University of Dayton Law Review

Volume 45 | Number 3 Article 5

7-1-2020

Fairness versus Welfare in Compulsory Licensing on Essential Medicines

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FAIRNESS VERSUS WELFARE IN COMPULSORY LICENSING ON ESSENTIAL MEDICINES

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ABSTRACT

The debate about intellectual property rights, namely patents, for pharmaceuticals has been polarized between those who favor a strong property view based on a type of absolute right for patents, and a weak patent view based both on some type of deontological perspective dealing with hierarchy of rights. Therefore, compulsory licensing is viewed as a "taking" affecting the absolute right by the former group; and as an act of fairness by the latter group because it allows the less advantaged access to medicines. This Article argues that a "welfare utilitarian" approach might help to harmonize this discussion. If a utilitarian view is accepted, there would likely be an optimal level of compulsory licensing, maximizing total welfare of present and future generations. This Article supports the argument that, in applying welfare criterion to patents, any non-utilitarian notion of fairness

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might lead to inconsistency.

I. INTRODUCTION

Patents have been the focus of an extensive debate over the last thirty years.[1] The legal monopoly generated by specific types of property rights has split the debate between those favoring "Strong Patent Rights" ("SPR") and those advocating for "Weak Patent Rights" ("WPR").[2] Advocates of WPR argue that fundamental rights other than property rights take higher importance and ultimately triumph over intellectual property rights.[3]

SPR supporters argue that patents are a key element to support research and development ("R&D") activities.[4] Namely, they argue that a lack of proper protection on intangible assets will create an absence of proper incentives for continued research activities.[5] This is mainly due to the characteristic of public goods that are involved in the R&D process.[6] SPR supporters argue that strong patents are a way to solve the public goods issue, as well as internalize the positive externality created in public goods.[7]

On the opposite side, WPR supporters can be divided into two subgroups: moderately weak intellectual property rights supporters and extremely weak property rights supporters. While the former subgroup accepts that some property rights are needed for R&D, they propose different alternatives to the present patent system. First, moderately weak intellectual property rights supporters traditionally have a broader view of the problem and propose revisions to the patent system, arguing that the incentive scheme is not as useful as was intended.[8] Some advocates in this group propose a

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[1] *See, e.g.*, David E. Adelman & Kathryn L. DeAngelis, *Frontiers of Intellectual Property: Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677, 1679 (2007); John M. Golden, *Principles for Patent Remedies*, 88 TEX. L. REV. 505, 506 (2010); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patent-Prizes Debate*, 92 TEX. L. REV. 303, 304 (2013).

[2] David Orozco & James G. Conley, *Friends of the Court: Using Amicus Briefs to Identify Corporate Advocacy Positions in Supreme Court Patent Litigation*, 2011 U. ILL. J.L. TECH. & POL'Y 107, 114 (2011).

[3] *See* Joseph Millum, *Are Pharmaceutical Patents Protected by Human Rights?*, 34 J. MED. ETHICS e25 (Nov. 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4704437/pdf/nihms740552.pdf.

[4] *See* Wen Chen, *Do Stronger Intellectual Property Rights Lead to More R&D-Intensive Imports*, 26 J. INT'L TRADE & ECON. DEV. 865, 875 (2017).

[5] *See generally id.*

[6] Public goods have two defining characteristics in that they are (1) nonexcludable and (2) nonrivalrous. Nonexcludable means that is it impossible or too hard to prevent someone from using the good; whereas nonrivalrous means that when one person uses the good, another person is not precluded from using the good. *What are Public Goods?*, KHAN ACAD., https://www.khanacademy.org/economics-finance-domain/microeconomics/market-failure-and-the-role-of-government/externalities-topic/a/public-goods-cnx (last visited July 28, 2020).

[7] Basically, since the underlying asset of a patent is knowledge, patents are a way to "privatize" knowledge so that the creator of that knowledge might benefit from the creation. This is a classical argument supporting patents. *See* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 9 (2003) (presenting an extensive review of the arguments for and against patents).

[8] *See generally* Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, HEALTH & HUM. RTS. J. (Nov. 23, 2015), https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/.

rewards scheme instead of a patent scheme.[9] Moderately weak intellectual property supporters also concentrate their criticism on exploiting the benefits of the current patent system and on a redistributive concern, without paying too much attention to the innovation dilemma.[10] On the other hand, extremely weak property rights supporters tend to base their claims through the lens, or perspective, of fairness. They usually advocate for relaxing the scope of patentability in developing countries so that developing countries can imitate patents without investing in R&D.[11]

Other WPR arguments highlight and propose a higher hierarchy of rights. For example, some posit that access to medicines should be prioritized over property rights. This view supports the idea that there is a hierarchy of rights and that healthcare is central to the rights that must be granted to every human being. They also argue that certain human rights have priority (for example, the right to life) over other human rights (private property rights, for example).[12]

Supporting this view, many non-governmental organizations ("NGOs"), policy makers, and physician organizations insist that patent rights should never go so far as to hinder access to healthcare by human beings.[13] This is based on a self-evident proposition—at least for proponents of WPR—that access to healthcare is a benefit that cannot be denied under any circumstances.[14] Other considerations are grounded in the notion that it would be unfair to allow pharmaceutical companies to make large profits at the expense of low-income countries, where individuals cannot afford such medicines.[15]

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[9] Kristina M. L. Acri née Lybecker, *How to Promote Innovation: The Economics of Incentives*, IPWATCHDOG (July 21, 2014), https://www.ipwatchdog.com/2014/07/21/promote-innovation-the-economics-of-incentives/id=50428/.

