some extent – cognizant of the inherent contradictions that the "obvious to try" test might give rise to in research-based industries such as pharmaceuticals and biotechnology. This issue was picked up even more clearly in *Conor v. Angiotech* ([262]), where Lord Walker cited a passage from an extrajudicial article by Sir Hugh Laddie ([263]), stressing that:

> "[o]n its face, [the 'obvious to try' notion] produces an unworkable or irrational test. If the reward for finding a solution to a problem and securing a monopoly for that solution is very high, then it may well be worthwhile for large players to examine all potential avenues to see if one gives the right result, even though the prospects of any one of them succeeding are much less than 50/50. What makes something worth trying is the outcome of a simple risk to reward calculation. Yet, if the reward is very large, the avenues worth trying will be expanded accordingly. So, the more commercially attractive the solution and the more pressing the public clamour for it, the harder it will be to avoid an obviousness attack".

To counterbalance this finding, English courts have generally embraced a rather thorough approach to the "obvious to try" analysis, taking into account and weighing all relevant factors ([264]).

([260]) *St Gobain v Fusion Provida* [2005] EWCA Civ 177, § 28 ("[m]ere possible inclusion of something within a research programme on the basis you will find out more and something might turn up is not enough. If it were otherwise there would be few inventions that were patentable"). Jacob J however arguably set the obviousness threshold quite low when he claimed that "[t]he "obvious to try" test really only works where it is more-or-less self-evident that what is being tested ought to work": see ENGLAND, *Obvious to try, one year on*, cit., 116; ENGLAND, *Saint Gobain – patron of pharmaceutical patentees?*, in *JIPLP*, 2007, vol. 2(8), 532.

([261]) *Actavis v. ICOS* [2019] UKSC 15, § 65.

([262]) *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49, § 48. The Court also stressed, at § 47, that "[d]uring the last forty years the volume of high-tech research has increased enormously, especially in the fields of pharmaceuticals and biotechnology. The resources committed to research are enormous, because the potential rewards in world-wide markets are so great. Competition is fierce. In this climate 'obvious to try' has tended to take on a life of its own as an important weapon in the armoury of those challenging the validity of a patent".

([263]) LADDIE, cit., 93.

([264]) *Pfizer's Patent* [2002] EWCA Civ 1, § 57.

Nevertheless, in *Actavis v. ICOS*, the UK Supreme Court found that, since a prior art document ([265]) disclosed that the active ingredient tadalafil could be used for the treatment of erectile disfunction, a dosage regime patent (5 mg/day dose) ([266]) was obvious since "the skilled team was engaged in familiar and routine testing […] to establish the appropriate dosage […] for tadalafil" and "it was obvious to embark on that exercise and carry out tests […] until that appropriate dose was ascertained" ([267]). While the path to the 5mg dose required the skilled team to take a number of steps and value judgements, the crucial expert testimony had held that it was a "no brainer" to go ahead and test such dose ([268]), necessarily leading to the invention. In turn, the additional unexpected benefit of reduced side effects was considered a mere "bonus" which does not prevent the finding of obviousness ([269]).

Actavis v. ICOS is an important precent also on other grounds. On the one hand, the Supreme Court took the chance to draw a parallel with the problem-solution approach. In particular, Lord Hodge held that he was "not persuaded that the problem-solution approach would necessarily lead to give a different answer" ([270]). Based on the evidence available, he concluded that the fact that the skilled person would not have had an expectation of effectiveness at the 5 mg dose does not affect the conclusion that the team would have nevertheless investigated such dose ([271]). On the other hand, the tadalafil litigation demonstrated that European courts are often aligned in the assessment of inventive step. Indeed, both German and Italian courts reached the same conclusions of obviousness in parallel litigations on the same patent ([272]). Despite following different approaches to the question of obviousness – and, in particular, structuring the inventive step analysis

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([265]) The "Daugan" patent: WO 97/03675 or EP 0 839 040.

([266]) EP 1 173 181.

([267]) *Actavis v. ICOS* [2019] UKSC 15, § 88.

([268]) *Actavis v. ICOS* [2019] UKSC 15, §§ 84 and 96.

([269]) *Actavis v. ICOS* [2019] UKSC 15, § 96.

([270]) *Actavis v. ICOS* [2019] UKSC 15, § 96.

([271]) *Actavis v. ICOS* [2019] UKSC 15, § 96.

([272]) BGH, 21 January 2020, X ZR 65/18 (*Tadalafil*) and Court of Milan, 30 July 2018, *Sandoz Italia S.p.a. v. ICOS Corporation et al.*, in *Darts-ip*. It should be noted that the Italian decision is a preliminary order in the context of urgent proceedings.

starting from a technical problem to be solved – German and Italian judges found that EP '181 was obvious due to the routine and step-by-step nature of the clinical trails to be undertaken, which were envisaged also by regulators and would have led the skilled person to the invention ([273]).

More in general, German and Italian courts have long adopted "obvious to try" and "reasonable expectation of success" as a fundamental factors in the assessment of obviousness ([274]). In a recent seminal decision concerning a medical use patent on the active ingredient fulvestrant, the BGH – broadly aligning with the UK approach described above – stressed that the "reasonable expectation of success" standard cannot be formulated in general terms, but must be determined on a case-by-case basis, taking into account the technical field at issue, the size of the incentive for the skilled person, the effort required to adopt and pursue a certain approach and the alternatives that may be considered, as well as their respective advantages and disadvantages ([275]). On the facts of the case, the Court then found the patent at stake obvious. Italian courts deciding on patents from the same family also found that they did not meet the inventive step standard based on similar arguments, making specific references to the German decisions ([276]).

([273]) ibid.

([274]) See e.g., in the Italian case law: Court of Rome, 18 October 2010, *Actavis Group HF v. Menarini Industrie Farmaceutiche Riunite et al.*, in *Darts-ip* ("Nel campo farmaceutico la ricerca è di routine e quindi l'attività media del tecnico del settore implica la ricerca e la sperimentazione sui composti noti").

([275]) BGH, 14 April 2019, X ZR 59/17 (*Fulvestrant*). Notably, the same principle was reaffirmed a few months later in the pemetrexed decision, although in this case the BGH found that the invention was not obvious: BGH, 7 July 2020, X ZR 150/18 (*Pemetrexed II*). See also BPatG, 19 November 2019, 3 Ni 32/17 (where the German federal patent court found that also a divisional patent application covering fulvestrant lacked inventive step).

([276]) Court of Turin, 23 July 2018 (unpublished); Court of Milan, 24 July 2019, *Actavis Group PCT EHF et al. v. AstraZeneca AB et al.*, in *Darts-ip*; Appeal Court of Turin, 12 June 2020 (unpublished); Court of Milan, 3 December 2020, *AstraZeneca S.p.a.et al. v. Teva Italia S.r.l.*, in *Darts-ip*; Court of Milan, 24 December 2020, *AstraZeneca S.p.a. et al. v. Teva Italia S.r.l.*, in *Darts-ip*. See also: TRABUCCO, *Another Italian take on the Fulvestrant Saga. The Court of Milan on technical prejudice, plausibility and off-label use*, in *IPLens*, 30 April 2019, https://iplens.org/2021/04/30/another-italian-take-on-the-fulvestrant-saga-the-court-of-milan-on-technical-prejudice-plausibility-and-off-label-use/.

6. Secondary indicia of non-obviousness

Finally, as a further element to the obviousness analysis, patent offices and courts have established a number of so-called secondary indicia ([277]) of non-obviousness ([278]), i.e., objective elements that can provide *ex post* evidence that the invention was indeed inventive.

Secondary indicia of non-obviousness include, for instance, the fact that the invention fulfils a long-felt but previously unsolved need ([279]), represents a technical progress ([280]), delivered unexpected results ([281]) or obtained a relevant commercial success ([282]). Another secondary indicator that is often relied on is the existence of an established "technical prejudice" in the field as to the possibility that the invention could work ([283]). Overcoming such technical prejudice might be where the inventive step lies. In general terms, it is important to stress that secondary indicia are considered only insofar as they have a nexus to the technical features of invention. Commercial success based on marketing ability alone is irrelevant ([284]).

Secondary indicia often come up in patent cases. For instance, we have seen that the fact that an invention delivered unexpected results is often taken into account in "obvious to try cases" ([285]). The proper weight to be given to secondary considerations in the inventive step analysis is debated, but nowadays most scholars agree that they should come into play only to validate conclusions, or in case of doubt ([286]). This is also the position of the Boards

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([277]) Also known as "secondary indicators" or "secondary considerations".

([278]) EPO GUIDELINES, *Secondary indicators*, § G-VII.10. See also FRANZOSI, *I requisiti di brevettabilità*, cit., § 3.23; BERGIA, *Article 48 c.p.i.*, cit., 671 ff.

([279]) EPO GUIDELINES, *Secondary indicators*, § G-VII.10.3.

([280]) BERGIA, *Article 48 c.p.i.*, cit., 673.

([281]) ibid.

([282]) ibid.

([283]) EPO, T 1212/01, 3 February 2005 (*Pyrazolopyrimidinones for the treatment of impotence/PFIZER*) (no technical prejudice found even though the patent holder had relied on 30 scientific papers as evidence). See e.g., Court of Milan, 25 October 2022, *Novartis Farma S.p.a. v. Mylan S.p.a.*, in *Darts-ip*. (highlighting that the threshold for the finding of a technical prejudice is quite high).

([284]) *ibid*.

([285]) See e.g., *Actavis v. ICOS* [2019] UKSC 15.

([286]) FRANZOSI, *I requisiti*, cit., § 3.23; GALLI, BOGNI, *Il requisito dell'attività inventiva*, cit., 578 ff.; FABRIS, cit., 698-699.

of Appeal ([287]). In contrast, Italian scholars have traditionally dedicated ample doctrinal discussions to secondary indicia as counterbalancing factors to the perceived subjectiveness of the analysis of inventive step ([288]).

7. The necessarily nuanced approach to the inventive step assessment

The broad overview of the inventive step assessment carried out has illuminated the inherent complexities that the "obviousness" analysis gives rise to. The rich case law developed all across Europe, however, has also shown a broad area of convergence and, perhaps most importantly, dialogue between courts. Any inventive step analysis needs to grapple with the fact that a multitude of factors need to be weighed against one another. Inventive step inevitably requires a nuanced approach.

In *Actavis v. ICOS* the UK Supreme Court stressed this point by listing ten factors that were relevant to establish obviousness in that case, including: (*i*) whether at the priority date a specific piece of research was "obvious to try" with a reasonable or fair prospect of success; (*ii*) whether the research was routine in nature; (*iii*) the burden and cost of the research programme; (*iv*) the necessity and the nature of the value judgements during the research programme; (*v*) the existence of alternative or multiple paths of research; (*vi*) the motive of the skilled person to undertake the research; (*vii*) whether the results of the research are unexpected or surprising; (*viii*) the need to avoid hindsight (especially in running a step-by-step analysis); (*ix*) whether a feature of a claimed invention provides an added benefit; and (*x*) the fact that there is no blanket prohibition against dosage regime patents ([289]). Despite the fact that the Supreme Court did not provide guidance

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([287]) EPO CASE LAW, cit., § I.D.10.1 ("[s]econdary indicia [of non-obviousness] are only of importance in cases of doubt, i.e., when objective evaluation of the prior art teachings has yet to provide a clear picture").

([288]) DI CATALDO, *L'originalità dell'invenzione*, cit., 83 ff.; See also FABRIS, cit., passim. Similar positions have been raised also in the U.S. scholarship, see e.g., CERULLA, cit., 151-152; DURIE, LEMLEY, *A realistic approach to the obviousness of inventions*, in *WM. Mary L. Rev.*, 2008, vol. 50, 1004; DUFFY, *A timing approach to patentability*, in *Lewis & Clark L. Rev.*, 2008, vol. 12, 343.

([289]) *Actavis v. ICOS* [2019] UKSC 15, §§ 64-74.

on how to weigh the different factors ([290]), Lord Hodge's list is bound to become a litmus test for obviousness in the UK ([291]) and, it is submitted, it provides a useful framework also for the following discussion.

C. AI AS A TOOL AND INVENTIVE STEP

1. Preliminary remarks

The growing use of AI tools in R&D activities ([292]) suggests that their integration into the "means and capacity" of the skilled person is inevitable ([293]). On the one hand, AI is arguably a "general purpose" technique that is broadly applicable across all fields of technology and engineering ([294]). On the other hand, the skilled person is a dynamic model, which is "involved in constant development in the relevant technical field" ([295]) and this may well include advanced computational methods.

([290]) HOAR, *AIPPI Event Report: Actavis v ICOS Supreme Court Rapid Response*, in *IPKat*, 17 April 2019, https://ipkitten.blogspot.com/2019/04/aippi-event-report-actavis-v-icos.html (reporting the opinion of Tom Mitcheson QC – the barrister for ICOS/Lilly in this case – according to whom "[w]e now have a list of '10 factors' that will be quoted for ever more, but no guidance as to any relative weighting to be applied to them. The Supreme Court has not given us much help in resolving similar issues in the future").

([291]) HOAR, cit. (reporting the opinion of Mark Chacksfield QC – the barrister for Actavis in the case – according to whom "the Supreme Court stress[ed] the statutory test for obviousness, all the rest being gloss and not obligatory. Lord Hodge will no doubt be disappointed when in five years' time we are all quoting his 10 factors").

([292]) See § I.C above.

