

11-2020

## REFORMING U.S. PATENT LAW TO ENABLE ACCESS TO ESSENTIAL MEDICINES IN THE ERA OF ARTIFICIAL INTELLIGENCE

Elif Kavusturan  
*Suffolk University*

Follow this and additional works at: <https://scholarlycommons.law.northwestern.edu/njtip>

---

### Recommended Citation

Elif Kavusturan, *REFORMING U.S. PATENT LAW TO ENABLE ACCESS TO ESSENTIAL MEDICINES IN THE ERA OF ARTIFICIAL INTELLIGENCE*, 18 NW. J. TECH. & INTELL. PROP. 51 (2020).  
<https://scholarlycommons.law.northwestern.edu/njtip/vol18/iss1/2>

This Article is brought to you for free and open access by Northwestern Pritzker School of Law Scholarly Commons. It has been accepted for inclusion in Northwestern Journal of Technology and Intellectual Property by an authorized editor of Northwestern Pritzker School of Law Scholarly Commons.

N O R T H W E S T E R N  
JOURNAL OF TECHNOLOGY  
AND  
INTELLECTUAL PROPERTY

**REFORMING U.S. PATENT LAW TO ENABLE  
ACCESS TO ESSENTIAL MEDICINES IN  
THE ERA OF ARTIFICIAL INTELLIGENCE**

*Elif Kavusturan, S.J.D.*



---

November 2020

VOL. 18, NO. 1

## REFORMING U.S. PATENT LAW TO ENABLE ACCESS TO ESSENTIAL MEDICINES IN THE ERA OF ARTIFICIAL INTELLIGENCE

*ELIF KAVUSTURAN, S.J.D.*

**ABSTRACT**—The patent system has long been criticized for limiting access to pharmaceuticals. Patents grant inventors a limited period of exclusivity with an attempt to allow recoupment of investments in the invention process. In the pharmaceutical industry, this exclusivity and the resulting lack of competition leads to exorbitant prices. High prices limit access to potentially life-saving medicines and hinder achievement of the “highest attainable standard of health,” which several international instruments recognize as a human right.

The pharmaceutical industry claims patents are essential to encourage innovation in risky, lengthy and costly research and development (R&D) processes. But it has yet to put forward indisputable evidence to the actual effects of patents on innovation.

Increasing use of artificial intelligence (AI) in research intensifies the existing debates on pharmaceutical patents. Inventions created or enabled by AI raise questions about patentability and patent policy in general. Faster and more efficient R&D weakens justifications for pharmaceutical patents.

While continued incentivization is essential, lawmakers must consider alternative systems, which prioritize access alongside incentivization in order to advance health care as a human right. One way to increase access while maintaining the necessary incentives for innovation is to reform standards of patentability, leaving some essential medicines enabled by AI outside the sphere of patent protection, and fund R&D through prize funds and tax incentives in the absence of patents. Alternatively, a shorter exclusivity term, followed by a licensing period allowing competitors to make and sell the related medicines against a licensing fee, will enable competing products to enter the market earlier and drive prices down and provide innovating companies a method to recoup investments.

INTRODUCTION .....	52
I. AI REVOLUTIONIZING PHARMACEUTICAL INNOVATION .....	55

A. *Defining Intelligence: Natural and Artificial*..... 55  
 B. *Machine Learning and Deep Learning*..... 57  
 C. *AI in Pharmaceutical R&D*..... 59  
 II. PATENTS IN THE CONTEXT OF AI SYSTEMS AND PHARMACEUTICAL INNOVATION..... 64  
 A. *A Brief Primer on Patent Law*..... 64  
 B. *Evaluating the Costs and Benefits of the Patent System*..... 65  
 C. *Patents and Exclusivity in the Pharmaceutical Industry* ..... 69  
 D. *Patentability of AI Systems and AI-Generated Inventions*..... 73  
 E. *The Need for Reform*..... 78  
 III. RECALIBRATING ACCESS AND INCENTIVIZATION ..... 79  
 A. *Main Considerations*..... 80  
 B. *Rethinking Patent Law for Essential Medicines Enabled by AI* ..... 83  
 C. *Evaluating the Potential Effects of Proposed Law Reforms* ..... 85  
 D. *Incentivizing R&D for Essential Medicines in the Absence of Patents* ..... 86  
 CONCLUSION ..... 89

INTRODUCTION

“[A]nd supporting their master were attendants made of gold, which seemed like living maidens. In their hearts there is intelligence, and they have voice and vigor, and from the immortal gods they have learned skills.”<sup>1</sup>

Robotic handmaidens helped Vulcan in his workshop in Homer’s *Iliad*. The handmaidens resembled people and had knowledge, sense, and reason. Twenty-eight centuries later, robot scientists and artificial intelligence (AI) systems aid researchers in the lab, much like Vulcan’s handmaidens.<sup>2</sup>

While AI has not reached human level intelligence yet, it is already reshaping industries.<sup>3</sup> One of the fields that stands to benefit the most from

<sup>1</sup> HOMER, THE ILIAD 137 (Caroline Alexander trans., HarperCollins 2016).

<sup>2</sup> See, e.g., Ying Chen, Elenee Argentinis & Griff Weber, *IBM Watson: How Cognitive Computing Can Be Applied to Big Data Challenges in Life Sciences Research*, 38 CLINICAL THERAPEUTICS 688, 698 (2016); Kevin Williams et al., *Cheaper Faster Drug Development Validated by the Repositioning of Drugs Against Neglected Tropical Diseases*, J. ROYAL SOC’Y INTERFACE, Mar. 6, 2015, at 1, 2.

<sup>3</sup> See Iain M. Cockburn, Rebecca Henderson & Scott Stern, *The Impact of Artificial Intelligence on Innovation* (Nat’l Bureau of Econ. Rsch., Working Paper No. 24449, 2018); Erica Fraser, *Computers as Inventors—Legal and Policy Implications of Artificial Intelligence on Patent Law*, 13 SCRIPTED 305, 327 (2016), <https://script-ed.org/article/computers-as-inventors-legal-and-policy-implications-of-artificial-intelligence-on-patent-law/> [<https://perma.cc/PS5X-RTBT>]; Business Insider Intelligence, *The AI Disruption Bundle: The Guide to Understanding How Artificial Intelligence is Impacting the World*, BUS. INSIDER (Oct. 6, 2017, 2:30 PM), <http://www.businessinsider.com/understanding-artificial-intelligence-impacting-world-2017-10> [<https://perma.cc/LVX4-CVM5>]; Paul Heltzel, *8 Technologies That Will Disrupt Business in 2020*, CIO (Aug. 26, 2019, 3:00 AM), <https://www.cio.com/article/3254744/emerging-technology/technologies-that-will-disrupt-business.html> [<http://perma.cc/5FTA-A9SX>]; Gil Press, *5 Top Technologies for Digital Disruption*, FORBES (Apr. 27, 2017, 9:15 AM), <https://www.forbes.com/sites/gilpress/2017/04/27/5-top-technologies-for-digital->

AI is health care.<sup>4</sup> AI has the potential to decrease the time it takes for pharmaceutical companies to research, develop, and bring new drugs to market.<sup>5</sup> AI will reduce the cost of pharmaceutical research and development (R&D) and increase the efficiency of the innovation process.<sup>6</sup>

Patent rights enable patent holders to exclude others from making, using, offering for sale or selling their inventions during the patent term.<sup>7</sup> This right of exclusion aims to “promote the progress of science and useful arts.”<sup>8</sup> According to the Supreme Court, the right serves to compensate inventors for their labor and expenses in bringing inventions to practice and disclosing them to the public.<sup>9</sup> Under the existing “one-size-fits-all” system, all inventions that satisfy the standards of patentability are eligible for patent protection, without regard to their social effects, their costs, or the technologies used in the innovation process.<sup>10</sup>

Patents allow patent holders to operate without competition, thus enabling higher prices.<sup>11</sup>

---

disruption/2/#32b1eca677fc [https://perma.cc/96R9-27V9]; Anne Vandermeij, *The 12 Disruptive Tech Trends You Need to Know*, FORTUNE (July 22, 2015, 4:09 PM), <http://fortune.com/2015/07/22/mckinsey-disruptive/> [https://perma.cc/38W8-T42X].

<sup>4</sup> See PETER STONE ET AL., ONE HUNDRED YEAR STUDY ON A.I., ARTIFICIAL INTELLIGENCE AND LIFE IN 2030: REPORT OF THE 2015 STUDY PANEL 25 (2016), [https://ai100.stanford.edu/sites/default/files/ai100report10032016fml\\_singles.pdf](https://ai100.stanford.edu/sites/default/files/ai100report10032016fml_singles.pdf) [https://perma.cc/3RFV-7WPT].

<sup>5</sup> See Williams et al., *supra* note 2, at 8 (arguing that full automation and standardization of processes could lead to a “radical decrease in the cost and increase in the speed of drug discovery”); David Rotman, *AI is Reinventing the Way We Invent*, MIT TECH. REV. (Feb. 15, 2019), <https://www.technologyreview.com/2019/02/15/137023/ai-is-reinventing-the-way-we-invent/> [https://perma.cc/9HK6-55JN] (arguing that deep learning has the potential to “speed up the process” of finding drug candidates).

<sup>6</sup> Cockburn et al., *supra* note 3, at 7 (claiming that learning-based AI technologies can result in “dramatically lower costs and improved performance in R&D projects”); Bertin Martens, *The Importance of Data Access Regimes for Artificial Intelligence and Machine Learning* 5 (Eur. Comm’n Joint Rsch. Ctr., Working Paper No. 2018-09, 2018) (asserting machine learning “reduces the cost and increases the efficiency of decision making”).

<sup>7</sup> 35 U.S.C. § 154.

<sup>8</sup> See U.S. CONST. art. I, § 8, cl. 8 (indicating 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”).

<sup>9</sup> See *Seymour v. Osborne*, 78 U.S. 516, 533 (1870) (holding that patent rights are “public franchises granted to the inventors of new and useful improvements for the purpose of securing to them, as such inventors, for the limited term therein mentioned, the exclusive right and liberty to make and use and vend to others to be used their own inventions, as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit”).

<sup>10</sup> See 35 U.S.C. §§ 101–103.

<sup>11</sup> See Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1054–55 (2005).

High prices are especially problematic in the pharmaceutical industry. Consumers in the United States pay more for pharmaceuticals than consumers in any other country.<sup>12</sup> A prescription worth \$1,362 in the United Kingdom costs \$2,669 in the United States.<sup>13</sup> In 2017, 11.4 percent of patients prescribed drugs chose to forego treatment as a direct result of high prices, while 24.9 percent asked for a cheaper alternative or opted for alternative therapies.<sup>14</sup>

Pharmaceutical companies cite lengthy and costly R&D to justify the high prices of pharmaceuticals, asserting high returns are necessary to incentivize innovation.<sup>15</sup> However, the actual effects of patents on innovation are not clear, and studies showing the excessive investment requirements for pharmaceutical R&D have been widely criticized for inflating costs.<sup>16</sup> AI's potential to enable faster and cheaper drug development undermines the industry's arguments for patent protection.

As AI starts to play a bigger role in R&D, patent law must be reformed to reflect AI's effects on pharmaceutical innovation to recalibrate public and private interests. Lawmakers must address the disruption caused by AI in the pharmaceutical innovation process and evaluate alternative mechanisms that prioritize access to pharmaceuticals while providing the necessary incentives for pharmaceutical companies.

The chief reason why patent law must be reformed for AI-enabled pharmaceuticals is to advance health care as a human right.<sup>17</sup> Lawmakers must prioritize essential medicines—those that must be available at all times in adequate amounts at affordable prices—as these are fundamental to

---

<sup>12</sup> Irene Papanicolas, Liana R. Woskie & Ashish K. Jha, *Health Care Spending in the United States and Other High-Income Countries*, 319 [JAMA 1024, 1031 (2018)].

<sup>13</sup> See Sarah Kliff, *The True Story of America's Sky-High Prescription Drug Prices*, VOX (May 10, 2018, 9:19 AM), <https://www.vox.com/science-and-health/2016/11/30/12945756/prescription-drug-prices-explained> [<https://perma.cc/V54J-B3J4>]; see generally Robert Langreth, *Drug Prices*, BLOOMBERG (Feb. 5, 2019, 9:39 AM), <https://www.bloomberg.com/quicktake/drug-prices> [<https://perma.cc/QUD5-9HT6>].

<sup>14</sup> See ROBIN A. COHEN ET AL., NAT'L CTR. FOR HEALTH STATS., DATA BRIEF NO. 333, STRATEGIES USED BY ADULTS AGED 18–64 TO REDUCE THEIR PRESCRIPTION DRUG COSTS, 2017 at 1, 2 (2019), <https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf> [<https://perma.cc/6QU8-VJKZ>].

<sup>15</sup> F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, J. ECON. PERSPS., Summer 1993, at 97, 103; Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 510–11 (2009); Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, BIOSOCIETIES, Feb. 7, 2011, at 1, 1–2.

<sup>16</sup> See discussion *infra* Part II, Section C.3.

<sup>17</sup> A number of international organizations recognize health as a human right. See, e.g., G.A. Res. 217 (III) A, Universal Declaration of Human Rights, art. 5 (Dec. 10, 1948) [hereinafter Universal Declaration of Human Rights]; International Convention on the Elimination of All Forms of Racial Discrimination art. 5, *opened for signature* Mar. 7, 1966, 660 U.N.T.S. 195 [hereinafter ICERD]; Constitution of the World Health Organization pmb., *opened for signature* July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185 [hereinafter WHO Constitution].

achieving health care as a human right, and aim to increase access to these pharmaceuticals in order to make sure that the human right to health is enjoyed by all.<sup>18</sup>

This Article is structured in three parts. Part I defines AI and related concepts and demonstrates how technology is revolutionizing innovation. This Part illustrates increasing use of AI in pharmaceutical research and provides examples of cases where AI has reduced the length and cost of pharmaceutical R&D.

Part II provides a brief overview of the existing patent system and patentability issues arising from AI-enabled inventions. This Part also discusses the leading arguments for and against the existing patent system and evaluates issues specific to exclusivity rights in the pharmaceutical industry, as well as the controversy over the effects of the patent system as a method of incentivization for pharmaceutical R&D. This Part demonstrates how the patent system's overemphasis on incentivization is limiting access to essential medicines and hindering the realization of health care as a human right, creating a health crisis as exorbitant prices deprive millions of essential medicines.

Part III presents alternative models to incentivize pharmaceutical innovation while increasing access to essential medicines. This Part critically assesses reforming standards of patentability, leaving some essential medicines developed utilizing AI outside the scope of patentability, and using prize funds and tax incentives to incentivize pharmaceutical innovation in the absence of patents. This Part also evaluates an alternative model that provides essential medicines enabled by AI with a shorter patent term, followed by a licensing scheme where the patent holder will allow competitors to make and distribute the products for a reasonable licensing fee in line with the related R&D costs.

