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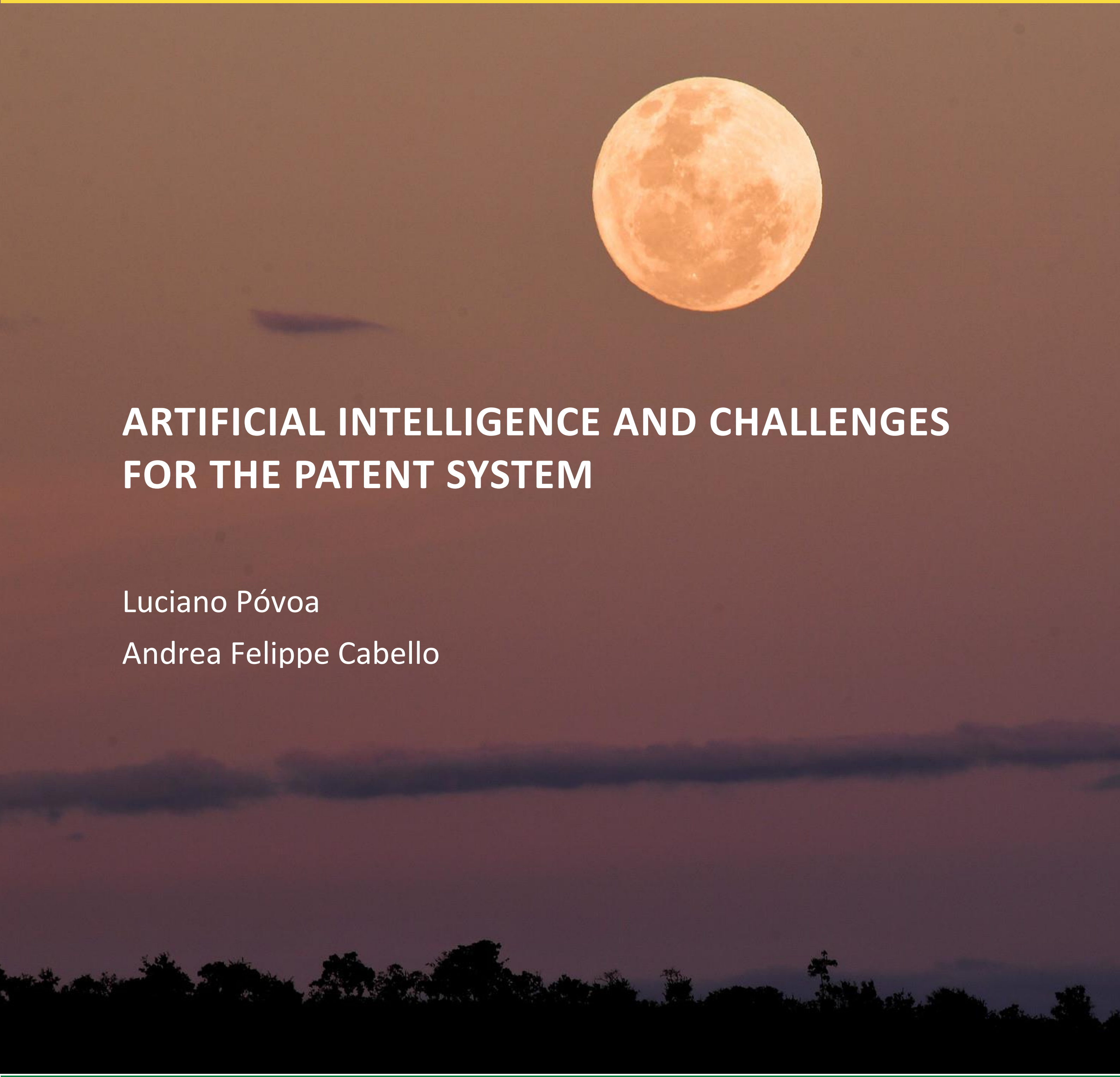

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Foto da Capa: Lua cheia de inverno ao entardecer

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ARTIFICIAL INTELLIGENCE AND CHALLENGES FOR THE PATENT SYSTEM*

ABSTRACT

Artificial Intelligence (AI) has a transformative influence over inventive activity, posing challenges for the current patent system. We argue that the unique attributes of AI, particularly its role in reducing the costs and uncertainty associated with discovery and innovation, its status as a general-purpose technology that enhances productivity in various sectors, and its potential to shift the economic logic from user exclusion to inclusion, challenge the core principles of the patent system. This analysis aims to elucidate the complex interaction between the innovation process and intellectual property, offering insights into the future trajectory of patent laws. We assess the application of AI in drug development and the broader implications for the patent system amidst current economic and social changes, particularly demographic ones. As a result, we argue that there will be a decrease in the relative importance of patents as a mechanism for protecting intellectual property.

KEYWORDS: Artificial Intelligence. Patents. Innovation.

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SUMÁRIO

1 INTRODUCTION

Artificial Intelligence (AI) holds the potential to influence how inventive activities and discoveries are made. In 2020, DeepMind, an AI laboratory affiliated with Google, introduced AlphaFold. This AI system can predict the three-dimensional structure of proteins from their amino acid sequence with precision and at a reduced cost. [1] This task is recognized as one of the most challenging in biochemical research, as determining the structure of a protein is crucial for understanding the nature of diseases and for the more effective development of vaccines and medicines. AlphaFold transformed an activity that was traditionally experimental and could take months or even years to complete, allowing it to be done in minutes. In 2022, the AlphaFold code and the AlphaFold Protein Structure Database were made publicly available. This database includes the most complete human proteome to date, as well as that of over twenty other organisms, totaling more than 350,000 protein structures.

AI has been widely acknowledged by experts as a disruptive technology at least since 2012, with the advancement of the technique known as deep learning.[2] Over the past decade, significant advancements have been achieved, with applications across various fields. Particularly notable is the application of these advancements to guide and accelerate scientific research and discoveries.

The emergence of these technologies immediately sparked debates on intellectual property issues, particularly regarding the authorship of AI-generated content and potential copyright infringements associated with the training of AI models (NYTimes, December 27, 2023). Furthermore, AI has impacted an activity once considered inherently human: the ability to invent and generate hypotheses.

