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ACCREDITING THE PHARMACEUTICALS WITH ARTIFICIAL INSIGHT

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ABSTRACT

In the wake of a court decision involving a selfie-taking monkey, the United States Copyright Office updated its interpretation of "authorship" in 2016 to clarify that it would not register works produced by a machine or a mere mechanical process that operates randomly or automatically and stressed that copyright law only protects "the fruits of intellectual labour" that are "founded in the creative powers of the mind". However, no such guidance has been provided and much less dialogue has taken place regarding the repercussions of Artificial Intelligence ("AI") on US patent law. While machine-creation or art (or algorithmic creativity) has a surprisingly long history, going back at least to the 18th century, only now do we find applications reaching the market that requires a serious rethink of the role of copyright law in providing incentives and protecting investment for artists and the industries that depend on them. In the face of AI's rapid technological changes and societal effects, further discussions on AI's patent law implications are paramount to facilitate any necessary changes in the US patent system so that it can continue to achieve its main objectives which are acceptable to the public and help avoid negative social, economic and ethical effects. The AI chatbot is constantly learning and can be kept up to date on the latest medical research. In the face of AI's rapid technological changes and societal effects, further discussions on AI's patent law implications are paramount to facilitate any necessary changes in the US patent system so that it can continue to achieve its main objectives which are acceptable to the public and help avoid negative social, economic and ethical effects. Also, the question of the skill level of the person of ordinary skill in the art may have to be answered irrespective of whether an AI is recognized as an inventor or not. Early recognition and resolution of these issues will allow patent law to keep pace with the evolution of these thinking machines.

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AN INCEPTION

The World Health Organisation estimates that amongst over 1.7 billion people nearly one-third of the world population have inadequate or even no access to essential medicines and such lack of access is particularly concentrated in India[1] The link between medical patents and the human right to health has become a subject of central concern at the international level, as exemplified by the debates at the 2001 World Trade Organization ("WTO") "Ministerial" Conference.[2] International attention to the issue has focused in large part on the HIV/AIDS crisis and the question of access to drugs for patients in developing countries, which are the most severely affected by the epidemic.[3] Generally, for a new drug molecule, the cost of research and development is about $2.558 billion[4]. Without a guarantee of exclusivity, innovative drug companies would be unable to generate enough revenue to overcome these high costs and in total, the loss to society from the monopoly power granted to the inventor is significantly outweighed by the potential gains "that" society receives from the acceleration of the technological process[5]. Human rights law, in particular through the Covenant on Economic, Social and Cultural Rights, has made a significant contribution to the codification of the human right to health and our understanding of its scope.[6] The increasing scope of patentability in the health sector, codified in the Agreement on Trade Related Aspects of Intellectual Property Rights, constitutes one of the most significant changes in law for developing countries that are WTO members.[7] Intellectual property rights, in particular patents, are deemed to provide the necessary

[1] Andrew Creese et al., THE WORLD MEDICINES SITUATION REPORT 2004, WORLD HEALTH ORGANISATION [WHO] (2004) 61, 616. , https://www.who.int/medicines/areas/policy/world_medicines_situation/en/.

[2] World Trade Organisation (WTO), Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002), https://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm, (The exclusive discussion on medicines in the context of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was in response to the growing controversy concerning the impact of TRIPS in the health sector for most developing countries, and in particular the HIV/AIDS tragedy in sub-Saharan Africa).

[3] World Health Organization (WHO), Rep. on Sources and Prices of Selected Drugs and Diagnostics for People Living with HIV/AIDS, May, 2002, WHO/EDM/PAR/2002.2, http://apps.who.int/medicinedocs/pdf/s2285e/s2285e.pdf.

[4] Thomas Sullivan, A Tough Road: Cost to develop one new drug is $2.6 billion; Approval Rate for Drugs entering Clinical Development is less than 12%, POLICY & MEDICINE, (Mar. 21, 2019), https://www.policymed.com/2014/12/a-tough-road-cost-to-develop-one-new-drug-is-26-billion-approval-rate-for-drugs-entering-clinical-de.html.

[5] WTO, supra note 2.

[6] International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S 3 [hereinafter ICESCR]. (The International Covenant on Economic, Social and Cultural Rights is a multilateral treaty adopted by the United Nations General Assembly on 16 December 1966. It commits its parties to work toward the granting of economic, social, and cultural rights (ESCR) to the Non-Self-Governing and Trust Territories and individuals, including labour rights and the right to health, the right to education, and the right to an adequate standard of living.)

[7] 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] https://treaties.un.org/doc/Publication/UNTS/Volume%201867/volume-1867-I-31874-English.pdf.

incentives for research and technological development.[8]Patents are time-bound monopoly rights,[9] and they constitute a derogation from the principle of free trade by offering exclusive rights to an inventor to exploit the invention and stop others from using it without the creator's consent.[10] The rationale for granting patents is the need to reward an inventor and in practice, this translates mainly into a right to commercialize the invention and simultaneously to stop others from doing so.[11]The exception to the free trade rule is balanced by limiting the duration of the right and by forcing the inventor to disclose the invention so that society at large benefits from scientific advancement.[12] Human rights protect the fundamental rights of individuals and groups. Fundamental rights can be defined as entitlements that belong to all human beings by virtue of their being human.[13]This is in direct contrast to property rights, which can always be ceded in voluntary transactions.[14]As codified in the two United Nations covenants and other relevant instruments,[15]human rights constitute the basic framework guiding state actions at the domestic and international levels.[16]As a result, states must bear in mind their human rights obligations when they negotiate and implement international rules on intellectual property rights or trade liberalization.[17]

INGRESSION TO THE DRUG PLATFORM- A HUMAN RIGHTS PERSPECTIVE

Access to drugs is one of the fundamental components of the human right to health.[18] Accessibility generally refers to the idea that health policies should foster the availability of drugs, at affordable prices, to all those who need them.[19]A large proportion of people in developing countries does not have access to medical insurance

[8] § 5, The Patents Act, No. 39 of 1970, India Code, (Inventions where only methods or processes of manufacture patentable), omitted by the Patents (Amendment) Act, No. 15 of 2005, http://ipindia.nic.in/ipr/patent/patent_Act_1970_28012013_book.pdf.