## I. AI REVOLUTIONIZING PHARMACEUTICAL INNOVATION

### A. *Defining Intelligence: Natural and Artificial*

From the beginning of the twentieth century, the most popular method of quantifying human intelligence had been by the “intelligence quotient” or “IQ,” which represents a ratio of an individual's mental age to their actual age.<sup>19</sup> In the 1980s, an American psychologist offered a different approach

---

<sup>18</sup> *Essential Medicines*, WORLD HEALTH ORG. [WHO], [https://www.who.int/topics/essential\\_medicines/en/](https://www.who.int/topics/essential_medicines/en/) [<https://perma.cc/6C9P-PPNT>] [hereinafter WHO Essential Medicines].

<sup>19</sup> HOWARD GARDNER, *MULTIPLE INTELLIGENCES: NEW HORIZONS* 3 (2006); *see also* ANNA T. CIANCIOLO & ROBERT J. STERNBERG, *INTELLIGENCE: A BRIEF HISTORY* 30–55 (2004).

to intelligence. This so-called pluralistic view of the mind based human intelligence on various abilities and mental skills of the individual.<sup>20</sup>

According to this approach, intelligence is “a computational capacity” entailing the ability to “solve problems or fashion products that are of consequence in a particular cultural setting or community.”<sup>21</sup> Removing the human aspect from this definition, a good way to define intelligence would then be the “quality that enables an entity to function appropriately and with foresight in its environment.”<sup>22</sup>

Experts in the field have not reached a consensus on a single definition for AI.<sup>23</sup> John McCarthy, who was the first to use the term, defines it as “the science and engineering of making intelligent machines.”<sup>24</sup> Others have defined it as the task of designing rational agents that maximize their expected utility given what they learn from their environment.<sup>25</sup> For the purposes of this Article, AI can simply be defined as the science of creating machines and systems that are capable of understanding their environment and functioning accordingly.<sup>26</sup>

---

<sup>20</sup> GARDNER, *supra* note 19, at 6.

<sup>21</sup> *Id.*

<sup>22</sup> NILS J. NILSSON, THE QUEST FOR ARTIFICIAL INTELLIGENCE: A HISTORY OF IDEAS AND ACHIEVEMENTS 13 (2010).

<sup>23</sup> *See* AI NOW, THE AI NOW REPORT: THE SOCIAL AND ECONOMIC IMPLICATIONS OF ARTIFICIAL INTELLIGENCE TECHNOLOGIES IN THE NEAR-TERM 2 n.1 (2016), [https://ainowinstitute.org/AI\\_Now\\_2016\\_Report.pdf](https://ainowinstitute.org/AI_Now_2016_Report.pdf) [<https://perma.cc/X8VW-VZXS>].

<sup>24</sup> John McCarthy, *What is Artificial Intelligence?*, *Articles*, PROFESSOR JOHN MCCARTHY 2 (Nov. 12, 2007, 2:05 AM), <http://jmc.stanford.edu/articles/whatisai/whatisai.pdf> [<https://perma.cc/4KEK-7H5G>].

<sup>25</sup> *See* STUART J. RUSSELL & PETER NORVIG, ARTIFICIAL INTELLIGENCE: A MODERN APPROACH 1044 (3d ed. 2010).

<sup>26</sup> The United States has not yet adopted an official legal definition of AI. A 2017 bill defines AI systems broadly:

(A) Any artificial systems that perform tasks under varying and unpredictable circumstances, without significant human oversight, or that can learn from their experience and improve their performance. Such systems may be developed in computer software, physical hardware, or other contexts not yet contemplated. They may solve tasks requiring human-like perception, cognition, planning, learning, communication, or physical action. In general, the more human-like the system within the context of its tasks, the more it can be said to use artificial intelligence.

(B) Systems that think like humans, such as cognitive architectures and neural networks.

(C) Systems that act like humans, such as systems that can pass the Turing test or other comparable test via natural language processing, knowledge representation, automated reasoning, and learning.

(D) A set of techniques, including machine learning, that seek to approximate some cognitive task.

### B. Machine Learning and Deep Learning

Depending on the purpose and capacity of an AI system, it may be categorized as weak or strong. Weak AI, also called narrow AI, is programmed to carry out a single task, and is not capable of solving problems outside of its field.<sup>27</sup> A driverless car, for instance, is capable of driving autonomously.<sup>28</sup> Yet, it cannot perform any other task. Strong AI, on the other hand, has the ability to think and reason autonomously.<sup>29</sup> General AI is comparable to a human being in terms of “cognitive, emotional and social behavior[.]”<sup>30</sup>

The ultimate aim of the field of AI is to create general AI, capable of “solv[ing] problems and achiev[ing] goals in the world as well as humans.”<sup>31</sup> However, matching human abilities is not a necessary condition for a system to be considered intelligent.<sup>32</sup> While incapable of performing diverse tasks, many existing systems exceed human performance in certain aspects, most notably in speed.<sup>33</sup>

Until recently, so-called expert systems required scientists to supply inputs in the form of data and interpret the outputs offered by the system.<sup>34</sup> To program these systems, programmers had to collaborate with experts from each field to learn the rules and decision-making criteria relating to the

---

(E) Systems that act rationally, such as intelligent software agents and embodied robots that achieve goals via perception, planning, reasoning, learning, communicating, decision making, and acting.

FUTURE of Artificial Intelligence Act of 2017, H.R. 4625, 115th Cong. § (3)(a)(1) (2017).

<sup>27</sup> See UK-RAS NETWORK, ARTIFICIAL INTELLIGENCE AND ROBOTICS 6 (2017), [https://www.ukras.org/wp-content/uploads/2018/09/UK\\_RAS\\_wp\\_AI\\_web.pdf](https://www.ukras.org/wp-content/uploads/2018/09/UK_RAS_wp_AI_web.pdf) [<https://perma.cc/U26M-K8HJ>].

<sup>28</sup> See, e.g., James Armstrong, *How Do Driverless Cars Work?*, TELEGRAPH (Nov. 2, 2018, 5:10 PM), <https://www.telegraph.co.uk/cars/features/how-do-driverless-cars-work/> [<https://perma.cc/RB2A-QUU6>]; Alex Davies, *The WIRED Guide to Self-Driving Cars*, WIRED (Dec. 13, 2018, 6:00 AM), <https://www.wired.com/story/guide-self-driving-cars/> [<https://perma.cc/SDK8-JT8Z>].

<sup>29</sup> See UK-RAS NETWORK, *supra* note 27.

<sup>30</sup> H.R. 4625.

<sup>31</sup> McCarthy, *supra* note 24, at 5.

<sup>32</sup> See ONE HUNDRED YEAR STUDY ON A.I., *supra* note 4, at 13.

<sup>33</sup> *Id.*

<sup>34</sup> RUSSELL & NORVIG, *supra* note 25, at 1044.

problem at hand.<sup>35</sup> They would then translate these rules into code.<sup>36</sup> Machine learning changed this burdensome approach.<sup>37</sup>

Machine learning is a statistical process where the system autonomously derives rules and procedures from a set of data and comes up with explanations or predictions.<sup>38</sup> The biggest advantage of machine learning is that it does not focus on solving a single problem but offers solutions to different problems based on available data.<sup>39</sup> Machine learning operates by finding patterns in data and using these patterns to formulate and test hypotheses about the task at hand.<sup>40</sup> Today, many commercial applications of AI use machine learning.<sup>41</sup> Object identification in images, speech-to-text services, recommendation services, and search result customization are a few examples of machine learning in action.<sup>42</sup> A significant benefit of machine learning is that it reduces costs and increases efficiency in decision-making processes.<sup>43</sup> As such, machine learning is also a valuable tool to aid researchers in pharmaceutical innovation.<sup>44</sup>

Deep learning is a sub-field of machine learning, which uses structures similar to the human brain.<sup>45</sup> Deep learning networks are capable of recognizing complex and precise patterns in large datasets, by using layers and units referred to as “neurons,” in a manner that is similar to the operations of the human brain.<sup>46</sup> With increased ability to interpret data, deep

---

<sup>35</sup> SUBCOMM. ON MACH. LEARNING AND A.I., NAT’L SCI. & TECH. COUNCIL, PREPARING FOR THE FUTURE OF ARTIFICIAL INTELLIGENCE 8 (2016), [https://obamawhitehouse.archives.gov/sites/default/files/whitehouse\\_files/microsites/ostp/NSTC/preparing\\_for\\_the\\_future\\_of\\_ai.pdf](https://obamawhitehouse.archives.gov/sites/default/files/whitehouse_files/microsites/ostp/NSTC/preparing_for_the_future_of_ai.pdf) [<https://perma.cc/QJ2L-DMHX>].

<sup>36</sup> *Id.*

<sup>37</sup> See Kurt Benke & Geza Benke, *Artificial Intelligence and Big Data in Public Health*, INT’L J. ENVTL. RSCH. & PUB. HEALTH, Dec. 10, 2018, at 1, 4–5, <https://www.mdpi.com/1660-4601/15/12/2796/htm> [<https://perma.cc/9FYX-BTEE>].

<sup>38</sup> See *id.* For a study of machine learning as a tool for mining chemical information for drug design, see Yu-Chen Lo et al., *Machine Learning in Chemoinformatics and Drug Discovery*, 23 DRUG DISCOVERY TODAY 1538, 1540–41 (2018).

<sup>39</sup> See Benke & Benke, *supra* note 37, at 4–5.

<sup>40</sup> Trishan Panch, Peter Szolovits & Rifat Atun, *Artificial Intelligence, Machine Learning and Health Systems*, J. GLOB. HEALTH, Dec. 2018, at 1, 3.

<sup>41</sup> NAT’L SCI. & TECH. COUNCIL COMMITTEE ON TECH., *supra* note 35, at 8.

<sup>42</sup> See Yann LeCun, Yoshua Bengio & Geoffrey Hinton, *Deep Learning*, 521 NATURE 436, 436 (2015); Erik Brynjolfsson & Andrew McAfee, *The Business of Artificial Intelligence*, HARV. BUS. REV. (July 21, 2017, 10:55 AM), <https://hbr.org/cover-story/2017/07/the-business-of-artificial-intelligence> [<https://perma.cc/VWJ4-K8EH>].

<sup>43</sup> Martens, *supra* note 6, at 7.

<sup>44</sup> Lo et al., *supra* note 38, at 1538.

<sup>45</sup> SUBCOMM. ON MACH. LEARNING AND A.I., NAT’L SCI. & TECH. COUNCIL, *supra* note 35, at 9.

<sup>46</sup> *Id.* at 9–10.

learning outperforms machine learning techniques in image and speech recognition, as well as predicting the activities of potential drug molecules.<sup>47</sup>

### C. AI in Pharmaceutical R&D

Medicine and health care stand to benefit substantially from AI.<sup>48</sup> AI is used in the health care industry for such purposes as enhancing the capabilities, know-how, and expertise of doctors and medical professionals, helping monitor patients' conditions in a constant and comprehensive manner, increasing quality of life for people with certain diseases or disabilities, predicting diseases, and customizing treatments.<sup>49</sup> AI systems

<sup>47</sup> LeCun et al., *supra* note 42, at 436.

<sup>48</sup> See ONE HUNDRED YEAR STUDY ON A.I., *supra* note 4, at 25; CTR. FOR DEVICES AND RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN 1–2 (2017), <https://www.fda.gov/media/106331/download> [<https://perma.cc/W2RF-9G8P>]; AM. MED. ASS'N, AUGMENTED INTELLIGENCE IN HEALTH CARE 2–3 (2018), <https://www.ama-assn.org/system/files/2019-01/augmented-intelligence-policy-report.pdf> [<https://perma.cc/37UK-5HAL>]; Fei Jiang et al., *Artificial Intelligence in Healthcare: Past, Present and Future*, 2 STROKE & VASCULAR NEUROLOGY 230, 230–31 (2017); Mike Miliard, *FDA Chief Sees Big Things for AI in Healthcare*, HEALTHCARE IT NEWS (Apr. 30, 2018, 08:51 AM), <https://www.healthcareitnews.com/news/fda-chief-sees-big-things-ai-healthcare> [<https://perma.cc/2VW6-87SK>].

<sup>49</sup> See, e.g., News Release, U.S. Food and Drug Admin., FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems (Apr. 11, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604357.htm> [<https://perma.cc/GF94-QBL3>] (indicating that an AI device can detect eye disease without interpretation from a doctor or clinician); News Release, U.S. Food and Drug Admin., FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User (Feb. 7, 2020), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user> [<https://perma.cc/LTR8-RKS9>] (indicating that the AI tool allows “medical professionals who may not be experts in ultrasonography” to diagnose heart diseases); *About da Vinci Systems*, INTUITIVE, <https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems> [<https://perma.cc/6BPS-TFVG>] (discussing the da Vinci Surgical System that allows surgeons to operate on patients through small incisions via a magnified vision system, enhancing surgeon's capabilities by reducing the effects of shaking hands and enabling finer movements than naturally possible); News Release, Johns Hopkins Med., The Johns Hopkins Hospital Launches Capacity Command Center to Enhance Hospital Operations (Oct. 26, 2016), [https://www.hopkinsmedicine.org/news/media/releases/the\\_johns\\_hopkins\\_hospital\\_launches\\_capacity\\_command\\_center\\_to\\_enhance\\_hospital\\_operations](https://www.hopkinsmedicine.org/news/media/releases/the_johns_hopkins_hospital_launches_capacity_command_center_to_enhance_hospital_operations) [<https://perma.cc/KN5D-WBZV>] (discussing Johns Hopkins Medicine's AI-powered command center, which led to thirty percent faster bed assignments, and a sixty percent increase in patient transfers from other hospitals, while decreasing by seventy percent the delays in transfer of patients from operating rooms following procedures); News Release, Taunton and Somerset NHS Found. Tr., New Mobile App for the Digital Age (June 21, 2017) (on file with author) (discussing Google Deep Mind Health's deployment to observe critical patients, and alert doctors and nurses where the data indicates an urgent need for care).

are also used in various stages of the drug development process, ranging from initial drug screening to designing clinical trials.<sup>50</sup>

The pharmaceutical industry is the most research-intensive industry in the United States.<sup>51</sup> Researchers alone, however, are limited in their capacity to innovate in an efficient and rapid manner.<sup>52</sup> AI improves performance and decreases costs of R&D.<sup>53</sup> Pharmaceutical companies use AI to enhance R&D capabilities, increase efficiency, and decrease the time and investment required by the drug development process.<sup>54</sup>

Machine learning is most commonly used in drug discovery<sup>55</sup> to aid researchers in understanding relationships between chemicals and their activities.<sup>56</sup> Deep learning algorithms are capable of processing vast amounts of data to make accurate predictions about the effects of molecules.<sup>57</sup> These predictions help researchers focus on a smaller number of drug candidates

<sup>50</sup> See, e.g., H.C. Stephen Chan et al., *Advancing Drug Discovery via Artificial Intelligence*, 40 TRENDS IN PHARMACOLOGICAL SCI. 592, 592–604 (2019); Stefan Harrer et al., *Artificial Intelligence for Clinical Trial Design*, 40 TRENDS IN PHARMACOLOGICAL SCI. 577, 577–91 (2019).