This paper aims to explore the impacts of employing AI tools on inventive activity, its economic aspects, and their repercussions on the patent system.

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1 Andrew W Senior *et al*, "Improved protein structure prediction using potentials from deep learning" (2020) 577:7792 Nature 706–710.

2 Yann LeCun, Yoshua Bengio & Geoffrey Hinton, "Deep learning" (2015) 521:7553 Nature 436–444.

In doing so, it seeks to contribute to the understanding of the complex interactions between technological innovation and intellectual property.

Throughout the 20th century, a series of technological innovations spurred the need to reinterpret or refine the framework of copyright laws to encompass new forms of intellectual creations.[3] This need emerged with the advent of technologies such as xerography, software, and, later on, data transfer via the internet, which enabled the widespread dissemination of texts, images, and sounds to millions of users at nearly zero marginal costs.

These technological innovations induced significant transformations in the *process of reproducing* materials protected by copyright, leading to social and legal frictions. The historical response to these tensions often involved specific adjustments in the intellectual property regime, aiming to accommodate the new paradigms of content creation and distribution.

In contrast to the dynamism observed in the realm of copyright laws, patent legislations remained relatively stable and indifferent to innovations during the same period. While innovations may influence the pace and direction of patenting activities, they rarely provoke substantive changes in patent legislation.

However, this paper posits that the emergence and diffusion of AI represent a departure from previous trends, potentially triggering profound revisions in the foundations of patent law. We argue that AI, due to its distinctive characteristics, may challenge central premises of the patent system, including the extent of the conferred monopoly, the criteria for inventorship, and the requirements for patentability.

We highlight three distinctive features of AI. First, AI directly influences the *process of generating* discoveries, inventions, and intellectual creations, going beyond mere reproduction. AI contributes to a significant reduction in the costs associated with prediction and creation, thereby lowering Research and Development (R&D) expenses and affecting the demand and supply of inventions.

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3 David D Friedman, "Does Technology Require New Law?" (2001) 25 Harv J Law Public Policy.

Secondly, from an economic perspective, AI stands out as a *general-purpose technology*, characterized as an enabling technology that can be employed across a wide range of sectors, enhancing productivity, and fostering new opportunities and complementary inventions.[4] It can lead to changes in the relative economic importance of sectors and to the overall significance attached to patents as a mechanism for recouping investments in innovation. In the past, similar technologies, such as electricity and the internal combustion engine, had profound impacts on various sectors, reshaping the urban structure of the 20th century and labor relations, but without the strategy of patents.

Thirdly, the configuration of the intellectual property system is shaped by economic and political factors. Intellectual property rights are often interpreted by economists as an incentive mechanism, where the state grants a temporary monopoly to stimulate the creation, development, and dissemination of inventions in society.[5] AI has the potential to alter this economic logic, favoring a model that privileges inclusion and access over exclusion and the appropriation of consumer surplus (the practice of charging the maximum price that consumers are willing to pay).

We emphasize that our analysis is based on theoretical arguments, given the lack of empirical evidence on the concrete impacts of AI on the economy and society. We also dismiss the notion that an AI that completely replaces human reasoning is imminent. Therefore, this work aims to explore the *potential challenges* that AI poses to the current patent system. The remainder of this paper is structured as follows: Section 2 discusses how AI can influence the R&D activities and the innovation process. Section 3 exemplifies the application of AI in the development of new medicines. Section 4 presents some challenges of AI for the patent system. Section 5 briefly examines how the current economic and social context, including the digital economy and demographic changes, might diminish the relevance of patents as a mechanism for appropriating the benefits of inventive activities, challenging patent legislation. Section 6 concludes the article.

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4 Manuel Trajtenberg, *AI as the next GPT: a Political-Economy Perspective* (National Bureau of Economic Research, 2018) DOI: 10.3386/w24245.

5 Roberto Mazzoleni & Richard R Nelson, "The benefits and costs of strong patent protection: a contribution to the current debate" (1998) 27:3 Res Policy 273–284.

2 HOW AI INFLUENCE R&D ACTIVITIES AND THE INNOVATION PROCESS

Innovative activity is generally characterized as expensive, complex, and fraught with uncertainties. From an economic perspective, employing AI as a tool in R&D activities can lead to at least three effects on the innovation process: cost reduction, uncertainty reduction, and the improvement of firm's absorptive capacity. The combined effect results in greater efficiency of the resources used for R&D. This aspect also implies a decrease in opportunity cost, encouraging companies to invest in multiple invention projects simultaneously, without the fear of incurring significant losses for not exploring other opportunities.

Firstly, AI can substantially reduce the costs associated with the innovation process, covering from financial expenses and skilled labor to the time required to develop new inventions. A predominant strategy of reducing these costs is through the automation of tasks at various stages of the innovation process, including model identification, conducting tests, and collecting and analyzing data. Moreover, AI enables the optimization of these processes and the improvement of decision-making.

For example, the incorporation of new technologies associated with AI, such as machine learning and deep learning, began to revolutionize medical research. These technologies have shown tremendous promise in the development of new medicines and the discovery of vaccines.[6] Bagabir *et al* report that AI was employed to optimize mRNA sequences, significantly contributing to production efficiency. The integration of robotic automation and AI enabled Moderna to manufacture over 1,000 mRNA sequences per month, a notable increase from the previous manual production capacity of only 30 sequences.[7] In other words, what took a month could now be produced in a day.

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6 Sali Abubaker Bagabir *et al*, "Covid-19 and Artificial Intelligence: Genome sequencing, drug development and vaccine discovery" (2022) 15:2 J Infect Public Health 289–296.

7 Ashwani Sharma *et al*, "Artificial Intelligence-Based Data-Driven Strategy to Accelerate Research, Development, and Clinical Trials of COVID Vaccine" (2022) 2022 BioMed Res Int 7205241.

The use of AI in medical research has accelerated stages that traditionally took months or years to conduct with conventional research methods. Even more remarkably, AI has enabled the acceleration and the discovery of new connections and outcomes previously unforeseen by scientific hypotheses[8] and beyond human perception using traditional methods.