([293]) KIM ET AL., *Clarifying assumptions* , cit., 12. ABBOTT, *I think*, cit., 1122 ff; FRASER, cit., 320 f.; DORNIS, *Artificial Intelligence and Innovation*, cit., 125 ff ("the use of AI to support human inventiveness implies groundbreaking changes for the concept of the PHOSITA"); YANISKY-RAVID, LIU, cit., 41 ("[a]dvances in AI may require redefining "ordinary skill" and the "PHOSITA" assessment"); CERULLA, cit., 89.

([294]) DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit.

([295]) EPO GUIDELINES , cit., § G-VII.3; KIM ET AL., *Clarifying assumptions*, cit., 12. See also EPO, *Comments by the EPO on the Revised Issues Paper on Intellectual Property Policy and Artificial Intelligence (WIPO/IP/AI/2/GE/20/1 REV.)*, www.wipo.int/export/sites/www/about-ip/en/artificial_intelligence/conversation_ip_ai/pdf/igo_epo.pdf, 7 (the PSITA "is a theoretical concept which is sufficiently flexible to allow assessing patentability of inventions in the AI area"). Similarly, a recent AIPPI consultation on the impact of AI on the inventive step requirement showed a broad consensus among responding Groups in that "[t]he increasing use of AI in the inventive process should not

Hence, if and when AI becomes a "normal" or "standard" research tool within a certain technical field, it should be framed as part of the skilled person in that field ([296]).

More broadly, it is submitted that AI tools – like any new major and cross-sector technological advancement, such as computer programs beginning in the 70s and, perhaps, quantum computing in the future ([297]) – might end up impacting every stage and aspect of the inventive step analysis, including the identity of the notional skilled person, their knowledge, their abilities, and what would be obvious to them.

Notably, there are quite a few overlaps to this enquiry ([298]). For example, asking if the skilled person is knowledgeable in AI systems (what they know) or if the skilled team would include an AI expert (who they are) are essentially two sides of the same coin. The attributes of the skilled person and what would be obvious for them are also inevitably interdependent questions ([299]). However, going through the various stages of the inventive step analysis systematically, and looking at the question from every relevant viewpoint, "ensures that there is a measure of discipline, reasoning and method in one's approach" ([300]).

The bottom line is that – irrespective of whether AI was actually used or not by the inventor – to assess the inventive step of an invention one must go through the whole analysis, i.e., properly identify the technical field and the state of the art, construe the skilled person and their common general knowledge, and then determine whether the invention would have been obvious taking into account all relevant factors. The structured approaches to

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change the definition of the person skilled in the art". See also, more broadly, SIMON, *The Implications of Technological Advancement for Obviousness*, in *Michigan Telecommunications and Technology Law Review* 2013, vol. 19, 331.

([296]) ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 865. See in general SANSEVERINO, *The ability to chase down our dreams. Inventive step and artificial intelligence*, in *I battelli del* Reno, 2018, https://www.ibattellidelreno.it/wp-content/uploads/2022/01/SANSEV ERINO-AI.pdf.

([297]) BROOKS, *Quantum computers: what are they good for?*, in *Nature*, 24 May 2023, vol. 617, S1.

([298]) ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 866.

([299]) See § IV.A.1 above.

([300]) *DSM NV's Patent*, 61 - [2001] R.P.C. 35 at [55].

inventive step (e.g., problem-solution or Windsurfing/Pozzoli) are useful frameworks to conduct this analysis.

That said, one must keep in mind that inventive step is also a strictly objective requirement. There is no room to suggest an *a priori* distinction between "normal" inventions and AI-assisted inventions ([301]). Both shall be evaluated against the properly construed skilled person ([302]). For the same reason, it is improper to suggest that the growing prevalence of AI-assisted inventions will "raise the bar" of inventive step, as often put forward in the literature ([303]). The "bar" of inventive step is by definition movable and, more often than not, needs to be surgically calibrated.

Before going into the detailed analysis of the impact of AI tools on inventive step, however, two premises are in order, namely: (*i*) that the notion of "machine skilled in the art" must be rejected; and (*ii*) that the guiding principle of this analysis is that AI is not a monolith, but an umbrella term.

1.1 The "machine skilled in the art"

The scholars arguing that AI is capable of inventing "autonomously" often also suggest that the skilled person will soon need to be replaced by a "thinking machine" ([304]) an "inventive machine" ([305]) or a "machine of ordinary skill in the art" ([306]) to which eventually "everything [will be]

([301]) GALLI, BOGNI, *Intelligenza artificiale*, cit., 131. In the U.S. scholarship, see also ROMM, cit., 1443 ("the mere fact that an invention is created in part or entirely by an AI machine does not render it obvious under the current doctrine").

([302]) GALLI, BOGNI, *Intelligenza artificiale*, cit., 131.

([303]) See e.g., HERVEY, DRIVER, WOODHOUSE, cit., 286 (suggesting that "the threshold for inventive step will rise"); *Contra* STRAUS, cit., 631 (expressing pointed criticism against the idea that the bar for inventive step would "rise").

([304]) VERTINSKY, cit., 502 ("policymakers might have to consider whether the PHOSITA should be modified to include thinking machines"); CUBERT, BONE, *The law of intellectual property created by artificial intelligence*, in BARFIELD, PAGALLO (eds.), *Research Handbook on the Law of Artificial Intelligence*, Edward Elgar, Cheltenham, 2018, 421.

([305]) ABBOTT, *Everything is obvious*, cit., 26 ff.

([306]) FABRIS, cit., 692. See also LUGINBÜHL, cit., 196-197 (wondering if inventive step will be abolished "once AI is able to create inventions autonomously" and the "standard AI" is the PSITA). See also TULL, MILLER, *Patenting Artificial Intelligence: Issues of Obviousness, Inventorship, and Patent Eligibility*, in *Robotics, Artificial Intelligence & Law*, 2018, vol. 1(5), 320.

obvious" ([307]). According to one author, the "machine skilled in the art" will know "all the existing prior art and all its possible correlations" ([308]).

These proposals must be rejected ([309]).

The very idea of a "machine skilled in the art" presupposes, from a technical point of view, the existence of AI systems that are capable of inventing "autonomously", if not that of artificial general intelligence. However, as discussed above, most scholars now agree that, at the current state of technology, AI does not invent "autonomously" but is at most a powerful computational tool in the hands of researchers ([310]). When and if AI were to improve to the point that humans do not play any role in innovation – other than perhaps giving generic instructions to an AI system, "pushing a button" – the most pressing issue would not be the appropriate determination of the skilled person/machine, but perhaps the justification of the patent system altogether ([311]).

In the meantime, introducing the notion of a "machine skilled in the art" is confusing and unnecessary. The person skilled in the art is a flexible model that can and must be adapted to technological developments and thus take into account also very advanced AI tools (provided that those are the normal means and capacities in the field). It is unclear how changing the paradigm to that of a "machine skilled in art" would impact the obviousness assessment from the perspective of an examiner or the court ([312]).

([307]) ABBOTT, *Everything is obvious*, cit.; see also MCLAUGHLIN, cit.

([308]) FABRIS, cit., 692.

([309]) ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 865 (arguing that the skilled person should not be seen as an AI system, at least as a rule). See also ROMM, cit., 1449.

([310]) See § III.B.2.4 above.

([311]) ibid.

([312]) OUELLETTE, *We Robot Comments on Ryan Abbott's Everything is Obvious*, in *Written Description*, 27 April 2018, https://writtendescription.blogspot.com/2018/04/we-robot-comments-on-ryan-abbots.html ("as a practical matter I don't think that asking courts to assess obviousness from the perspective of a computer that is even more skilled than the ordinary human researcher would have much effect").

1.2 *"AI is not a monolith"*

The second overarching premise is that, in carrying out the inventive step analysis, one should always bear in mind that AI is an *umbrella term*, that comprises different techniques. These techniques have varying levels of complexity and can be used in different ways, to achieve different results.

In particular, in machine learning there are many moving parts. The *training* data (i.e., the data provided to the training algorithm at the training stage) and the *input* data (i.e., the data provided to the trained model for analysis) profoundly affect the functioning and output of the ML system. As discussed above, a ML model is only as good as the data it is fed with (a concept more pithily known as: "garbage in, garbage out") ([313]). Data also needs to be processed (e.g., reduced, partitioned, transformed, formatted etc.) in order to be used and different training algorithms might need different amounts of data. Deep learning models generally require more data to be trained than non-deep machine learning models, but less human involvement ([314]). And, in any case, the formulation of the objective or loss function requires both skills and strategic choices ([315]). Conversely, while evolutionary algorithms are not based on data, they include, by default, elements of "randomness". Running an EA system twice might not give back the same results ([316]).

The broad notions of ML, EA and expert systems each comprise several different techniques, which can also be combined ([317]). And, of course, as shown by the discussion on AI tools in the pharmaceutical sector, different AI techniques can be used at different stages or segments of a R&D program (e.g., target identification, validation, etc.) ([318]).

The examples and caveats could go on. In short, one should be very cautious to draw sweeping generalisations about the impact of "artificial intelligence" on the inventive step assessment (and patentability in

([313]) See § I.B.4.1 above

([314]) See § I.B.4.1 above.

([315]) KIM, *Clarifying assumptions*, cit., 398.

([316]) BLOK, cit., 70.

([317]) HERVEY, DRIVER, WOODHOUSE, cit., 285.

([318]) DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 24.

general): "AI is not a monolith" ([319]). Care should be taken in trying to understand precisely the "Ws" of the technology at stake, i.e.,: which AI tool is used, why, when, where, how and by whom.

2. AI tools and the person skilled in the art

2.1 Normal AI tools of the skilled person

As discussed above, the identification of the skilled person – their identity, skills and knowledge – sets the bar for the inventive step assessment. In order to conduct an objective assessment one must not look at the research path that the inventor took, but at what the skilled person would have done facing the technical problem. It follows that, before asking whether an invention would have been obvious to the skilled person using AI tools, one must ask whether the skilled person *would* have used AI tools as a matter of course (and the *very specific* characteristics of those tools).

The easiest way to think of this question is perhaps by reference to the "means and capacities" of the skilled person. We saw that, in the EPO parlance, the skilled person has "the *means and capacity* for routine work and experimentation which are *normal* for the field of technology in question" ([320]). It follows that, from this angle, AI shall be framed as part of the *equipment* of the skilled person only if and when it is a "normal" tool for routine work and experimentation in the respective field ([321]). That is the most basic and important question to be asked at this stage ([322]). Depending on the answer, the inventive step assessment might change considerably.

More in detail:

(i) if AI *is not* a "normal" tool in the relevant technical field, the invention

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([319]) EBRAHIM, *Artificial Intelligence Inventions*, cit., 151, fn 7.

([320]) See § IV.A.1.6 above.

([321]) EPO, *Comments by the EPO on the Revised Issues Paper on Intellectual Property Policy and Artificial Intelligence*, 7 ("if AI is used in the relevant field of technology, it will be used by the skilled person and their skill will raise accordingly"). See also ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 866; LIBERTINI, *I prodotti inventivi dell'intelligenza artificiale*, cit., 101 (reluctantly allowing that this is perhaps the best available solution, but that it likely generates excessive complexities).

([322]) BLOK, cit., 70-71.

will be patentable as long as the solution would have been non-obvious to a skilled person who *did not* use AI — even if the inventor *did* use AI tools;

(ii) on the other hand, if AI *is* a "normal" tool in the relevant technical field, the abilities of the skilled person will increase accordingly, and the invention is patentable only if the solution would have been non-obvious to a skilled person who *did* rely on AI tools — even if the inventor *did not* use AI tools ([323]).

An example might help better illustrate the point. Assume that a team of pharmaceutical researchers developed, trained and used a deep learning model to repurpose known compounds to target rare disease X and found out that known drug Y has great potential to treat the disease ([324]). In principle, that is a patentable "second medical use" invention under Article 54(4) EPC (e.g., if claimed as "substance Y for use in the treatment of rare disease X"). However, said "second medical use" invention might be deemed obvious if the skilled person *would* have routinely developed, trained and used a similar DL model as part of their research and, by doing so, *would* have reached the invention. In other words, the invention would not be patentable if: (*i*) the DL was a "normal" means for the skilled person at the priority date; and (*ii*) faced with the technical problem (e.g., find alternative treatment for disease X) the AI-augmented skilled person would have arrived to the invention starting from the closest prior art ([325]).

2.2 Normal AI tools and the common general knowledge

Based on the above, the first stage in the inventive step analysis in an AI-augmented world is precisely to find out whether AI tools are "normal

([323]) ibid.; RAMALHO cit. 25. HERVEY, DRIVER, WOODHOUSE, cit., § 8-093; NAKAYAMA, cit., 109-110; NÄGERL, NEUBURGER, STEINBACH, cit., 338.

([324]) Cf. the halicin and abaucin case studies in § I.C.3.2 above.

([325]) In this example, the closest prior art is particularly difficult to choose, in testament to the criticisms raised against the PSA above. If one were to pick the repurposed known drug, there is a great risk of hindsight. However, if the rare disease was previously not treated, there would be no closest prior art to pick.

means" for the skilled person or not ([326]).

Of course, that question needs to be unpacked since "AI tools", as such, are hardly a precise object of enquiry. One must more carefully look at their various components. In case of ML, for instance, one should look, e.g., at the training algorithm, the model architecture, the objective/loss function, the training data and the input data. Indeed, asking whether AI is a "normal tool" in a technical field can hardly be answered is such abstract terms and requires a case-by-case assessment.