[10] *See, e.g.*, Gregory N. Mandel, *Innovation Rewards Towards Solving the Twin Market Failures of Public Goods*, 18 VAND. J. ENT. & TECH. L. 303, 306 (2016); Ted Sichelman, *Patents, Prizes, and Property*, 30 HARV. J.L. & TECH. 279, 279 (2017).

[11] There is extensive literature explaining the problem of north-south tradeoff in patent rights generally and in compulsory licensing in particular. *See* Eric W. Bond & Kamal Saggi, *Compulsory Licensing and Patent Protection: A North-South Perspective*, 128 ECON. J. 1157, 1176 (2016) (discussing an example of the north-south tradeoff problem); *see also* HANS LÖFGREN & OWAIN DAVID WILLIAMS, THE NEW POLITICAL ECONOMY OF PHARMACEUTICALS: PRODUCTION, INNOVATION AND TRIPS IN THE GLOBAL SOUTH 23 (Hans Löfgren & Owain David Williams eds., 2013) (discussing the north-south tradeoff in compulsory licensing).

[12] Lisa Froman, *An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law*, 14 J. WORLD INTELL. PROP. 155, 155 (2011); Hans Morten Haugen, *Human Rights and TRIPS Exclusion and Exception Provisions*, 11 J. WORLD INTELL. PROP. 345, 365 (2009). *But see* E. Richard Gold, *Patents and Human Rights: A Heterodox Analysis*, 41 J.L. MED. & ETHICS 185, 193 (2013).

[13] Emmanuel Kolawole Oke, *Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes*, HEALTH & HUM. RTS. J. (Dec. 6, 2013), https://www.hhrjournal.org/2013/12/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-law-disputes/.

[14] LAURENCE R. HELFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE 503–04 (2011); Millum, *supra* note 3.

[15] *See* Doris Schroeder *Does the Pharmaceutical Sector Have a Responsibility for the Human Right to Health*, 20 CAMBRIDGE Q. OF HEALTHCARE & ETHICS 298, 301 (2011); Udo Schüklenk & Richard E.

The problem with both SPR and WPR views is that they only go halfway. There is no conclusive empirical data that demonstrates a relaxation of patent protections will hurt innovation. To the contrary, many believe that it may be possible to develop a system that creates incentives similar to patents but with less distortion.[16] This might be consistent with the moderately weak property rights view.[17] However, some literature still exists arguing one consistent finding in patent research, something that is claimed to be a canonical truth or fact: the pharmaceutical industry needs patents to survive.[18]

This Article deals only with the following issues that arise from the previous discussion. First, the best way to explain the existing system of compulsory licensing is based on a utilitarian view. Broadly speaking, compulsory licensing is the process by which a government allows the production of a patented product without the consent of the patent holder under specific circumstances and following a specific procedure established by law.[19] Second, there may be an acceptable level of compulsory licensing that could be efficient. Therefore, any justification of an optimum level of compulsory licensing using a fairness perspective, rather than a utilitarian one, will lead to an incoherent understanding of the compulsory licensing mechanism. This line of reasoning is consistent with Kaplow and Shavell's ("KS") main argument in their book *Fairness Versus Welfare*.[20] Finally, if compulsory licensing is overused, it might create negative externalities on R&D activities that will affect future generations' well-being. This limitation could be seen in a decrease in the level of R&D necessary to approve drugs for future diseases.

The overall conclusion of this Article is that future generations are the most affected by an inefficient use of the compulsory licensing mechanism, and that this increases in probability if we use a fairness criterion instead of a utilitarian model. In other words, if the present patent system were based on utilitarian grounds, then property rights derived from it should be understood on utilitarian grounds too. Therefore, the most consistent way of understanding an exception to a property right might also be with a

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Ashcroft, *Affordable Access to Essential Medication in Developing Countries: Conflicts Between Ethical & Economic Imperatives*, 27 J. MED. & PHIL. 179, 180 (2002).

[16] *See, e.g.*, Petra Moser, *Innovation Without Patents: Evidence from World's Fairs*, 55 J. L. & ECON. 43, 70 (2012).

[17] *See, e.g.*, *id.*; Petra Moser, *Patents and Innovation: Evidence from Economic History*, 27 J. ECON. PERSP. 23, 40 (2013).

[18] *See, e.g.*, Frank A. Sloan & Chee-Ruey Hsieh, *The Effects of Incentives on Pharmaceutical Innovation*, *in* INCENTIVES AND CHOICE IN HEALTH CARE 227 (Frank A. Sloan & Hirschel Kasper eds., 2008); Joseph A. Dimasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 793 (1987).