In another example, AI was used to analyze over one hundred million chemical molecules in just a few days, identifying potential antibiotic candidates with innovative mechanisms of action, divergent from those used in existing medicines. This process resulted in the discovery of a new and potent antibiotic.[9]

Thus, AI has played a revolutionary role in inventive activities and innovation by providing greater efficiency to the R&D process, reducing operational costs, and the time required for various stages of research.

Ajai Agrawal *et al* highlight that the most significant aspect of this revolution is the drastic reduction in the *cost of prediction*.[10] In this context, prediction refers to the process of using a large set of available information (big data) to generate unknown information, such as filling gaps, anticipating future events, recognizing patterns, or generating insights. As the authors emphasize, we tend to utilize a resource (prediction) more when its costs are drastically reduced, often approaching zero, as happened with the spread of digital technology, which enabled the representation of information in bits. The transition to digital representation contributed to reducing the cost of searching for information, bringing various economic consequences, such as an increase in the diversity of available goods, the emergence of the sharing economy, and the development of platforms like Airbnb.[11]

8 Jens Ludwig & Sendhil Mullainathan, *Algorithmic Behavioral Science: Machine Learning as a Tool for Scientific Discovery* (Rochester, NY, 2022).

9 "Artificial intelligence yields new antibiotic", (20 February 2020), online: *MIT News Mass Inst Technol* <https://news.mit.edu/2020/artificial-intelligence-identifies-new-antibiotic-0220>.

10 Ajay Agrawal, Joshua Gans & Avi Goldfarb, "Prediction, Judgment, and Complexity: A Theory of Decision-Making and Artificial Intelligence" in *Econ Artif Intell Agenda* (University of Chicago Press, 2018) 89.

11 See Avi Goldfarb & Catherine Tucker, "Digital Economics" (2019) 57:1 J Econ Lit 3–43.

Thus, recent advances in AI have facilitated the execution of automated and low-cost predictions, applied in task automation, image recognition, autonomous vehicles, and analysis of large datasets. This predictive capability of AI has significant implications for innovation. In this way, AI can be considered a *new method of invention*, characterizing itself as a general-purpose technology with the potential to fundamentally change the way R&D is conducted and innovation strategies.[12] According to Cockburn *et al*:

> One of the important insights to be gained from thinking about [the invention of a method of inventing], therefore, is that the economic impact of some types of research tools is not limited to their ability to reduce the costs of specific innovation activities – perhaps even more consequentially they enable a new approach to innovation itself, by altering the 'playbook' for innovation in the domains where the new tool is applied (p. 116).[13]

AI as a general-purpose technology has the potential to influence various sectors of the economy. One way to verify the validity of this observation is through the analysis of how many inventions are currently related to AI, and how many technological fields are impacted. The U.S. Patent and Trademark Office (USPTO) published the report "Inventing AI: Tracing the diffusion of artificial intelligence with U.S. patents"[14] in 2020, which shows that the volume and percentage of public patent applications related to AI grew 100% between 2002 and 2018. The study also shows that this technology is becoming increasingly important for invention and is rapidly diffusing across other sectors. The report highlights that "[i]n 1976, patents containing AI appeared in about 10% of the subclasses. By 2018, they had spread to more than 42% of all patent technology subclasses" (p. 7).

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12 Iain M Cockburn, Rebecca Henderson & Scott Stern, "The Impact of Artificial Intelligence on Innovation: An Exploratory Analysis" in *Econ Artif Intell Agenda* (University of Chicago Press, 2018) 115; Stefano Bianchini, Moritz Müller & Pierre Pelletier, "Artificial intelligence in science: An emerging general method of invention" (2022) 51:10 Res Policy 104604.

13 Cockburn, Henderson & Stern, *supra* note 13.

14 https://www.uspto.gov/sites/default/files/documents/OCE-DH-AI.pdf. (last visited 8 February 2024).

The predictive capability of AI also has implications for reduction of uncertainty, which is crucial for the decision-making process.

Firms engaged in innovation activities face *economic and technical uncertainties*. As highlighted by technology historian Nathan Rosenberg, the bulk of corporate R&D efforts are focused on development (D).[15] It is at this stage of the inventive activity that solutions are sought to reduce the costs arising from uncertainties.

Economic uncertainties can be mitigated through firms' enhanced ability to collect data and use AI to make better predictions about consumer behavior, supply and demand for products and services, anticipate changes in the supply chain, conduct consumer testing, obtain feedback, and make improvements before launching products or services.

Data-driven tools coupled with AI also contribute to the reduction of technical uncertainties through the improvement of the quality of predictions and the ability to identify patterns and envision new connections that were previously challenging for the human mind. Technical uncertainty is further reduced through AI-driven prototyping, which accelerates the stages of creation, offers design options and uses in a more agile manner and at a lower cost than traditional methods. From prototypes, it is possible to conduct tests and obtain feedback to correct flaws and enhance the quality of products and services.

Finally, AI is being employed in the innovation process to enhance the recognition of the value of external information by companies and individuals, as well as to expedite the trial-and-error cycle and foster knowledge accumulation. Cohen and Levinthal introduce the concept of absorptive capacity as crucial for innovation and organizational learning.[16] They argue that a firm's ability to recognize the value of new, external information, assimilate it, and apply it for commercial purposes is fundamental to its innovative capabilities. AI has been used for large-scale information gathering and transforming this information into knowledge. While "learning by doing" focuses on learning

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15 Nathan Rosenberg, *Schumpeter and the endogeneity of technology: some American perspectives*, The Graz Schumpeter lectures 3 (London ; New York: Routledge, 2000).

16 Wesley M Cohen & Daniel A Levinthal, "Absorptive Capacity: A New Perspective on Learning and Innovation" (1990) 35:1 Adm Sci Q 128–152.

through continuous practice in activities in which the firm is already engaged and holds importance in generating internal information and knowledge, absorptive capacity enables an increase in the diversity of knowledge, especially when combining knowledge from other areas to generate innovative solutions. In our view, both processes are important for innovation and can be enhanced with the use of AI.

As previously mentioned, there is a limited body of research regarding the impact of AI applications on the innovation process. In particular, the most reliable data originate from extensive innovation surveys conducted by government agencies. However, these studies are typically carried out at intervals that have yet to encompass the most recent developments in AI and its application in the economy.