Also, it is submitted that asking whether certain tools and equipment are "normal means" of the skilled person is simply rewording – or, at least, is to be assessed following the same principles – a more classical patent law question, that is the determination of the *common general knowledge* of the skilled person ([327]).

Hence, to construe the skilled person in a field where AI-assisted inventions *might* be commonplace, one should first understand if the reference literature (e.g., textbooks and encyclopaedias) suggests the use of AI as a research tool in that field. If not, one could look at more specialised sources, like research papers and patents, but also unconventional sources such as YouTube tutorials ([328]) or GitHub libraries ([329]), provided this is justified in that field. As discussed at length above, the crux of the common general knowledge's determination lies not as much in the *source* that contains the information *per se*, but rather on whether the information is

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([326]) NAKAYAMA, cit., 112-114 (putting forward statistical data about Japanese inventors from 2020 which would suggest that AI might not have been used widely, bit it is forecasted to be more widespread).

([327]) SUOMINEN, DE LANGE, RUDGE, cit., 192 (suggesting that the "means and capacity" of the skilled person are "similar to the common general knowledge"). See also SHEMTOV, GABISON, *The inventive step requirement and the rise of AI machines*, in ABBOTT (ed.), *Research Handbook on Intellectual Property and Artificial Intelligence*, Edward Elgar, Cheltenham, 2022, 432. In the U.S. scholarship, see SAMORE, cit., 483, who proposes a four-factor test to determine whether AI tools (and specifically genetic programming) should be framed as part of the skilled person, namely: (*i*) whether the invention was actually designed by AI; (*ii*) the proportions of skilled person in the field having access to AI; (*iii*) the cost associated with the use of AI; (*iv*) the amount of time and effort required to operate AI.

([328]) SHEMTOV, GABISON, cit., 428.

([329]) Which might be equated to a database see § IV.A.1.5.2 above.

"commonly accepted" in the field and can be used "without doubts or further research work" by the skilled person ([330]). As long as the use of AI tools is experimental, requires significant skills or is riddled with doubts (e.g., as to its configuration and utility) it will not be part of the CGK ([331]). In this regard, UK courts may also suggest to limit the CGK to the information generally accepted by the notional skilled person in the country, whereas the EPO would probably not approve of a similar territorial limitation ([332]).

Furthermore, from the narrower visual angle of the skilled person's "equipment", one should also factor in that the means and capacities for routine work and experimentation shall be the "normal" ones also in terms of time and resources needed for their implementation, which shall be determined based on the technical field at stake ([333]). If adopting AI tools requires costly equipment or implementation times that are not standard in the field, it might not qualify as a "normal" tool for routine research and experimentation.

At this point, it is important to stress that suggesting that AI is a "normal tool" in the technical field, it is not sufficient that the *existence* of AI techniques is common general knowledge, or that the skilled person *could* have used it if they wanted to. It shall be common general knowledge to *actually use* said tools.

The matter was neatly illustrated by Birss J in *AP Racing v. Alcon* ([334]), albeit in relation to traditional software. Alcon, the defendant in an infringement case concerning a brake caliper patent for F1 racing owned by AP Racing, had raised a number of invalidity arguments. Among other things, Alcon contended that the patented device was obvious over the common general knowledge. Alcon's argument was that the "structural optimisation software" used by AP Racing to design the brake caliper was CGK.

([330]) See § IV.A.1.5.2 above.

([331]) See also ZOBOLI, cit., 159-160.

([332]) See § IV.A.1.5.2 above.

([333]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 136.

([334]) *AP Racing Ltd v Alcon Components Ltd* [2013] EWPCC 3 (05 February 2013). This decision was later reversed in appeal by *AP Racing Ltd v Alcon Components Ltd* [2014] EWCA Civ 40 (28 January 2014) but not on this point.

Therefore, using such software to design brake calipers was totally obvious. If one did so, calipers with the patented shape would result.

Briss J rejected the very premise of the argument. He first described the functioning of structural optimisation software as follows:

> "29. A general shape is defined. […]. All the fixed points which must be included are given. For a caliper this would include things such as mounting points and pistons. […] The software then carries out a finite element analysis and removes material where it is not needed. This is repeated iteratively until a target weight is achieved. The process produces a final shape. Very often using this technique the final shape is rather organic in appearance, no doubt because in some ways the process has similarities to evolution by natural selection.
>
> 30. The key difference between this technique and the conventional design process using CAD/CAM and FEM is that in the conventional process the designer designs the shape of the article and uses software, including FEM, to model its behaviour in various load cases. […] The structural optimisation technique does not really start with a design: it might start simply with the volume in which the component will reside. The final shape arises from the iterative removal of material found to be unnecessary by the computer.
>
> 31. Nevertheless, although much of the design work is carried out by the computer, the shape […] will depend on *decisions made by the engineers using it*. Two obvious examples are the choices about which load scenarios to model, and about the starting shape and volume of material. The technique works by removing material from within the given volume. Looking ahead to the obviousness argument, structural optimisation software will not produce a design for a caliper with parts […] which are located beyond the normal envelope of a caliper body unless the engineer decides in the first place to define a starting volume beyond the normal envelope of a caliper".

Notably, structural optimization software sounds quite a lot like evolutionary algorithms. In any case, looking at the evidence available, Birss J found that the use of that software was not common general knowledge:

> "37. At the priority date the skilled person knew that there was such a thing as optimisation software. Its existence was part of the common general knowledge. […] If a skilled person wanted to use optimisation software I am sure they would have been able to arrange for it to be done. The tools and the technique itself are not trivial to use but […] engineers of the kind working in this field were not going to be put off from using a tool of this kind just because it might be difficult to implement.
>
> 38. However I am quite sure that *the use of optimisation software in brake caliper design was not common general knowledge*, nor was it common general knowledge to a brake engineer that optimisation software *might have any tangible benefit in designing calipers*. The engineers knew what it was and understood in general terms how it worked but did not have any basis, from what was publicly known, to think its use in their particular field would be worth the effort".

While structural optimisation software is not an AI tool strictly speaking ([335]), the court's conclusions are broadly applicable, *mutatis mutandis*, to any computational method used in R&D.

2.3 The many moving parts of the "normal" AI tools

The *AP Racing* case was a relatively easy one. The parties had a rather clear understanding of what the tool was (i.e., structural optimisation software) of which only a couple of commercial products existed at the priority date (i.e., TOSCA and Opistruct).

However, to fully understand whether an AI tool could be considered CGK of the skilled person it is necessary to dig much deeper into the hypothetical. Simplifying the number of variables for the purposes of this discussion, one would need to assess: (*i*) the characteristics of the AI tool used ([336]); and (*ii*) for data-intensive AI tools such as ML/DL, also the characteristics of the training and/or input data relied on. I take them in turn.

2.3.1 *The characteristics of the "normal" AI tools*

Identifying what is the "normal" or "standard" AI tool in a technical field will not be an easy task ([337]). On the one hand, applicants will hardly disclose the specific type and the role played by the AI tools they have used or, in any case, might fail to do so with a sufficient level of detail. In most cases, patent specifications will not include information ([338]). On the other hand, the sheer variety of potential options might muddle the analysis. There is no "one-size-

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([335]) But AI has been used also in structural optimization, see e.g.: NGUYEN, VU, *Application of Artificial Intelligence for Structural Optimization*, in TIEN KHIEM, VAN LIEN, XUAN HUNG (eds.), *Modern Mechanics and Applications. Lecture Notes in Mechanical Engineering*, Springer, Singapore, 2022 https://doi.org/10.1007/978-981-16-3239-6_8; MIRRA, PUGNALE, *Comparison between human-defined and AI-generated design spaces for the optimisation of shell structures*, in *Structures*, 2021, vol. 34, 2950.

([336]) An additional problem is where (at which stage in the inventive process) is the AI used: DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 24.

([337]) BLOK, cit., 71. See also GURGULA, cit., 17 (suggesting to use "best" ML tool available); CERULLA, cit., 125-130 (also discussing the difficulties in determining the "standard" AI system for the assessment of inventive step).

([338]) See § IV.D below.

fits-all" AI technique ([339]). However, there are a number of factors that can and should orient this analysis.

First, one should distinguish along a spectrum between "bespoke", "off-the-shelf" and "commercial" AI tools. I use these terms quite loosely. A "bespoke" model is one that the skilled person would have to build from scratch. An "off-the-shelf" model is one that is perhaps available in online libraries ([340]), but would need some customisation ([341]). A "commercial" model/application is one that is available as a finished product (either under license or open source) and is used "as is". The amount and complexity of the evidence required to show that any of these tools is "normal" in a technical field is inversely proportional to how finite they are in nature, with a "commercial" model obviously being the most finite.

Wherever the common general knowledge would suggest that a "commercial" tool (e.g., ChatGPT, Google's DeepMind) is not only widely disseminated, but also commonly accepted and used in the technical field, as shown for instance by publications and studies, that would make it a good candidate to be qualified as a "normal tool" in that field ([342]), similar to the specific "structural optimisation software" discussed in *AP Racing v. Alcon* ([343]). The more bespoke the allegedly "normal" model, the more one would need to provide evidence of what specifically is "normal" in the field. For instance, one might show that skilled person would be oriented to pick a specific type of ML model/architecture from a library such as GitHub – the same way that the skilled person can consult a database when that is CGK ([344]) – and would have known how to train it and/or tweak it for use in solving the technical problem at stake. The following image is helpful to illustrate this first point (Fig. 18).

([339]) KIM ET AL., *Clarifying assumptions*, cit., 389.

([340]) See e.g., ZOBOLI, cit., 58.

([341]) ibid.

([342]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 868. For sake of clarity, it is important to stress that the "normal" AI tool does not need to be necessarily a fictitious "average" one.

([343]) See § IV.C.2.2 above.

([344]) See § IV.A.1.5.2 above.

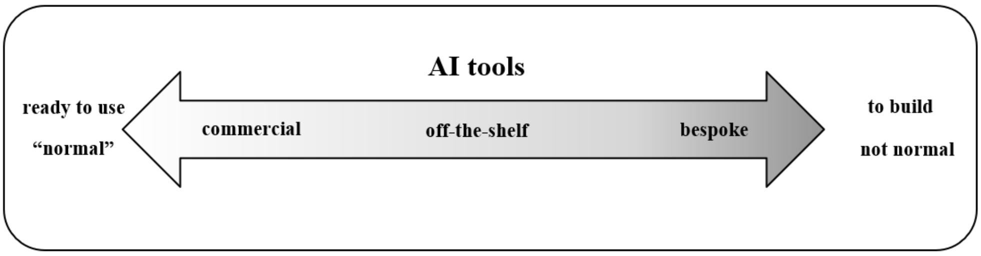

Fig. 18 – AI tools' spectrum

Second, there might be field- or problem-specific proclivities. For instance, EAs have shown promising results for antenna and circuit design ([345]). In those fields, one might thus posit that employing EAs for antenna design is part of the common general knowledge. Conversely, ML has shown promising results for tasks that require pattern identification, such as drug repurposing and target validations in pharmaceutical research ([346]). Keeping in mind that ML and EA are broad categories themselves, if some of those research methods were to become established and commonly accepted in the field, they would become part of the CGK (and, which is essentially the same, could be considered the "normal tools" of the skilled person).

Third, even assuming that the specific *type* of AI tool used in a field is part of common general knowledge, that would most likely not be enough to build an adequate obviousness assessment (unless it is a "commercial" tool). That is because the so-called hyperparameters – such as the architecture of an ANN in terms of number of the nodes and layers, or the fitness/objective functions implemented, the learning rate etc. – are also needed ([347]). For instance, *Kim et al.* observe that (*i*) "fitness functions in GP or EAs are highly specific to the application, and their design usually requires a great deal of expertise"; (*ii*) "[w]hile boilerplate functions most commonly applied with ANNs exist, human influence manifests in the decision-making regarding the hyperparameters"; and (*iii*) "[w]here an existing objective function is used, it might need to be adjusted to a specific problem" ([348]).

([345]) See § I.C.2.2 above.

([346]) See § I.C.3.1 above.

([347]) See also SCHELLEKENS, cit., 96 ("the question is to what extent every new problem requires new modelling and adaptation to the algorithm. This may make it difficult to develop an algorithm that functions as a reference").

([348]) KIM ET AL., *Clarifying assumptions*, cit., 317.

Fourth, in assessing the characteristics of the "normal" AI tool, the interpreter must be cognizant, even more than usual, that there is a high risk of hindsight bias. In many cases, AI systems are constantly improving ([349]). However, any improvement in the performance of an AI system which took place after the priority/application date must be discounted in the assessment of inventive step ([350]). This might prove particularly difficult when "commercial" AI tools are at stake. Framing the capabilities of ChatGPT's versions could imply considerable differences in a few months' time ([351]).

Finally, it should be stressed that the threshold of dissemination and acceptance for information and methods to be considered common general knowledge is quite high. Hence, the difficulty for the court or the examiner to get a clear picture of the kind of AI tools that are commonly used (and, one should add, *how* they are used) should probably suggest that there is no such thing as a "normal" AI tool in the field. Part of that difficulty will lie in the secrecy that companies that are investing in AI-assisted innovation will keep on their projects (precisely to avoid, among other things, obviousness attacks) ([352]). However, in the long(er) run it is probable that research trends and tools would emerge anyhow with sufficient information to be framed as part of the skilled person's model.

2.3.2 *The characteristics of the "normal" data used by the AI tools*

Focusing on machine learning techniques, similar issues arise with respect to the data used either for training purposes or as input to the "normal" AI model.