[19] *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG., https://www.wto.org/english/tratop_e /trips_e/public_health_faq_e.htm (last updated Mar. 2018).

[20] *See generally* LOUIS KAPLOW & STEVEN SHAVELL, FAIRNESS VERSUS WELFARE (2002).

utilitarian perspective. But this does not imply that access to healthcare should not receive consideration, nor that it is not a desirable goal for humanity.

Of course, it might be argued that the patent system should not be based on utilitarian grounds, or that compulsory licensing should be based on granting access to healthcare based on any view but the utilitarian one (for example, the "needs principle"). This approach may be perfectly possible. However, there is a problem with consistency in claiming an absolute right to healthcare, or an absolute right to private property, with a patent system based on utility. So, the rhetoric for strong or weak patents in healthcare must come from a consequentialist perspective. In my view, one of the best tools that we have in that line of reasoning is efficiency.

Part II of this Article addresses a brief description of the current legal framework of compulsory licensing. Next, it briefly reviews three traditional views that might contribute to the distributive implication debate in the compulsory licensing realm. Then, in Part III, this Article demonstrates that the efficiency welfare criterion is a better justification for the current system. Finally, in Part IV, this Article offers some open questions and topics for further research.

II. BACKGROUND

A. The Basics of Pharmaceutical Patents and Compulsory Licensing on Essential Medicines

The debate referred to above is very prevalent in the field of medicine.[21] The discussion can be analyzed at the fairness/distributive level, as well as the legal framework level. Although this Article is mainly concerned with the former, a brief review of the latter seems reasonable to set the stage for the discussion.[22] Since the 1980s, laboratories have argued that a strong patent system will create the proper incentive to continue fueling R&D for new drugs.[23] However, many countries have not allowed entities or individuals to file patents on drugs based on the *order publique* issue that medicines are essential for all citizens.[24]

The discussion reached the international public policy debate mainly in the Uruguay and Doha Rounds of the General Agreement on Tariffs and

[21] *See, e.g.*, Haugen, *supra* note 12; Millum, *supra* note 3.

[22] This Article does not propose changes in the legal regime, although some might be necessary.

[23] KEVIN J. HICKEY ET AL., CONG. RES. SERV., DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 18 (2019), https://fas.org/sgp/crs/misc/R45666.pdf.

[24] *See generally* Emilie Cloatre & Martyn Pickershill, *International Law, Public Health, and the Meanings of Pharmaceuticalization*, 33 NEW GENETICS & SOC'Y 434–49 (2014).

Trade ("GATT").[25] The Uruguay Round of the GATT can be seen as a huge victory for SPR supporters because it imposed a basic rationale for patents, including medicines, for all countries subscribing to the Agreement on Trade Related Intellectual Property Rights ("TRIPS Agreement").[26] As a result of the new international framework enacted in 1994, patents "shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology[,] and whether products are imported or locally produced."[27]

Despite the protections that the TRIPS Agreement confers onto patents, it also contains many exceptions concerning patentable subject matter and the rights of patent holders.[28] Most prominent among the exceptions on patentable subject matter is that pharmaceutical drugs are not listed as one of the exceptions—they are patentable.[29] Generally, the existence of these exceptions imply a limit to the rights granted by Article 27 of the TRIPS Agreement.[30]

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[25] Signed by 23 countries in 1947, the GATT was intended to boost economic recovery after World War II. The GATT agreement minimized international trade barriers by eliminating or reducing quotas, tariffs, and subsidies while leaving other significant regulations in place. Christina Majaski, *General Agreement on Tariffs and Trade (GATT)*, INVESTOPEDIA (Oct. 24, 2019), https://www.investopedia.com/terms/g/gatt.asp. The Uruguay Round and the Doha Round are subsequent rounds of trade negotiations among World Trade Organization (WTO) member states. *See The Doha Round*, WORLD TRADE ORG. https://www.wto.org/english/tratop_e/dda_e/dda_e.htm (last visited July 28, 2020); *The Uruguay Round*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited July 28, 2020).

[26] The TRIPS Agreement was negotiated and adopted during the Uruguay Round of the GATT between 1986 to 1994. It is binding on WTO member states and sets minimum standards that all WTO member states must respect in the field of intellectual property protection—such as copyrights, patents, and trademarks. *See The Uruguay Round*, WORLD TRADE ORG., *supra* note 25. After the Uruguay Round, most developing countries amended their patents laws to extend the scope of patent rights to medicines. JC Cohen et al., *TRIPS, the Doha Declaration and Increasing Access to Medicines: Policy Options for Ghana*, 1 GLOBALIZATION & HEALTH 17 (Dec. 9, 2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1334179/pdf/1744-8603-1-17.pdf.

[27] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 ILM 1197, 1869 U.N.T.S. 299 (1994), https://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS Agreement].

[28] *See infra* note 29–33 and accompanying text.

[29] TRIPS Agreement, *supra* note 27, art 27.

[30] The TRIPIS Agreement excludes things such as genetic modifications of vegetables or medical treatments from patentability stating:

> 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. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Id. at art. 27(2), (3)(a)–(b).