One of the studies that manages to derive some analysis of the influence of AI use on innovation is carried by Christian Rammer *et al*[17] when analyzing data from the German part of the Community Innovation Survey (CIS) 2018. The authors show that companies using AI are 8.5% more likely to introduce a new product to the market. Thus, AI plays a significant role in companies' ability to innovate and achieve economic gains.

It is important to note that firms that adopt artificial intelligence tend to be naturally more innovative. This is because they invest in R&D and skilled personnel, which enhances their capacity to absorb cutting-edge scientific and technological knowledge. Nevertheless, the main point of these results is to recognize that innovative companies are integrating AI into their innovation activities and, according to the study of Christian Rammer *et al*, increasing its rate of innovation, particularly those most relevant innovations (new to the world). If this makes them more innovative than others, it is likely that other companies will follow suit.

In summary, the use of AI in the innovation process tends to reduce costs and uncertainties, as well as enhance the absorptive capacity of companies. Such factors result in improved efficiency in the inventive process, manifesting in an increase in the quantity and quality of inventions, or in both. In the following section, we will apply these insights to explore the use of AI in the development of new medicines.

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[17] Christian Rammer, Gastón P Fernández & Dirk Czarnitzki, “Artificial intelligence and industrial innovation: Evidence from German firm-level data” (2022) 51:7 Res Policy 104555.

3 AI AND DRUG DEVELOPMENT

In this section, we detail the application of AI in the pharmaceutical sector, specifically in the development of new medicines. The particular interest in this sector stems from its traditional reliance on patents as a crucial mechanism to secure a return on investments in R&D. Based on national innovation surveys, Hall *et al* highlight that, generally, patents do not represent the primary method of intellectual property protection, being surpassed by the use of trade secrets and the advantage of lead time.[18] This trend applies to both product and process innovations. However, specifically for innovations in sectors focused on "discrete" products, such as pharmaceuticals and chemicals, patents remain the most valued strategy to safeguard the profits derived from IP. Thus, any eventual change in the dynamics of innovation and patent protection tends to affect these sectors more.

It has long been said that research and development (R&D) in the pharmaceutical industry has become too expensive. From uncertain drug development to costly clinical trials in which need patient participation rates to meet regulatory minimum standards, every step of the process has been criticized over time. This has driven the search for safe strategies aiming cost reductions in research of new medicines and processes.

Over the past few years, new technologies such as AI brought new hopes to research in general and to pharmaceutical R&D in particular. The Covid-19 pandemic accelerated even more the excitement over the use of these techniques in the industry, due to its desperate and immediate nature.

Much of the literature discussing the use of AI in the pharmaceutical field outlines how this technology can be applied across various steps, ranging from disease tracking and management to all phases of pharmaceutical R&D. Vora *et al*. describe the use of machine learning in experimental design, pharmacokinetics prediction, and optimization of lead compounds, emphasizing how AI can reduce development costs and increase

[18] Bronwyn Hall *et al*, "The Choice between Formal and Informal Intellectual Property: A Review" (2014) 52:2 J Econ Lit 375–423.

the likelihood of approval for new medicines.[19] In their study, a significant focus is given to drug discovery, where AI assists in therapeutic target identification, virtual screening, structure-activity relationship modeling, new drug design, drug candidate optimization, drug repurposing, and toxicity prediction. These processes benefit from AI's ability to rapidly analyze large volumes of individual and biological data to identify patterns and predict interactions between targets and drug candidates.

For example, during the Covid-19 pandemic, early on, simulation and prediction models were used to try to *track contamination patterns and disease development*. Models such as SIR (susceptible-infected-recovered) soon became very popular among health officials in the whole world.[20] As Wim Naudé points out, some of the uses of AI on disease management are early warnings and alerts, tracking and prediction and data dashboards.[21] These are much more useful in a scenario like a pandemic, which possibly explain why these instruments became so popular back in 2020.

In the *pre-clinical stage*, the use of natural language processing on scientific literature, unstructured electronic medical records and insurance claims is mentioned as a promising way to identify patterns and research targets. Much of the literature here focuses on protein structure prediction and drug repurposing.[22]

Especially in the early days of the pandemics, the focus of the literature was on *drug repurposing*. Drug repurposing leads to shorter development and research time and lower costs, including during clinical trial phases, which are some of the most expensive stages of pharmaceutical

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19 Lalitkumar K Vora *et al*, "Artificial Intelligence in Pharmaceutical Technology and Drug Delivery Design" (2023) 15:7 Pharmaceutics, online: <https://www.ncbi. nlm.nih. gov/pmc/articles/PMC10385763/>.

20 Nick H Ogden *et al*, "Modelling scenarios of the epidemic of COVID-19 in Canada" (2020) Can Commun Dis Rep 198–204.

21 *Artificial Intelligence against COVID-19: An Early Review*, Working Paper, by Wim Naudé, www.econstor.eu, Working Paper 13110 (IZA Discussion Papers, 2020).

22 Arash Keshavarzi Arshadi *et al*, "Artificial Intelligence for COVID-19 Drug Discovery and Vaccine Development" (2020) 3 Front Artif Intell 65; Sheela Kolluri *et al*, "Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development: a Review" (2022) 24:1 AAPS J 19; Sweta Mohanty *et al*, "Application of Artificial Intelligence in COVID-19 drug repurposing" (2020) 14:5 Diabetes Metab Syndr Clin Res Rev 1027–1031.

R&D.[23] The use of AI on drug repurposing predates the pandemic but it was certainly accelerated during it.[24] For a systematic review of medicines considered during the Covid-19 pandemic, see Carla Pires.[25]

This ability to lower costs has to do with AI prediction capacities, dealing with statistical issues that are complex without these tools. According to Sheela *et al*:

> [...] predictive modeling is used to predict protein structures and facilitate molecular compound design and optimization for enabling selection of drug candidates with a higher probability of success. The increasing volume of high-dimensional data from genomics, imaging, and the use of digital wearable devices, has led to rapid advancements in ML methods to handle the "Large p, Small n" problem where the number of variables ("p") is greater than the number of samples ("n").[26]

Other uses include developing predictive biomarkers and precision medicine to define target population and dose regimes, that is, identify types of patients who may benefit more from one group of treatment compared to others, which also reduce development time and costs. Much of this is based on evaluating and predicting success of different strategies and outcomes in automated ways beforehand without incurring in costly trajectories.