<sup>51</sup> F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED. 927, 927 (2004).

<sup>52</sup> See Rotman, *supra* note 5 (discussing the reasons for declining productivity in research in the recent years, and how technology companies are trying to use AI to increase R&D productivity to overcome problems with research, including efforts to shorten research time).

<sup>53</sup> Cockburn et al., *supra* note 3, at 7.

<sup>54</sup> See Nic Fleming, *Computer-Calculated Compounds*, 557 NATURE S55, S55 (2018) (indicating that the likes of Pfizer and Sanofi invest in AI and that if advocates are right in their claims, AI will help achieve the goal of “quicker, cheaper and more-effective drug discovery”); Ben Hirschler, *Big Pharma Turns to AI to Speed Drug Discovery, GSK Signs Deal*, REUTERS (July 1, 2017, 8:10 PM), <https://www.reuters.com/article/us-pharmaceuticals-ai-gsk/big-pharma-turns-to-ai-to-speed-drug-discovery-gsk-signs-deal-idUSKBN19N003> [<https://perma.cc/3UFC-7YDU>] (reporting that a GlaxoSmithKline (GSK) executive expects an in-house system will decrease the time it takes to find a target for disease intervention and identify a molecule fighting it from its current average of 5.5 years to one year, and chief executive of Exscientia claims that their AI system can deliver drug candidates in roughly twenty-five percent of the time and cost of traditional approaches); Bryn Nelson, *Why Big Pharma and Biotech are Betting Big on AI*, NBC NEWS (Mar. 1, 2018, 11:58 AM), <https://www.nbcnews.com/mach/science/why-big-pharma-betting-big-ai-ncna852246> [<https://perma.cc/MH24-LY73>] (reporting that AI groups are aiming to cut down the initial stage of pharmaceutical research, which consists of identifying a disease target and testing drug candidates against that target, from its current time of four to six years to one year); Rotman, *supra* note 5 (claiming that deep learning has the potential to speed up the process of finding drug candidates, which is a critical and lengthy portion of the drug development process).

<sup>55</sup> Drug discovery is the first stage of drug development where researchers identify target diseases and test drug candidates against such targets. See Ingrid Torjesen, *Drug Development: The Journey of a Medicine from Lab to Shelf*, PHARMACEUTICAL J. (May 12, 2015), <https://www.pharmaceutical-journal.com/publications/tomorrows-pharmacist/drug-development-the-journey-of-a-medicine-from-lab-to-shelf/20068196.article?firstPass=false> [<https://perma.cc/825B-N5YL>].

<sup>56</sup> Lo et al., *supra* note 38, at 1538.

<sup>57</sup> Chan et al., *supra* note 50, at 601.

that are more likely to pass clinical trials.<sup>58</sup> AI systems can also bring the traditional number of screened compounds from one million to several billion, while decreasing the time it takes to screen such compounds from several months to a few days.<sup>59</sup>

Big data represents endless opportunities in medicine.<sup>60</sup> However, the sheer volume of data and the velocity with which data becomes available represents serious challenges.<sup>61</sup> In 2016, researchers had access to “nearly 200,000 active clinical trials, 21,000 drug components, 1,357 unique drugs, 22,000 genes, and hundreds of thousands of proteins,” as well as more than twenty-four million medical and scientific articles.<sup>62</sup> According to a 2012 study conducted in five universities in the United States, however, faculty members read around twenty-one scholarly articles per month, or an average of 252 articles annually.<sup>63</sup>

In addition to the vast amount of data researchers must be familiar with to keep up-to-date with progress in their field, drug development further requires analysis of existing literature, preclinical study reports, clinical trial data, and patents.<sup>64</sup> No individual researcher is capable of sifting through big data in the amount of time that an intelligent system can. Furthermore, humans are limited in their knowledge; even an expert in a given field will have limited-to-no know-how in another field of expertise.<sup>65</sup>

AI enables researchers to cope with big data and synthesize data from different fields. IBM’s AI system, Watson, reads, reasons, learns and makes inferences from available data, and offers solutions based on its learnings.<sup>66</sup> Watson starts the learning process by accessing the “Watson corpus” database to review available data corresponding to the related field.<sup>67</sup> Separate datasets consisting of external, public, private, and licensed sources

---

<sup>58</sup> See *id.* at 592–99.

<sup>59</sup> *Id.* at 601.

<sup>60</sup> See, e.g., Chen et al., *supra* note 2, at 689.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> CAROL TENOPIR, RACHEL VOLENTINE & LISA CHRISTIAN, CTR. FOR INFO. AND COMM. STUD., SCHOLARLY READING BY FACULTY IN THE UNITED STATES: SUMMARY RESULTS OF A STUDY CONDUCTED IN 2012 IN FIVE UNIVERSITIES 3–4 (2013), <http://www.libvalue.org/documents/libvalue/publications/tenopir-volentine-christian-us-faculty-2013.pdf> [<https://perma.cc/HF9R-YAKC>].

<sup>64</sup> Chen et al., *supra* note 2, at 696.

<sup>65</sup> See Hiroaki Kitano, *Artificial Intelligence to Win the Nobel Prize and Beyond: Creating the Engine for Scientific Discovery*, AI MAG., Spring 2016, at 39, 41–43 (discussing cognitive limitations as they relate to the biomedical sciences, such as the inability of humans to keep up with the vast amount of available data).

<sup>66</sup> Chen et al., *supra* note 2, at 691–94.

<sup>67</sup> *Id.* at 691.

exist for each field that Watson is used in, including law, finance, and medicine.<sup>68</sup> Watson also has access to ontologies on genes, proteins, drugs, and diseases,<sup>69</sup> as well as dictionaries and thesauri to ensure it fully understands what it reads.<sup>70</sup>

In one demonstration, it took Watson less than a single minute to process twenty-four million article abstracts and provide researchers with 177 documents mentioning genes connected with multiple sclerosis.<sup>71</sup> It then created a network map, from which researchers could access summaries of relationships between the disease and different genes, and a link to the relevant section of the related article.<sup>72</sup>

IBM and GlaxoSmithKline (GSK) recently carried out a pilot project to demonstrate the ability of Watson to detect insights and relationships from separate domains of data.<sup>73</sup> The aim of the project was to identify any compounds in GlaxoSmithKline's existing drug portfolio that could potentially be used to treat malaria.<sup>74</sup> Malaria is a disease mostly found in developing countries where investment in R&D for malaria drugs is limited.<sup>75</sup> However, it has been the subject of extensive research, with 60,000 articles in the Medline database referring to the disease.<sup>76</sup>

In the pilot project, Watson was deployed to review this literature, searching for drugs approved for use in humans and statements about efficacy against malaria.<sup>77</sup> Following its literature review, Watson analyzed GSK's existing drug portfolio to search for drugs with similar chemical structures to drugs that are known for treating malaria.<sup>78</sup> Within one month, Watson came up with fifteen candidates.<sup>79</sup> The company had been carrying out the same research with a team of ten researchers for the last fourteen months.<sup>80</sup> The research team had come up with a similar number of candidates, although half of the candidates Watson identified were not on their list.<sup>81</sup> The project was a clear indication of Watson's potential to

---

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 696.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 694.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.* at 697–98.

<sup>74</sup> *Id.* at 698.

<sup>75</sup> SCOTT SPANGLER, ACCELERATING DISCOVERY: MINING UNSTRUCTURED INFORMATION FOR HYPOTHESIS GENERATION 151 (2015).

<sup>76</sup> *Id.*

<sup>77</sup> Chen et al., *supra* note 2, at 698.

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

outperform human researchers in terms of time spent in the drug discovery process.<sup>82</sup> It also demonstrated Watson's ability to diversify approaches to resolving presented problems.<sup>83</sup>

Recent years have witnessed an increasing number of similar cases of AI deployment in pharmaceutical innovation. One AI system, which analyzes data from clinical trials and academic articles to find new drug candidates and potential uses for existing drug candidates,<sup>84</sup> took a single week to come up with five drug candidates for the disease ALS.<sup>85</sup> Another AI system analyzed oncological data and discovered a treatment for pancreatic cancer, which is currently in Phase II of clinical trials.<sup>86</sup> Researchers at Carnegie Mellon University used the predictive capabilities of a machine learning system to decrease the number of tests run on new drugs by seventy percent.<sup>87</sup>

Most recently, a machine learning algorithm that can screen over “a hundred million chemical compounds in a matter of days” helped researchers identify a new antibiotic compound that “killed many of the world's most problematic disease-causing bacteria, including some strains that are resistant to all known antibiotics.”<sup>88</sup> Another AI system helped invent a new compound aimed at treating obsessive-compulsive disorder, which will be the first compound created by AI to be tried on humans.<sup>89</sup> The system

<sup>82</sup> GSK and IBM have yet to publish the outcome of further tests on the candidates offered by Watson in the pilot project.

<sup>83</sup> See Steve Lohr, *And Now, From I.B.M., Chef Watson*, N.Y. TIMES (Feb. 27, 2013), [http://www.nytimes.com/2013/02/28/technology/ibm-exploring-new-feats-for-watson.html?\\_r=0](http://www.nytimes.com/2013/02/28/technology/ibm-exploring-new-feats-for-watson.html?_r=0) [<https://perma.cc/4CH2-NTG8>].

<sup>84</sup> João Medeiros, *This AI Unicorn is Disrupting the Pharma Industry in a Big Way*, WIRED: WIRED HEALTH (Mar. 31, 2021), <https://www.wired.co.uk/article/benevolent-ai-london-unicorn-pharma-startup> [<https://perma.cc/6ZM5-64BJ>]; see also *Using Artificial Intelligence to Optimise Small-Molecule Drug Design*, BENEVOLENTAI (Mar. 28, 2019), <https://benevolent.ai/blog/using-artificial-intelligence-to-optimize-small-molecule-drug-design> [<https://perma.cc/UF6A-FBTH>].

<sup>85</sup> Nelson, *supra* note 54.

<sup>86</sup> Press Release, BERG, BERG Announces FDA Orphan-Drug Designation of BPM31510 for the Treatment of Pancreatic Cancer (Jan. 22, 2018), <https://www.berghealth.com/berg-announces-fda-orphan-drug-designation-of-bpm31510-for-the-treatment-of-pancreatic-cancer/> [<https://perma.cc/FEC6-W44F>].

<sup>87</sup> Chris Wood, *Machine-Learning Robot Could Streamline Drug Development*, NEW ATLAS (Feb. 10, 2016), <http://newatlas.com/machine-learning-drug-development/41759/> [<https://perma.cc/6ELE-EQFJ>]; see Carnegie Mellon Univ., *Drug Discovery System*, NAT'L ROBOTICS ENG'G CTR., <https://www.nrec.ri.cmu.edu/nrec/solutions/otherindustries/drug-discovery-system.html> [<https://perma.cc/R72H-LMWQ>].

<sup>88</sup> Anne Trafton, *Artificial Intelligence Yields New Antibiotic*, MIT NEWS (Feb. 20, 2020), <http://news.mit.edu/2020/artificial-intelligence-identifies-new-antibiotic-0220> [<https://perma.cc/635K-E6Q3>].

<sup>89</sup> Jane Wakefield, *Artificial Intelligence-Created Medicine to be Used on Humans for First Time*, BBC (Jan. 30, 2020), <https://www.bbc.com/news/technology-51315462> [<https://perma.cc/GFP6-MJJP>].

“generate[d] tens of millions of potential molecules, sift[ed] through the candidates and [made] a decision about which ones to synthesize and test,” allowing researchers to test only 350 compounds, one fifth of the normal number of candidates that would need to be tested under the traditional R&D process.<sup>90</sup> The compound is now entering human clinical trials after only twelve months, as opposed to the average 4.5 years.<sup>91</sup>

These are some of the cases that demonstrate AI’s potential to “dramatically lower costs and improve[] performance” in R&D, including pharmaceutical innovation.<sup>92</sup> Patents, and associated exclusivity rights, represent a trade-off between innovation and lower prices resulting from competition.<sup>93</sup> Social costs of the patent system are the most significant in the pharmaceutical industry, as lack of access to pharmaceuticals denies a considerable portion of the world’s population from their most basic of human rights—the right to health.<sup>94</sup> AI’s disruption of pharmaceutical innovation further weakens justifications for pharmaceutical patents, especially for patents on essential medicines.

## II. PATENTS IN THE CONTEXT OF AI SYSTEMS AND PHARMACEUTICAL INNOVATION

### A. *A Brief Primer on Patent Law*

A patent grant entitles inventors to a right to exclude others from making, using, offering for sale, or selling their inventions (or in cases of patented processes, any resulting products) throughout the United States, as well as importing these inventions into the United States, during the term of the related patent.<sup>95</sup> The basic principle behind patent law is that patent

---

<sup>90</sup> Madhumita Murgia, *AI-Designed Drug to Enter Human Clinical Trial for First Time*, FIN. TIMES (Jan. 29, 2020), <https://www.ft.com/content/fe55190e-42bf-11ea-a43a-c4b328d9061c> [https://perma.cc/GB4H-354D].

<sup>91</sup> *Id.*

<sup>92</sup> Cockburn et al., *supra* note 3, at 7.

<sup>93</sup> See COPENHAGEN ECON., STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE (2018), <https://www.copenhageneconomics.com/dyn/resources/Publication/publicationPDF/5/445/1527517171/copenhagen-economics-2018-study-on-the-economic-impact-of-spcs-pharmaceutical-incentives-and-rewards-in-europe.pdf>. [https://perma.cc/4UKH-DCX7].

<sup>94</sup> See Paul Hunt (Special Rapporteur), Rep. of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. DOC. A/63/263, at 15 (Aug. 11, 2008) (indicating that almost 2 billion people around the world lack access to essential medicines).

<sup>95</sup> See 35 U.S.C. § 154.

holders are granted a limited period of exclusion, during which they can restrain competition from using the patented invention.<sup>96</sup>

According to the Supreme Court, this right of exclusion is compensation for inventors' "labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit."<sup>97</sup> The right to exclude is a quid pro quo for the benefit the public derives from the disclosure and availability of inventions.<sup>98</sup> Courts have further ruled that the ultimate goal of the patent system is the public use and disclosure of inventions.<sup>99</sup>

Patent law is a "one-size-fits-all system," which does not distinguish inventions and associated rights based on technology.<sup>100</sup> Patent law also does not address the problem of balancing incentivization against the need for equitable access. In providing incentives for innovation, the existing system does not differentiate between luxury goods and life-saving drugs, effectively prioritizing private over public interest.

### B. Evaluating the Costs and Benefits of the Patent System

The most widely cited justification for patent law is that it provides a method for inventors to reap the benefits of their inventions and recoup R&D investments, which in turn encourages innovation and progress.<sup>101</sup> The pharmaceutical industry often claims patents are essential for innovation, as they provide a method for compensating costly R&D associated with drug

---

<sup>96</sup> Bronwyn H. Hall, *Patents and Patent Policy*, 23 OXFORD REV. ECON. POL'Y, 568, 568 (2007).