Additionally, Article 28 further explains the extent of the intellectual property ("IP") holder's rights.[31] The TRIPS Agreement contains extensive exceptions to patent holder rights.[32] Among those exceptions, compulsory licensing is the most prominent.[33] Under a compulsory licensing procedure, a government may allow the production of a patented product without the consent of the patent holder under specific circumstances, including a health

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[31] "A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product." *Id.* at art. 28.

[32] *Id.* at art. 30–31.

[33] The TRIPS Agreement allows for the following:

> Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (a) authorization of such use shall be considered on its individual merits; (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly; (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; (d) such use shall be non-exclusive; (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use; (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances; (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member; (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur; (l) where such use is authorized to permit the exploitation of a patent ('the second patent') which cannot be exploited without infringing another patent ('the first patent'), the following additional conditions shall apply: (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment.

Id. at art. 31.

emergency.[34] As a result of this "taking," the patent holder has a right to compensation.[35]

Supporters of extremely weak intellectual property rights consider the outcome of the TRIPS Agreement unfair for developing countries. They consider the scope for using compulsory licensing under the TRIPS Agreement as extremely narrow and unclear.[36] As a result, extremely weak property rights advocates claim that this leaves developing countries void of any real tools for ensuring access to drugs to their population, especially if they were to face the threat of an epidemic.[37]

To rebalance the issue of access to medicines in emergency cases, during negotiations at the Doha Round, Paragraph 6 of the Doha Declaration was included to allow countries to determine under what circumstances they can impose compulsory licenses.[38] As a result, under the Doha Declaration, countries can issue compulsory licenses when they face a national health emergency.[39] The Doha Declaration and its contents were viewed as a major victory, not only for developing countries but also for those who support extremely weak property rights.[40]

At the same time, it is important to keep in mind that drug production is a complex process that involves several years of research, as well as clinical trials. Patent protection is only one minor step in this process. Moreover, we find only faint arguments supporting weakened patent protection as a way to guarantee access to medicines. Getting access to medicines is a complex process and, even if achieved, access does not guarantee availability for those in need. Despite the political economy and the legal technicalities regarding the interpretation of treaties, there are strong distributive claims under the different views on patent rights depicted above.[41] A proper understanding of those claims may provide adequate solutions to the dilemma of access to

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[34] *Compulsory Licensing of Pharmaceuticals and TRIPS*, *supra* note 19.

[35] *See* CONG. RES. SERV., COMPULSORY LICENSING OF PATENTED INVENTIONS 1 (2014), https://crs reports.congress.gov/product/pdf/R/R43266.

[36] Dina Halajian, *Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem*, 38 BROOK. J. INT'L L. 1191, 1191, 1210 (2013).

[37] *See generally* James Thuo Gathii, *How Necessity May Preclude State Responsibility for Compulsory Licensing Under the TRIPS Agreement*, 21 N.C. J. INT'L L. & COM. REG. 943 (2006); Patrick Marc, *Compulsory Licensing and the South African Medicine Act of 1997: Violation or compliance of the Trade Related Aspects of Intellectual Property Rights Agreements*, 21 N.Y.L. SCH. J. INT'L & COMP. L. 109 (2001).

[38] World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/W/2, 41 ILM 755 (2002) [hereinafter Doha Declaration].

[39] *The Doha Declaration on the TRIPS Agreement and Public Health*, WORLD TRADE ORG., https:// www.who.int/medicines/areas/policy/doha_declaration/en/ (last visited July 28, 2020).

[40] *See* Carlos M. Correa, *Intellectual Property Rights and Inequalities in Health Outcomes in*, GLOBALIZATION AND HEALTH: PATHWAYS, EVIDENCE, & POLICY 263–88 (Ronald Labonté et al. eds., 2009). *See also* Carlos M. Correa, *TRIPS Agreement and Access to Drugs in Developing Countries*, 17 EMORY INT'L L. REV. 25, 26 (2003).

[41] *See supra* notes 2–20 and accompanying text.

medicines.

B. Patents as Property Rights and Philosophical Justifications for Compulsory Licensing

There are vast amounts of scholarly literature dealing with the philosophy behind intellectual property rights.[42] Yet, in comparison, there is limited literature on the philosophy behind compulsory licensing. There are three traditional views to analyze compulsory licensing: (1) the Lockean tradition; (2) Rawlsian tradition; and (3) the utilitarian tradition. In my opinion, the utilitarian consequentialist view is the most consistent tradition for balancing the competing interests at stake when discussing compulsory licensing—the general public's access to medicines versus the patent holder's property rights.