[9] Jay Erstling, Using Patent to Protect Traditional Knowledge, 15 TEX. WESLEYAN L. REV. 295, 334 (2009).

[10] 1 V KAHUJA, INTELLECTUAL PROPERTY RIGHTS IN INDIA, (1st ed., 2009).

[11] INTELLECTUAL PROPERTY RIGHTS, (Bibek Debroy ed., 1998).

[12] Gregory N. Pate, Analysis of the Experimental Use Exception, 3(2) N.C. J. L. & TECH. 253, 254-72 (2002).

[13] Martha C. Nussbaum, Capabilities, human rights and the universal declaration, in THE FUTURE OF INTERNATIONAL HUMAN RIGHTS, (Burns H. Weston & Stephen P. Marks eds., 1999).

[14] Guido Calabresi & A. Douglas Melamed, Property Rules, Liability Rules, And Inalienability: One View of The Cathedral, 85(6) HARV. L. REV. 1089 (1972).

[15] ICESCR, supra note 6; International Covenant on Civil and Political Rights, Dec. 16, 1966, 999 U.N.T.S 171, 6 ILM 368.

[16] Id., Cf. Preamble of the ICESCR.

[17] World Conference on Human Rights, Vienna Declaration and Programme of Action, art. 1, U.N. Doc. A/CONF.I57/23, (June 25, 1993), https://www.ohchr.org/en/professionalinterest/pages/vienna.aspx (which states that human rights and fundamental freedoms are the birth right of all human beings; their protection and promotion is the first responsibility of the Government).

[18] U.N. High Comm'n for Human Rights, Rep. on Access to medication in the context of pandemics such as HIV/AIDS on its Fifty-Seventh Session, UN Doc E/CN.4/RES/2001/23 (Apr. 23, 2001), https://ap.ohchr.org/documents/alldocs.aspx?doc_id=8220.

[19] United Nations Development Programme (UNDP), Human Development Report 2001: Making New Technologies Work For Human Development, 3 (2001), http://hdr.undp.org/en/content/human-development-report-2001 (estimating that about 2 billion people do not have access to low-cost essential drugs).

and more often than not pay for drugs themselves[20]. In the field of patents, the final agreement stipulates the patentability of inventions, whether products or processes, in all fields of technology.[21]The objective clause of the TRIPS Agreement provides that intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology[22]. The implementation of this provision requires a certain level of flexibility in implementing the substantive clauses of the agreement.[23]The agreement specifically indicates that states can adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their socioeconomic and technological development.[24]The potential of these provisions has not been lost on developing countries, as is clear from a statement by India to the WTO that Articles 7[25] and 8(2)[26] of the TRIPS Agreement are overarching provisions that should qualify other provisions of TRIPS meant to protect intellectual property rights.[27] The TRIPS Agreement has left some room for countries to take public interest measures, including measures to protect the public health. The flexibility provides the government with opportunities to tune the protection granted to meet social goals, the concerns of the developing world with regard to pharmaceutical patent has been clarified and enhanced by the 2001 DOHA declaration on TRIPS and public health, and the 2003 design enabling countries who cannot manufacture medicines themselves to import pharmaceutical made under compulsory licence.[28]It includes,

1. the freedom to exclude new forms of known drugs from patent protection,

[20] World Health Organization and World Trade Organization Secretariats, Workshop on Differential Pricing and Financing of Essential Drugs, Report of The Workshop on Differential Pricing and Financing of Essential Drugs, (2001), http://apps.who.int/medicinedocs/en/d/Jh2951e/.
[21] TRIPs Agreement, supra note 7, at art. 27(1), https://www.wto.org/english/docs_e/legal_e/27-trips.pdf.
[22] TRIPs Agreement, supra note 7, at art. 7; Germin Velasquez & Pascale Boulet, Globalization and access to drugs: implications of the WTO/TRIPS Agreement, in GLOBALIZATION AND ACCESS TO DRUGS - PERSPECTIVES ON THE WTO/TRIPS AGREEMENT, WHO DOC. WHO/DAP/98.9 (1998).
[23] Statement of the Committee on Economic, Social and Cultural Rights on Human Rights and Intellectual Property, in Comm. on Econ., Soc. and Cult. Rts, Rep. on the Twenty-Fifth, Twenty-Sixth & Twenty-Seventh Sessions, UN Doc. E/2002/22-E/C.12/2001/17, Annex XIII at p. 214.
[24] TRIPs Agreement, supra note 7, at art. 8. (However, it would be difficult to justify an exception not foreseen in TRIPS under article 8 unless it were an exception to a right which is not protected under TRIPS).
[25] TRIPs Agreement, supra note 7, at art. 7. (The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations).
[26] TRIPs Agreement, supra note 7, at art. 8. (Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology).
[27] World Trade Organization, Communication from United States of America in SCOPE AND MODALITIES OF NON-VIOLATION COMPLAINTS UNDER THE TRIPS AGREEMENT, WTO Doc. IP/C/W/I95 (2000), https://www.jstor.org/stable/3095545.
[28] ELIZABETH VERKEY, LAW OF PATENTS, 565 (2nd ed. 2012).