<sup>97</sup> *Seymour v. Osborne*, 78 U.S. 516, 533 (1870).

<sup>98</sup> *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

<sup>99</sup> *See, e.g., Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002); *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561 (Fed. Cir. 1987).

<sup>100</sup> Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1155 (2002); *see* John R. Allison, Mark A. Lemley & David L. Schwartz, *Our Divided Patent System*, 82 U. CHI. L. REV. 1073, 1074 (2015); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 364 (2007); Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 678 (2014).

<sup>101</sup> *See, e.g.,* WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 294 (Harvard Univ. Press 2003); Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002*, 89 REV. ECON. & STAT. 436, 436 (2007); E. Richard Gold et al., *Are Patents Impeding Medical Care and Innovation?*, 7 PLOS MED. 1 (2010), <https://journals.plos.org/plosmedicine/article/file?id=10.1371/journal.pmed.1000208&type=printable> [<https://perma.cc/GP4S-PS3R>]; Daniel J. Gifford, *How Do the Social Benefits and Costs of the Patent System Stack up in Pharmaceuticals*, 12 J. INTELL. PROP. L. 75, 81 (2004); Jonathan M. Barnett, *Private Protection of Patentable Goods*, 25 CARDOZO L. REV. 1251, 1253 (2004).

development.<sup>102</sup> However, evidence on how the patent system actually affects innovation is inconclusive.<sup>103</sup>

Economically, patents offer a bargain between the inventor and the general public.<sup>104</sup> The right of exclusion granted to patent holders is aimed at encouraging innovation by preventing imitation by third parties during the patent term.<sup>105</sup> In return, patent holders are required to disclose their inventions to the public.<sup>106</sup> This is the “classic patent trade-off,”<sup>107</sup> a quid pro quo for the benefit the public derives from the disclosure and availability of inventions.<sup>108</sup>

Patent law aims to advance social welfare by mandating disclosure of inventions to the public, enabling third parties to access the know-how necessary to make and use the inventions.<sup>109</sup> Public disclosure of inventions

---

<sup>102</sup> See, e.g., FED. TRADE COMM’N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY ch. 3, at 1, 4, 9 (2003), <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> [<https://perma.cc/NX57-E5HR>] [hereinafter FTC REPORT ON COMPETITION AND PATENT LAW]; Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 94–99 (2004); Eisenberg, *supra* note 100, at 346, 350; Christopher Rowland, *Drug Executives Grilled in Senate Over High Prices*, WASH. POST (Feb. 26, 2019), [https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137\\_story.html?noredirect=on&utm\\_term=.65388d498909](https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html?noredirect=on&utm_term=.65388d498909) [<https://perma.cc/99KZ-ZP45>]; Light & Warburton, *supra* note 15, at 34–35; Roin, *supra* note 15, at 510–11; Scherer, *supra* note 15, at 103.

<sup>103</sup> Some empirical research supports the view that greater patent protection is correlated with higher R&D expenditure. See, e.g., Sunil Kanwar & Robert Evenson, *Does Intellectual Property Protection Spur Technological Change?*, 55 OXFORD ECON. PAPERS 235, 235–64 (2003); Yongmin Chen & Thitima Puttitanun, *Intellectual Property Rights and Innovation in Developing Countries*, 78 J. DEV. ECON. 474, 474–93 (2005). However, there is also conflicting research indicating that patent protection does not have a significant impact on R&D investments. See, e.g., Mariko Sakakibara & Lee Branstetter, *Do Stronger Patents Induce More Innovation?*, 32 RAND J. ECON. 77, 77–100 (1992).

<sup>104</sup> Hall, *supra* note 96, at 571; see also Richard A. Posner, *Intellectual Property: The Law and Economics Approach*, 19 J. ECON. PERSPS. 57, 57 (2005); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1580 (2003).

<sup>105</sup> Hall, *supra* note 96, at 568.

<sup>106</sup> *Id.*

<sup>107</sup> Robert W. Hahn, *The Economics of Patent Protection: Policy Implications from the Literature* 6 (Oct. 30, 2003) (unpublished working paper), <https://ssrn.com/abstract=467489> [<https://perma.cc/RPB8-2N9L>].

<sup>108</sup> *Brenner v. Manson*, 383 U.S. 519, 534 (1966); see also Liza Vertinsky, *Thinking Machines and Patent Law*, in RESEARCH HANDBOOK ON THE LAW OF ARTIFICIAL INTELLIGENCE 489, 495 (Woodrow Barfield & Ugo Pagallo eds., 2018).

<sup>109</sup> 35 U.S.C. § 112(a) (requiring the specification accompanying the patent application to describe the invention “in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use” the invention); CRAIG ALLEN NARD, *THE LAW OF PATENTS* 35 (4th ed. 2017); World Intell. Prop. Org. [WIPO], *Report on the International Patent System*, at 10, SCP/12/3 Rev.2 (Feb. 3, 2009), [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_12/scp\\_12\\_3\\_rev\\_2.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf) [<https://perma.cc/5X2T-KMNP>]

also aims to reduce duplicative R&D efforts and serves as guidance for competitors on deciding where to target their R&D investments.<sup>110</sup>

Whether these benefits of the patent system justify its social and economic costs has been an issue of much debate.<sup>111</sup> One significant cost associated with the patent system is that patents can lead to higher prices.<sup>112</sup> The right to exclude competitors from introducing alternative products to the market allows patent holders to charge exorbitant prices.<sup>113</sup> In the case of pharmaceuticals, prices mostly exceed what is necessary to recoup R&D investments.<sup>114</sup>

For instance, a 2019 study of ninety-nine cancer drugs approved by the Food and Drug Administration (FDA) showed that high prices allowed pharmaceutical companies to recoup “maximum possible risk-adjusted cost[s]” of R&D within an average of five years, and that these drugs continued to generate significant revenue thereafter, even following expiration of any exclusivity terms.<sup>115</sup> Exorbitant prices restrict access for some potential customers, leading to a misallocation of social resources, or

---

[hereinafter *WIPO Report on the International Patent System*]; see also LANDES & POSNER, *supra* note 101, at 328.

<sup>110</sup> See *WIPO Report on the International Patent System*, *supra* note 109, at 10 (indicating that the patent system allows dissemination of knowledge and access by the public to such knowledge through disclosure requirements, which in turn decreases duplicative R&D efforts); FTC REPORT ON COMPETITION AND PATENT LAW, *supra* note 102, at 1, 4 (indicating that representatives of the pharmaceutical and biotechnology industries use disclosures to direct their R&D efforts, while generic manufacturers use disclosures to “design-around” patented pharmaceuticals to avoid infringement).

<sup>111</sup> See, e.g., *WIPO Report on the International Patent System*, *supra* note 109, at 78–81 (indicating that the patent system has been a subject of skepticism and providing an analysis of the issues concerning health); Gifford, *supra* note 101, at 78 (indicating that pharmaceutical patents are “on the forefront of controversies” about their effects on “pricing and exclusion”).

<sup>112</sup> See ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 13 (4th ed. 2006); Gifford, *supra* note 101, at 83; Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents–Prizes Debate*, 92 TEX. L. REV. 303, 312 (2013).

<sup>113</sup> MERGES ET AL., *supra* note 112, at 13; see Gifford, *supra* note 101, at 83; see also Hemel & Larrimore Ouellette, *supra* note 112, at 312.

<sup>114</sup> See LANDES & POSNER, *supra* note 101, at 296.

<sup>115</sup> Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, [J]AMA NETWORK 1 (Jan. 4, 2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2720075> [https://perma.cc/EYH6-6V5Q].

a so-called “deadweight loss.”<sup>116</sup> Deadweight loss is particularly concerning in the case of pharmaceuticals, as lack of access poses health risks.<sup>117</sup>

Another significant cost of the patent system is that it indirectly encourages innovation in larger markets, leading to a misallocation of R&D efforts.<sup>118</sup> The current system encourages patent holders to maximize the revenue generated from their patents and does not duly incentivize innovation in areas where there is less market demand.<sup>119</sup> In the pharmaceutical industry, this results in redirection of R&D funds away from products that may better serve the needs of society.<sup>120</sup>

Wasteful rent-seeking is another important cost of the patent system.<sup>121</sup> Innovating companies compete with each other, invest heavily, and sometimes waste resources in a “patent race” to become the first to file a patent.<sup>122</sup> Rent-seeking within the patent system may result from a race to obtain patents, both during patenting and preceding R&D processes, which may cause competing parties to over-invest.<sup>123</sup> In the case of pharmaceuticals, excessive investments arising from patent races translate to higher costs for consumers.<sup>124</sup>

---

<sup>116</sup> Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1023–24 (2014); see Gifford, *supra* note 101, at 83, 102 n.118 (2004); Barnett, *supra* note 101, at 1269; see also Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 247 (1994); see also Michael J. Burstein & Fiona E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J. L. & TECH. 401, 410 (2016).

<sup>117</sup> Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J. L. & TECH. 153, 161 (2016); Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 186 (2009); Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 201–02 (2005); see Gifford, *supra* note 101, at 1023.

<sup>118</sup> See Outterson, *supra* note 117, at 218.

<sup>119</sup> Gifford, *supra* note 101, at 82.

<sup>120</sup> See GRAHAM DUTFIELD, *INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: A TWENTIETH CENTURY HISTORY* 97 (2003); Dean Baker, *Financing Drug Research: What are the Issues?* 11–13 (Sept. 22, 2004) (2008 Industry Studies Conference Paper), <https://ssrn.com/abstract=1134983> [<https://perma.cc/WNE8-QWFF>]; Ryan Abbott, *Balancing Access and Innovation in India’s Shifting IP Regime, Remarks*, 35 WHITTIER L. REV. 341, 341 (2014); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1713 (2008).

<sup>121</sup> LANDES & POSNER, *supra* note 101, at 17; Barnett, *supra* note 101, at 1269.

<sup>122</sup> LANDES & POSNER, *supra* note 101, at 17–18; Stiglitz, *supra* note 120, at 1706–07; Michele Boldrin & David K. Levine, *The Economics of Ideas and Intellectual Property*, 102 PNAS 1252, 1255 (2005).

<sup>123</sup> Dam, *supra* note 116, at 251.

<sup>124</sup> Outterson, *supra* note 117, at 218.

Lastly, patents limit access to knowledge and inventions.<sup>125</sup> The patent system hinders subsequent innovation by restricting access to knowledge, data, materials, and processes necessary for research.<sup>126</sup> As the number of patents innovators need to take into account increases, probability of follow-up innovation decreases, indicating that the system set up to incentivize innovation discourages it by imposing additional costs and hurdles to R&D.<sup>127</sup>

### C. Patents and Exclusivity in the Pharmaceutical Industry

#### 1. The Human Right to Health Care

Several international organizations and instruments recognize health as a human right.<sup>128</sup> The Universal Declaration of Human Rights provides that every individual has the right to health, which includes the right to medical care.<sup>129</sup> The World Health Organization's (WHO) Constitution similarly acknowledges enjoyment of "the highest attainable standard of health" as a fundamental human right.<sup>130</sup>

The United Nations recognizes the right of all individuals to the "enjoyment of highest attainable standard of physical and mental health"<sup>131</sup> and defines health as a "fundamental human right indispensable for the exercise of other human rights."<sup>132</sup> According to the International Covenant on Economic, Social and Cultural Rights (the "Covenant"), states must take steps to realize this right, including steps to ensure treatment of diseases.<sup>133</sup>

While the Covenant is directly applicable only to states, and not private parties, the United Nations Committee on Economic, Social and Cultural

<sup>125</sup> *Id.* at 201–02; Stiglitz, *supra* note 120, at 1710; Roin, *supra* note 116, at 1023; NAT'L RSCH. COUNCIL OF THE NAT'L ACADS., REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH 136 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006).

<sup>126</sup> Gold et al., *supra* note 101, at 1.

<sup>127</sup> See Boldrin & Levine, *supra* note 122, at 1255 (asserting that "the probability of innovation under monopoly is smaller than that under competition and drops towards zero" as the number of rights that innovators need to take into account increases and that the "additional incentive for innovation under an intellectual property regime is more than completely offset by the additional cost" in such cases); Barnett, *supra* note 101, at 1269 (referring to "restricted access to the patented good by subsequent improvers" as one of the costs of the patent system).

<sup>128</sup> See, e.g., Universal Declaration of Human Rights, *supra* note 17, art. 5; ICERD, *supra* note 17, art. 5; WHO Constitution, *supra* note 17, pmb1.

<sup>129</sup> Universal Declaration of Human Rights, *supra* note 17, art. 25.

<sup>130</sup> WHO Constitution, *supra* note 17, at 1.

<sup>131</sup> International Covenant on Economic, Social and Cultural Rights, art. 12, *opened for signature* Dec. 19, 1966, 993 U.N.T.S. 3.

<sup>132</sup> Comm. on Econ., Soc. and Cultural Rts., Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social, and Cultural Rights: General Comment No. 14, ¶ 1, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

<sup>133</sup> See *id.* ¶ 16.

Rights (the “Committee”) declared that all members of society, including private businesses, have responsibilities in achieving the level of health foreseen by the Covenant.<sup>134</sup> The Committee proposed that states facilitate the realization of these responsibilities by such means as enacting framework laws.<sup>135</sup>

The patent system directly affects realization of health care as a human right. It enables higher prices, which effectively restrict access to essential medicines.<sup>136</sup> It also encourages investment in larger markets and fails to provide sufficient incentives for socially valuable pharmaceutical inventions.<sup>137</sup> A successful system should incentivize innovation while advancing health as a human right.<sup>138</sup> The current patent system must thus be reformed to recalibrate the balance between access and incentivization, and public and private interest.

## 2. *Comparing Pharmaceutical Prices in the United States and Other Countries*

Facing criticism over exorbitant prices and monopolistic pricing practices, pharmaceutical companies claim that high average returns are necessary to incentivize pharmaceutical R&D, given its high-risk nature.<sup>139</sup>

---

<sup>134</sup> *Id.* ¶ 42.

<sup>135</sup> *Id.* ¶¶ 42, 56.

<sup>136</sup> See Daniel J. Hemel & Lisa Larrimore Ouellette, *Knowledge Goods and Nation-States*, 101 MINN. L. REV. 167, 168 (2016).

<sup>137</sup> See Hunt, *supra* note 94, ¶¶ 19, 22–23 (reporting that Ministers, senior public officials and others claim pharmaceutical companies’ practices, including exorbitant prices and lack of investment in R&D for drugs aimed at developing countries, hinder States’ implementation of the right to the highest attainable standard of health and, in particular, their endeavors to enhance access to medicines); Sachs, *supra* note 117, at 160–71 (claiming that the patent system and FDA regulations “fail to encourage the production of important, socially valuable pharmaceutical interventions,” and discussing the ways these systems lead to certain “innovation distortions”).