1. The Lockean View of Intellectual Property in Conjunction with Compulsory Licensing

The Lockean theory of property has a long tradition of providing justifications for property rights in general, and intellectual property in particular.[43] His proposal begins by acknowledging, similar to most of his contemporaries, that God has given the Earth to mankind. For example:

> God, who hath given the World to Men in common, hath also given them reason to make use of it to the best Advantage of Life, and Convenience. The Earth, and all that is therein, is given to Men for the Support and comfort of their Being. And tho' all the Fruits it naturally produces, and Beasts it feeds, belong to Mankind in common, as they are produced by the spontaneous Hand of Nature; and no body has originally a private Dominion, exclusive of the rest of Mankind, in any of them, as they are thus in their Natural State: yet being given for the use of Men, there must be of necessity be a means to appropriate them some way or other, before they can be of any use, or at all beneficial to any particular Man.[44]

This point is essential in Lockean theory, as appropriation makes sense only to the extent that it is consistent with the "Divine gift."[45] Locke's theory rests

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[42] *See, e.g.*, Lawrence C. Becker, *Deserving to Own Intellectual Property*, 68 CHI.-KENT L. REV. 609, 609 (1993); Dan L. Burk, *Feminism and Dualism in Intellectual Property*, 15 AM. U.J. GENDER SOC. POL'Y & L. 183, 185 (2007); Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988).

[43] Adam Mossoff, *Why Intellectual Property Rights? A Lockean Justification*, LAW & LIBERTY (May 4, 2015), https://www.lawliberty.org/liberty-forum/why-intellectual-property-rights-a-lockean-justification/.

[44] *See generally* JOHN LOCKE, SECOND TREATISE OF GOVERNMENT AND A LETTER CONCERNING TOLERATION 15 (Mark Goldie ed., Oxford Univ. Press 2016) (1690).

[45] *See id.* at 14–27.

on the assumption of a quasi-natural rights scheme. With this view, Locke proposes his vision of the endowment of property rights: natural resources are given by God's will to humankind.[46] Then, Locke derives the way that those natural resources can be subjected to fair appropriation by human beings—namely appropriation through "labor mixing."[47] In other words, resources exist in their natural state, and by removing these resources through labor, a man acquires property rights over these resources.

From the general intellectual property perspective, Locke contributes to the understanding of the public domain concept. Accordingly, it has been argued that knowledge is part of the public domain, and only by adding the human effort required to process and crystalize that knowledge does it become a materialized invention.[48] Another key feature of Locke's theory is that property rights are not about exclusivity, but rather are granted as a condition of human flourishing.[49] However, the starting point here deals with what happens once property rights exist. What can Locke tell us about limits to property rights?

Upon narrowing the scope of the analysis to the compulsory licensing issue, Locke's most prominent contribution to this topic would be the idea of "provisos." Locke mentions that: "For this labour being the unquestionable Property of the labourer, no Man but he can have a Right to what that is once joined to, at least where there is enough, and as good left in the common for others."[50] Then he continues: "But how far has he given it to us? To enjoy. As much as any one can make us of to any Advantage of Life before it spoils . . . Whatever is beyond this is more than his Share and belong to others."[51] Finally, Locke states that: "Nor was this Appropriation of any parcel of Land by improving it, any Prejudice to another Man, since there was still enough, and as good left; and a more than the yet unprovided."[52]

These passages are particularly important for the debate concerning patents, specifically for compulsory licensing, as they limit the right of fair appropriation of things by human beings. They set a limit to the property right. Many Lockean scholars claim that the idea of solidarity and sufficiency provisos should be understood as a limitation on property rights.[53]

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[46] *Id.* at 15.

[47] Labor mixing is a key component of Lockean theory on the inception of property rights or ownership. Thomas Mautner, *Locke on Original Appropriation*, 19 AM. PHIL. Q. 259, 262 (1982).

[48] *See generally* Steven J. Horowitz, *Competing Lockean Claims to Virtual Property*, 20 HARV. J.L. & TECH. 443, 454–455 (2007) (discussing argument proposing analogy between conventional meaning of labor under Lockean theory to appropriation needed to acquire virtual property in Second Life game).

[49] ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY 38 (2011).

[50] LOCKE, *supra* note 44, at 15–16.

[51] *Id.* at 17.

[52] *Id.* at 18.

[53] *See, e.g.*, A. JOHN SIMMONS, THE LOCKEAN THEORY OF RIGHTS (1992); Jan Narveson, *Property Rights: Original Acquisition and Lockean Provisos*, 13 PUB. AFF. Q. 205 (1999); Jeremy Waldron, *Enough and as Good Left for Others*, 29 PHIL. Q. 319 (1979).

But the Lockean universe mainly discusses physical goods, not intellectual goods. With intellectual goods, the distinction about what we have to leave others is a tricky one. The first question is: what should I leave for others—knowledge in the public domain, or the result of my knowledge applied through the invention or creation of goods? Locke assumes that all men can equally labor to obtain property. At a basic level, it is true that most human beings have similar capacity for activities like hunting, cutting a tree, etc. But, what if the "good" I can bestow on humankind is a certain type of knowledge that can only be obtained by a very sophisticated genetic engineering, yet human technology is not advanced enough to apply that knowledge? Is technology affected by the provisos too?