2. the freedom to adopt the principle of international exhaustion of patent rights to facilitate the parallel importation of drugs,[29]
3. regulatory review exemption for producers of generic drugs,
4. (d) research exception, and
5. (e) delinking the grant of marketing approval for generic drugs from the patent status of branded drugs.[30]

PARLIAMENTARY INITIATIVES- AN INDIAN OUTLOOK

The Indian Patent Act provides that an application for the grant of compulsory license can be made only after three years from the date of the grant of patent unless exceptional circumstance like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date.[31]Three broad grounds for the grant of compulsory licenses have been spelt out thus; i) reasonable requirements of the public with respect to the patented invention have not been satisfied, ii) the patented invention is not available to the public at a reasonably affordable price, and iii) the patented invention is not worked in the territory of India. The Patents Act sets out the circumstances under which "reasonable requirements of the public" would not have been met.[32]Such circumstances would arise if the patent holder refuses to grant a license on reasonable terms, and which, in turn, affects,[33][34] i) development of new trade or industry in the country; ii) establishment or development of commercial activity within India; and iii) the major impact of this provision can be felt in the pharmaceutical sector where India could well emerge as a major supplier of the generic pharmaceutical to those developing countries which do not have sufficient domestic manufacturing facilities. The presence of a strong and effective patent system may bring numerous benefits such as dissemination of information and providing an incentive to invest in the development of new products and process which will eventually fall into the public domain.[35]The generics from India have pushed down prices for older anti-AIDS drugs by 99% and Indian generic versions of Glives sell for INR 8,000 ($ 174) for a month's

[29] TRIPs Agreement, supra note 7, at art. 6.
[30] Uwe Perlitz, India's Pharmaceutical Industry on Course of Globalisation, DEUTSCHE BANK RESEARCH, (Apr. 9, 2008), https://www.dbresearch.com/.
[31] S.L. Soujanya, Compulsory Licensing of Patents, an Indian Outlook, PROMETHEUS IP (May 29, 2017), https://www.prometheusip.com/blog/patents/compulsory-licensing-of-patents-an-indian-outlook.
[32] BISWAJIT DHAR AND K.M. GOPAKUMAR, INTELLECTUAL PROPERTY AND SUSTAINABLE DEVELOPMENT AGENDAS IN A CHANGING WORLD, 106 (Ricardo Melendez-Ortiz & Pedro Roffe eds., 2009).
[33] Pradeep S. Mehta, TRIPS and Pharmaceuticals: Implications for India, 17 SWISS DEV. POL'Y Y.B. 97, 97-106 (1998), https://journals.openedition.org/sjep/718.
[34] Patents Act, supra note 8, at § 89. (The powers of the controller upon an application made under s. 84 shall be exercised with a view to securing the following general purpose, that is to say:
   a) That patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;
   b) That the interest of any person for the time being working or developing an invention in the territory of in India under the protection of a patent is not unfairly prejudiced.).
[35] P. NARAYANAN, INTELLECTUAL PROPERTY LAW, 21 (3rd ed., 2001).

treatment compared with INR 120,000 for the brand name version, supply of cheap, copycat drugs for the developing world could be badly threatened.[36]

THE DAWN OF ARTIFICIAL INTELLIGENCE

Artificial intelligence is one of the most important technologies of this era.[37]Once considered a remote possibility reserved for science fiction, AI has advanced enough to approach a technological tipping point of generating ground-breaking effects on humanity and is "likely to leave no stratum of society untouched".[38]It is rapidly transforming the world of medicine as the recent decades have marked a surge in the development of medical AI.[39]Progress in AI has shown tremendous potential for benefitting mankind by improving efficiency and savings in production, commerce, transport, medical care, rescue, education and farming,[40]as well as for significantly cultivating "the ability and level of social governance".[41]But the technological advances of AI are also expected to disrupt numerous legal frameworks, including various aspects of US patent law.[42]

ARTIFICIAL INTELLIGENCE AND MEDICINE

AI techniques utilized in medicine include artificial neural networks, fuzzy expert systems, evolutionary computation, and hybrid intelligent systems.[43]Artificial neural networks are used extensively in clinical diagnosis and image analysis because of the parallel processing power that allows the networks to learn from historical examples and known patterns and these networks have been used for diagnosing prostates as benign or malignant, cervical screening, and imaging analysis (including radiographs,

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[36] Penny MacRae, India patent case threatens cheap drug supply: MSF, SCIENCEX, (Sept. 5, 2011), https://medicalxpress.com/news/2011-09-india-patent-case-threatens-cheap.html.

[37] Lauren Goode, Google CEO Sundar Pichai compares impact of AI to electricity and fire, THE VERGE (Jan.19, 2018), https://www.theverge.com/2018/1/19/16911354/google-ceo-sundar-pichai-ai-artificial-intelligence-fire-electricity-jobs-cancer ("Google CEO Sundar Pichai, speaking at a taped television event hosted by MSNBC and The Verge's sister site Recode, said artificial intelligence is one of the most profound things that humanity is working on right now and compared it to basic utilities in terms of its importance."); Sam Shead, Microsoft exec: 'AI is the most important technology that anybody on the planet is working on today, BUSINESS INSIDER (Aug. 5, 2016), ("Dave Coplin, chief envisioning officer at Microsoft UK, told an audience of business leaders at an AI conference that AI is 'the most important technology that anybody on the planet is working on today.").