<sup>138</sup> See DUTFIELD, *supra* note 120, at 130; Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 425, 435 (2003).

<sup>139</sup> See FTC REPORT ON COMPETITION AND PATENT LAW, *supra* note 102, at 1, 4, 9; Kuhlik, *supra* note 102, at 94–99; Eisenberg, *supra* note 100, at 346, 350; Scherer, *supra* note 15, at 103; Light & Warburton, *supra* note 15, at 34–35; Rowland, *supra* note 102.

Yet, with pharmaceutical companies ranking among the most profitable,<sup>140</sup> pharmaceutical prices have sparked controversy throughout the years.<sup>141</sup>

According to a study based on data from 2013 to 2016, the United States has a higher per capita spending on health care than any other country.<sup>142</sup> The study found that pharmaceutical spending per capita in the United States was \$1,443, where the mean for all countries under investigation was \$749.<sup>143</sup> Prices in the United States for four common drugs ranked higher than all of the other countries analyzed in the study, with the prices of three of these drugs more than doubling the next highest price on the list.<sup>144</sup>

A 2018 study by the U.S. Department of Health and Human Services had similar results.<sup>145</sup> The study compared the prices for twenty-seven physician administered non-retail drugs covered by the Medicare Part B program with prices in sixteen other countries.<sup>146</sup> The researchers found that Medicare paid almost twice as much as it would have paid for the same or equivalent drugs as it would in any other country included in the study.<sup>147</sup>

### 3. *Understanding Cost of Pharmaceutical R&D in the United States*

A frequently cited 2003 study estimated the average out-of-pocket cost (i.e., the actual cash spending) of R&D for each FDA-approved new drug at \$403 million, and the capitalized cost at \$802 million (in 2000 dollars).<sup>148</sup>

<sup>140</sup> CONG. BUDGET OFF., PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 4 (2006), <https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/10-02-drug-d.pdf> [<https://perma.cc/94KT-LBAH>]; MICHELE BOLDRIN & DAVID K. LEVINE, AGAINST INTELLECTUAL MONOPOLY 226 (Cambridge Univ. Press 2008); Outterson, *supra* note 117, at 221; Scherer, *supra* note 51, at 929; Livan Chen, *The Most Profitable Industries in 2016*, FORBES (Dec. 21, 2015, 4:19 PM), <https://www.forbes.com/sites/liyanchen/2015/12/21/the-most-profitable-industries-in-2016/#5f9a5c3e5716> [<https://perma.cc/W3RE-9JZR>]; Sam Kaplan, *Why Our Drugs Cost So Much*, AARP: BULL. (May 1, 2017), <https://www.aarp.org/health/drugs-supplements/info-2017/rx-prescription-drug-pricing.html> [<https://perma.cc/X6V3-C63G>].

<sup>141</sup> Scherer, *supra* note 15, at 97; Scherer, *supra* note 51, at 927; Gifford, *supra* note 101, at 78; Joseph, *supra* note 138, at 427–28.

<sup>142</sup> The study compared the United States to ten high income countries (United Kingdom (including England, Scotland, Wales, and Northern Ireland), Canada, Germany, Australia, Japan, Sweden, France, Denmark, the Netherlands, and Switzerland) and analyzed data in such domains as general spending, structural capacity, labor costs, and pharmaceutical spending. Papanicolas et al., *supra* note 12.

<sup>143</sup> *Id.*

<sup>144</sup> The study compared the prices of the pharmaceuticals Crestor, Lantus, Advair, and Humira. *Id.* at 1031.

<sup>145</sup> OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS., COMPARISON OF U.S. AND INTERNATIONAL PRICES FOR TOP MEDICARE PART B DRUGS BY TOTAL EXPENDITURES (2018).

<sup>146</sup> *Id.* at 5–6.

<sup>147</sup> *Id.* at 8–12.

<sup>148</sup> Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003) [hereinafter DiMasi 2003]. The most recent study by the same scholars indicates that the total out-of-pocket R&D cost for each new

While the industry asserts the numbers represent a good measure of its R&D costs, the study has been widely criticized.<sup>149</sup>

One significant issue with the study is that it does not rely on public and market-wide data but relies on undisclosed data from only ten pharmaceutical companies.<sup>150</sup> Critics also question the participating companies' calculation of R&D costs.<sup>151</sup> Some commentators criticize the lack of clarification as to what expenditures are included within the scope of R&D costs,<sup>152</sup> while others argue that the final number is inflated due to the inclusion of marketing expenditures, which is not traditionally accepted as an item under R&D costs.<sup>153</sup>

Another important factor is that the study does not differentiate between successful and failed drugs<sup>154</sup> and divides the total amount of R&D costs only by the number of drugs that successfully obtain marketing approval from the FDA.<sup>155</sup> The study was criticized for its limited focus on new molecular entities (i.e., drugs that contain an active substance not previously approved for marketing), as opposed to improvement drugs, which are less costly to develop.<sup>156</sup>

A critique of the study underlines that both R&D time and investments vary substantially from one drug to another, and the cost of research is

compound approved by the FDA is \$1,395 million, while the capitalized R&D cost per approved new compound is \$2,558 million, in 2013 dollars. These numbers increase to \$1,861 million and \$2,870 million, respectively, once the R&D costs incurred after the FDA approval are added. See Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 26–27 (2016) [hereinafter DiMasi 2016]. Compared to the 2003 study, estimated out-of-pocket expenses increased by 166 percent, while estimated capitalized costs increased by 145 percent. *Id.* at 31. The scholars reasoned that the increase resulted from higher real out-of-pocket costs, as well as higher failure rates in human-subject testing. *Id.*

<sup>149</sup> The comments cited here relate to both the 2003 and the follow-up 2016 studies.

<sup>150</sup> DiMasi 2003, *supra* note 148, at 156; DiMasi 2016, *supra* note 148, at 22.

<sup>151</sup> In addition to the issues raised here, one commentator argued that R&D costs are high because pharmaceutical companies pay excessive marketing fees to researchers and doctors for their support in clinical trials and lobbying activities and base their choices for research locations not on cost-minimization, but on an attempt to maximize their political influence. Baker, *supra* note 120, at 8–15.

<sup>152</sup> Light & Warburton, *supra* note 15, at 5 (indicating that the costs taken into account by the companies in calculating R&D costs are not clear, and that large and indirectly related costs (e.g., cost of land and buildings used not only in relation to the R&D activities, cost of company-wide software or hardware upgrades, legal expenses for developing patent protection, and legal defense against challenges, etc.) are often indicated as R&D costs by pharmaceutical companies).

<sup>153</sup> Burk & Lemley, *supra* note 104, at 1616 n.131.

<sup>154</sup> DiMasi 2003, *supra* note 148, at 171–72.

<sup>155</sup> CONG. BUDGET OFF., *supra* note 140, at 19; Emily Marden, *Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?*, 11 MINN. J.L. SCI. & TECH. 217, 234 (2010).

<sup>156</sup> CONG. BUDGET OFF., *supra* note 140, at 19; Light & Warburton, *supra* note 15, at 38; see, e.g., THE INST. FOR HEALTH & SOCIO-ECONOMIC POL'Y, THE R&D SMOKE SCREEN: THE PRIORITIZATION OF MARKETING & SALES IN THE PHARMACEUTICAL INDUSTRY 6 (2016), [https://nurses.3cdn.net/e74ab9a3e937fe5646\\_afm6bh0u9.pdf](https://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf) [<https://perma.cc/D8UM-T2SK>].

“unknown and highly variable.”<sup>157</sup> The critique indicates a significantly lower amount of \$43.4 million as a more realistic R&D cost per new drug.<sup>158</sup>

#### D. Patentability of AI Systems and AI-Generated Inventions

Two issues lie at the intersection between AI and patents. The first issue is the patentability of AI systems, and the second is the patentability of inventions generated by these systems. For the purposes of patentability both in the United States and other jurisdictions, AI systems are treated as software inventions.<sup>159</sup> However, given the potential economic, social and ethical impacts of these systems, some commentators argue that their patentability should be evaluated separately from other kinds of software inventions.<sup>160</sup> Essential medicines enabled by AI must be subject to different standards of patentability due to similar considerations. The importance of access to essential medicines in ensuring that the human right to health is enjoyed by all and AI’s disruption of pharmaceutical innovation, requires a higher bar of patentability for essential medicines enabled by AI.

The role of AI systems in the innovation process varies from one invention to another. In some cases, AI systems assume the role of assistance tools, aiding inventors in performing certain tasks, like a calculator or a computer.<sup>161</sup> In other cases, AI systems act autonomously, carrying out all steps of the invention process without human intervention.

Questions of patentability arise where the role of AI systems increases in the innovation process and human involvement and direction diminish. A number of issues need to be resolved in order to answer the question of whether inventions created by AI can and should be eligible for patent

<sup>157</sup> Light & Warburton, *supra* note 15, at 39–40.

<sup>158</sup> *Id.* at 43–47.

<sup>159</sup> In the United States, software can be patented provided that the claim passes the *Alice-Mayo* test, which requires courts to identify the abstract idea in a claim and assess whether the claim adds “significantly more” to it. See *Mayo Collaborative Servs. v. Prometheus Lab’ys Inc.*, 566 U.S. 66, 73 (2012); *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 215 (2014); NARD, *supra* note 109, at 221–32. In Europe, the European Patent Office (EPO) responded to the rapid growth in the use of AI by issuing guidelines concerning examination of AI inventions. According to the guidelines, AI and machine learning “are *per se* of an abstract mathematical nature,” even if they can be trained, and AI inventions are not patentable, absent the use of technical means. See EUR. PAT. OFF., GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE pt. G, ch. II-5, § 3.3.1 (2018), [http://documents.epo.org/projects/babylon/eponet.nsf/0/2A358516CE34385CC125833700498332/\\$File/guidelines\\_for\\_examination\\_2018\\_hyperlinked\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/2A358516CE34385CC125833700498332/$File/guidelines_for_examination_2018_hyperlinked_en.pdf) [<https://perma.cc/KF5G-PU9W>].

<sup>160</sup> KAY FIRTH-BUTTERFIELD & YOON CHAE, WORLD ECON. F., ARTIFICIAL INTELLIGENCE COLLIDES WITH PATENT LAW 8–9 (2018), [http://www3.weforum.org/docs/WEF\\_48540\\_WP\\_End\\_of\\_Innovation\\_Protecting\\_Patent\\_Law.pdf](http://www3.weforum.org/docs/WEF_48540_WP_End_of_Innovation_Protecting_Patent_Law.pdf), [<https://perma.cc/GHH2-65GL>].

<sup>161</sup> Ryan Abbott, *I Think, Therefore I Invent: Creative Computers and the Future of Patent Law*, 57 B.C. L. REV. 1079, 1093–94 (2016).

protection. The issues, most of which are also raised in the United States Patent and Trademark Office’s (USPTO) Request for Comments on Patenting Artificial Intelligence Inventions,<sup>162</sup> include the legal definition of inventorship, interpretation of the patent eligibility standard of obviousness, and the need for incentivization.

The issue of whether AI-enabled inventions require incentivization relates directly to economic justifications of patent law. The purpose of the patent system is to incentivize innovation, and it is uncertain whether automated inventions also require incentivization.<sup>163</sup> While it is clear that AI systems themselves do not need any incentivization to innovate, some commentators argue that the patent system should expand to inventions created by AI, as patents provide the necessary incentives for developers of these systems.<sup>164</sup>

---

<sup>162</sup> The Request for Comments refers to

“[i]nventions that utilize AI, as well as inventions that are developed by AI” as AI inventions, and seeks answers to the following questions: . . .

2. What are the different ways that a natural person can contribute to conception of an AI invention and be eligible to be a named inventor? . . .
3. Do current patent laws and regulations regarding inventorship need to be revised to take into account inventions where an entity or entities other than a natural person contributed to the conception of an invention?
4. Should an entity or entities other than a natural person, or company to which a natural person assigns an invention, be able to own a patent on the AI invention? . . .
5. Are there any patent eligibility considerations unique to AI inventions?
6. Are there any disclosure-related considerations unique to AI inventions? . . .
7. How can patent applications for AI inventions best comply with the enablement requirement, particularly given the degree of unpredictability of certain AI systems?
8. Does AI impact the level of a person of ordinary skill in the art? If so, how? For example: Should assessment of the level of ordinary skill in the art reflect the capability possessed by AI?
9. Are there any prior art considerations unique to AI inventions?
10. Are there any new forms of intellectual property protections that are needed for AI inventions, such as data protection?

Request for Comments on Patenting Artificial Intelligence Inventions, 84 Fed. Reg. 44889, 44889 (Aug. 27, 2019).

<sup>163</sup> See Fraser, *supra* note 3, at 325–28 (discussing issues arising from incentivizing “automated invention[s]” through the patent system); see also Shlomit Yanisky Ravid & Xiaoqiong Liu, *When Artificial Intelligence Systems Produce Inventions: An Alternative Model for Patent Law at the 3A Era*, 39 CARDOZO L. REV. 2215, 2240 (2018) (asserting that only people, not AI systems need incentives to innovate).

<sup>164</sup> See, e.g., Abbott, *supra* note 161, at 1104 (asserting that allowing patent protection to inventions generated by AI would “encourage innovation under an incentive theory”); Anne Lauber-Rönsberg & Sven Hetmank, *The Concept of Authorship and Inventorship Under Pressure: Does Artificial Intelligence Shift Paradigms?*, 14 J. INTELL. PROP. L. & PRAC. 570, 575–76 (2019) (asserting that while AI systems

A second issue raised by the increasing use of AI in the innovation process is whether the obviousness standard of patentability must be reevaluated. The issue of obviousness is particularly important as it relates not only to inventions created autonomously by AI systems but also to inventions enabled by these systems.

In order to be eligible for patent protection, inventions must be non-obvious.<sup>165</sup> The Patent Act references a notional “person having ordinary skill in the art” (PHOSITA) in determining whether an invention is obvious.<sup>166</sup> An invention is not eligible for patent protection if the difference between the invention and related prior art is obvious to PHOSITA.<sup>167</sup> PHOSITA varies based on the invention, the field of related art, and the level of education of those active in the related field.<sup>168</sup> Certain fields, such as pharmaceuticals, will likely require a higher skill level.<sup>169</sup> In any case, the more sophisticated the PHOSITA becomes, the more likely a new invention will be deemed obvious.<sup>170</sup> Once a legal fiction, developments in technology have made an entity with full knowledge of prior art a reality.<sup>171</sup> Some commentators thus advocate for redefining the concept of PHOSITA and the standard of obviousness.<sup>172</sup>

The final, and perhaps most important question raised by inventions created by AI systems is whether these systems can be deemed as inventors under the existing patent system. Neither the Patent Act nor the USPTO has

---

do not need incentivization, patentability of their inventions may be “necessary to stimulate investments in the research and development of AI”).

<sup>165</sup> See 35 U.S.C. § 103.