Leaving these questions aside, mixing labor with an unowned object creates—at best—*prima facie* claims on that object. However, provisos create conditions that this presumptive claim will be unchallenged and is absolute; thus, imposing duties of noninterference onto others.[54]

Lockean property rights leave an open and fruitful field for discussing redistribution of intellectual property rights in fulfillment of the provisos suggested by Locke—especially the rights related to the technologies required to abstract the fruits of intangible goods from their natural state. Applying the previous statements to medicinal patents, the question to ask is: would Locke require patent holders to fulfill the provisos? The answer is yes. Locke clearly states that goods in the state of nature should be left so that others can also enjoy it.[55] Therefore, he recognizes that privatizing certain knowledge over medicines might "have a just power over the life of another by right of property" thereby constituting a violation of the charity proviso.[56] The implication is that the patent simply cannot, or should not, be granted when the patent gives the patent holder power to produce a monopoly.

Lockean provisos are not the most useful tools in understanding compulsory licensing. In a contemporary Lockean world, compulsory licensing would not exist, at least not in essential medicines. This can be argued on two levels. On one hand, compulsory licensing is not the property right on the invention, but the possibility of performing a taking based on fairness. In other words, I do not want you to leave enough for me because I want what is already yours. On the other hand, it is possible to speculate whether or not the provisos could fit in the industry of essential medicines. A Lockean view would oppose the granting of property rights over medicines that would create a monopoly because other laboratories should be allowed to produce similar medicines based on the natural resources remaining from

[54] Clark Wolf, *Contemporary Property Rights, Lockean Provisos, and the Interests of Future Generations*, 105 ETHICS 791, 793 (1995).

[55] LOCKE, *supra* note 44, at 17, 18.

[56] JOHN LOCKE, TWO TREATISES OF GOVERNMENT 170 (Peter Laslett ed., Cambridge Univ. Press 1988) (1690).

the original patent holder's consumption. This is due to the fact that the proviso of leaving enough for others can only be achieved by granting the invention in the public domain.

If the above is true, it might be hard to fit the existent patent regime into Locke's view. Here again, there is a problem of incentives for inventors or creators of medicines. If a person cannot appropriate the benefit of an invention, the best move is not to invent. If there are certain goods that cannot be produced because the appropriation of said goods would violate the sufficiency proviso, no one will produce those goods in fear of not receiving fair renumeration for their investment.

The concept of non-rivalry is of specific importance in this moment, because it is related with the technology problem posed in the previous paragraphs. The proprietary knowledge used to invent a specific drug is still there; a variation is attainable, so there is enough for all the others. That might explain why only a limited number of medicines trigger intellectual property issues at the compulsory licensing level: because (on most occasions) variations are attainable. The problem is when there is no technology available for producing an alternative good. Therefore, what is discussed concerning compulsory licensing is not a problem with the appropriation of knowledge, but with appropriation of the skills required for the production of that knowledge.

The Lockean theory of property rights have a limited application to the scope of compulsory licensing. First, the idea that Lockean theory is grounded in non-utilitarian views makes it difficult to apply to a compulsory licensing scheme based on a consequentialist view. If property rights do not fit into any of the provisos, then they are a sort of absolute right, which is inconsistent with the application of today's legal rules. Second, Lockean provisos of sufficiency are hardly applicable to non-material goods. As such, there is no way to appropriate what one will consume because nobody creates a drug for their own consumption. Instead, medicines are created for accumulation and trading.

However, it is important to preserve a point of Locke's theory that might be useful for the discussion. This point involves the charity proviso in which Locke states:

> no man could ever have a just power over the life of another by right of property in land or possessions; since it would always be a sin, in any man of estate, . . . so charity gives every man a title to so much out of another's plenty as will keep him from extreme want, where he has no means to subsist otherwise: and a man can no more justly make use of another's necessity to force him to become his vassal, by withholding that relief God requires him to afford to the

> wants of his brother, than he that has more strength can seize upon a weaker, master him to his obedience, and with a dagger at his throat offer him death or slavery.[57]

So, Locke realized that there might be a higher requirement that would limit property rights. This limitation is based on the nature of human beings and commands us to assist others by means of our own property in order to prevent others from falling into extreme need. This seems similar to what some extremely weak property rights proponents might suggest. Apparently, Locke's law of reason claims a certain hierarchy of rights granted by something different from individual well-being that may create an obligation to grant access to healthcare.

Nevertheless, although not directly related to this Article, Lockean theory might not be useful for some kinds of libertarians who support the current patent law system. For libertarians, once an individual or company creates an invention, they could claim an absolute right on it that would be equal to an appropriation of an idea. This argument, on certain occasions, is supported by those who favor strong intellectual property views.[58]

Certainly, no patent system grants property rights on ideas. The only thing that can be claimed as a right is the proven utility of that invention, if it meets the requirements that the legal system imposes.[59] To sum up, although Lockean philosophy might have strong influences on intellectual property, the theory is not well-suited for a debate concerning compulsory licensing on essential medicines, mainly because Locke's theory was developed around material, tangible goods. However, it is worth noting that SPR supporters usually use Lockean views to acknowledge a certain kind of absolute property right on their invention. This is a mistake. Because if intellectual property rights, or in this case patents, were absolute, then rules about patentable subject matter, as well as those discussing the length of the right, might be completely out of the question—and they are certainly not.