In the *halicin* study ([353]), for instance, the research team put together a training data of more than 2.000 molecules' structures, labelling them hit/non-hit against *E. Coli* ([354]). The molecular structure data was then converted into

([349]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 869.

([350]) NÄGERL, NEUBURGER, STEINBACH, cit., 338.

([351]) See § I.A.2 above.

([352]) DORNIS, *Artificial intelligence and innovation*, cit., 132 (arguing that information about the AI technologies will be inevitably scarce because the market is dominated by few, enormous operators).

([353]) See § I.C.3.2.1 above.

([354]) STOKES ET AL., cit., 690.

a linear vector to be processed ([355]). The DL model was trained based on this processed dataset to predict the features of an effective new antibiotic. Once trained, the team fed the DL model an input dataset of more than 6.000 molecules, and this delivered the first hits. In both cases the molecular information was drawn from publicly available databases. However, the skilled team made purposeful selections within those datasets.

The *halicin* research path illustrates a few of the variables to be considered when construing the "normal" means available to the skilled person. These include, for instance, the choice of the training and input data (both in terms of source and the specific data items), the processing/conversion method of those data, and the different rounds of training in which the data is used ([356]).

In this respect, it is crucial to point out that the training and input data that the inventors use might be not be publicly available, e.g., because they are internal secret information of the company (or proper *trade secrets*) ([357]) and/or covered by data protection rules. The typical example of non-accessible data are clinical trial data in the hands of a pharmaceutical company ([358]).

([355]) STOKES ET AL., cit., 690 ("For this purpose, we utilized a directed-message passing deep neural network model […], which translates the graph representation of a molecule into a continuous vector via a directed bondbased message passing approach. This builds a molecular representation by iteratively aggregating the features of individual atoms and bonds. The model operates by passing 'messages' along bonds that encode information about neighboring atoms and bonds. By applying this message passing operation multiple times, the model constructs higher-level bond messages that contain information about larger chemical substructures. The highest-level bond messages are then combined into a single continuous vector representing the entire molecule").

([356]) HERVEY, DRIVER, WOODHOUSE, cit., § 8-094; DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 24.

([357]) GALLI, BOGNI, *Intelligenza artificiale*, cit., 132; EMMERICH, cit., 96 and 106. SHEMTOV, GABISON, cit., 435.

([358]) KIM, *Access to non-summary clinical trial data*, cit., 289 (arguing that, at the EU level, "[w]hile there are no property-type rights in 'raw' patient-level data, trial sponsors can exercise de facto exclusive control over [individual patient data]. Such control stems from the obligation under the EU Clinical Trials Regulation—motivated by pharmacovigilance reasons—that trial sponsors have to store and protect all data and information gathered in trials against unauthorised access, in particular, by implementing technical measures of

Hence, even assuming that the specific kind of ML model that would be considered "normal" in the field and its specific settings are both part of the CGK, that would still not be enough to conclude that the average skill person would have "normally" access to these ML techniques (and even less so, that it would have some reasonable expectation of success) ([359]).

Whether the *status quo* is desirable and sufficiently encourages innovation might deserve a separate analysis, and might need to be assessed by legislative instruments that fall outside the remit of patent law, for instance in the context of the European Union open data initiatives ([360]).

2.3.3 *Alternatives to the "normal" AI tools*

The above discussion brought several scholars to argue that determining the "normal" AI tools in the hands of the skilled person might be extremely difficult, if not impossible ([361]).

Hence, a few alternatives were proposed, including reliance on: (*i*) the AI tool concretely used by the inventor; (*ii*) multiple AI tools commonly used in the field; (*iii*) the best AI tool used in the field; or (*iv*) the reproduction of the function of specific AI tools. I take these options in turn.

(*i*) *Relying on the AI tool concretely used by the inventor* (or an equivalent one) would obviously simplify the inventive step assessment for that invention ([362]). However, there are two major issues with respect to this option. On the one hand, inventors are not bound to (and generally do not) disclose the R&D approach they have adopted to obtain the invention.

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protection. Besides, drug companies' control over IPD can be reinforced through contracts and supported by non-property regimes of protection, such as trade secrets").

([359]) SCHELLEKENS, cit., 94.

([360]) SHEMTOV, GABISON, cit., 436. See also KIM, *Access to non-summary clinical trial data*, cit., 290 ff. (summarizing a number of *de lege ferenda* proposals to improve access to non-summary clinical trial data in the EU).

([361]) DORNIS, *Artificial intelligence and innovation*, cit., 131.

([362]) SCHELLEKENS, cit., 94 (dismissing the idea as unworkable); See also ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 866 (fearing that this option might end up making all inventions made using such an AI system by definition non inventive).

Therefore, obtaining that information might be unrealistic ([363]). On the other hand, and most importantly, this proposed approach is fraught by hindsight. Indeed, it is based on the assumption that the AI tool that the inventor used corresponds to that of the skilled person, whereas that might not be the case.

(*ii*) *Relying on multiple AI tools that are commonly used in the field* (e.g., Bard and ChatGPT) might limit the risk that picking only one of these systems as a reference for the skilled person would end up pre-empting all inventions from that company (respectively, Google or OpenAI) only because they are market leaders ([364]). In particular, according to *Abbott*, it would be advisable to reject (or invalidate) a patent application only when it would have been obvious for *all* systems considered, since this option would "continue to reward advances in inventive machines" ([365]). This argument is quite simply wrong ([366]). If a commercial AI tool (e.g., Bard) is indeed *commonly used*, and using it would obviously lead to the invention, there is plainly no inventive step. It is absolutely irrelevant if, using *another* common tool (e.g., ChatGPT), the skilled person would not get to the invention. In a scenario where selecting a research path is purely routine – here: picking one out of multiple *commonly used* AI tools – the existence of alternative research paths, some of which would not lead to the invention, does not undermine that fact that at least one would.

(*iii*) *Relying on the best AI tool used in the field* (e.g. Google's DeepMind) would also ease the complicated analysis of what constitutes a normal AI tool in the field (the assumption being that the *best* tools are not necessarily the *normal* ones) ([367]). This approach however runs contrary to the fundamental notion that the skilled person has *average* means and

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([363]) GURGULA, cit., 17. To remedy this hindrance, several scholars have proposed to introduce a disclosure obligation focused on the R&D approach adopted. As discussed later on, these proposals are untenable: see § IV.D.2 below.

([364]) ABBOTT, *Everthing is obvious*, cit., 40.

([365]) ibid., 40-41.

([366]) Along the same lines, see A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 866.

([367]) GURGULA, cit., 18. The author's argument pivots on the generous wording of Mustill LJ in *Genentech*, but as discussed above the reasoning in that case is hardly the expression of a general principle and should be extended by analogy with great caution.

capacities. Furthermore, while this route might not harm the patentability of the invention at stake (e.g., because the inventors have used an even better bespoke AI tool and their invention is still non-obvious) it would unjustly disadvantage both the developers of those AI systems (e.g., Google), whose product would unreasonably set the bar of inventive step, and at the same time all their competitors whose AI tools are not at least as powerful ([368]).

(*iv*) As to the possibility of *concretely reproducing/testing AI tools/data* ([369]), that would obviously be an impractical solution for patent examiners and courts ([370]). Besides, it would run into the same difficulties discussed above (e.g., choosing the right model, task, training data, etc.) ([371]). Actually these difficulties would be exacerbated in this "reproducibility" scenario. In order to materially reproduce the functioning of an AI system, one would need to make a number of exact, potentially arbitrary, choices (e.g., how to pick one *specific* AI system, how *many hours/days* the test should last) and there are problems inherent in each of these choices ([372]). Also, experiments in patent prosecution and litigation are notoriously riddled with complexities and risks of failure for all parties involved ([373]). That is all the more true in the AI context where, e.g., differences that are *prima facie* small in the set up of a system can lead to quite different outcomes ([374]) and certain AI techniques such as evolutionary algorithms encompass an element of randomness by design. Hence, while experiments that attempt to reproduce the functioning of a specific AI system in certain conditions would most likely be considered valid evidence for the construction of the person skilled in the art, that cannot be the general rule.

([368]) DORNIS, *Artificial Intelligence and Innovation*, cit., 113. Similarly, also A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 866.

([369]) ABBOTT, *Everything is obvious*, cit., 44.

([370]) For a similar critical appraisal, see also CERULLA, cit., 149-151.

([371]) DORNIS, *Artificial Intelligence and Innovation*, cit., 134; see also SCHELLEKENS, cit., 95 (wondering whether it would be possible to build up alternative public databases to counter-check for inventiveness when the inventor has used proprietary ones).

([372]) OUELLETTE, *We Robot Comments on Ryan Abbott's Everything is Obvious*, in *cit.*

([373]) HERVEY, DRIVER, WOODHOUSE, cit., § 8-094.

([374]) DORNIS, *Artificial Intelligence and Innovation*, cit., 134.

2.3.4 *Evidence on the "normal" AI tools*

In conclusion, it is submitted that determining the AI tools that are "normal" for the person skilled in the art (if any) will turn into a complex evidentiary problem ([375]). Patent examiners and, after grant, patentees, opponents and competitors in invalidity cases will have to bring to the table – depending on where the burden of proof lies – evidence of CGK on AI tools, potentially supplemented by expert testimony and opinions, and perhaps also experiments ([376]). As with all major technological advancement, this might be a particularly complex task at first and, as the dust settles down, become progressively more manageable for sophisticated actors.

2.4 AI tools and the state of the art

There are at least three different angles to look at the impact of AI tools on the state of the art: (*i*) whether and when the relevant technical field of the invention shall include also AI; (*ii*) whether AI tools changes the relative distance of certain technical fields from that of the invention; (*iii*) whether prior art concerning AI tools can be considered when assessing the inventive step of an AI-assisted invention. I take them in turn.

2.4.1 *The relevant technical field*

Assessing the technical field in which the invention arises is generally the very first step when assessing inventive step – and more in general when interpreting a patent. Given the emergence of AI tools in R&D, one might wonder whether or under what circumstances the technical field of a non-AI invention (e.g., chemistry) shall be extended so as to include also artificial intelligence and, therefore, construe the skilled person as one who would have access to all the prior art also in that field.

It is submitted that this is acceptable only if the problem prompts the skilled person to look for the solution in the field of AI ([377]). Whether this is

([375]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 866.
([376]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 868.
([377]) See § IV.A.1.3 above.

the case will depend on the degree that AI is actually used within the field or on a specific pointer in the prior art.

Looking at this issue from the angle of the "identity" of the skilled person is perhaps easier. The basic principle, as discussed above, is that "where a new technology [is] about to spread into a traditional field, it [is] common practice to group people from both technical fields into a development team" ([378]). In turn, when a new technology *has* spread into a traditional field, it arguably makes no sense to distinguish the two fields. In both cases, the relevant technical field would include the "traditional field" (e.g., chemistry) and that of the new technology (e.g., AI).

Notably, this conclusion does not alter – but is coextensive to – the discourse on equipment/CGK. Common general knowledge is a *type* of prior art. Hence, whenever the technical field of the invention comprises two different fields (e.g., chemistry and computer science) the skilled team might have *access* to the full stack of prior art in those fields, but its *skills/tools* would still be dictated by the CGK. The distinction is perhaps nuanced and hangs on a different level of proximity of the art, but would be nevertheless particularly relevant in the obviousness analysis from an EPO perspective ([379]).

2.4.2 *AI tools and neighbouring or remote prior art*

From a different point of view, several authors suggest that the emergence of AI as a tool might cause the distinction between the neighbouring and remote technical fields to fade ([380]). In general terms, they contend that it makes no sense to distinguish which prior art the AI would or would not consult and

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([378]) EPO, T 15/15, 15 April 2016, cit., § 4.4.

([379]) See § IV.B.4.1.4 above.

([380]) NÄGERL, NEUBURGER, STEINBACH, cit., 338 (arguing that AI will be less tied to departmental boundaries or to conventional patent classification, which have been so far based on human capabilities); SCHELLEKENS, cit., 97 ("because of greater efficiency with which AI can scour a search area, the threshold for considering a [neighboring or general] field as a potential source for a solution may be lowered").

combine, since there is no such thing as a "remote" field for an AI tool ([381]). For instance, *Abbott* argues that "there is no reason to limit a computer's database to a particular subject matter" ([382]). Indeed, while a human inventor "may not think to combine cooking recipes with advances in medical science, […] a computer would not be limited to such […] restrictions" ([383]). Instead, *Ramalho* suggests that AI systems would not be hindered by unfounded technical prejudice in the same way that humans are ([384]).

However, these arguments are not well posed, at least not in these general terms. To start with, they generally only apply to data-intensive forms of AI such as machine learning and expert systems, but not to evolutionary algorithms, whose functioning is not linked to data. That said, of course ML models and expert systems – as computational tools – would not be "hindered" by the proximity or remoteness of certain documents, or by mental prejudices *per se*. However, to assume that these computational tools are encyclopaedic *by definition* is imprecise.

As for expert systems, they are – at least in the classic notion of the category – an inherently limited type of AI that needs specific expert programming on both the knowledge base and the inference engine. As for ML models, it all depends on the data that the model is trained with and, once trained, the input data that the user runs through the model. Besides, the training data is generally "not stored […] during the training process, and once the training process is completed, the model is fully usable independently of the data" ([385]). In other words, a ML model learns correlations (and thus would be able to "combine" and predict properties)

([381]) BENGI, HEATH, cit., 141 ("nor is there a reason to confine the analysis to two prior art documents alone"); DORNIS, *Artificial Intelligence and Innovation*, cit., 127-128; EMMERICH, cit., 96; FRASER, cit., 321; VERTINSKY, cit., 503; CLIFFORD, *Creativity Revisited*, in *IDEA: The IP Law Review*, 2018, vol. 59, 37. Considering whether AI might determine an "extension" to the state of the art see also ZOBOLI, cit., 158-161.