Peter Henstock[27] argues that, although the use of AI in pre-clinical phases and drug discovery predates the pandemic and has been going on for years with "increasing sophistication", its use on later stages such as clinical trials is recent.[28] The literature has emphasized the promises of clinical trial

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[23] Kumaraswamy Gandla *et al*, "A Review of Artificial Intelligence in Treatment of Covid-19" (2022) J Pharm Negat Results 254–264.

[24] Kolluri *et al*, "Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development", *supra* note 24.

[25] Carla Pires, "A Systematic Review on the Contribution of Artificial Intelligence in the Development of Medicines for COVID-2019" (2021) 11:9 J Pers Med 926.

[26] Kolluri *et al*, "Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development", *supra* note 24.

[27] Peter Henstock, "Artificial Intelligence in Pharma: Positive Trends but More Investment Needed to Drive a Transformation" (2021) Volume 2:Issue 2 Arch Pharmacol Ther 24–28.

[28] Kolluri *et al*, "Machine Learning and Artificial Intelligence in Pharmaceutical Research and Development", *supra* note 24.

design and analysis using nonparametric Bayesian learning[29] and tools for clinical trial oversight.

During *clinical trial phases*, the use of AI tools includes patient selection, trial monitoring, data collection and analysis, including the reports required by regulators, which can be very costly and time-consuming to produce. This is especially important as some experts argue that a large number of clinical trials are unsuccessful due to problems with patient enrollment. Arash Keshavarzi *et al* suggests that artificial intelligence and machine learning tools can make patient selection smarter and lead to regulatory submission data packages, making the whole process easier.[30]

Several critical points regarding the use of AI in research have been raised in the literature. However, we note that the rapid advancement of AI techniques in the last three years has made such criticisms less relevant, and many obstacles are being overcome. Given that it is an ongoing revolution, many of these advancements have yet to be evaluated in terms of causality in academic studies, but they are being received with great enthusiasm by the academic community.[31]

One of the concerns we judge relevant refers to the fact that AI tools rely on data availability. This has implications that must be addressed. Firstly, they can be limited by the lack of (public) data.[32] Much of data here concerns health information that in most countries are protected by privacy laws at some extent. This is something that must be considered as either as a limitation of scope or something to be addressed. Secondly, even if all this data becomes available, it is a lot of data – and a lot of data not always makes decisions easier, as it may drive to false leads, instead of shortcuts. Thirdly, this means that not all is cost reduction when it comes to AI tools – investment to make these tools more efficient is also needed.[33] Lastly, this increased efficient may not be enough

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29 Subrat Kumar Bhattamisra *et al*, "Artificial Intelligence in Pharmaceutical and Healthcare Research" (2023) 7:1 Big Data Cogn Comput 10.

30 Keshavarzi Arshadi *et al*, *supra* note 24.

31 Ewen Callaway, "'A Pandora's box': map of protein-structure families delights scientists" (2023) 621:7979 Nature 455–455; Artur M Schweidtmann, "Generative artificial intelligence in chemical engineering" (2024) 1:3 Nat Chem Eng 193–193.

32 Naudé, *supra* note 23.

33 Henstock, "Artificial Intelligence in Pharma", *supra* note 31.

(or may not act fast enough) to offset the diminishing returns that these tools probably present – that is, as they work on existing data, the more they are used, the harder it gets for them to bring back expected results.

It is still too early for rigorous academic studies to have sufficient data to test the actual effects of using AI on reducing the total cost for the pharmaceutical sector. However, as we have previously shown, various reports from academics and companies already indicate a significant reduction in the time required to complete many of the R&D stages. For example, the McKinsey Global Institute (MGI) estimates that AI could generate an annual economic value of $60 billion to $110 billion for the pharmaceutical and medical-product industries. This substantial economic impact is largely attributed to the technology's ability to enhance productivity. It accelerates the identification of compounds for potential new medicines, expedites their development and approval processes, and enhances marketing strategies.[34]

It is important to note that estimating changes and gains on the long run is a complex task, as not all R&D can be replaced by automated AI tools – there is still everyday R&D that needs to be done, which is time-consuming, prone to failure and must meet regulatory standards.

However, drawing from our research and considering the available evidence on the current uses of AI in R&D activities, we are confident in the transformative potential of artificial intelligence. While the full extent of AI's impact remains to be seen, the trajectory is clear: AI is revolutionizing the way the pharmaceutical field discovers, develops, and delivers new medicines.

4 AI AND THE CHALLENGES FOR THE PATENT SYSTEM

If AI can be used as a powerful research tool as a *method for inventing inventions*, what will be its effect on the patent system?

In this paper, the patent system refers to the set of institutions that ensure the effectiveness of patent protection. In this context, a country's patent

34 "Economic potential of generative AI | McKinsey", online: <https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/the-economic-potential-of-generative-ai-the-next-productivity-frontier#introduction>.

legislation and courts constitute the fundamental elements of the patent system that enforce the rights of patent holders.

We highlight three main impacts that the use of AI may have on the patent system: inventiveness, criteria for novelty and non-obviousness, and the increase in the number of inventions that "hide" AI as one of the authors, presented below.

4.1. Inventiveness/Ingenuity

In 2021, the South African Patent Office granted the world's first patent that identified an artificial intelligence as the inventor, the Device for the Autonomous Bootstrapping of Unified Sentience (DABUS). Some authors argue that this decision aligns with South Africa's AI policy or suggest that the Patent Act can be amended to recognize AI as an inventor.[35] It's important to note that the South Africa patent law does not mandate a substantive examination of patent applications; it merely checks for compliance with application formalities. This procedural approach is why the patent was granted.

The decision of the South African Patent Office was in stark contrast to the approach of the U.S. Patent and Trademark Office (USPTO), which had previously denied the patent application of Stephen Thaler, the developer of the DABUS system. The legal dispute escalated to the Court of Appeals for the Federal Circuit, where it was established that, under current law, an inventor must necessarily be *human*.