<sup>166</sup> *Id.*

<sup>167</sup> See *id.*

<sup>168</sup> See *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (indicating that the level of ordinary skill will be determined based on a non-exhaustive list of factors, including “type of problems encountered in [the] art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field”).

<sup>169</sup> See Ryan Abbott, *Everything is Obvious*, 66 UCLA L. REV. 2, 19 (2019).

<sup>170</sup> *Id.* at 17.

<sup>171</sup> Abbott, *supra* note 161, at 1124–25 (arguing that creative computers will not only have full knowledge of the prior art in the relevant field but also in other fields, expanding the “universe of prior art”).

<sup>172</sup> See *id.* (arguing that as the role of creative machines in the innovation process increases, standards for determining PHOSITA and obviousness should evolve accordingly); Liza Vertinsky & Todd M. Rice, *Thinking About Thinking Machines: Implications of Machine Inventors for Patent Law*, 8 B.U. J. SCI. & TECH. L. 574, 608 (2002) (arguing that tests of patentability, including “usefulness, novelty and non-obviousness, need to be” reevaluated to accommodate the changes in the concepts of inventorship and the innovation process); Fraser, *supra* note 3, at 320 (arguing that PHOSITA and the bar for obviousness may need to be reevaluated in light of increased use of AI).

an explicit prohibition against patentability of AI-generated inventions.<sup>173</sup> That said, the Patent Act defines inventor as the “individual . . . who invented or discovered the subject matter of the invention,”<sup>174</sup> and failure to correctly indicate inventorship may result in invalidity of the patent.<sup>175</sup> Accordingly, the requirement that individuals be inventors would not only prevent AI systems from holding patent rights but also the patentability of the resulting inventions.

A recent significant development in this area involves patent applications for two inventions created autonomously by an AI system, which listed the system itself as the inventor.<sup>176</sup> The system, called DABUS, uses neural networks and general information in a given field to formulate problems and create novel solutions without human intervention.<sup>177</sup> It does not need to be trained or tasked with solving particular problems; it is capable of identifying problem areas and offering solutions completely autonomously.<sup>178</sup>

The system’s creator and a team of experts applied for patents in the United States, the European Union, and the United Kingdom, as well as under the Patent Cooperation Treaty, for two inventions created by DABUS.<sup>179</sup> The applications marked the first time an AI system, not its creator, was listed as the inventor.<sup>180</sup> The USPTO, as well as the European Patent Office (EPO) and the United Kingdom Intellectual Property Office (UKIPO), discussed the issue of inventorship in their responses to the applications.

---

<sup>173</sup> The U.S. Copyright Office, on the other hand, explicitly requires human authorship for a work to be copyrightable. According to the Copyright Office, any work “produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or intervention from a human author” will not be protected under copyright. See U.S. COPYRIGHT OFF., COMPENDIUM OF U.S. COPYRIGHT OFFICE PRACTICES § 313.2 (3d ed. 2017), <https://www.copyright.gov/comp3/docs/compendium.pdf> [<https://perma.cc/ZTC9-U6WF>].

<sup>174</sup> 35 U.S.C. § 100(f).

<sup>175</sup> NARD, *supra* note 109, at 866.

<sup>176</sup> See *Patent Applications*, ARTIFICIAL INVENTOR, <http://artificialinventor.com/patent-applications/> [<https://perma.cc/YS6A-YT6D>].

<sup>177</sup> *Id.*; see generally *IEI’s Patented Creativity Machine® Paradigm*, IMAGINATION ENGINES, [http://imagination-engines.com/iei\\_cm.php](http://imagination-engines.com/iei_cm.php) [<https://perma.cc/UHE8-SKS6>].

<sup>178</sup> See *Patent Applications*, *supra* note 176.

<sup>179</sup> The two inventions are a beverage container that provides better grip, allowing easier transportation, and an alarm signal that more effectively attracts attention. *Id.*

<sup>180</sup> Other AI systems, such as the Invention Machine, have autonomously created patentable inventions before, but the patents have been issued to the creator of the system. See, e.g., Jonathan Keats, *John Koza Has Built an Invention Machine*, POPULAR SCI. (Apr. 19, 2006), <https://www.popsi.com/scitech/article/2006-04/john-koza-has-built-invention-machine/> [<https://perma.cc/KM63-GSGU>]; U.S. Patent No. 6,847,851 (filed July 12, 2002).

The USPTO responded to the application with a Notice to File Missing Parts of Nonprovisional Application, due to the applicant's failure to "identify each inventor by his or her legal name."<sup>181</sup> The USPTO's final decision on the applicant's petition to vacate the notice discussed the issue of inventorship and machine inventors in detail. The decision underlined that the legal definition of invention under Section 100(a) of the Patent Act refers to an "individual," and that by using such wording as "whoever invents or discovers" in Section 101 and pronouns "himself" and "herself" in Section 115, the Patent Act suggests that inventors must be natural persons.<sup>182</sup> The USPTO noted that "patent statutes preclude such a broad interpretation" to construe the term inventor to cover machines.<sup>183</sup> The decision went on to explain that the idea of human inventorship is further supported by several Federal Circuit decisions, Title 37 of the Code of Federal Regulations, as well as the Manual of Patent Examining Procedure.<sup>184</sup>

The EPO similarly rejected the applications on the grounds that they failed to "meet the requirement of the [European Patent Convention] that an inventor designated in the application has to be a human being, not a machine."<sup>185</sup> In its decisions, the EPO pointed out that AI systems lack legal personality and thus cannot have rights that arise from being an inventor.<sup>186</sup> The EPO also declined the applicants' assertion that they should acquire the rights associated with the patent as DABUS's employers, asserting that AI systems "can be neither employed nor can they transfer any rights to a successor in title."<sup>187</sup> Similarly focusing on inventorship issues, the UKIPO concluded that the application did not include a proper statement of

---

<sup>181</sup> *In re* Application No. 16/524,350 at 1 (Decision on Petition Apr. 22, 2020), [https://www.uspto.gov/sites/default/files/documents/16524350\\_22apr2020.pdf](https://www.uspto.gov/sites/default/files/documents/16524350_22apr2020.pdf) [<https://perma.cc/5AUV-TM2R>] [hereinafter DABUS Application]. Stephen Thaler, developer of DABUS, has filed a complaint for declaratory and injunctive relief against the USPTO, claiming that the rejection of DABUS's patent application "create a novel substantive requirement for patentability that is contrary to existing law and at odds with the policy underlying the patent system." Complaint for Declaratory and Injunctive Relief at 2, *Thaler v. Iancu*, No. 1:20-cv-00903-LMB-TCB (E.D. Va. Aug. 6, 2020), <https://artificialinventor.com/wp-content/uploads/2020/09/Complaint.pdf>.

<sup>182</sup> DABUS Application, *supra* note 181, at 4.

<sup>183</sup> *Id.*

<sup>184</sup> *See id.* at 4–6.

<sup>185</sup> *EPO Refuses DABUS Patent Applications Designating a Machine Inventor*, EUR. PAT. OFF. (Dec. 20, 2019), <https://www.epo.org/news-issues/news/2019/20191220.html> [<https://perma.cc/8GG9-HRDK>].

<sup>186</sup> Eur. Pat. Off., Grounds for Decision: App. No. 18 275 163.6, ¶ 27 (Jan. 27, 2020), <https://register.epo.org/application?documentId=E4B63SD62191498&number=EP18275163&lng=en&npl=false> [<https://perma.cc/3S7X-V94D>] [hereinafter App. No. 18 275 163.6]; Eur. Pat. Off., Grounds for Decision: App. No. 18 275 174.3, ¶ 28 (Jan. 27, 2020), <https://register.epo.org/application?documentId=E4B63OBI2076498&number=EP18275174&lng=en&npl=false> [<https://perma.cc/32NX-ZEDT>].

<sup>187</sup> APP. NO. 18 275 163.6, *supra* note 186, ¶ 30.

inventorship, and accepted the applications withdrawn accordingly.<sup>188</sup> In its evaluations, the UKIPO ruled that as “DABUS is a machine and not a natural person, . . . it cannot be regarded as an inventor.”<sup>189</sup>

### *E. The Need for Reform*

The pharmaceutical industry asserts that robust patent protection is required for innovation and that the current system helps reimburse the unpredictable, costly and lengthy R&D processes associated with drug development.<sup>190</sup> The ultimate goal of the patent system is to provide incentives for innovation for the benefit of the public.<sup>191</sup> However, studies on whether the patent system has a positive impact on innovation are inconclusive.<sup>192</sup>

Moreover, social costs of the patent system, especially as they relate to access, are particularly concerning in the case of pharmaceuticals.<sup>193</sup> Pharmaceuticals are different from other products, as their consumption is mostly based on need, as opposed to choice.<sup>194</sup> Users of pharmaceutical products are not consumers in the traditional sense of the word.<sup>195</sup> They are patients who depend on the products for purposes of treatment and health care.<sup>196</sup> Lack of access to certain drugs thus poses a risk to the health and

<sup>188</sup> Stephen L. Thaler, BL O/741/19, ¶¶ 24–27, 30 (U.K. Intell. Prop. Off. Dec. 4, 2019) (decision), <https://www.ipo.gov.uk/p-challenge-decision-results/o74119.pdf> [<https://perma.cc/6E4D-K4UW>].

<sup>189</sup> *Id.* ¶ 20.

<sup>190</sup> See FTC REPORT ON COMPETITION AND PATENT LAW, *supra* note 102, at 1, 4, 9; Eisenberg, *supra* note 102, at 346, 350; Kuhlik, *supra* note 102, at 94–99; Light & Warburton, *supra* note 15, at 1–2; Roin, *supra* note 15, at 510–511; Scherer, *supra* note 15, at 103; Rowland, *supra* note 102.

<sup>191</sup> MERGES ET AL., *supra* note 112, at 13, 17; Lemley, *supra* note 11, at 1031.

<sup>192</sup> WIPO *Report on the International Patent System*, *supra* note 109, at 9–10 (indicating that it is difficult to assess the effectiveness of the patent system on innovation due to a lack of conclusive empirical evidence); Baker, *supra* note 120, at 11 (indicating that it is not clear that the patent system is “the most efficient way to direct research”); HAHN, *supra* note 107, at “Executive Summary” (reviewing literature on “the role of patent strength in spurring innovation, diffusing information, transferring technology, speeding commercial development of inventions, and stimulating economic growth,” and concluding that there is no clear answer to the question of appropriate scope and duration of patent rights); Sakakibara & Branstetter, *supra* note 103, at 78 (concluding that the Japanese patent reforms strengthening patent protection did not result in increased R&D efforts and innovation output).

<sup>193</sup> Sachs, *supra* note 117, at 161 (asserting that in the case of pharmaceuticals, deadweight loss may put patients’ lives at stake); Gifford, *supra* note 101, at 123–24 (indicating that deadweight loss is large in the pharmaceutical industry on a global scale); Flynn et al., *supra* note 117, at 186 (indicating that deadweight loss has added significance for drugs essential to life and health); Outterson, *supra* note 117, at 201–02 (discussing the social cost of pharmaceutical patents, and indicating that higher prices hinder medical access).

<sup>194</sup> Joseph, *supra* note 138, at 436.

<sup>195</sup> See David Henry & Andrew Searles, *Pharmaceutical Pricing Policy*, in MANAGING ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES 9.1, 9.6 (Martha Embrey & Marian Ryan eds., 2012).

<sup>196</sup> Joseph, *supra* note 138, at 436.

lives of individuals.<sup>197</sup> As such, balancing access and incentivization is particularly important in the pharmaceutical industry.

While pharmaceutical companies are for-profit entities, the nature of their products begs the question of whether a different approach should be adopted towards their products. Under the current system, pharmaceutical companies use exclusivity rights to charge exorbitant prices.<sup>198</sup> The human right to health care cannot be achieved without proper access to essential medicines. The next Part proposes models that maintain the benefits of the patent system without compromising access to essential medicines.

### III. RECALIBRATING ACCESS AND INCENTIVIZATION

The patent system, and the intellectual property regime in general, is one of the many available models aimed at incentivizing innovation.<sup>199</sup> Government incentives such as prizes and grants currently complement patents in fields of research where additional incentivization is necessary.<sup>200</sup> Many countries also rely on tax incentives to increase R&D activity.<sup>201</sup> The United States offers tax incentives for research and experimental expenditures, as well as R&D tax credits, including a credit for pharmaceutical companies engaged in orphan drugs<sup>202</sup> research.<sup>203</sup> While prizes and grants directly contribute to R&D funds, tax incentives decrease R&D costs.<sup>204</sup>

---

<sup>197</sup> See Sachs, *supra* note 117, at 161; Flynn et al., *supra* note 117, at 186; Outtersson, *supra* note 117, at 202.

<sup>198</sup> MERGES ET AL., *supra* note 112, at 13; Gifford, *supra* note 101, at 83; Hemel & Larrimore Ouellette, *supra* note 112, at 312.

<sup>199</sup> See SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 38, 228 (2004); Michael Kremer & Heidi Williams, *Incentivizing Innovation: Adding to the Tool Kit*, 10 INNOVATION POL'Y & ECON. 1, 2 (2010); Hemel & Larrimore Ouellette, *supra* note 112, at 304; Posner, *supra* note 104, at 58–59; Amy Kapczynski, *Innovation Policy for a New Era*, 37 J.L. MED. & ETHICS 264, 264 (2009).

<sup>200</sup> Hemel & Larrimore Ouellette, *supra* note 112, at 316.

<sup>201</sup> Jacob Nussim & Anat Sorek, *Theorizing Tax Incentives for Innovation*, 36 VA. TAX REV. 25, 48 (2017); SILVIA APPELT ET AL., ORG. FOR ECON. CO-OPERATION & DEV., POLICY PAPERS NO. 32, R&D TAX INCENTIVES: EVIDENCE ON DESIGN, INCIDENCE AND IMPACTS 6 (2016), <https://www.oecd-ilibrary.org/docserver/5jlr8fldqk7j-en.pdf> [<https://perma.cc/76YT-F65G>]. As of 2019, thirty out of the thirty-six member countries for the Organisation for Economic Co-operation and Development (OECD) provide preferential tax treatment to R&D expenditures. See *Measuring Tax Support for R&D and Innovation: Indicators*, OECD, <http://www.oecd.org/sti/rd-tax-incentive-indicators.htm> [<https://perma.cc/T3HG-K6U6>].

<sup>202</sup> Orphan diseases are those that affect fewer than 200,000 people in the United States. A disease may also be categorized as an orphan disease if it affects more than 200,000, but there is no reasonable expectation that the cost of developing and offering the drug in the market would be recovered from sales. 21 U.S.C. § 360bb(a)(2).

<sup>203</sup> 26 U.S.C. §§ 41, 45C, 174.