([382]) ABBOTT, *I think*, cit., 1125.

([383]) ABBOTT, *I think*, cit., 1125. Along the same lines see also: ABBOTT, *Everything is obvious*, cit., 37 ("Machine augmentation suggests that the analogous arts test should be modified or abolished once inventive machines are common, and that there should be no difference in prior art for purposes of novelty and obviousness").

([384]) RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 94.

([385]) DREXL ET AL., cit., 8.

only with respect to the datasets that the developer has used for training or as input: i.e., if they are programmed to do so ([386]).

Hence, to move from *Abbott*'s point, while a ML model might be able to derive useful information from data concerning cooking recipes and apply it to a pharmaceutical problem, this presupposes that the model was trained on and/or fed said information. Take the *halicin* example once again ([387]). In that case, the research team had trained the algorithm on 2,000 molecules and then had it scan 6,000 additional molecules. Thanks to the training data, the ML model was able to learn what makes a compound exhibit antibiotic properties. The ML then scanned the input data to predict whether those compounds exhibited said property. The same model was then fed with 100 million molecules and had them scanned again. However, despite being quite powerful, the Collins Lab's model would *not* have been able to draw prior art from a remote field such as cooking recipes since that data was never fed to it in the first place.

As to technical prejudices, while it is possible that AI tools might "see behind" an apparent technical hindrance that is perceived in the field, it is widely known that ML systems also tend to pick up on inherent biases in the data the are trained on, in a variety of different fields and measures ([388]).

([386]) RAMALHO, *Intellectual property protection for AI-generated creations*, cit., 94 (the author also raises the point that "while a human being might not think to look into very removed technical fields for a solution to a given problem, an AI-system may be more capable of "out-of-the-box thinking" but appropriately stresses that this would be the case only "*depending of course on its underlying programming*"; and at 135-136, "[u]ltimately, it is the programming and the setting of an AI system that leads it to 'look' into removed fields"); SHEMTOV, GABISON, cit., 430 ("if programmed to do so"); HUGENHOLTZ ET AL., cit., 110 (arguing that the skilled person "is assumed to know their field of endeavor. An AI system would have no such limitation unless it were specifically programmed to look at a clearly delineated set of data. This might affect the definition of remoteness of technical fields").

([387]) See § I.C.3.2 above.

([388]) Typically the matter of bias in AI is discussed in relation to sensitive topics such as racial or gender discrimination (see e.g., MCKINSEY, *Tackling bias in artificial intelligence (and in humans)*, 6 June 2019, https://www.mckinsey.com/featured-insights/artificial-intelligence/tackling-bias-in-artificial-intelligence-and-in-humans; HAO, *This is how AI bias really happens—and why it's so hard to fix*, in *MIT Technology Review*, 4 February 2019, Hence, it is rather uncertain whether the generalized claim that AI tools are not (or, at least, are less) susceptible to technical prejudices is valid.

It follows that, assuming that a ML tool is part of the skilled person's CGK, the right question to ask is whether the skilled person would have trained the (specific) ML on prior art from neighbouring or remote technical fields ([389]). *Mutatis mutandis*, the same applies to expert systems, i.e., the question is whether the programmer would have included certain information or not in the knowledge base and/or the inference engine.

Then again, ML systems might be built so to have access to the Internet. For instance, in March 2023, ChatGPT added a web browser plugin that allows the system to browse the internet, read websites' content, and elaborate responses based on the information obtained ([390]). Other plugins might allow systems like ChatGPT to parse company documents and information, and interact with other AI systems ([391]). In these cases – depending on the concrete capabilities of the AI system, and assuming that it is a "normal" tool in the field – there would be stronger reasons to believe that the skilled person's reach into the prior art might expand also into remote technical fields.

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https://www.technologyreview.com/2019/02/04/137602/this-is-how-ai-bias-really-happensand-why-its-so-hard-to-fix/). However, the same concerns would broadly apply to scientific research as well.

([389]) See also CERULLA, cit., 118-119 (which suggest that assuming an automatic expansion of the scope of prior art might be unwarranted, also because an AI system trained on very disparate data might result in correlations that are not useful).

([390]) OPENAI, *ChatGPT Plugins*, 23 March 2023, https://openai.com/blog/chatgpt-plugins#browsing.

([391]) SAVAGE, cit., 585-586. Whether ChatGPT – which is based on a large language model with a proclivity for hallucinations and factual inaccuracies – can be useful in R&D is a different question (see e.g., KIM, *On words that come easy*, cit., 434: "[g]iven the mathematical optimisation at the heart of ML, the raw output of derivative AI tends to constitute 'a semantic average' which might stand as a proxy for 'non-original' and 'non-inventive', including for the purposes of copyright and patent laws. If surpassing such average is where LLMs as model-based computational techniques fall short, we might come to appreciate the instances where words do not come easy"). However, some are optimistic about it, also in the pharmaceutical field (see SAVAGE, cit.).

2.4.3 *AI-implemented inventions as prior art to AI-assisted inventions*

Finally, *Straus* raises an interesting argument as to the definition of the state of the art for AI-assisted inventions ([392]). He suggests to consider publicly available documents that disclose AI tools as prior art to (their respective) AI-assisted inventions. He demonstrates his point drawing an example from the DABUS applications.

In particular, *Straus* highlights that in relation to the DABUS food container patent application in the UK ([393]), Thaler had provided rather interesting comments on the inventive process. An excerpt from Patent Form 7 before the UKIPO reads:

> "<u>A machine called "DABUS" conceived of the present invention</u>
>
> The invention disclosed and claimed in this British patent application was generated by a specific machine called "DABUS", which is a type of "Creativity Machine". […]
>
> In the case of the present invention, the machine only received training in general knowledge in the field and proceeded to independently conceive of the invention and to identify it as novel and salient. If the teaching had been given to a person, that person would meet inventorship criteria as inventor.
>
> […] DABUS was not created to solve any particular problem, was not trained on any special data relevant to the present invention, and the machine rather than a person identified the novelty and salience of the present invention.
>
> A detailed description of how DABUS and a Creativity Machine functions is available in, among others, the following US patent publications: 5,659,666 ["US '666"] […]".

Picking up on this description, *Straus* notes that the US '666 patent – disclosing the allegedly inventive "Creativity Machine" – specifically disclosed the possibility to use the invention to design, among other things, a coffee mug (Fig. 19).

([392]) STRAUS, *Some lessons from "DABUS" patent applications*, cit., 625-627. The same argument was put forward also in STRAUS, *Will artificial intelligence change some patent law paradigms?*, cit., 37-39.

([393]) See above III.C.2.1.

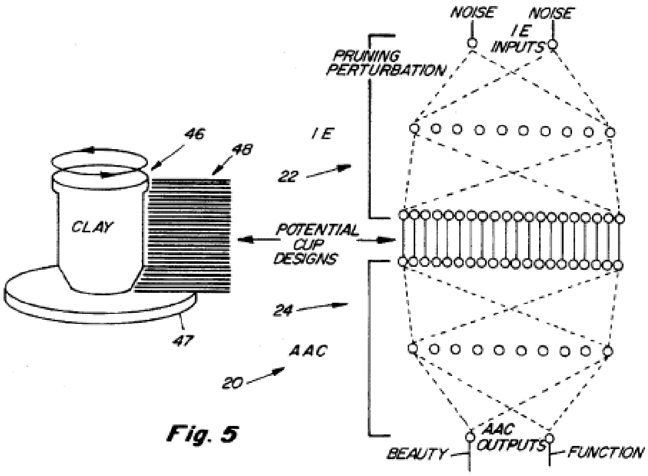

Fig. 19 – Figure 5 of US '666

In turn, also the food container application (EP '144) disclosed containers for liquids such as beverages and other flowable products ([394]). Hence, *Straus* argues that – on the account of the inventor's own declarations – US '666 should be considered relevant prior art to EP '144. While, according to the author, this does not imply automatically that the disclosure of the EP '144 application would have been obvious, the US '666 patent "should offer more guidance to the fictitious person skilled in the art […] when assessing the inventive step requirement". As such, the author argues that US '666 ought to have been disclosed by the applicant in the EP '144 specification ([395]).

Furthermore, *Straus* argues that modifications to the EPO Guidelines or Implementing Regulations should be considered to impose the disclosure of "such patent documents as the US '666 because only then could examiners effectively detect and assess the relevant prior art" and, consequently, make the "necessary adjustments of the capabilities of the fictitious 'person skilled in the art' to those of researchers/inventors assisted by AI tools" ([396]).

The approach proposed by *Straus* is compelling. Patents like US '666 can undoubtedly qualify as state of the art for a skilled person whose technical field is defined as comprising also artificial intelligence. In other words, if the

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([394]) EP '144, § [0006].

([395]) Further to Rule 42(b) EPC under which applicants shall indicate "the background art which […] can be regarded as useful to understand the invention, […] and preferably cite the documents reflecting such art".

([396]) STRAUS, *Some lessons from "DABUS" patent applications*, cit., 631.

skilled person is construed as (including an) AI expert, documents detailing AI technologies will be included in the relevant state of the art. And their inclusions in the patent specification might indeed assist patent offices in landscaping technical fields where AI tools are used to invent and thus properly construe the skilled person's model ([397]). Furthermore, US '666 arguably also include a "pointer" towards using the disclosed AI system to design liquid containers.

However, the author seems to suggest that such "AI tool" prior art (mandatory) disclosure should concern "[a]pplicants like Thaler" ([398]) that is to say "applicants claiming inventions generated by the use of AI tools" ([399]). While the position is not articulated explicitly, the author seems to suggest that inventors should indirectly disclose in the applications their *method* of invention. In turn, it is submitted that – although the example of the DABUS patent is particularly striking – the mandatory disclosure of the inventive process is an unwarranted addition to patent law, which contravenes the principle according to which the inventor's subjective inventive step is irrelevant. This point is further discussed below with respect to similar proposal to introduce mandatory disclosures of the inventive process ([400]).

2.5 AI tools and the identity of the skilled person or skilled team

Finally, we come to the identity of the skilled person. It is submitted that, even assuming that AI tools are routinely used in R&D tasks in a certain field, the skilled person should be construed, once again, along a spectrum, depending "on the reality of the position at the time" ([401]). On one end we have a mere "user" of a commercial AI product, that they licensed and use "as is" ([402]). At the opposite end we have instead an AI expert that is able to put together a bespoke model ([403]).

([397]) STRAUS, *Some lessons from "DABUS" patent applications*, cit., 631.
([398]) STRAUS, *Some lessons from "DABUS" patent applications*, cit., 631.
([399]) STRAUS, *Some lessons from "DABUS" patent applications*, cit., 629.
([400]) See § IV.D below.
([401]) *Schlumberger Holdings Ltd. V Electromagnetic Geoservices AS*, cit., § 41.
([402]) This point is raised also by CERULLA, cit., 122.
([403]) ibid.

Furthermore, the skilled person can be construed also as an interdisciplinary team that includes a computer scientist with average knowledge and ability in AI techniques ([404]) or, alternatively, a skilled person that, in order to implement specific AI tools, would be prompted to reach out to an AI expert ([405]). As to the nuanced difference between these two positions, reference is made to the discussion of the skilled team above ([406]).

3. AI tools and obviousness

Further to the construction(s) of the person skilled in the art in the context of AI-assisted inventions carried out so far, this section addresses the core of the inventive step requirement, i.e., the obviousness analysis. Indeed, it goes without saying that even where AI tools are part of the CGK, an invention might still be non-obvious to the AI-assisted skilled person.

To properly frame the discussion on obviousness, the first two paragraphs take a step back and address two "classic" inventive step topics, i.e., (*i*) the so-called "problem inventions", and (*ii*) cases where the skilled person might *not* have AI tools at hand. The following paragraphs instead are built on the assumption that AI tools are part of the CGK and discuss, in turn, many factors and approaches to the question of obviousness and, in particular, the "obvious to try" doctrine.

3.1 AI tools and problem inventions

Problem-inventions are an established category in patent law ([407]). It is generally accepted that the discovery of an unrecognised problem may, in certain circumstances, give rise to patentable subject-matter – and, in particular, meet the inventive step requirement – in spite of the fact that the

([404]) GURGULA, cit., 18; DREXL ET AL., *Artificial Intelligence and Intellectual Property Law*, cit., 24-25.

([405]) GURGULA, cit., 19.

([406]) See § IV.A.1.7 above.

([407]) JOHNSON, cit., 57.

claimed solution is retrospectively obvious or even trivial in itself ([408]). The famous "Anyway Cup" example ([409]) made by Jacob LJ in *Actavis v. Novartis* is illustrative of the idea ([410]):

> "[t]he invention [in the 'Anyway Cup' case] was a baby's drinker cup fitted with a known kind of valve to prevent it leaking. Babies drinker cups had been known for years. Parents all over the world had put up with the fact that if they were dropped they leaked. No-one had thought to solve the problem. So when the patentee had the technically trivial idea of putting in a valve, there was an immediate success. The invention was held non-obvious, a conclusion with which most parents would agree. […] [B]y identifying the problem as leakage and suggesting it can be solved, one is halfway to the answer – put in a valve".