The UK Supreme Court also took a stance against the possibility of AI being recognized as an inventor in patent applications. In both legal scenarios, the courts emphasized that their decisions were based on the interpretation of current patent laws, which explicitly provide that the inventor must be a *natural person*. Therefore, for an AI to be recognized as an inventor, legislative reform would be essential, which in turn would bring complex legal challenges, including issues related to the transfer of ownership and the distribution of benefits derived from patents. To date, the possibility of amending patent legislation to accommodate AI as an inventor has not been a priority topic in

[35] C Ncube *et al*, *Artificial Intelligence and the Law in Africa* (2023).

debates on patent law reform. This situation reflects the complexity and ethical and legal implications involved in integrating AI into the field of intellectual property.

Ernest Fok, analyzing the case in the United States, presents arguments that the patent system could significantly benefit from recognizing inventing AI as inventors, shifting the global balance between economic incentives and societal costs.[36] Furthermore, this technology will continue to develop rapidly despite decisions not to recognize AI as an inventor in patents.

A similar argument is presented by Abbott, advocating that creative computers (AI) should be recognized as inventors under the Patent and Copyright Clause of the U.S. Constitution as a way to lead to scientific advances and stimulate innovation, reinforcing the patent system's goal of promoting the progress of science and useful arts.[37] To this end, the author suggests a dynamic interpretation of the existing patent legislation and the U.S. Constitution to accommodate the concept of computers as inventors. This involves interpreting the term "inventor" in a way that includes non-human entities that perform creative acts resulting in patentable inventions, with the assignment of patent rights to the owners or operators of the creative computers.

Schuster[38] uses the Coase Theorem – which holds that aggregate wealth is maximized through transactions between firms when property rights are clearly allocated and transaction costs are zero – to propose that the efficiency of the patent system is best achieved by allocating AI property rights to the parties that value these rights the most, which would be the AI users (firms that purchase AI software and use it for invention).

In the debate on the patentability of inventions conceived by AI, Martin Kretschmer *et al.* present a thoughtful analysis with a focus on the United Kingdom, advocating for the maintenance of the current legal framework

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36 Fok, Ernest, "Challenging the International Trend: The case for Artificial Intelligence Inventorship in the United States" (2021) 19:1 St Clara J Int Law 51.

37 Ryan Abbott, *I Think, Therefore I Invent: Creative Computers and the Future of Patent Law* (Rochester, NY, 2016).

38 W Michael Schuster, "Artificial Intelligence and Patent Ownership" (2019) 75:4 Wash Lee Law Rev 1945.

without the need for reforms. [39] This position is based on the lack of compelling economic evidence or political rationale to justify the formal recognition of AI as an inventor, coupled with the perception that the debate around AI inventorship has been overly valorized, diverting attention from more pressing issues. The authors highlight the ability of the existing patent system to accommodate technological advancements, as demonstrated with biotechnology, and emphasize the importance of consistency and harmonization at the international level. Thus, in light of TRIPS, any changes to a national patent law would involve multilateral negotiations, which increases the transaction costs associated with potential legal changes. Moreover, the legal certainty provided by the current jurisprudence in the UK, which already establishes that AI cannot be designated as an inventor, is underscored, and the viability and necessity of a new form of protection for AI-generated inventions are questioned, given the lack of evidence that AI systems can, in fact, invent autonomously and effectively.

In our brief analysis, we observe that institutions responsible for the patent system have adopted a conservative stance regarding the recognition of AI as an inventor (Supreme Court, Patent Offices, Congress). However, we see young academics presenting interesting arguments about the possibility, and necessity, of accommodating this remarkable technological advance within the legal framework of patents.[40]

In this debate, we believe that a perspective to be considered is the dual role of AI in technological innovation. On one hand, AI can perform functions that replace human interventions, while on the other, it acts as a catalyst that amplifies human inventive potential. We believe that AI will have a greater impact as a research tool than as an autonomous generator of

39 Martin Kretschmer, Bartolomeo Meletti & Luis H Porangaba, "Artificial intelligence and intellectual property: copyright and patents—a response by the CREATe Centre to the UK Intellectual Property Office's open consultation" (2022) 17:3 J Intellect Prop Law Pract 321–326.

40 Fok, Ernest, "CHALLENGING THE INTERNATIONAL TREND", *supra* note 43; Lexi Heon, "Artificially Obvious but Genuinely New: How Artificial Intelligence Alters the Patent Obviousness Analysis" (2022) 53:1 Seton Hall Law Rev, online: <https://scholarship.shu.edu/shlr/vol53/iss1/8>; Lindsey Whitlow, "When the Invented Becomes the Inventor: Can, and Should AI Systems be Granted Inventorship Status for Patent Applications?" (2020) 2:2 Leg Issues Digit Age 3–23.

inventions. As Ianin Cockburn *et al* highlight, AI contributes to the reduction of costs associated with prediction[41]. However, the interpretation of results and the assessment of potential innovations generated by AI remain inherently human competencies. This distinction underlines the importance of synergistic collaboration between human and algorithmic capabilities in driving the innovation process.

To conclude, it is relevant to consider the analysis of the eminent scholar on innovation Keith Pavitt, which emphasizes that "major innovation decisions are a largely political process, often involving professional groups advocating self-interested outcomes under conditions of uncertainty (i.e. ignorance), rather than balanced and careful estimates of costs, benefits and measurable risk" (p. 108).[42]

4.2. AI AND THE CRITERIA OF NOVELTY AND INVENTIVE STEP

For an invention to be patentable, it must be new, involve an inventive step (non-obvious), and have the capacity for industrial applicability (article 27 TRIPS). The use of AI in the inventive process, as well as in the process of evaluating patent applications, has the potential to affect the criteria of novelty and non-obviousness, imposing additional changes on the patent system.

With the regarding to the novelty criterion, patent law requires that all claims made in a patent application be novel. The ability of AI to rapidly process large volumes of data and discern patterns or solutions may increase the possibility of a higher volume of inventions but also obscure the assessment of the inventiveness criterion necessary for patent grants due to a lack of transparency or difficulty in directly linking the process to human action.[43] Furthermore, there is evidence that the innovation process is primarily combinatorial, emphasizing the reuse and combination of existing

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[41] Cockburn, Henderson & Stern, *supra* note 13.