2. The Rawlsian View of Compulsory Licensing

When discussing distribution of property rights, it is best served to highlight the Rawlsian theory. As in the previous section, this Article does not attempt to give a full analysis of the application of Rawls's theory on intellectual property, but instead simply focuses on the basic Rawlsian framework as applied to compulsory licensing. Rawls's theory of justice is

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[57] *Id.*

[58] *See generally* Alan Ryan, *Self-Ownership, Autonomy, and Property Rights*, 11 SOC. PHIL. & POL'Y 241–48 (1994). It should be noted that in many occasions, libertarians do not agree with Patents because they consider them against free market. Nonetheless, this initial acquisition theory could be applied to those supporting strong intellectual property rights.

[59] *See generally Patent Eligibility Requirements FAQ*, FINDLAW, https://smallbusiness.findlaw.com/intellectual-property/patent-eligibility-requirements-faq.html (last visited July 27, 2020).

based on two famous principles: (1) "each person is to have an equal right to the most extensive total system of equal basic liberties compatible with a similar system of liberty for all" and (2) "[s]ocial and economic inequalities are to be arranged so that they are both: (a) to the greatest benefit of the least advantaged, consistent with the just saving principle, and (b) attached to offices and positions open to all under conditions of fair equality of opportunity."[60]

As a primary issue, the Rawlsian approach asks what role intellectual property rights play. Under this view, intellectual property rights can be considered, in a broader sense, as tickets to an "autonomous life."[61] Ownership represents a societal reward for hard work. Accordingly, intellectual property rights generally, and patents specifically, can be viewed in this sense as rewards for hard work and innovation.[62]

Generally speaking, Rawls would accept an unequal distribution of intellectual property rights, because the developments of those individuals with better skills in R&D would eventually benefit the least advantaged.[63] This might also be true in the pharmaceutical patent landscape, so long as this advantage does not lead to a violation in the provision of any primary goods. Hence, Rawls might agree with a moderately weak property rights view of granting property rights to R&D in the pharmaceutical industry, so long as some technology transfer is promoted in less developed countries. Supporters of this view would allow for this future technology transfer if developing countries create their own manufacturing capacity.[64]

Some scholars consider that a basic principle of the Rawls's vision is the "needs principle," which declares that health-related goods (pharmaceutical patented drugs in this case) are special for two reasons.[65] First, according to the Norman Daniels view, health is not subjected to individual choice.[66] For example, a person can choose whether to drive or walk to work, but a person cannot choose when they will contract a disease or choose the severity of said disease. Second, health is of vital importance to living life to the fullest. These two reasons lead to the conclusion that

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[60] JOHN RAWLS, A THEORY OF JUSTICE 266 (Harvard Univ. Press, rev. ed. 1999) (1921).

[61] Gregory Hagen, *Merges on Just IP: Are IP Rights Basic?*, *in* INTELLECTUAL PROPERTY FOR THE 21ST CENTURY: INTERDISCIPLINARY APPROACHES 352 n.8 (B Courtney Doagoo et al. eds., 2014).

[62] *See* MERGES, *supra* note 49, at 127.

[63] *See id.* at 129.

[64] *See generally* Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research*, *in* WORLD INTELLECTUAL PROPERTY ORGANIZATION, THE ECONOMICS OF INTELLECTUAL PROPERTY: SUGGESTIONS FOR FURTHER RESEARCH IN DEVELOPING COUNTRIES AND WITH ECONOMIES IN TRANSITION, https://www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo_1012_e.pdf, (last visited July 28, 2020).

[65] *See* Peter Dietsch, *Patents on Drugs—the Wrong Prescription?*, *in* INTELLECTUAL PROPERTY AND THEORIES OF JUSTICE 234 (Axel Gosseries et al. eds., 2008).

[66] Norman Daniels, *Health-Care Needs and Distributive Justice*, 10 PHIL. & PUB. AFF. 146, 158–60 (1981).

patents on drugs might hurt the "needs principle" on several fronts.

Intellectual property scholar Robert Merges has addressed the implications of Rawls's work on intellectual property, including the problem with patents for lifesaving drugs.[67] According to his view, property is not considered a primary good under Rawlsian terminology.[68] However, because access to healthcare is a primary good, healthcare must prevail over other considerations, and so appropriate measures (including perhaps compulsory licensing) are required to assure the supply of that primary good.[69]

The concern with that interpretation on Rawls's view is that distribution takes place once the drug exists. Yet, some inequalities might be accepted if a new disease presented itself. In that situation, the effort exerted by all countries to create a cure to the disease would make it likely that when that cure is produced, it may get into the hands of the less advantaged. Differential pricing would be more consistent with Rawls's view because it promotes greater liberty with similar results at the distribution level.[70] Namely, you might allow those individuals in a better situation get the benefits of their inventions without affecting liberty, while at the same time improving the position of those individuals that are in a worse situation. Moreover, a price discriminating strategy might serve Rawls's sense of justice while at the same time fulfilling efficiency, since it is similar to a perfect discriminating monopoly scheme.[71]

The final problem is that of intergenerational fairness from a Rawlsian point of view and its impact on the compulsory licensing problem. Rawls says that the present generation cannot just do as it pleases; instead, the present generation is bound to the principles chosen in the "original position," which are applied not only to the present generation but future generations as well.[72] So, the principles of justice that a society chooses also impose duties for the future too. Men have natural duties to uphold institutions for the improvement of civilization to a certain extent.[73] Rawls realizes that the "just saving principle" must be combined with the two other principles set up in the contract.[74]

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[67] *See* MERGES, *supra* note 49, 102–87, 277–87.