In the AI-generated inventions narrative, the idea that the human contribution is limited to merely to "posing a problem", which is then solved entirely by the AI, had scholars wondering whether the concept of "problem inventions" could be applied by analogy ([411]). However, the question can hardly be answered in these terms, since the term "problem" is being used in two different ways.

With respect to AI tools, "posing a problem" often times implies formulating it as a mathematical function that approximates the result wanted in order to be understood by the machine. While the problem, in itself, might be obvious from a conceptual point of view, the computational part might require considerable skill. For instance, asking an AI tool to design a novel

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([408]) In the EPO case law see: EPO, T 2/83, 15 March 1984 (*Simethicone Tablet / Rider*); EPO, T 764/12, 18 February 2014 (*Gumlink*); EPO, T 109/82, 15 May 1984 (*Hearing aid/Bosch*). In the Italian case law: Court of Milan, 4 July 2017, *Probiotical Spa c. Sacco Srl*, in *Darts-ip (*discussing the EPO case law on problem inventions and specifying that the assessment of an inventive step must be particularly rigorous and restrictive in these cases); Court of Milan, 30 December 2008, in *SSPII* 2007-2008, *Drin.it Italia Srl c. Samsung Electronics Italia Spa et al.* (confirmed also in Court of Milan, 14 June 2016, *Samsung Electronics Italia Spa et al.* et al. c. *Hop Mobile*, in *OneLegale*). *Contra*, Court of Milan, 17 December 2014, *Bolton Alimentari S.p.a* c. *Paul Paulet Etablissements et al.*, in *DeJure*; Court of Milan, 23 September 2003, *MAUT S.p.a.* v. *Soraluce et al.* in *Darts-ip* (arguing that the inventive activity is that directed to finding a solution, not a problem). In the UK case law: *Actavis UK Ltd v Novartis AG* [2010] EWCA Civ 82 at [35]; *TQ Delta, LLC v Zyxel Communications UK Ltd* [2019] EWHC 562 (Ch) at [242]–[245]. See also UKIPO Manual of Patent Practice s.3.79.

([409]) *Haberman v Jackel International* [1999] FSR 683.

([410]) *Actavis UK Ltd v Novartis AG* [2010] EWCA Civ 82 (17 February 2010).

([411]) KIM, *Clarifying assumptions*, cit., 298.

manufacturing process to overcome a known hindrance poses an *obvious* problem to the machine, whose solution might be inventive. The skill required to pose that problem to the AI tool, i.e., to translate it mathematical optimisation terms, does not make that problem any less obvious ([412]). It follows that, in similar cases, the "problem inventions" doctrine would not apply since the inventive contribution to the art does not lie in the identification of the a problem, but in its solution ([413]).

Of course there might be cases where an inventor appreciates a previously unrecognized problem and solves it, obviously, by using an AI tool. That would probably qualify as a "problem invention". However, there is nothing quite AI-specific to that finding ([414]).

3.2 Inventive step when AI is not a "normal" tool

If the skilled person is *not* skilled in the use of AI (i.e., AI is not a "normal" tool for the skilled person), the inventive step may lie in the decision to apply an AI method to solve the technical problem ([415]). In a similar case, the non-obviousness questions would thus be: would the skilled person have found it obvious to consult prior art in the AI field and/or to seek help from a person skilled in AI techniques? And, if they did, would they have arrived to the solution as a matter of course?

The assumption being that, from the perspective of the skilled person, the AI prior art would be found either in a remote filed or, at least, in a neighbouring one. Indeed, in the words of Jacob LJ, "marry[ing] the skills of two different arts to solve a problem […] may be obvious or it may not" ([416]).

A similar case prompts a so-to-say "classic" inventive step analysis. Following the EPO approach, the relative distance between the closest prior art and prior art concerning AI would be factored in as part of the could-would approach. If the closest prior art prompted the person skilled in the art to

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([412]) But it might be sufficient as a contribution to the inventive process: see above § III.B.2.2.2.

([413]) JOHNSON, cit., 57.

([414]) KIM, *Clarifying assumptions*, cit., 300.

([415]) HERVEY, DRIVER, WOODHOUSE, cit., 284.

([416]) *Schlumberger Holdings Ltd. V Electromagnetic Geoservices AS*, cit.

use (a specific) AI tool to solve the problem, which is then solved, the invention would not present an inventive step ([417]). However, construing the skilled person as *not* skilled in AI would significantly lower the likelihood that combining prior arts from different fields would have been obvious for the skilled person.

The reasoning in *AP Racing v. Alcon* is once again informative of how a similar analysis might be carried out. Addressing the inventive step attack that Alcon had raised based on the optimisation software – which the court had found *not* to belong to the CGK ([418]) – Birss J held:

> "116. […]. Assuming the skilled person has decided to use optimisation software, then they will naturally acquire it, possibly with the assistance of someone skilled in optimisation software […]. Having made the decision to go this far, the acquisition would be obvious and I do not believe the difficulties in using the software would put the skilled person off. So, on this hypothesis the skilled person now notionally sits before their computer running optimisation software such as TOSCA or Optistruct, with the assistance if necessary of someone uninventive […] [to operate said software]. At this point decisions have to be made as to […several different parameters, including the overall volume of the device to be designed]. […]
>
> 119. […] Taking [the expert's witness] evidence as a whole, one thing was fairly clear, that the decision about how much volume to specify to the computer was a decision for the designer himself and was not something which derived from the use of the software. Thus using optimisation software means that a designer has the opportunity to take the step of giving the computer the leeway to make a wider caliper but there is no more to it than that. The decision by a designer still has to be made.
>
> 120. […]. Without hindsight I can see no reason why an uninventive skilled person would take that step. I do not think it was obvious to do that […]".

For the same reasons, when an AI tool is not part of the CGK, and even assuming that the skilled person would somehow consider to use said tool, the fact that they would need to make additional decisions to go forward would discourage a finding of inventive step. Furthermore, when using computational tools, one should also assume that the invention *would* have been materially reached, at least given adequate time. In the *Alcon* case the Court was able to establish the non-obviousness of the invention before that

([417]) HERVEY, DRIVER, WOODHOUSE, cit., 8-090.
([418]) See § IV.C.2.2 above.

point, so it needed not to investigate that factual conclusion ([419]). But in other cases that might be necessary.

3.3 Inventive step when AI is a "normal" tool

Instead, when AI is a "normal" tool in a certain technical field ([420]), a skilled person using AI tools would generally be the yardstick against which to examine the inventive step of the invention ([421]).

However, that does not imply – or at least not *automatically*, as some authors seem to suggest ([422]) – that everything will be obvious to that skilled person ([423]). The enquiry remains a fact specific one. As suggested by *Shemtov* and *Gabison* ([424]), patent examiners would "still need to establish whether the […] uninventive skilled person's value judgement may suffice to implement the AI prior art in relation to the relevant field in a manner that renders the invention obvious. Having AI expertise and access to AI tools does not mean that using such skills and tools in an unimaginative manner may necessarily lead to the invention".

([419]) *id.*, at [113]: "I am not convinced that it has been shown that a shape within claim 1 is the inevitable result of applying structural optimisation software to a motorsport brake caliper given the available space envelope around the caliper and the application of the static and torque load cases, but I will make that assumption in Alcon's favour".

([420]) Of course, the "normalcy" of an AI tool is not a black/white matter. There are a many shades of gray in between the two alternative discussed in § 3.2 and § 3.3, which I am simplifying for exposure purposes.

([421]) See e.g., CERULLA, cit., 117 ("se dunque ciascun inventore in un determinato settore è provvisto di [strumenti di AI], ne deriva ragionevolmente che qualunque tecnico del ramo, e dunque la persona esperta costruita per il giudizio di attività inventiva sarebbe "aumentata" da tali tecnologie").

([422]) ABBOTT, *Everything is obvious*, cit., passim; FABRIS, cit., passim.

([423]) See e.g., BGH, 17 December 2019, X ZR 115/17 (*Autoantikörpernachweis*) (according to which the "use of a generally available tool [such as a particular technique] can be deemed inventive if the advantages sought and realised by the invention are not immediately obvious and the person skilled in the art does not receive sufficient suggestions from the prior art that the tool is suitable for achieving the desired purpose […] and can be used without difficulty", my translation).

([424]) SHEMTOV, GABISON, cit., 432. Along the same lines, see also EMMERICH, cit., 97; GURGULA, cit., 19-20.

For instance, even when certain AI tools are "normal" in a field, a human inventor could still outperform an AI-assisted skilled person ([425]). The inventor might have developed a bespoke AI system that is designed specifically to solve the technical problem addressed by the invention and performs better than the "normal" AI tools. If reaching the invention hangs upon using *that* bespoke tool, and conversely it would not have been obvious to the skilled person, the invention could still have inventive step ([426]). Furthermore, the inventor might also have used a "normal" AI tool in an non-obvious way ([427]), for instance training it with far-fetched, absurd or "synthetic" data ([428]). These options (e.g., human out-performance, improved bespoke tool and non-obvious use) might also be combined and a number of further variations could be put forward.

3.4 AI as a tool and the "obvious to try" test

Within this background, many scholars suggest that the "obvious to try" approach is the most useful to frame the inventive step assessment in cases where the skilled person has AI tools at hand ([429]). The contention is that AI "significantly elevates the level of an expectation of success" and "in some

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([425]) BLOK, cit., 71.

([426]) SHEMTOV, GABISON, cit., 432; GALLI, BOGNI, *Intelligenza artificiale*, cit., 132; BLOK, cit., 71; NÄGERL, NEUBURGER, STEINBACH, cit., 339; NÄGERL, NEUBURGER, STEINBACH, cit., 338. See also ROMM, cit., 1444.

([427]) SHEMTOV, GABISON, cit., 432; NÄGERL, NEUBURGER, STEINBACH, cit., 338; IRELAND, cit., 35 ("even if the use of a particular AI is the norm [this…] does not preclude a new or inventive use of that AI – perhaps putting it towards a new purpose, or pointing it towards a different set of data to that which it is known to use"). See also ROMM, cit., 1444.

([428]) On synthetic data's role in AI training see: GAL, LYNSKEY, *Synthetic Data: Legal Implications of the Data-Generation Revolution*, in *LSE Legal Studies Working Paper No. 6/2023*, 2023, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4414385 (the authors define synthetic data as "artificially-generated data, created using generative AI, that has analytical value").

([429]) GURGULA, cit., 22-24; SCHELLEKENS, cit., 97 (arguing that "with AI on hand, many more permutations of (possible) solutions can be tried in an efficient way. Hence, with AI an obvious to try situation may occur more often"); VERTINSKY, cit., 502 ("[w]ith thinking machines in the equation, the notion of what is obvious for a [skilled person] to try may expand dramatically").

cases might provide grounds for establishing a *prima facie* reasonable expectation of success" ([430]).

While this argument is descriptively appealing, it is also analytically imprecise. ML systems can certainly parse data quicker and perhaps better that humans ([431]). And AI can also "spot" correlations that humans could not have figured out ([432]). However, these findings do not allow the overarching conclusion that the person skilled in the art will generally have a higher expectation of success when embarking on a research project that involves AI tools. Even assuming that the skilled person was well acquainted with AI and that they would have routinely used it, that does not *necessarily* mean that the invention is obvious ([433]).

Shemtov and *Gabison* more conservatively suggest that research routes that involve AI might become "economically rational – hence obvious-to-try – because both time and costs are reduced due to AI activity" ([434]). Therefore, they suggest to consider AI tools as an "additional factor" in the assessment of obviousness: "where following research routes involving AI tools is considered customary […] inventions may be found obvious even where the expectations of success were relatively low" ([435]).

But this is nothing new. The authors are essentially – and correctly – reciting the established case law. As we have seen above, the "reasonable expectations of success" is not a bright-line rule, neither at the EPO, nor before national courts ([436]). When "implementation and the testing of an approach suggested by the prior art does not involve any particular technical difficulties" ([437]) also a try-and-see approach, which implies a particularly

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([430]) GURGULA, cit., 23. Similarly, also MAZZI, *Patentability of AI Generated Drugs*, in *EPLR*, 2020, 27 (suggesting that "if courts will apply […] considerations of obvious to try to judge inventiveness of AI generated drugs, there might be an obstacle to their patentability").

([431]) BURK, cit., 9.

([432]) BURK, cit., 9.

([433]) BURK, cit., 9 ("'obvious to try using an AI system' is not necessarily synonymous with statutory patent obviousness").

([434]) SHEMTOV, GABISON, cit., 434.

([435]) SHEMTOV, GABISON, cit., 435.

([436]) See § IV.B.5 above.

([437]) See § IV.B.5.1 above.

low level of expectation of success, could justify a finding of lack of obviousness ([438]).

To the contrary, depending on the features of the AI system that the skilled person would use, there might be cases where it cannot be established whether using an AI tool would have resulted in a certain output or not. This is the case of evolutionary algorithms, for example, that include an element of randomness ([439]). With respect to random techniques such as mutagenesis, the EPO established in T 737/96 that "like […] in a lottery game, the expectation of success always ranges *irrationally* from nil to high, so it cannot be evaluated in a rational manner based on technical facts" and is not a meaningful or reliable tool in the assessment of inventive step ([440]). In that case, the Board nevertheless found that the patent lacked inventive step, irrespective of this element of randomness. However, implicit in T 737/96 is that not only the technique was entirely routine, but also that the skilled person knew that at some reasonable point in time the random technique would have worked ([441]). It was just a matter of perseverance. Conversely, it is questionable whether the same reasoning could be applied to an AI technique. In turn, the possibility that the AI-assisted invention is a matter of pure luck might speak for inventiveness.