[38] Civil Law Rules on Robotics, EUR. PARL. DOC. P8_TA (2017) 0051, (2017), http://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html?redirect; Notice of the State Council Issuing the New Generation of Artificial Intelligence Development Plan, No. 35 of 2017, (China), https://flia.org/notice-state-council-issuing-new-generation-artificial-intelligence-development-plan.

[39] A.N. Ramesh et al, Artificial Intelligence in Medicine, 86 ANNALS ROYAL COLL. SURGEONS ENG., 334-338 (2004).

[40] Civil Law Rules., supra note 38.

[41] China AI Plan, supra note 38 at 2.

[42] Ben Hattenbach & Joshua Glucoft, Patents in an Era of Infinite Monkeys and Artificial Intelligence, 19(2) STAN. TECH. L. REV. 32 (2015), ("The coming wave of computer-generated material is on a collision course with our patent laws."); Liza Vertinsky and Todd M. Rice, Thinking About Thinking Machines: Implications of Machine Inventors for Patent Law, 8(2) B.U. J. SCI. & TECH. L. 574, 576-77 (2002) (discussing the growing use of computers to augment human capabilities and replace human operators, as well as its effects on the invention process that cannot easily be accommodated within the current patent system).

[43] WHO, supra note 3.

ultrasounds, CTs, and MRIs), as well as for analysing heart waveforms to diagnose conditions such as atrial fibrillation and ventricular arrhythmias; as done by researchers at Stanford University, who trained a deep convolutional neural network to classify skin lesions into either benign or malignant groupings based on known images, using only pixels and disease labels as inputs.[44]The researchers started with an algorithm developed by Google to perform image recognition and then trained their neural network to recognize skin cancer using 129,450 clinical images of 2,032 different diseases.[45]Medical chatbots utilize neural networks to learn from medical textbooks, scientific research, patient records, and messages between actual patients and doctors.[46]The AI chatbot is constantly learning and can be kept up to date on the latest medical research.[47]Baidu, a Chinese search engine, utilizes a chatbot named Melody within its Baidu Doctor app.[48]When a patient asks a question to the doctor, the chatbot asks appropriate follow-up questions to help learn more about the patient's symptoms so the doctor can make a more informed decision on treatment.[49] Interventional radiologists at the University of California at Los Angeles have developed a chatbot to assist physicians in providing real-time evidence-based answers to the patient about the next phase of treatment, or information about their interventional radiology treatment.[50]Fuzzy logic AI is applicable in medicine because diseases, symptoms, and diagnoses are not described in precise terms and tend to be vague.[51]Fuzzy logic AI[52] has been applied to cancer diagnosis for lung cancer, acute leukaemia, breast cancer,

[44] Andre Esteva et al., Dermatologist-Level Classification of Skin Cancer with Deep Neural Networks, 542 NATURE 115- (2017).

[45] Taylor Kubota, Deep Learning Algorithm Does as Well as Dermatologists in Identifying Skin Cancer, STAN. NEWS (Jan. 25, 2017), http://news.stanford.edu/2017/01/25/artificial-intelligence-used-identify-skin-cancer/.

[46] Jelor Gallego, An AI-Powered Chatbot is Helping Doctors Diagnose Patients, FUTURISM, (Oct. 13, 2016), https://futurism.com/an-ai- powered-chatbot-is-helping-doctors-diagnose-patients/.

[47] Katpro, Artificial Intelligence ChatBots—Explore Intelligence in a Bot!, KATPRO TECH. (June 7, 2017), https://katprotech.com/artificial-intelligence-chatbots-explore-intelligence-in-bot/, ("AI Chatbots can read up to 25 million and more published medical papers in about a week and scan the web for references to latest research. They can be trained to read, interpret and analyse medical literature. A continuous input, learning, understanding and analysing, which is never forgotten").

[48] Gallego, supra note 46; Dyllan Furness, Baidu releases Melody, a medical assistant chatbot to keep physicians humming, DIGITAL TRENDS (Oct. 11, 2016), https://www.digitaltrends.com/health-fitness/baidu-melody-medical-chatbot/.

[49] Gallego, supra note 46; Furness, supra note 48.

[50] K. Seals et al., Utilization of Deep Learning Techniques to Assist Clinicians in Diagnostic and Interventional Radiology: Development of a Virtual Radiology Assistant, 28(2) J. VASCULAR &INTERVENTIONAL RADIOLOGY S153 (2017); Future is now: Artificial intelligence virtual consultant helps deliver better patient care, SOC. INTERVENTIONAL RADIOLOGY, (Mar. 8, 2017), https://www.sirweb.org/advocacy-and-outreach/media/news-release-archive/news-release-artificial_intelligence/.

[51] Angela Torres & Juan J. Nieto, Fuzzy Logic in Medicine and Bioinformatics, J. BIOMEDICINE & BIOTECHNOLOGY, 549-555 (2006).