<sup>204</sup> Hemel & Larrimore Ouellette, *supra* note 112, at 311. There are at least two other incentives that are particularly important for the pharmaceutical industry. Under advance market commitments (AMCs),

In recent years, costs associated with the patent system have increased interest in alternative incentive methods.<sup>205</sup> “[S]trong public interest” in access<sup>206</sup> has led to a number of proposals specific to the pharmaceutical industry. These proposals include a global R&D treaty<sup>207</sup> and a national medical innovation prize fund,<sup>208</sup> both relying on a portion of the gross domestic product (GDP) to fund R&D in the health care industry.<sup>209</sup> The models proposed in the following section rely on funding through similar mechanisms to accommodate innovating companies in the absence of patent rights.

### A. Main Considerations

#### 1. Different Approaches to Essential and Non-Essential Medicines

In evaluating access to pharmaceuticals, WHO differentiates between essential and non-essential medicines. Essential medicines are those that must be available at all times in adequate amounts at affordable prices.<sup>210</sup> WHO has been publishing essential medicines lists based on current health

---

sponsors undertake to purchase a certain number of products at a predetermined price prior to development. AMCs aim to encourage investment by increasing expected revenues and allowing pharmaceutical companies to foresee and calculate potential returns. See Ernst R. Berndt et al., *Advance Market Commitments for Vaccines Against Neglected Diseases: Estimating Costs and Effectiveness*, 16 HEALTH ECON. 491, 493 (2007); Ernst R. Berndt & John A. Hurvitz, *Vaccine Advance-Purchase Agreements for Low-Income Countries: Practical Issues*, 24 HEALTH AFFS. 653 (2005); Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. ECON. PERSPS. 67, 83 (2002). In addition to systems that directly or indirectly effect R&D costs, first-mover advantages resulting from being the first to market a product also have a significant role in the pharmaceutical industry. Studies indicate that various reasons such as reputation, slow information diffusion, and capturing the medical profession earlier, lead to a significant advantage for first entrants in the pharmaceutical industry and that pharmaceutical companies use their position as first entrants to build brand loyalty, as well as prevent competitors from using such assets as manufacturing and distribution chains. See Jonathan M. Barnett, *Private Protection of Patentable Goods*, 25 CARDOZO L. REV. 1251, 1257 (2004); Michele Boldrin & David K. Levine, *The Economics of Ideas and Intellectual Property*, 102 PNAS 1252, 1254 (2005); Marvin B. Lieberman & David B. Montgomery, *First-Mover Advantages*, 9 STRATEGIC MGMT. J. 41, 42–46 (1988).

<sup>205</sup> Baker, *supra* note 120, at 25; Kremer & Williams, *supra* note 199, at 1.

<sup>206</sup> WIPO *Report on the International Patent System*, *supra* note 109, at 79.

<sup>207</sup> Proposals focus on a global treaty where each country will contribute a certain percentage of their gross domestic product to fund pharmaceutical R&D. See, e.g., Baker, *supra* note 120, at 14–15; Comm. on the Env’t, Pub. Health & Food Safety, Report on EU Options for Improving Access to Medicines, Doc. A8-0040/2017, at 36 (Feb. 14, 2017); DIMITRA PANTELI & SUZANNE EDWARDS, WORLD HEALTH ORG. [WHO], POLICY BRIEF NO. 29, ENSURING ACCESS TO MEDICINES: HOW TO STIMULATE INNOVATION TO MEET PATIENTS’ NEEDS? 14 (2018); Gifford, *supra* note 101, at 124; Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 0147, 0147–50 (2004).

<sup>208</sup> The Medical Innovation Prize Fund Act of 2017 proposes an R&D fund in place of any exclusion rights in relation to drugs, biological products, and related manufacturing processes. See Medical Innovation Prize Fund Act of 2017, S. 495, 115th Cong. § 5 (2017).

<sup>209</sup> See sources cited *infra* note 245.

<sup>210</sup> WHO Essential Medicines, *supra* note 18.

needs since 1977.<sup>211</sup> WHO's periodically updated lists provide a guideline for countries to develop their own lists.<sup>212</sup> The latest WHO list includes drugs ranging from antibiotics to drugs used for the treatment of cancer, HIV, and malaria.<sup>213</sup>

Access to essential medicines is “a key component of the fulfillment of the human right to health.”<sup>214</sup> The models here thus focus on essential medicines. The models aim to increase access by reforming patentability standards to leave some essential medicines enabled by AI outside the scope of patentability, or alternatively, decreasing the patent term available for such medicines. Non-essential medicines will remain under the existing system, as they are less likely to have a significant impact on global health. Patents on these medicines will allow innovating companies to freely decide prices in the absence of competitors and help raise funds for future R&D investments.

## 2. *The Path to Patent Law Reform*

Congress is limited by the United States Constitution in determining the sphere of patent protection and granting exclusivity for limited terms.<sup>215</sup> That said, Congress is free to decide the scope and breadth of intellectual property rights.<sup>216</sup> It may impose conditions on patent rights, limit duration, refuse granting privileges, or provide special rights for certain industries, as opposed to employing a uniform intellectual property system.<sup>217</sup> As such, Congress has the authority to subject inventions concerning essential medicines enabled by AI to different eligibility standards, as well as to confer a different scope of rights to such inventions.

Nevertheless, any reform to the existing patent system must be compliant with the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS).<sup>218</sup> TRIPS requires patentability of all novel, useful, and non-obvious inventions, and prohibits differential treatment based on

<sup>211</sup> *Id.*

<sup>212</sup> Frederick Abbott et al., *Global Health Law*, 77 INT'L L. ASS'N REP. CONF. 203, 210 (2016).

<sup>213</sup> See WORLD HEALTH ORG. [WHO], MODEL LIST OF ESSENTIAL MEDICINES (21st ed. 2019), <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1> [<https://perma.cc/R3DM-HL2D>].

<sup>214</sup> *Id.*

<sup>215</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>216</sup> ROBERT L. HARMON, HARMON ON PATENTS: BLACK-LETTER LAW AND COMMENTARY 30 (2007).

<sup>217</sup> *Id.*

<sup>218</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

technology.<sup>219</sup> Article 27.2 provides an exception to this rule in cases where protection of human life and health require exclusion of patentability.<sup>220</sup> However, the provision indicates that an invention cannot be excluded from patentability based on this exception “merely because the exploitation is prohibited by . . . law.”<sup>221</sup>

The models proposed here do not exclude pharmaceuticals from patentability in general but merely change the standard of patentability, or alternatively the exclusivity period, for essential medicines enabled by AI with an aim to ensure wider access to pharmaceuticals. There is thus an argument to be made that the proposed law reforms fall within the scope of the exception. However, the best course of action is to urge the World Trade Organization to recognize the right of countries to subject essential medicines enabled by AI to different standards.<sup>222</sup>

### 3. *Regulatory Exclusivity Conferred by the FDA*

In addition to patents, FDA regulations provide two types of regulatory exclusivities for certain groups of pharmaceuticals.<sup>223</sup> The first type, market exclusivity, prohibits the FDA from granting marketing approval to substitute drugs within the exclusivity period; while the second type, data exclusivity, prohibits competitors from relying on innovator company data to receive marketing approval but allows approval of drugs that rely on the competitor’s own data.<sup>224</sup> To allow the proposed law reforms to have their full effect and maximize access to essential medicines, Congress must also abolish these marketing and data exclusivity practices.

---

<sup>219</sup> *Id.* art. 27.1.

<sup>220</sup> *Id.* art. 27.2.

<sup>221</sup> *Id.*

<sup>222</sup> A similar proposal has been made before by International Law Association’s Global Health Law Committee. *See* Abbott et al., *supra* note 212, at 216 (proposing that the UN General Assembly adopt a resolution to urge the World Trade Organization (WTO) Ministerial Conference to “provide an authoritative interpretation of articles 27 and 30” that allows member states to exclude essential medicines from patentability).

<sup>223</sup> As of 2017, the FDA enforces sixteen exclusivities, “relating to new chemical entities, new clinical studies, orphan drugs, pediatric studies, generic drugs, antibiotics, qualified infectious disease products, enantiomers, and biologics.” *See* JOHN R. THOMAS, CONG. RES. SERV., R44951, REGULATORY EXCLUSIVITY REFORM IN THE 115TH CONGRESS 1–3 (2017), <https://fas.org/sgp/crs/misc/R44951.pdf> [<https://perma.cc/5N87-JELL>].

<sup>224</sup> *See, e.g.*, 21 C.F.R. § 314.108 (2020); 21 U.S.C. § 360bb(a)(2); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 505(A), 111 Stat. 2296, 2305 (1997); 21 U.S.C. § 355(j)(5)(B)(iv); Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001, 124 Stat. 804 (2010); *see also* JOHN R. THOMAS, *supra* note 223, at 4.

### B. Rethinking Patent Law for Essential Medicines Enabled by AI

Pharmaceutical patents are relatively new in many countries. France, Germany, Switzerland, and a number of other jurisdictions did not allow patent protection for pharmaceutical products until after the mid-1900s.<sup>225</sup> Before TRIPS, over forty countries did not protect pharmaceutical products under a patent regime.<sup>226</sup> While these countries issued patents for manufacturing processes, third parties were allowed to produce the same product through different, unpatented processes.<sup>227</sup>

This pre-TRIPS model may be ideal where the ultimate aim is to maximize access. However, renouncing incentivization in favor of access is an unrealistic approach given the industry's overemphasis on its reliance on the patent system.<sup>228</sup> The models proposed in this Article thus aim to maintain the benefits of the patent system and increase access to essential medicines.

#### 1. Reforming Patent Eligibility Standards

Redefining standards of patentability and patentable subject matter, to leave essential medicines enabled by AI outside the scope of the patent system will increase access by ensuring a competitive market, which will drive prices down. In this model, non-essential medicines will still be entitled to patent protection, provided that the invention satisfies existing requirements for patent eligibility. Innovating companies will similarly be entitled to patent protection if they can demonstrate that their R&D processes do not rely on AI systems.

The reform will be accompanied by a ten-year transition period where an otherwise ineligible essential medicine will be entitled to patent protection if (i) documentation from the FDA shows it to be more effective than alternative products in the market, or (ii) if the innovating company demonstrates the associated R&D costs to be considerably higher than industry average.<sup>229</sup>

---

<sup>225</sup> BOLDRIN & LEVINE, *supra* note 140, at 215–18; DUTFIELD, *supra* note 120, at 127–28.

<sup>226</sup> *WTO and the TRIPS Agreement*, WORLD HEALTH ORG. [WHO], [https://www.who.int/medicines/areas/policy/wto\\_trips/en/](https://www.who.int/medicines/areas/policy/wto_trips/en/) [perma.cc/P8SB-S4HJ].

<sup>227</sup> BOLDRIN & LEVINE, *supra* note 140, at 215–18; DUTFIELD, *supra* note 120, at 127–28.

<sup>228</sup> See FTC REPORT ON COMPETITION AND PATENT LAW, *supra* note 102, at 1, 4, 9; Kuhlik, *supra* note 102, at 94–99; Eisenberg, *supra* note 100, at 346, 350; Light & Warburton, *supra* note 15, at 1–2; Roin, *supra* note 15, at 510–11; Scherer, *supra* note 15, at 103; Rowland, *supra* note 102.

<sup>229</sup> A similar system of exceptions is proposed by F. M. Scherer, who proposes shortened patent terms except in cases where first mover advantages are not sufficient or the related firm is small and has a limited market, or an individual request is made based on a number of claims, including extraordinarily high R&D costs compared to the relevant industry. See F. M. Scherer, *First Mover Advantages and Optimal Patent Protection* 13–14 (Harv. Kennedy Sch. Mossavar-Rahmani Ctr. for Bus. & Gov't, Working Paper No. RPP-2015-05, 2015).

The first exception will aid in directing R&D efforts to inventions with potential for more social value. Under the second exception, innovating companies investing heavily in their R&D processes, such as those developing in-house AI systems, will be entitled to patent protection for both essential and non-essential medicines. Through these exceptions, the new system will retain some of the incentives available under the current regime for a period of ten years. This transition period will allow for observation of the new system and for adjustment of its application if necessary.

## 2. *Shorter Exclusivity Term for Essential Medicines Enabled by AI*

An alternative model is to maintain the existing rules and standards of patentability and shorten the exclusivity term for essential medicines enabled by AI to five years.<sup>230</sup> The five-year term will commence on the earlier date of marketing approval by the FDA or date of marketing. Upon expiration of the five-year exclusivity term, third parties will be entitled to manufacture and sell the patented product against a royalty to be paid throughout the patent term.<sup>231</sup> Similar to the first model, non-essential medicines, as well as

---

[https://www.hks.harvard.edu/sites/default/files/centers/mrcbg/files/RPP\\_2015\\_05\\_Scherer.pdf](https://www.hks.harvard.edu/sites/default/files/centers/mrcbg/files/RPP_2015_05_Scherer.pdf) [perma.cc/GQ6M-MQ2H].

<sup>230</sup> A study analyzing R&D profitability for different market conditions and patent terms concluded that R&D investment is profitable under most market conditions regardless of patent term. *See id.* at 5–8. The study indicated that the patent system aids innovation most significantly in smaller markets and that short patent terms affect R&D investment decisions only in such markets and offered a five-year patent term as an efficient alternative to the existing system. *Id.* at 6–7, 13.

<sup>231</sup> As opposed to compulsory licensing under the TRIPS Agreement, the parties will not be required to negotiate licensing conditions in advance. Scholars have entertained the idea of similar systems, where third parties would be entitled to use inventions or related data upon payment of a compensation to the innovator during a predetermined period. *See* J. H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation*, 53 VAND. L. REV. 1743, 1744–98 (2000) (proposing a “compensatory liability regime” for sub-patentable inventions, such as databases, where the amount of compensation would be negotiated between the parties on a case-by-case basis, with the option to resort to arbitration in case of failure to reach an agreement or where contribution would be determined based on predetermined percentages of the third party’s gross revenue depending on how significant use of the original invention is in the subsequent product); James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS HEALTH L. 155, 180–86 (2009) (discussing a compensatory liability system, which can range from a mandatory compulsory license to less stringent applications, allowing third parties to use the invention upon payment of appropriate remuneration); Lea M. Gulotta, *Pharming Out Data: A Proposal for Promoting Innovation and Public Health through a Hybrid Clinical Data Protection Scheme*, 51 VAND. J. TRANSNAT’L L. 1469, 1503–04 (2018) (proposing one-year regulatory data exclusivity for all pharmaceuticals, followed by four years of cost-sharing with subsequent users of related data); Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement*, 45 HARV. INT’L L.J. 443, 482–99 (2004) (proposing a system where generic manufacturers can use data from brand-name manufacturers upon payment of a compensation in proportion to the benefit they obtain from using such data, and providing a formula which can be altered based on market conditions, in terms of length of time during which the brand-name manufacturer is entitled to royalties, maximum number of competitors required to pay royalties, and interest rate to account for the time value of money).

inventions by companies which do not rely on AI in their R&D processes, will enjoy the current twenty-year exclusivity period. This reform will also similarly be accompanied by a ten-year transition period with exceptions for more effective drugs and R&D costs exceeding the industry average.