In the end, it is submitted that it cannot be determined *a priori* whether AI tools affect an obviousness assessment, and how. So far, despite considerable doctrinal discussion and abundant evidence that AI is used in

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([438]) See § IV.B.5.1 above.

([439]) BLOK, cit., 71.

([440]) EPO, T 737/96, 9 March 2000 (*Astaxanthin/DSM*). See also MINSSEN, cit., 78.

([441]) EPO, T 737/96, 9 March 2000 (*Astaxanthin/DSM*), § 10(b) ("[t]he application of these techniques does not presuppose much knowledge of the genetics of the target organism as they are based on a trial and error approach, [i.e.,] on treating in one or more rounds with a mutagenic agent(s) the organism of which [e.g.,] improved mutants are sought ([e.g.,] producing better yields of a metabolite), plating the survivors and simply testing them for the desired improved parameter ([e.g.,] for product production)".

R&D – perhaps even "normally" so in certain fields – we are not aware of cases that have thoroughly dealt with these issues ([442]).

A useful example nevertheless comes from a failed lack of inventive step attack raised against an *in silico* approach in T 1439/09 ([443]). The opponent Eli Lilly had argued that the skilled person, starting from the closest prior art, would have arrived at the claimed solution "on the basis of in silico analyses and without inventive skills". In their view, it was sufficient to: (*i*) parse a database for clones in the candidate region highlighted by the closest prior art; (*ii*) enter the clones in a gene prediction program; (*iii*) find a limited number of genes (most of which irrelevant); and (*iv*) arrived at a candidate gene with some homology to the required protein ([444]). The Board, however, did not accept the opponent's argument. They did not doubt that "the skilled person […] had the necessary skills to perform in silico analyses on the basis of the available genomic and other databases" ([445]), which belonged to the CGK ([446]). However, they found that the invention was nevertheless non-obvious since "the skilled person, following the in silico approach suggested by the appellant, would have had to take multiple decisions along the way to arrive at the claimed solution" and that "[a]t each point, the skilled person would have to take the right decision" ([447]). This was only possible with hindsight.

([442]) This might also be due to the fact that there is usually a lag time between the filing, publication and potential litigation of patent: see e.g., LOVE, *An empirical study of patent litigation timing: could a patent term reduction decimate trolls without harming innovators?*, in *U. Penn. L. Rev.*, 2013, vol. 161, 1309 (looking at average enforcement timelines and concluding that product-producing patent holders tend to enforce their patent much sooner, within the first five years, as opposed to non-practicing entities, which tend to enforce close to the end of the patent term).

([443]) T 1439/09, 16 April 2013 (*Sclerostin/UCB PHARMA*). Case discussed also in MAZZI, cit., 24-25.

([444]) T 1439/09, 16 April 2013 (*Sclerostin/UCB PHARMA*), § 33.

([445]) ibid., § 34.

([446]) ibid., § 42.

([447]) ibid., § 40.

Hence, the most sensible approach to the determination of obviousness in relation to AI-assisted inventions is the very standard one ([448]). That is, the interpreter needs to go through a factual enquiry that takes into account, for instance, the *Actavis v. ICOS* factors ([449]), thus weighing the routineness of the AI method with the value judgments that the skilled person would have to take; the reasonable expectations of success and the number of possible research paths, and so forth. Among those factors, secondary indicators will certainly play a role ([450]). However, secondary indicia per se are hardly ever sufficient to reach a solid conclusion on inventive step, and the same applies to AI-augmented inventive processes ([451]).

That said, the hypothetical scenario in which using an AI tool does not require any particular choice or effort and the skilled person can simply "push a button" and be rewarded with an invention ([452]) – often ventilated in the AI-generated inventions narrative – clearly speak against the finding inventive step ([453]).

3.5 Halicin case: inventive step framework

To conclude this comprehensive discussion on inventive step for AI-assisted inventions, the case study on *halicin* – and the legal scholarship that addressed it – is once again a useful example.

As discussed above, the literature suggested that the DL model developed by the Collins Lab was simply "*given a task* to find a compound

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([448]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 867 (arguing that "when using an AI system in the invention process, one could also take into account which […] AI method is used (e.g. a specific machine learning method, an expert system or an evolutionary algorithm)? How will it be designed, if at all? What data is used to train the AI system, how is it structured and how […] are parameters weighted? Are further investigations, data collection or (clinical) trials necessary for preparation or follow-up? The more of these decisions the expert has to make himself, even when using an AI system […] the lower his expectation can be that he will find a solution to the task with the AI system, the less the state of the art suggests the solution to him", my translation from German).

([449]) See § IV.B.7 above.

([450]) FABRIS, cit., 685. HUGENHOLTZ ET AL., cit., 111.

([451]) See § IV.B.6 above.

([452]) DORNIS, *Muddy waters*, cit., 580.

([453]) A. ENGEL, *Erfinderische Tätigkeit und Künstliche Intelligenz*, cit., 867.

with a desired property", it "was *let to crawl* chemical libraries" and finally "ranked halicin very high". In turn, this was a "*result* that *no human* […] was able *to control* or *have prior knowledge of*" ([454]). Since there was no human involved in "solving the problem […] or determining the inventive features of the solution" ([455]) the discovery of halicin as a potential powerful antibiotic – or, at least of other substances found through a similar process – would not deserve patent protection for both lack of an inventor and inventive step ([456]). While I have already disputed in Chapter I this representation of the facts ([457]), I now turn to the legal analysis ([458]).

First, the fact that no human being had "prior knowledge" of *halicin* as a potential antibiotic before it was spotted by the ML model is not only irrelevant but actually required. If the Collins Lab researchers had knowledge of *halicin*'s antibiotic properties beforehand there could be no invention to start with. The fact that no natural person had "control" of the result is also irrelevant. No patent system requires the invention to be *ex ante* "controllable" or "predictable" for the inventor ([459]). Rather the contrary, unexpected effects are a secondary indicator of inventive step ([460]) and, conversely, predictability is generally a symptom of obviousness ([461]). Besides, even traditional laboratory experiments often lead researchers to results that could not be foreseen ([462]).

Second, the R&D process used for finding *halicin* arguably does not belong to the CGK. To the contrary, the Collins Lab adopted what is *prima facie* a bespoke method, for which they selected both the specific models to use and the specific training and input datasets. There is no suggestion in the

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([454]) STANKOVÁ, cit., 4, emphasis added. Along the same lines, see DORNIS, *Künstliche Intelligenz als "Erfinder"*, cit., 443-444.

([455]) STANKOVÁ, cit., 4.

([456]) STANKOVÁ, cit., 4.

([457]) See § I.C.3.2.1 above.

([458]) To be perfectly clear, I am not making a specific claim as to the inventive step (or patentability more in general) of halicin, which would require a fact-specific assessment, but rather using it as an example.

([459]) BURK, cit., 311-312.

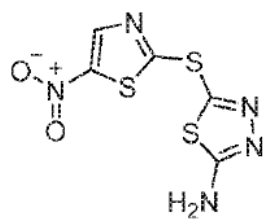
([460]) EPO GUIDELINES, cit., § G-VII.10

([461]) BURK, cit., 311-312.

([462]) KIM ET AL., *Clarifying assumptions*, cit., 42. See also BURK, cit., 311.

scientific literature that the AI tools used were "normal" for the uninventive skilled person. To the contrary, the *halicin* project received considerable media attention as a unique and potentially groundbreaking discovery ([463]). Furthermore, the Collins Lab approach is arguably not part of the CGK to this date. For instance, because it was first described in a specialized paper and it does not appear "usable […] without doubts or further research work" for other projects. Soon after the *halicin* paper was published, experts criticized the group for having poorly trained the model (using "only a couple thousand molecules") and questioned their predictions on toxicity ([464]).

Third, a preliminary confirmation of the novelty and inventive step of the Halicin Patent Application can be derived from the written opinion of the International Searching Authority ("ISA") published on 9 February 2021 ([465]). The ISA reviewed the claims of the Halicin Patent Application and found, in particular, that claim 1 therein would meet the patentability criteria of novelty, inventive step and industrial applicability. Claim 1 as filed reads:

> 1. A pharmaceutical composition for treating or preventing a microbial infection in a subject comprising a therapeutically effective amount of:
>
> 
>
> 5-[(5-nitro-l,3-thiazol-2-yl)sulfanyl]-l,3,4-thiadiazol-2-amine, or a pharmaceutically acceptable salt or stereoisomer thereof, and a pharmaceutically acceptable carrier.

([463]) MARCHANT, *Powerful antibiotics discovered using AI*, in *Nature*, 20 February 2020, https://www.nature.com/articles/d41586-020-00018-3.

([464]) LEMONICK, *AI finds molecules that kill bacteria, but would they make good antibiotics?*, 26 February 2020, https://cen.acs.org/physical-chemistry/computational-chemistry/AI-finds-molecules-kill-bacteria/98/web/2020/02.

([465])https://patentscope.wipo.int/search/docs2/pct/WO2021050473/pdf/W_DrFoEd1UYDhU4IRN9fHQBVtyTbvW5cyclYS4GtNkU. Note that the ISA however objected that the patent lacked unity since claims 1-15 were directed to a pharmaceutical composition for treating or preventing a microbial infection, whereas claims 16-33 were directed to a *method* for identifying one or more molecules as predicted to possess antimicrobial activity comprising a machine learning program.

The compound "5-[(5-nitro-l,3-thiazol-2-yl)sulfanyl]-l,3,4-thiadiazol-2-amine" is *halicin*. Upon examination, the ISA concluded that claim 1 was not made obvious by the prior art ([466]).

Finally, aside from the merits of the case, suggesting that new drugs discovered through AI tools such as *halicin* might not deserve patent protection as a matter of principle is not advisable from a policy perspective. Antibiotic-microbic resistance is currently one of the major health threats in the world. It is projected that without "immediate action to discover and develop new antibiotics […] deaths attributable to resistant infections will reach 10 million per year in 2050" ([467]). Denying patent protection to new antibiotics discovered by using AI tools *per se* would risk hampering investments and research in this field and causing great damage to society, in conflict with the utilitarian justification of patent law.

D. DISCLOSURE OF AI AS A TOOL

The following section addresses the possibility to introduce an obligation to disclose the use of AI as a R&D tool upon patent applicants ([468]).

1. Proposals to introduce the mandatory disclosure of the inventive process

As discussed at length above, whether the use of AI is a "normal" tool in the

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([466]) The ISA Report reads, in the relevant part: "Claims 1-4 and 10-15 meet the criteria set out in PCT Article 33(2)-(3) [i.e., novelty and inventive step] because *the prior art does not teach or fairly suggest the subject matter claimed*. Regarding Claim 1, WO 2018/220365 […] discloses a pharmaceutical composition for treating or preventing a microbial infection (abstract), but does not disclose a compound of formula listed: [halicin]. WO 2008/118626 A2 […] discloses a compound of formula listed: [halicin] […], but does not disclose a pharmaceutical composition for treating or preventing a microbial infection in a subject. A document entitled […] to Barot et al. […] discloses wherein compounds comprising a 1,3,4-thiadiazole moiety have antimicrobial properties […], but does not disclose a pharmaceutical composition comprising formula listed: [halicin]. […] Claims 1-4 and 10-15 have industrial applicability as defined by PCT Article 33(4) because the subject matter could be made or used in industry".

([467]) STOKES ET AL., cit., 688.

([468]) The topics in this section are based on my previous research in: TRABUCCO, cit., 31-35. I refer to that work also for the discussion of similar proposals under U.S. patent law.

hands of the skilled person or not depends requires a case-by-case assessment, focused on the prior art and CGK in the field at stake.

In this respect, patent specifications are not particularly helpful. Article 83 EPC provides that patent applications shall disclose the invention "in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art" ([469]). The skilled person should thus be able to carry out the *invention* "without undue burden" ([470]). Of course, the patentee may provide background information on the inventive process, but the required disclosure concerns *only* the *invention*. As a result, patents typically do not mention the R&D process/tools adopted by the inventor(s).

Within this background, several scholars have suggested the introduction of an *ad hoc* disclosure obligation, which would impose applicants to describe the AI tools through which the invention was devised – or more generally their inventive process – in the specification ([471]). The assumption is that a broader disclosure obligation, concerning also the inventive process, would allow patent offices and third parties to gather relevant information on the use of AI tools in the real world ([472]). If most patents in a specific field (e.g., novel antibiotics) were to disclose that the inventors have relied on an AI tool – or better yet, a specific ML model and dataset – that might provide useful evidence to considered said tool a

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([469]) This provision also reprises Article 29 TRIPS.

([470]) EPO, T 32/85, 5 June 1986, § 5.

([471]) RAMALHO cit. 26; STANKOVÁ cit. 26-27; GURGULA cit. 17 (rather sceptical on the feasibility of a similar solution); FRASER, cit., 333; See also GHIDINI ET AL., *Brevetti & Robot. Perché l'Europa deve battersi per le regole degli algoritmi*, in *Corriere della sera*, Milan, 15 March 2021. Likewise, in the U.S. scholarship, see Abbott, *Everything is* obvious, cit., 35 (the author supports the introduction of "a requirement for patent applicants to disclose the role of computers in the inventive process" where "[f]ailure to do so can invalidate a patent or render it unenforceable"); EBRAHIM, *Artificial Intelligence Inventions*, cit., 147 (proposing to introduce incentives to facilitate the disclosure of "the inner workings and the use of AI in the inventive process" for transparency purposes); WAMSLEY, cit., iv (proposing an "encouraged disclosure" of AI use to enable fact gathering of inventive processes to facilitate future decision makers in working out how to deal with these and other inventive techniques).