[52] See id., (Fuzzy logic or "neuro-fuzzy" systems have become popular because they can absorb some of the "noise" generally present in the neural network. Fuzzy logic AI is applicable in medicine because diseases, symptoms, and diagnoses are described in imprecise and terms. As fuzzy logic rests on the premise that everything is a matter of degree, it can recognize "partial truth logics," beyond just the true and false values applied in traditional programming).

pancreatic cancer, tuberculosis, aphasia, arthritis, and hypothyroidism.[53]Combining these AI techniques generates hybrid intelligent systems that incorporate the advantages of each technology like the combination of neural networks and fuzzy logic or "neuro-fuzzy" systems have become popular because they can absorb some of the "noise" generally present in the neural network.[54]

UNCERTAINTIES IN PATENTING AI

The U.S. patent system only recognizes individuals as inventors,[55]not companies[56] or machines.[57]Inventorship is determined by conception, or "the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention.[58]The use of AI, particularly deep machine learning or self-evolving and coding AI, raises questions as to who, or what, conceived of the invention and should thus be named as an inventor and indeed, AI has already advanced to the point where the AI itself is generating new inventions, as opposed to a human programmer or logic developer.[59]This can especially be the case where AI systems develop their own code as a result of the system's training.[60]Recently, both Google and Facebook have seen their respective AI systems develop new languages to perform the assigned tasks, eschewing known human languages in favour of a more efficient means of communication.[61]As the use of AI grows in medicine and the life sciences, it is more and more likely that the AI will be the entity taking the inventive step, drawing new conclusions between the observed and the unknown, and creating new programming to further identify and exploit those connections.[62]As AI continues to advance, the Patent and Trademark Office ("PTO") will receive more patent applications in which AI could be considered the inventor, or at least a co-inventor, the PTO and the courts will have to decide whether

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[53] V. Prasath et al., A Survey on the Applications of Fuzzy Logic in Medical Diagnosis, 4 INT'L J. SCI. & ENG'G RES. 1199 (2013).

[54] Georgios Dounias, Hybrid Computational Intelligence in Medicine, RESEARCH GATE (2014), https://www.researchgate.net/profile/Georgios_Dounias/publication/228596764_Hybrid_computational_intelligence_in_medicine/links/09e4150b72b8ded221000000/Hybrid-computationalintelligence-in-medicine.pdf.

[55] Patents Act, 35 U.S.C. § 100(f).

[56] New Idea Farm Equip. Corp. v. Sperry Corp., 916 F.2d 1561, 1566 n.4 (Fed. Cir. 1990).

[57] Hattenback & Glucoft, supra note 42.

[58] Townsend v. Smith, 36 F.2d 292, 295 (C.C.P.A. 1929); Hybritech, Inc. v. Monoclonal Antibodies Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986), (Quoting 1 ROBINSON, ON PATENTS 532 (1890)).

[59] Hattenback & Glucoft, supra note 42 at 35 & 43. (Describing inventions conceived by machines such as proportional-integrative-derivative electrical controllers, nose cone design for a train, and piston geometry for a diesel engine).

[60] Toby Bond, How Artificial Intelligence Is Set to Disrupt Our Legal Framework for Intellectual Property Rights, IPWATCHDOG, (June 18, 2017), http://www.ipwatchdog.com/2017/06/18/artificial-intelligence-disrupt-legal-framework-intellectual-property-rights/id=84319/.

[61] Tony Bradley, Facebook AI Creates Its Own Language in Creepy Preview of Our Potential Future, FORBES, (July 31, 2017), https://www.forbes.com/sites/tonybradley/2017/07/31/facebook-ai-creates-its-own-language-in-creepy-preview-of-our-potential-future/#99fd191292c0; Sam Wong, Google Translate AI Invents Its Own Language to Translate with, NEW SCIENTIST, (Nov. 30, 2016), https://www.newscientist.com/article/2114748-googletranslate-ai-invents-its-own-language-to-translate-with/.

[62] Ryan Abbott, I Think, Therefore I Invent: Creative Computers and the Future of Patent Law, 57 B.C.L. REV. 1079, 1097 (2016).

the current Patent Act encompasses computer-based inventors while some have already advocated that computers should qualify as legal inventor,[63]some have argued that AI will soon "displace humans from the inventive process altogether[64]" and thus no patent protection should be given unless a human provides a material contribution to the conception of an invention.[65]In copyright law, regulation prevents copyright protection being granted to works produced solely by a machine "without any creative input or intervention from a human author".[66]It remains to be seen whether the PTO will adopt this strict requirement of human intervention or collaboration. If the PTO and courts determine that patent protection will not be granted to an AI, then who among the humans responsible for the AI should be considered an inventor, the list of possible human inventors includes the AI software and hardware developers, the medical professionals or experts who provided the data set with known values or otherwise provided input into the development of the AI, and/or those who reviewed the AI results and recognized that an invention had been made.[67]AI may confuse the question of ownership for medical inventions generated by the AI itself and patent ownership often turns on the question of inventorship,[68]thus will be equally complicated when AI develops its own code and conceives its own inventions. One approach would be to allow AI-inventors to be designated as the first owner, requiring assignment and licensing of all inventions.[69] Another approach would be to allow the computer's owner or the algorithm's owner to be the first owner, separating inventorship from ownership from the beginning.[70]

THE PATENT ELIGIBILITY CONCERN

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention and is a construct applied to multiple patentability analyses, including obviousness and enablement.[71]At some point, AI may become the "person" of skill in the art, possessing actual knowledge of all known publications, patents, and prior art, transforming the hypothetical construct into