[42] Keith Pavitt, "Innovation Processes" in Jan Fagerberg & David C Mowery, eds, *Oxf Handb Innov* (Oxford University Press, 2006) 0.

[43] Cockburn, Henderson & Stern, *supra* note 13.

technological capabilities to generate new inventions.[44] An implication is that the use of AI may accelerate this process.

For similar reasons, AI influences the assessment of the non-obviousness criterion. In the analysis of patent applications whose inventions were developed with the aid of AI tools, it now becomes necessary to consider that what may be classified as "non-obvious" to a skilled individual may be trivial for an AI system.

Thus, AI can challenge patent offices in three ways, all resulting in an increase in the number of patent applications: facilitating more discoveries; enabling well-founded patent applications for inventions with marginal novelties; causing a flood of applications for properly grounded "imitations" (inventing around).[45]

Should there be an observed increase in inventions stemming from the process of inventing around existing patents, an increase in litigation is expected, and pressures will likely arise for the granting of broader patents.

A natural evolution will be the expansion and intensification of AI use by patent lawyers, patent offices, and even courts, aiming to assess the compliance of patent applications more objectively with patentability criteria, or to resolve legal disputes. One particular challenge for patent offices lies in keeping up with patent applicants in the effective use of AI to fulfill their institutional functions, thereby raising the standard of competence of the hypothetical "person having ordinary skill in the art" (PHOSITA).[46] If patent offices and courts become proficient in identifying low-quality applications, it is possible that the phenomenon of a flood of applications may be mitigated.

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44 See Deborah Strumsky & José Lobo, "Identifying the sources of technological novelty in the process of invention" (2015) 44:8 Res Policy 1445–1461.

45 See Nancy T Gallini, "Patent Policy and Costly Imitation" (1992) 23:1 RAND J Econ 52–63.

46 Fok, Ernest, "CHALLENGING THE INTERNATIONAL TREND", *supra* note 17.

5 AI, Demography, and the relative importance of Patents as Intellectual Property

In this section, we develop the argument that AI, in conjunction with the current context of the most relevant economic sectors in terms of size and political influence, has the potential to impact corporate choices between formal and informal intellectual property. This combination tends to lead to a diminishment in the relative importance of patents as an intellectual property protection mechanism.

AI is rapidly integrating into the core business models of major global corporations, especially the so-called Big Techs (Apple, Microsoft, Alphabet, Amazon, and Meta/Facebook), which have significant resources to influence the regulation of this emerging technology. These corporations predominantly operate within the network economy paradigm – which is based on the principle that the value of a network grows proportionally to the increase in its users – promoting a *logic of inclusion*.

In this context, it is usual for such corporations to offer certain services for free to expand their user base. This approach contrasts sharply with the predominant commercial practices of the early 1990s, a period marked by the discussion and implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). At that time, large companies tended to base their business models on temporary monopolies, especially companies in the pharmaceutical sector, seeking to maximize consumer surplus extraction, which highlighted a *logic of exclusion*.

In the last three decades, TRIPS represented the most significant revision of the patent system for the majority of developing countries, which were required to accept the patentability of all inventions, both products and processes, across all technological fields, with few exceptions. Particularly for the chemistry and pharmaceutical sectors, this agreement imposed limitations on the public health policy tools available to populous countries, such as India and Brazil, even with the flexibilities provided by the agreement.[47] For instance, international pressures contributed to Brazil's decision not to adopt some of the

[47] Hiroyuki Odagiri, ed, *Intellectual property rights, development, and catch up: an international comparative study* (New York: Oxford University Press, 2010).

flexibilities, which included the transition period for implementing patents in the pharmaceutical sector.[48]

In 1994, the year the TRIPS agreement was signed, the pharmaceutical sector was represented by four companies (Merck, Johnson & Johnson, Bristol-Myers Squibb, and Pfizer) among the top 20 in terms of market capitalization in the Standard & Poor's index, whose combined capitalization exceeded that of Exxon Mobil, the largest company that year, by 1.5 times. In January 2024, Apple emerged as the highest market value corporation, with almost the double of the total capitalization of the listed pharmaceutical/ healthcare companies (Eli Lilly, UnitedHealth, and Johnson & Johnson).

Big Tech companies distinguish themselves not only by their size superiority compared to other firms but also through unique strategic approaches to their intellectual assets. As observed, companies like Google prioritize the development of their AI platforms through significant investments in computational capacity, recruitment of highly specialized teams, and a focus on the advantages of being a first mover over the valuation of patents.

An example is Meta's decision to freely provide its Llama artificial intelligence code tools for research and commercial uses. The company's strategy is to increase its user base with the goal of becoming the leading AI platform. "Progress is faster when it is open [...] You have a more vibrant ecosystem where everyone can contribute", says Yann LeCun, Meta's chief A.I. scientist (NYTimes 18 May 2023).

This highlights the importance of the first-mover strategy for Big Techs. They understand that network economies depend on who takes the lead. In Meta's case, this strategy was considered even more important than industrial secrecy.

Given the highly dynamic nature of the sector, patent litigation is unappealing, as by the time disputes are resolved, the sector has already evolved technologically.

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48 Thiago Caliari, Roberto Mazzoleni & Luciano Martins Costa Póvoa, "Innovation in the pharmaceutical industry in Brazil post-TRIPS" in *TRIPS Compliance Natl Pat Regimes Innov* (Edward Elgar Publishing, 2013) 16.

This suggests that patents as a strategy for reaping the benefits of innovations are losing importance. The world's largest companies are shifting their strategy towards a more intensive use of informal intellectual property.

On this aspect, Iain Cockburn *et al.* offer pertinent insights on the impact of AI in the digital economy domain.[49] One consequence is the change in data accessibility and sharing. The potential for AI to reduce the costs associated with the inventive process may widen opportunities for new market entrants, such as startups, intensifying competition. The offer of inventions increases. This could lead to a decreased need for strong intellectual property protections, particularly patents. Conversely, companies may be encouraged to resort to alternatives to gain from their innovations, such as intensifying the use of trade secrets and the exclusive control of vast data sets, limiting their sharing. The ownership and accessibility of these data emerge as fundamental issues, as the monopolization of significant data sets can confer substantial competitive advantages, raising concerns about exclusivity and access in the context of R&D activities, and privacy.