([472]) RAMALHO cit. 26; ABBOTT, *Everything is obvious*, cit., 35 (arguing that the idea behind such disclosure requirement would be to "see whether most inventors in a field […] are human or machine").

"normal" one in the field and, consequently, to construe the skilled person accordingly.

The precise way in which a similar obligation should be introduced, and its specific goals, are varied in the literature. For instance, *Ramalho* suggests to introduce the mandatory disclosure of the inventive process in the patent offices' guidelines for examination ([473]). *Stanková*, instead, proposes to amend the formal requirements under Rule 42 EPC so that AI-systems used in devising the invention must be disclosed as part of the technical problem and solution ([474]). The latter, however, seems also to suggest that the disclosure of AI as a tool in the patent application should be accounted also for the assessment of the inventive step (and inventorship) of that invention ([475]).

2. Arguments against the disclosure of the inventive process

The proposals suggesting to introduce a mandatory disclosure of the inventive process are not convincing.

First, that fact that the EPC does not require applicants to disclose their inventive process ([476]) is a deliberate legislative choice, which reflects the established principle – repeatedly discussed herein – that the manner in which the invention was actually reached – either by pure chance or thanks to a great deal of effort, through AI models, or by calculations on paper – is irrelevant for a finding of an inventive step, which requires an *objective* assessment ([477]). The question is never what the *inventor did* to get to the solution, but what the *skilled person*, with average knowledge and tools, *would have done*, faced with the technical problem and starting from the prior

([473]) RAMALHO, cit., 26.

([474]) STANKOVÁ, cit., 26-27 (the goal of the author, however, is more specifically to spot the cases where there is no human inventor, which in her view do not deserve protection; in her view, also, in case of non-compliance with this requirement, the author suggests that "the EPO should refuse the application under [Article] 90 EPC").

([475]) ibid.

([476]) EPO, cit., 2 (the EPC "does not contain any provisions which would prevent patenting certain subject-matter based on how or by whom it was generated").

([477]) LAUBER-RÖNSBERG, HETMANK, cit., 571; See also VANZETTI, DI CATALDO , cit., 401; FRANZOSI, *Non ovvietà*, cit., 567-568; REKTORSCHEK, BAUS, cit., 467.

art ([478]). For the same reason, it is unacceptable to suggest that the disclosure of the use of an AI tool in the inventive process should be taken into account to determine the inventive step of *that* invention. Whether or not the inventor used a tool is and should remain irrelevant for patent offices and courts ([479]).

Second, *de lege ferenda*, introducing an obligation to disclose the inventive process might be "unnecessarily burdensome" ([480]) for applicants. Indeed, the inventive process might be hard to conceptualize, summarize and describe in the first place, for instance in case of serendipitous inventions, erratic research paths, or extremely long R&D processes. Also, the level of detail that would be expected is unclear. Would "using a DL model" do, or would it be necessary to provide further information or even the code? Especially in the latter case, there is a non-negligible risk that asking applicants to disclose the AI tools used might also force them to reveal trade secrets and thus put them at the cross-roads between obtaining patent protection or preserve their other assets.

Third, an "inventive process" disclosure obligation might be hard or unfeasible to fulfil and enforce ([481]). Indeed, to properly enforce an alleged non-compliance with such obligation, examiners or third parties would need to find sufficient evidence that the applicant disclosed the inventive process incompletely or incorrectly. However, lacking public information or insider knowledge, it is hard to see how that evidence might be gathered. The inventive process generally cannot be reverse engineered starting from the invention. Besides, under current EPC law, patent applications cannot be rejected for the sole fact that the applicant behaved dishonestly or deceitfully

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([478]) GALLI, BOGNI, *Intelligenza artificiale*, cit., 131; CERULLA, cit., 123. See also in the U.S. scholarship, ROMM, cit., 1446-1447 ("the [nonobviousness] inquiry should not focus on the abilities of the actual AI involved in creating the claimed invention, but rather on the standard within the industry").

([479]) SHEMTOV, GABISON, cit., 431-432. For the same reason, the proposal to consider a "made with AI" as a secondary indicator of obviousness, proposed by RAMALHO, *Intellectual Property Protection for AI-generated Creations*, cit., 139, shall be rejected, as it ends up introducing a subjective element into the obviousness analysis.

([480]) KIM ET AL., *Claryfying assumptions*, cit., 44; DREXL ET AL., cit., 5.

([481]) KIM ET AL., *Claryfying assumptions*, cit., 44; DREXL ET AL., cit., 5; SHEMTOV, GABISON, cit., 431.

during prosecution – for instance giving an incomplete representation of the inventive process – as long as this does not reflect on the substantive patentability requirements ([482]). The grounds of invalidity under Article 138 EPC notably do *not* include false or misleading statements made by the applicant to the EPO and they do not seem to leave any margin of discretion to national courts when dealing with European patents ([483]).

Fourth, introducing a brand new requirement to disclose the inventive process may also run contrary to TRIPs ([484]). This could be the case, for instance, if the disclosure obligation was framed as a substantive patentability requirement, since: (*i*) Article 27 TRIPS provides that the members states must ensure that "patents *shall be available* for any inventions […] provided that they are *new*, *involve an inventive step* and are *capable of industrial application*" and is therefore questionable if WTO member states might introduce additional patentability requirements; and (*ii*) Article 29 TRIPS only asks the applicant to sufficiently "disclose the *invention*", but not the inventive process. From a different angle, the proposed disclosure requirements may also contravene the "technological neutrality" principle of Article 27 TRIPS, which provides that patents shall be available "*without discrimination* as to […] the field of technology". This could be the case, for instance, if it ended up significantly raising the bar of patentability in specific industries, such as the pharmaceutical one, without legitimate reasons ([485]). Given the inherent flexibilities of the TRIPS system, however, these hypotheticals can hardly be discussed in the abstract ([486]).

([482]) HOSS, *Deceptive Conducts before the Patent Office. Challenges for Patent Law and Competition Law*, MIPLC Studies, Nomos, Baden-Baden, 2019, 302 ff.

([483]) HOSS , cit., 86-87.

([484]) While the EPO is not party to the TRIPs Agreement and not bound by it, the EPC members (and the European Union) are, so that they may be under an obligation to see to it that the EPC is in conformity with TRIPS: G 2/02 and G 3/02 (OJ 2004, 483). See also EPO CASE LAW, cit., III.H.2.

([485]) DINWOODIE, DREYFUSS, *Diversifying without Discriminating: Complying with the Mandates of the TRIPS Agreement*, in *Mich. Telecomm. & Tech. L. Rev*., 2007, 13(2), 445.

([486]) As an examples of a comprehensive TRIPS-compatibility analysis in the pharmaceutical industry, see GROSSE RUSE-KHAN, ROMANDINI, *Patentability of Pharmaceutical Inventions Under TRIPS. Domestic Court Practice as a Test for*

Finally, if the purpose of the proposed disclosure requirement is to provide more information on the use of AI in R&D, the mechanism might also be redundant. Patent applications are not (and will not be) the only source of information on how inventions are made. On the one hand, in the inventive step assessment the EPO and third parties can also rely on scientific publications and news articles in the field and, more in general, on anything that was made available to the public (and, in particular, on the common general knowledge). Therefore, it should generally be possible to define the skilled person as versed in certain AI techniques without forcing inventors to disclose their specific inventive process. On the other hand, patent applications are, by definition, advanced technical knowledge. As repeatedly discussed herein, they are not *prima facie* part of the "common general knowledge" of the skilled person and, therefore, they are poor reference documents for assessing the "normal" research tools.

E. CONCLUSION

This chapter has amply discussed the notion of the skilled person and the requirement of inventive step in European patent law. However, the most relevant findings can be summed up rather concisely. A proper and balanced construction of the skilled person is a fundamental step for patentability assessments. While the skilled person is a legal fiction, they must be grounded in reality. In turn, the inventive step requirement is strictly objective and the inventor's own research path must be disregarded. In order to determine whether an invention meets the inventive step requirement the interpreter must take into account all relevant factors and circumstances. Therefore, the inventive step assessment requires a nuanced understanding of the deceptively simple question: is the invention obvious?

Within this framework, this chapter analysed the impact of AI tools on the constructions the skilled person and on the obviousness analysis. If AI is or becomes a "normal" research tool, it should be integrated in the model of

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International Policy Space, MPI Research Paper No. 16-02, https://ssrn.com/abstract=2736224.

the skilled person for the inventive step analysis. Inevitably, this will require a detailed analysis into the type of AI tool that the skilled person would use and, if relevant, also into the hypothetical training/input data.

Once the skilled person is construed, the inventive step analysis can take place. In this regard, there is no reason to assume that "everything" will be obvious for the AI-assisted skilled person. A finding of inventive step requires a case-by-case assessment, weighing all the relevant factors. As a result, the provocative statement sometimes aired in the literature that AI is capable of inventing by simply "switching on" is demonstrably false. Rather than a simple "on/off switch" in the inventive step assessment, factoring AI as part of the skilled person and in the obviousness analysis will require the interpreter to turn and calibrate multiple knobs of a complex "switchboard".

Finally, the proposals raised to introduce a new "inventive process" disclosure obligation, are not convincing. An "inventive process disclosure" obligation would only impose a high burden on applicants, while being hard to enforce and most likely unnecessary.

FINAL REMARKS

Artificial intelligence is a powerful and fascinating technology destined to impact the world profoundly. In the field of innovation, researchers are increasingly relying on AI to tackle complex R&D challenges. To some extent, AI is changing the way we invent.

Hence, it is legitimate to ask whether the advent of AI is compatible with the patent system, the field of law devoted to protecting inventions. To explore this question, this work carried out a systematic and comparative review of the core principles of European patent law – including the notions of invention, inventor, inventive step and skilled person. The purpose was to investigate whether and how these notions might need to be adapted to accommodate the use of AI tools in R&D.

The starting point was naturally the "invention". While the dogmatic discussion on the precise notion of "invention" is not entirely settled, a common understanding emerged. In general terms, inventions consist of technical subject-matter – where "technical" often implies the presence of physical means or some sort of materiality – as opposed to purely abstract creations. Instead, the notion of invention is completely detached from the figure of the inventor. The "invention" is a strictly objective concept. Thus, in principle, whether or not the inventor used AI in the inventive process is completely irrelevant for the existence of an invention.

Turning to the inventor revealed a more complex picture. The "inventor" was identified as the natural person who makes an intellectual contribution to the inventive concept. However, it is irrelevant whether said intellectual contribution was carefully planned and executed or the result of pure chance. Simply recognizing that subject-matter upon which one stumbles accidentally is an invention is enough to qualify as an inventor (recognition principle). It follows that, despite many bold statements and proposals in the scholarship, AI *is not* and *cannot be* an inventor. *First*, because mandatory formal requirements common to the EPO and national jurisdictions require patent applicants to identify a natural person as the inventor. *Second*, because, based on the recognition principle, it is possible to identify human inventor(s) in all but extreme and unrealistic cases. *Third*, because in the unlikely scenario of a truly "autonomous" AI invention, where it is not possible to identify a human inventor, the right to the patent would not arise at all.

The idea of an "AI-inventor" emerged as untenable also from a factual point of view. Indeed, despite significant technical advances, AI still needs plenty of human input to generate inventions. *De facto* AI is thus a powerful tool in the hands of inventors. Not an inventor.

And even if we were to assume that AI tools can generate inventions "autonomously" – thus allowing technological progress without risks and uncertainties – the fundamental justifications of patent law would seem to be lost. Indeed, patents are widely seen as legal instruments that encourage innovation by allowing patent holders to recoup their investments in R&D. If "autonomous" AI-generated invention were to become the norm, there would be hardly any R&D investments to protect.

The longstanding debate on AI-inventorship would thus seem to have obfuscated the arguably more relevant questions concerning the need to re-calibrate the substantive patentability requirements – and in particular the notions of inventive step and the skilled person – to take into account the increasing role of AI in R&D.

The person skilled in the art is a fictional figure representing the average practitioner in the technical field of the invention. The skilled person is the yardstick against which the patent – and technical teachings more in general – are interpreted. In turn, the inventive step requirement posits that only those inventions that are not obvious to the skilled person deserve patent protection. The question "what is obvious?" is perhaps the hardest one in patent law. While patent offices and courts have developed several structured approaches to answer that question, the inventive step assessment unfailingly requires a nuanced and fact-specific investigation into the invention and its technical field.

Since the skilled person is a flexible model that adapts to technological change, if AI is or becomes a "normal" research tool, it should be integrated as part of the skilled person for the inventive step analysis. Inevitably, this will require a detailed investigation into the type of AI tools the skilled person would use and, if relevant, the training/input data. Once the skilled person is construed, the inventive step analysis can take place. However, at the current state of technology, there is no reason to assume that “everything” will be obvious for the AI-assisted skilled person. To the contrary, a finding of inventive step still requires a case-by-case assessment, weighing all the relevant factors, potentially including the use of AI tools.

In the end, this work comes to the conclusion that, while the advent of AI might cause increased complexities and require some adaptations – especially with respect to the inventive step assessment – the fundamental principles of European patent law stand the test of time.

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