[63]Id. at 1113.
[64]Erica Fraser, Computers as Inventors—Legal and Policy Implications of Artificial Intelligence on Patent Law, 13 SCRIPTED 305, 333 (2016).
[65] Mark Lyon, Alison Watkins & Ryan Iwahashi, When AI Creates IP: Inventorship Issues To Consider, LAW360, (Aug. 10, 2017), https://www.law360.com/articles/950313/when-ai-creates-ip-inventorship-issues-to-consider.
[66] Copyright Office, Compendium of U.S. Copyright Office Practices (3d ed. 2014) § 313.2.
[67] Hattenback & Glucoft, supra note 42, at 46.
[68] Abbott, supra note 62, at 1095.
[69] Fraser, supra note 64, at 331, (Companies creating AIs have started including ownership provisions in the licensing agreements to account for this possibility. Cloudera Licensing Agreement, Section 5 Ownership, "Cloudera owns all right, title and interest in and to . . . all ideas, inventions, discoveries, improvements, information, creative works and any other works discovered, prepared or developed by Cloudera").
[70]Id.; Tracy Staedter, A.I. Computers Should Be Named as Inventors on Patents, SEEKER, (Oct. 20, 2016), https://www.seeker.com/a-i-computers-named-inventors-patents-2056008851.html, (Quoting Ryan Abbott as stating "I think the way it should work, the way it could work, is that we list Watson as the inventor and whoever owns Watson, which is IBM, as the patent owner").
[71] Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).

reality.[72]If the AI alone is not determined to be the person of ordinary skill in the art, it may also be determined that the hypothetical skilled person should be elevated to a person equipped with an AI system.[73]Thus, the ability and knowledge of a person of skill in the art may be elevated to match the sophistication of the AI. Elevating the standard of a person of ordinary skill in the art could impact multiple doctrines within patent law, including novelty, obviousness, and enablement, which are all determined from the perspective of a person of ordinary skill in the art. The test for non-obviousness takes into account the level of skill of the person of ordinary skill in the art and applies that perspective to determine if the difference between the invention and the prior art is obvious. If the person of ordinary skill in the art has a greater skill level and knowledge of prior art, it would be more difficult to argue that an invention was non-obvious over the prior art.[74]For more predictable areas of technology, modifications over the prior art that work in predictable way are already considered obvious. If it becomes predictable that an AI can generate inventive results, such as through brute force trial-and-error, it will be more difficult to argue that the invention is non-obvious, even where the "finite number of identified, predictable solutions" is beyond that of human calculation.[75]

THE JURIDICAL INTERVENTIONS OF INDIA

When pharmaceutical company Novartis challenged the rejection of its patent application for the Leukaemia drug Gleevec in Novartis AG v. Union of India,[76]it became the first major legal challenge to India's newly amended patent law. The ability of pharmaceutical companies such as Novartis to secure patent protection in India not only is important in creating incentives for pharmaceutical research, but also greatly affects the Indian generic drug industry, and therefore the price of medicine available to patients. India is the world's second most populous country,[77] and the second fastest growing major economy,[78]but has 70% of its population living on less than $2 per day,[79]making Novartis AG of paramount importance. Novartis challenged section 3(d)[80]

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[72] George Dyson, Turning's Cathedral, EDGE, (Oct. 23, 2005), https://www.edge.org/conversation/george_dyson-turings-cathedral, (quoting an unidentified Google employee as stating "we are not scanning all those books to be read by people. We are scanning them to be read by an AI," in referring to the Google Books Library Project).

[73] Vertinsky & Rice, supra note 42; Abbott, supra note 62 at 1125-26.

[74] Abbott, supra note 62 at 1124-25.

[75] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007); Vertinsky & Rice, supra note 42 at 595-96.

[76] Novartis AG v. Union of India, (2007) 4 Madras L.J. 1153.

[77] Central Intelligence Agency, Rank Order—Population, CENTRAL INTELLIGENCE AGENCY-THE 2007 WORLD FACTBOOK, 261 (2006), https://www.cia.gov/library/publications/download/download-2007/index.html.

[78] U.S. Dept. of Agriculture, Economic Research Service, Economic Research Service- India, https://www.ers.usda.gov/topics/international-markets-us-trade/countries-regions/india/.

[79] Fareed Zakaria, India Rising, NEWSWEEK, (Mar. 6, 2006), https://www.newsweek.com/india-rising-106259.

[80] Patents Act, supra note 8 ("the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation, - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size,

on the grounds that this section was not compatible to TRIPS and is arbitrary, illogical, vague and violates Article 14 and Article 27(2) of the Constitution of India,[81]which permit members to exclude certain inventions which is necessary to protect public order or morality and to protect human life. The Madras High Court,[82] in its interpretation mentioned that section 3(d) was introduced to prevent ever-greening so as to provide easy access to the citizens of this country for the life-saving drug and to discharge the constitutional obligation of providing good health care to its citizens.[83]Hence, the judges of the Supreme Court keeping in mind the interpretation of section 3(d) also intended to reduce the drug prices and make health care more affordable for the Indian patients.[84]In Bayer Corporation v. Cipla Union of India,[85] the petitioner Bayer was a corporation that got a patent on its renal cancer drug 'Sorefenib Tosylate', which was being sold for INR 2, 85,000 for one-month dosage. Indian patent office had granted a patent bearing number IN 215758 which covered Sorafenib tosylate. Bayer, the assignee of the patent filed a writ petition restraining DCGI from granting a license to Cipla "to manufacture and market, to imitate/ substitute sorafenib tosylate protected under this patent". A further request was for a direction to Cipla to furnish an undertaking that the drug for which it has made an application before DCGI was not an imitation of or a substitute for Bayer's patented drug "sorafenib tosylate" and consequently would not result in an infringement of subject patent. Further Cipla's product was said to be a spurious drug under section 17(b) and DCGI would exceed its jurisdiction in granting marketing approval to Cipla's generic product. It was contended that since it was known at the time of Cipla's application for marketing approval that Bayer held patent for Sorafenib tosylate, DCGI was under an obligation, flowing from collective reading of Section 2 of Drugs and Cosmetics Act and Sections 48 and 156 of Patents Act, to decline Cipla's application for marketing approval for Soranib.