The most important aspect of this model is to adopt a fair and efficient royalty scheme. Royalties will be determined based on the total cost of R&D, which the innovating company will submit to the USPTO during the patent application process,<sup>232</sup> and shared by the licensees wishing to manufacture and sell the product. The contribution of each licensee may be determined based on the markets where it plans to offer the product,<sup>233</sup> or the total cost may be shared equally by all licensees.<sup>234</sup>

Under the former scheme, the licensee will be liable for ten percent of the total costs to sell the product in a market that represents ten percent of the global market. In the latter, the total cost will be divided equally between the licensees, and the amount of royalties owed will decrease with new licensees. The maximum amount of compensation the innovating company can receive may be limited to the total cost of R&D or to a predetermined multiple of this amount.

### C. *Evaluating the Potential Effects of Proposed Law Reforms*

There are multiple advantages to the models proposed in this Article. In the first model, absence of exclusivity rights will enable competitors to enter the market as soon as the innovating company makes the drug available to the market. In the second model, a shortened exclusivity term will allow competitors to enter the market in the relatively shorter period of time of five years. In both cases, increased competition will bring down prices. In practice, this will translate into more people having access to essential medicines.<sup>235</sup> By removing the restrictions on access to inventions by competitors and innovators in other fields, the proposed models will also have a positive impact on subsequent innovation.<sup>236</sup>

---

<sup>232</sup> What items fall under R&D costs should be defined by the USPTO and the FDA, following consultations with the industry.

<sup>233</sup> For a similar method, see Gulotta, *supra* note 231, at 1503–04 (discussing a “*pro rata* data exclusivity and cost sharing” model).

<sup>234</sup> For a similar method, see Fellmeth, *supra* note 231, at 481–82 (discussing a “simple division royalties model”).

<sup>235</sup> For a discussion of high prices limiting access to pharmaceuticals, see Gifford, *supra* note 101, at 83, 102 n.118; see also Dam, *supra* note 116, at 247; Barnett, *supra* note 101, at 1269; Burstein & Murray, *supra* note 116, at 410; Roin, *supra* note 116, at 1023–24.

<sup>236</sup> For a discussion of the patent system’s effects on subsequent innovation, see Outterson, *supra* note 117, at 201–02; Stiglitz, *supra* note 120, at 1710; Roin, *supra* note 116, at 1023; NAT’L RSCH. COUNCIL OF THE NAT’L ACADS., *supra* note 125; Gold et al., *supra* note 101, at 1; Boldrin & Levine, *supra* note 122, at 1255.

One drawback is that both models require a determination of what constitutes enablement by AI. The USPTO will need to evaluate eligibility claims on a case-by-case basis and decide whether the role of the AI system amounts to more than a standard tool of research in each case. The models may also raise some concerns regarding incentivization. Especially in the absence of patent rights, innovating companies may shift their focus to non-essential medicines that will still be eligible for patent protection or opt out from using or disclosing their use of AI systems. The models must thus be accompanied by appropriate alternatives to preserve the benefits of the patent system. The incentive methods set forth in the next Section are designed to address these concerns. While these methods are aimed at incentivizing R&D in the absence of patent rights and associated exclusivity periods, they may be extended to the second model as necessary to supplement incentivization through royalties.

#### *D. Incentivizing R&D for Essential Medicines in the Absence of Patents*

##### *1. A National Prize Fund*

A 2017 bill, the Medical Innovation Prize Fund Act, recently proposed a national prize fund.<sup>237</sup> The bill recognized market exclusivity to be an “expensive, inefficient, and unfair mechanism to reward investments in new products”<sup>238</sup> and asserted that drug development would benefit from “greater sharing of knowledge, data, materials, and technologies.”<sup>239</sup> The bill recommended removing the link between R&D incentives and product prices, claiming that this will allow a dramatic decrease in the costs of innovation and an increase in access to inventions.<sup>240</sup> The bill thus proposed to abolish patents and market exclusivity for drugs and biological products, as well as related manufacturing processes,<sup>241</sup> and to fund R&D through a national prize fund.<sup>242</sup>

This Article similarly proposes a fund with a specific focus on essential medicines. Prizes will be awarded by a board, based on the impact of each drug on global public health,<sup>243</sup> and payments will be conditioned upon

---

<sup>237</sup> Medical Innovation Prize Fund Act of 2017, S. 495, 115th Cong. (2017).

<sup>238</sup> *Id.* § 2.

<sup>239</sup> *Id.* § 2(5).

<sup>240</sup> *Id.* § 2(3).

<sup>241</sup> *Id.* § 5.

<sup>242</sup> According to the bill, allocating 0.55 percent of the GDP in 2016 would have led to a fund of over \$100 billion. *Id.* § 2(4).

<sup>243</sup> In a 2019 Senate hearing, representatives of the pharmaceutical industry indicated that they favored “value-based” reimbursement, which would base compensation they receive from the market on how effective their drugs are. Rowland, *supra* note 102. For different methods of measuring health

abandonment of patents, if any. In addition to disclosure of all clinical trial data and other information enabling those “skilled in the art . . . to make and use” the invention,<sup>244</sup> eligibility for prizes will require disclosure of all relevant information on the AI system used in the R&D process.

A national prize fund designed in this manner will provide the incentives necessary to sustain essential medicines research. The government will also be in a position to allocate prizes to encourage investment in certain areas over others. For instance, higher prizes may be offered to essential medicines with smaller markets, such as orphan drugs. Prizes for AI-enabled essential medicines will also encourage the use of AI in the innovation process and allow access to data that will build a better understanding of how AI systems work.

## 2. *A Global R&D Treaty*

The need to balance access and incentivization has led to calls for a multilateral treaty to finance R&D and break the link between pharmaceutical prices and R&D costs.<sup>245</sup> Most notably, WHO proposed a global R&D treaty where all countries would commit at least 0.01 percent of their GDPs to government funded research focusing on the health needs of developing countries.<sup>246</sup> The United Nations supported the idea of a binding

---

impact, see AIDAN HOLLIS & THOMAS POGGE, *THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL* 27–34 (2008).

<sup>244</sup> 35 U.S.C. § 112(a).

<sup>245</sup> See, e.g., Baker, *supra* note 120, at 14–15 (proposing a system where countries contribute in proportion to their “comparable levels of development,” with the poorest countries contributing the least or nothing); Comm. on the Env’t, Pub. Health & Food Safety, *supra* note 207, at 13, 36 (acknowledging that access to medicine is a “shared responsibility of all actors” in the health care industry, and proposing consideration of a R&D financing pool made up of 0.01% of each member state’s GDP); Abbott et al., *supra* note 212, at 216–21 (proposing a Framework Convention on Pharmaceutical Innovation with an additional protocol on financing); PANTELI & EDWARDS, *supra* note 207, at 24 (arguing that a pooling financial mechanism is a “necessary first step” for a sustainable global solution to delink R&D costs from prices); Gifford, *supra* note 101, at 124 (arguing that the American public bears the cost of pharmaceutical R&D more than other nations, as pharmaceutical prices are higher in the United States, and proposing a system of public funding proportionate to each nation’s GDP or per capita income for a more equitable solution). See generally Hubbard & Love, *supra* note 207, at 0147–50 (proposing a new trade framework requiring countries to contribute a fixed percentage of their GDP and allowing them the freedom to choose granting patents on pharmaceuticals once such contribution is made).

<sup>246</sup> CONSULTATIVE EXPERT WORKING GRP. ON RES. & DEV.: FIN. & COORDINATION, WORLD HEALTH ORG. [WHO], *RESEARCH AND DEVELOPMENT TO MEET HEALTH NEEDS IN DEVELOPING COUNTRIES: STRENGTHENING GLOBAL FINANCING AND COORDINATION* 84 (2012), <http://apps.who.int/iris/bitstream/handle/10665/254706/9789241503457-eng.pdf;jsessionid=B990E9ACCB1DCE135E6F73EF0F5AD595?sequence=1> [<https://perma.cc/2R8M-8VGZ>].

R&D treaty focused on de-linking R&D costs from prices in the quest to promote access to pharmaceuticals and incentivize innovation.<sup>247</sup>

As equal global access requires each country to share the cost of research, a global R&D treaty should accompany the national prize fund. Party states should contribute incrementally based on their respective GDPs, with a certain percentage of the funds raised under the treaty dedicated to essential medicines. To ensure widest possible access, essential medicines that may be entitled to patent protection should be collected under a pool operated by WHO, and made available to third parties against due compensation.<sup>248</sup> Any revenue raised by the use of these pharmaceuticals would then be added to the R&D fund under the treaty.

### 3. *Tax Incentives*

In the United States, tax incentives related to R&D activities are regulated under both state and federal law.<sup>249</sup> At the federal level, Sections 41 and 174 of the Internal Revenue Code regulate tax incentives applicable to R&D in all industries.<sup>250</sup> Under Section 174, taxpayers are entitled to treat research and experimental expenditures as expenses subject to certain conditions.<sup>251</sup> Credit for increasing research activities, regulated under Section 41, provides a credit against tax for qualified research expenses.<sup>252</sup> In addition, Section 45C provides a credit specifically for pharmaceutical companies engaged in R&D for orphan drugs.<sup>253</sup>

While tax incentives do not result in direct funding of R&D, they decrease the overall cost of R&D.<sup>254</sup> Tax deductions and credits are thus a

<sup>247</sup> HIGH-LEVEL PANEL ON ACCESS TO MEDICINES, U.N. SECRETARY-GENERAL, PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES 31–32 (2016), <http://www.unsgaccessmeds.org/final-report> [https://perma.cc/YVT4-THDQ].

<sup>248</sup> Medicines Patent Pool offers a similar model to increase access to HIV, Hepatitis C, and Tuberculosis medicines in developing countries. See MEDICINES PATENT POOL, <https://medicinespatentpool.org/> [https://perma.cc/X5NL-FBFW].

<sup>249</sup> See Daniel J. Wilson, *Beggar Thy Neighbor? The In-State, Out-of-State, and Aggregate Effects of R&D Tax Credits*, 91 REV. ECON. & STAT. 431, 431–36 (2009) (discussing state-based incentives and their effect on R&D).

<sup>250</sup> 26 U.S.C. §§ 41, 174.

<sup>251</sup> *Id.* § 174(a). These expenditures include those incurred in connection with R&D and cover all costs that are incidental to the development or improvement of a product, including the cost of obtaining a patent, such as attorney fees. 26 C.F.R. § 1.174-2(a) (2014).

<sup>252</sup> 26 U.S.C. § 41(a). Expenses covered under Section 41 include in-house research expenses, as well as a percentage of the amounts incurred as a result of third-party services. *Id.* § 41(b). The “contract research expenses” are limited to sixty-five percent of any amount paid by the taxpayer to a third party, or seventy-five percent of the amount paid to a qualified research consortium, for qualified research. *Id.* § 41(b)(3).

<sup>253</sup> *Id.* § 45C. The credit is twenty-five percent of the qualified clinical testing expenses, which are expenditures related to human clinical testing.

<sup>254</sup> Hemel & Larrimore Ouellette, *supra* note 112, at 311.

good method to provide additional incentivization for R&D. In 2018, Section 174 decreased the tax liability of corporations by \$2 billion, Section 41 decreased it by \$8.9 billion, and Section 45C by \$1.1 billion.<sup>255</sup>

Expenses related to AI systems utilized in R&D likely fall within the scope of one or more of the existing tax incentives.<sup>256</sup> This Article offers an additional tax incentive to complement the proposed law reforms in the form of lower income tax for royalties and other profits generated from essential medicines enabled by AI as discussed in the preceding sections.<sup>257</sup>

### CONCLUSION

The patent system is widely criticized for its effect on restricting access and hindering subsequent innovation.<sup>258</sup> Effects of patents in the pharmaceutical industry have particularly been the subject of extensive debate.<sup>259</sup> Health care is a human right, which cannot be achieved without proper access to medicine.<sup>260</sup>

AI is revolutionizing pharmaceutical innovation.<sup>261</sup> Faster and more efficient R&D enabled by AI weakens justifications for pharmaceutical patents. AI is a “game changer” in the health care industry,<sup>262</sup> and the law must keep up to ensure that society reaps the benefits. The principal goal of the law reform proposals herein is to leverage AI’s disruption of pharmaceutical innovation to ensure that the human right to health is enjoyed by all.

---

<sup>255</sup> See JOINT COMM. ON TAX’N, ESTIMATES OF FEDERAL TAX EXPENDITURES FOR FISCAL YEARS 2018-2022 (2018), <https://www.jct.gov/publications.html?id=5148&func=startdown> [<https://perma.cc/YFX2-448W>] (estimating differences between tax liability under present legislation and a scenario without the benefits provided therein, assuming that tax payers would behave in the same manner under both circumstances).

<sup>256</sup> See 26 U.S.C. §§ 41, 174.

<sup>257</sup> See JANE G. GRAVELLE, CONG. RES. SERV., R44522, A PATENT/INNOVATION BOX AS A TAX INCENTIVE FOR DOMESTIC RESEARCH AND DEVELOPMENT 6 (2016) (discussing patent box tax incentives, a basis for the proposed model, in such countries as the United Kingdom, France, and China, offering lower income tax for various revenue generated from intellectual property).

<sup>258</sup> See WOLFGANG HEIN & SUERIE MOON, INFORMAL NORMS IN GLOBAL GOVERNANCE: HUMAN RIGHTS, INTELLECTUAL PROPERTY RULES AND ACCESS TO MEDICINES 143 (2013); Gifford, *supra* note 101, at 78; Joseph, *supra* note 138, at 428; Scherer, *supra* note 15, at 97; Scherer, *supra* note 51, at 927; WIPO Report on the International Patent System, *supra* note 109, at 78–81.

<sup>259</sup> See, e.g., HEIN & MOON, *supra* note 258, at 143; WIPO Report on the International Patent System, *supra* note 109, at 78–81; Scherer, *supra* note 15, at 97; Scherer, *supra* note 51, at 927; Joseph, *supra* note 138, at 428; Gifford, *supra* note 101, at 78.

<sup>260</sup> See *supra* notes 128–138 and accompanying text.

<sup>261</sup> See *supra* Part I.

<sup>262</sup> David Arney et al., A User-Focused Transdisciplinary Research Agenda for AI-Enabled Health Tech Governance 5–6 (Jan. 2019) (unpublished manuscript) (on file with the Berkman Klein Center for Internet and Society at Harvard University), [https://cyber.harvard.edu/sites/default/files/2019-02/2019-01\\_aihealth.pdf](https://cyber.harvard.edu/sites/default/files/2019-02/2019-01_aihealth.pdf)? [<https://perma.cc/3NB4-HAER>].

AI inventions raise questions about patentability and patent policy in general. Recent developments signal that patent law reform is inevitable.<sup>263</sup> Considering the lack of evidence on the efficiency of the patent system and health care's categorization as a human right, the pharmaceutical industry is long overdue for a system that prioritizes access alongside incentivization. AI's disruption of the innovation landscape gives lawmakers the chance to finally take action.

---

<sup>263</sup> See *supra* notes 176–189 and accompanying text.