If globalization was one of the key factors leading to the TRIPS agreement[50], we believe that any potential modification of the international patent system will be influenced by the impacts of AI on the innovation process and by demographic changes and their pressures on public health. Future amendments to patent law or copyright law in the near future, they will undoubtedly be influenced by Big Techs, just as in 1994, when TRIPS was heavily influenced by the pharmaceutical sector.[51]

The pharmaceutical sector stands out for significantly valuing patents as a crucial instrument for the return of investments made in R&D, much

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49 Cockburn, Henderson & Stern, *supra* note 13.

50 Suma Athreye, Lucia Piscitello & Kenneth C Shadlen, "Twenty-five years since TRIPS: Patent policy and international business" (2020) 3:4 J Int Bus Policy 315–328.

51 Charan Devereaux, Robert Z Lawrence & Michael Watkins, *Case studies in US trade negotiation* (Washington, DC: Institute for International Economics, 2006); Lori Wallach & Patrick Woodall, *Whose trade organization? a comprehensive guide to the WTO* (New York: New Press, 2004).

more than other sectors.[52] It was one of the main beneficiaries of the harmonization of intellectual property rights rules promoted by TRIPS.

However, it is unlikely that the future will see an increase in patent durations similar to that facilitated by TRIPS. On the contrary, demographic pressures suggest a trend towards the reduction of patent terms and more flexibilities related to specific inventions. It is important to remember that the main flexibilities and exceptions of the TRIPS agreement are related to public health and were incorporated into the agreement largely due to the pressure from developing countries, which face severe disease control problems. Now, the pressure for more flexibility and provisions on patents related to public health issues tends to emerge in wealthy countries.

According to the World Health Organization (WHO), the age profile of the global population is changing at an accelerated pace. By 2050, the population over 60 years of age will double.[53] The most recent censuses from the USA (2020)[54], China (2021)[55] and Canada (2021)[56] also confirm these data. On average, 1 in 6 people is over the age of 60, with a tendency for this percentage to increase in the coming decades. In the European Union, the average was already 1 in 4.7 people in 2022. This shift imposes pressures on the health and social systems of countries. Public health spending as a proportion of GDP has been increasing over the past decades. Canada raised its spending from 5.01% to 7.64% between 1980 and 2019 (a relative increase of 52%). The United States saw a relative increase of 300% in the same period, going from 3.46% to 13.81% of GDP.[57] For the United States, the projection is that it will reach 19.6% in 2031.[58]

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52 Hall *et al*, “The Choice between Formal and Informal Intellectual Property”, *supra* note 21.

53 https://www.who.int/news-room/fact-sheets/detail/ageing-and-health.

54 https://www.census.gov/library/stories/2023/05/2020-census-united-states-older-population-grew.html.

55 https://www.stats.gov.cn/english/PressRelease/202105/t20210510_1817185.html.

56 https://www150.statcan.gc.ca/n1/daily-quotidien/220427/dq220427a-eng.htm.

57 https://ourworldindata.org/grapher/public-health-expenditure-share-gdp?tab=table&time=1980..2019.

58 https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf.

Associated with this is the fact that a diffusion of the use of AI in medical research tends to reduce the costs of producing new medicines and treatments. Governments in more advanced countries have been pressured by the population in light of rising individual and public health expenditures. In this scenario, the usual justification provided by the pharmaceutical sector – that long durations are necessary to incentivize research and that a lengthy monopoly guarantees the continuity of pharmaceutical advances – is weakened, both politically and economically. Governments make decisions under pressure from voters. An electorate increasingly composed of senior individuals will support candidates sensitive to their budgetary concerns. A sign of this new reality is that, starting in 2024, Medicare in the United States will, for the first time, not accept drug pricing defined by the pharmaceutical industry for certain medicines.[59]

In this dispute, the interests of the pharmaceutical industry may not be aligned with the interests of Big Techs, which are focused on other business models.

These sectoral differences can drive the debate that is already happening among economists about the most efficient duration of patent terms to induce innovations. There are robust criticisms regarding the inefficiency of the current patent system. Michele Boldrin and David K. Levine, for example, argue that the patent system as a whole needs to be overhauled, arguing that the current system can, in fact, inhibit innovation rather than promote it, especially when long-duration patents create unnecessary monopolies in sectors where innovation costs are relatively low, and the product lifecycle is fast.[60] The authors propose a significant overhaul of the patent system, including reducing the duration of patents and introducing more flexibility to accommodate the varied needs of different industries.

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59 https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/29/fact-sheet-biden-harris-administration-announces-first-ten-drugs-selected-for-medicare-price-nego tiation/

60 Michele Boldrin & David K Levine, "The Case against Patents" (2013) 27:1 J Econ Perspect 3–22.

6 CONCLUSION

This article explores the transformative influence of Artificial Intelligence (AI) on innovation activities and the subsequent challenges to the patent system, analyzing the changes brought about by the integration of AI into research and development (R&D) processes. We argue that AI is not merely a technological advancement but can act in redefining creativity, invention, and the mechanisms of intellectual property protection. The advent of AI technologies and their use in various areas, such as AlphaFold, signifies not only an acceleration in scientific discovery and inventive activities but also raises profound questions about the nature of inventiveness, the criteria for novelty, and the essence of non-obviousness in patent legislation. These issues highlight the complexity and dynamism introduced by AI in the domain of patent law, challenging traditional paradigms that have long governed the realm of intellectual creations.

The lessons drawn from analyzing the impact of AI on R&D efficiency, particularly in the pharmaceutical sector, serve as an indication of AI's capacity to drastically reduce the timelines and costs associated with developing new medicines. This gain in efficiency, however, extends beyond operational improvements, also encompassing the regulatory and approval processes for new medicines.

Furthermore, we explore the socioeconomic and demographic influences that shape the relevance of patents in the evolving digital economy. The dominance of Big Tech and the shift towards a model of inclusion over exclusion of users illustrate a departure from traditional intellectual property protection strategies. This shift, driven by the strategic logic of network economies and the first-mover advantage, suggests that the relative importance of patents may diminish.

Thus, the influence of AI on the innovation landscape and the patent system underscores a transformation in the essence of the invention process and intellectual property.

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