HEADWAY TO THE HOLY GRAIL- A CONCLUSION

TRIPS is without doubt one of the most significant international treaties of the late twentieth century. In the field of health, it has had and will have sweeping impacts in most developing countries. India is currently one of the major drug-producing countries in the world, being the fourth-largest producer by volume and the thirteenth largest by

isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy").

[81] TRIPs Agreement, supra note 7, at art. 27(2), (Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law).

[82] Novartis, supra note 76.

[83] Priyamvada Gupta, Pharmaceutical Innovations in India: Balancing the Value of Incremental Innovations, 5(1) SUP CT. J. 17, 23 (2014).

[84] Ramesh et al., supra note 39.

[85] Bayer Corporation v. Cipla Union of India, 2009 (41) PTC 642 (Del).

value, with about a 20-22 percent share in global generic production.[86]One of the complications from an international law point of view is that TRIPS is being applied not in a vacuum but in a context where the right to health is a well-established human right codified in one of the two main international human rights treaties.[87]The introduction of patents on drugs has provoked a significant outcry in a number of developing countries where access to medicines is already abysmally low. The justifications offered for the existence of patents as incentives to innovation often do not appear convincing to patients in developing countries, who see that hardly any R&D is being invested in diseases specific to those countries. In other cases, such as HIV/AIDS, where drugs to alleviate the condition exist, the prices of these-for all practical purposes, life-saving-drugs have been so high as to render them unaffordable for all but the wealthiest in developing countries.[88]Further we see that the pharmaceutical companies can increase their research in developing drugs for such diseases if they know that the incentive for this research they will get a patent protection and can demand high monopoly prices from the affluent patients, government agencies and NGO's initially and after the term of patent protection is over in the long run a large number of people will be able to benefit so taking into account both sides.[89]The extension of strong intellectual property rights through TRIPS into less developed countries, burdens the poor disproportionately as they lose access to generic copies of drugs that are still under patent protection.[90]On the other hand, this extension of intellectual property rights may benefit the poor in the future, given that additional incentives are being provided to address health needs in developing countries. From a utilitarian perspective one might therefore argue that the overall benefits outweighed the overall losses. Pharmaceutical industry and trade negotiators alike should not forget the true goal of drug innovation: saving lives.[91] Profit should always be a means to this end, not vice- versa. Only by keeping this principle in mind and achieving a better understanding of the modern world health situation can we hope to effectively ensure the safety and well-being of the world's population in the twenty-first century and beyond.[92]Thus, we see that over-protection and under protection being both sides of the debate can be solved only when we take further

[86] Atsuko Kamiike & Takahiro Sato, The TRIPs Agreement and the Pharmaceutical Industry: The Indian Experience, in COMPARATIVE STUDIES ON EURASIAN CULTURE AND SOCIETY 77, 78-79 (Tetsuo Mochizuki & Shiho Maeda eds., 2012).

[87] T. G. Agitha, Global Governance for facilitating Access to medicines: Role of World Health Organisation, 18 J. INTELL. PROP. RTS., 589 (2013).

[88] For an overview of the various reports, see World Health Organization, Medicine Price information Sources, https://www.who.int/medicines/areas/access/med_price_info_sources/en/.

[89] International Centre for Trade and Sustainable Development, Indian Parliament Approves Controversial Patent Bill, 9(10) BRIDGES WEEKLY TRADE NEWS DIGEST (Mar. 23, 2005), http://www.ictsd.org/indian-parliament-approves-controversial-patent-bill.

[90] Ranjit Devraj, Global Poor to Suffer If Denied Indian Generic Drugs - Experts, INTER PRESS SERVICE NEWS AGENCY, (Feb. 22, 2005), http://www.ipsnews.net/2005/02/health-global-poor-to-suffer-if-denied-indian-generic-drugs-experts/.

[91] K. Srinath Reddy, Universal Health coverage is the best prescription, THE HINDU, (Dec. 7, 2017), https://www.thehindu.com/opinion/op-ed/universal-health-coverage-is-the-best-prescription/article21284698.ece.

[92] Memorandum from Amit Sen Gupta, National Working Group on Patent Laws, Changes in New Patents Bill, Mar. 22, 2005, http://www.cptech.org/ip/health/c/india/gupta03222005.html.

insights of the legal debate. Whether the "flexibilities" under TRIPS provide sufficient room for developing countries to secure their interest or not, is a question that will be answered by the times to come.

In this world, patents directed to inventions which are made during the course of further investigations, such as medical uses, dosage regimes, etc., may become more important than patents for the compounds per se. Under those hypothetical circumstances, a drug company might even choose to forego a patent application for the compounds per se, keeping the structure of the clinical candidate secret, and wait until further data are available before filing patent applications. That strategy would have the advantage of removing one of the key pieces of prior art which is currently available to cite against medical use and dosage patents, namely the patent to the compounds per se. The potential of AI to weaken patents for innovative drug substances may mean that pharmaceutical companies, who will be essential in the development and validation of the next generation of insilico drug development models, have an incentive not to make those models too good (or at least not to disclose how good they are). If AI never gets to the point where new active compounds can be identified without inventive skill, then the innovator who develops the active compounds can be reasonably confident that they will be entitled to a patent for those compounds. On the other hand, and looking even further ahead, if AI can take the pharmaceutical industry to the point where fewer clinical candidates fail, and the Research & Development cost per successful drug falls, then there could perhaps be a fundamental re-shaping of the industry and its relationship with patents. The Indian tailoring were enacted through less complex legislation with more discretion left to the Indian Patent Office and courts.[93]The law barring new forms and uses of known chemicals was meant to counteract criticism that pharmaceutical companies elsewhere have been able to gain protection for longer than their initial discoveries warrant through creative claiming of new forms and uses of chemicals.[94] Thus, it can be seen as an efficiency-enhancing law, solving a discrete problem in line with the purposes of flexibility. The legal arguments concerning the relationship between human rights and intellectual property rights, and the practical debates concerning access to drugs in developing countries, both point towards the existence of potential conflicts between the introduction of patents on drugs in developing countries and the realization of the right to health.[95]While states must endeavour as far as possible to reconcile their different international obligations, there seem to be some cases where the implementation of TRIPS directly implies a reduction in access to drugs and thus a step back in the implementation of the right to health

[93] Sajeev Chandran, Archna Roy & Lokesh Jain, Implications of New Patent Regime on Indian Pharmaceutical Industry: Challenges and Opportunities, 10(4) J. INTELL. PROP. RTS., 269 (2005).
[94] Ranjit Devraj, India: Lesser-Than-Evil Patent Law Pleases Drug Firms, INTER PRESS SERVICE NEWS AGENCY, (Mar. 24, 2005), http://www.ipsnews.net/2005/03/india-lesser-than-evil-patent-law-pleases-drug-firms/.
[95] Soumitra Ghosh, Indicators That Matter: On The Quality of Public Healthcare, THE HINDU, Sept. 9, 2017, https://www.thehindu.com/opinion/op-ed/indicators-that-matter/article19646168.ece.

which appears to be unacceptable under the ESCR Covenant[96] and countries in this situation would be expected to give priority to their human rights obligations. This solution, which gives primacy to human rights, is unlikely to meet with the approval of all states and would probably not stand if it came for adjudication in a WTO context. It nevertheless seems adequate from a legal and ethical point of view.

Four main patent law issues affected by AI that merit further discussions.

- First, the present standard on patent-eligible subject matter needs to be carefully evaluated to determine whether it has any material negative impact on AI or AI-driven technologies. If so, the relevant actors must search for possible adjustments to the standard that can better achieve the patent law's main objectives, such as promoting innovation, disseminating useful information and incentivizing investment in helpful technologies. The anticipated benefits from the contemplated changes must then be weighed against the negative social and ethical implications that may arise from those changes. The relevant actors should also consider other available mechanisms for promoting and protecting AI innovation (e.g. laws on trade secrets or copyrights) to help assess whether any of the identified shortfalls in the patent law's subject-matter eligibility standard can be rectified through other means.
- Second, the question of whether inventions that are created entirely by AI should be protected with patents needs to be answered. To help arrive at an effective solution, the relevant actors must diligently analyse the potential positive and negative effects – from technological, socio-economic and ethical viewpoints – from patenting AI-generated inventions, and then assess these effects in view of one another. Possible middle grounds between the competing interests must be identified to help the patent system achieve its main objectives in a well-balanced manner. If the relevant actors ultimately decide to allow AI-created inventions to be patentable, then they must also decide whether inventorship should be awarded to AIs that generated those inventive ideas.
- Third, the present liability laws do not account for situations where patent infringement is committed independently by an AI. The relevant actors need to explore "who" should be held liable in those situations and how remuneration should be assessed. The different existing liability frameworks must be analysed to identify their relative strengths, and new approaches should be researched to see if they can function more effectively than the existing liability systems.
- Fourth, further discussions are necessary on whether changes need to be made to the present definition of a "person of ordinary skill in the art" ("POSITA"), which is a hypothetical person through which obviousness of an invention is evaluated. As the use of AI becomes more prevalent, the actual people "of ordinary skill" that work in various industries will increasingly rely on AI. Thus, a

[96] ICESCR, supra note 6.

categorical exclusion of AI's involvement from the definition of a POSITA can risk having a non-obviousness standard that fails to accurately reflect the real-world level of obviousness. But on the flip side, as AI becomes "smarter", incorporating the use of AI into the definition of a POSITA would likely result in more inventions being deemed obvious and, ultimately, in a smaller number of patents being granted. In this scenario, if AI reaches super-intelligence one day, would that not mean that everything will be considered obvious? These questions must be studied to help arrive at a non-obviousness standard that is accurate.

Approaches to the issues must be comprehensive and multifaceted, so an optimal balance can be struck between the various competing factors. This will help the US patent law to continue adding the "fuel of interest to the fire of genius", as described by Abraham Lincoln,[97] in ways that are socially inclusive and ethically responsible.

[97] 3 ABRAHAM LINCOLN, THE COLLECTED WORKS OF ABRAHAM LINCOLN 356-363 (Roy P. Basler ed., 1953).