[68] *Id.* at 105, 277.

[69] *Id.* at 102–36, 279.

[70] A compulsory license is a non-voluntary disposal of someone's intellectual property right. Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT'L J. OF HEALTH CARE FIN. & ECON. 183, 200 (2003). A differential pricing scheme is a voluntary proposal according to which each pharmaceutical company decides to offer a price which is consistent with the maximum willingness to pay of each country. For a good review of the effects on differential pricing on pharmaceutical view *see generally id.*

[71] *See generally* Aaron S. Edlin et al., *Is Perfect Price Discrimination Really Efficient?: Welfare and Existence in General Equilibrium*, 66 ECONOMETRIA 897 (1998).

[72] RAWLS, *supra* note 60, at 258.

[73] *Id.*

[74] *Id.*

So, the open question remains: can it be argued that compulsory licensing faces a limit if it could be proven that R&D will decline in future generations? Rawls stated that:

> the saving of the less favored need not be done by their taking an active part in the investment process. Rather it normally consists of their approving of the economic and other arrangements necessary for the appropriate accumulation. Saving is achieved by accepting as a political judgment those policies designed to improve the standard of life of later generations.[75]

Thus, under a Rawlsian view, there is an obligation to future generations.[76] They must receive at least the same opportunities as the present generation.[77] This perspective is very enlightening, since future generations' access to R&D usually is not addressed in the debate surrounding compulsory licensing.[78]

3. The Rationale of the Contemporary Patent System Under a Utilitarian Point of View

A substantial portion of the scholarship on patents highlights how contemporary systems can be understood from a utilitarian perspective. The utilitarian theory is based on the idea that the patent system helps to solve a market failure: the public good and the subsequent externality problem.[79] The theory states that, absent the possibility to exclude patent grants, "copycats will quickly enter the market," imitating the product and driving prices below the price at which inventors can recover their R&D costs.[80] So, without patent protection, too little innovation would occur because the rational inventor will not bother to invent, knowing that she will not recoup the cost of the invention. In other words, it is cheaper to copy than to invent—due to the amount of risk involved with the latter—so, it is more economically viable to wait until somebody else invents something and then just imitate it. This all

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[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] There are objections to the just saving principle and the impact that it has on future generations. However, this is not in the scope of this Article. For an interesting discussion about the alternatives, see Frédéric Gaspart & Axel Gosseries, *Are Generational Savings Unjust?*, 6 POL., PHIL. & ECON. 193 (2007).

[79] *See* Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 50 (2001); Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. OF LEGAL STUD. 247, 247–48 (1994); Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805, 808–09 (1988); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 839, 871 (1990) (noting that "the economic significance of a patent depends on its scope: the broader the scope, the larger the number of competing products and processes that will infringe the patent" and further noting that "proprietary control of technology tend to cause 'dead weight' costs due to restrictions on use"); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 191 (2019).

[80] Olson, *supra* note 79, at 182–83.

culminates in little incentive to innovate in areas of high-risk.

It is also well recognized that this mechanism for incentivizing innovation might cause deadweight loss to society in the form of higher prices; thus, pushing consumers out of the market.[81] Accordingly, a properly crafted patent law should provide enough property rights to incentivize a socially desirable and efficient level of innovation, but no more. Therefore, patents that are broader in scope or longer in duration than the inventor needs to recoup their costs of invention (R&D costs, for example) would inevitably harm society in the form of higher prices on patented goods. This occurs because fewer numbers of consumers are able to purchase the patented goods, and the less purchasing that goes on in an economy results in decreased GDP—also known as deadweight loss.

Considering the actual patent system, an invention must meet the fundamental patentability requirements before a patent can be granted. The claimed invention must: (1) contain "eligible subject matter," and it must be (2) "useful," (3) "novel," and (4) "nonobvious."[82] Also, patents are limited by the patentable subject matter requirement as well as the scope of patentability rules.[83] In addition, there are regulations in patent law that establish a one-year limit on the patent, and after that year, patent protection no longer exists, and the invention becomes part of the public domain.[84] The main reason for that one-year limit is because the public might benefit from the invention of another.[85] Under these rules, there is a clear case that the utilitarian view justifies the existing patent regime.

C. Compulsory Licensing and Distributive Justice

In their seminal article, Kaplow & Shavell (KS) stated that a distributive attempt based on any criteria other than welfare criteria might violate the Pareto principle.[86] The fairness versus welfare debate poses the vexed question about what values should guide legislators, regulators, judges, and scholars in shaping policies affecting society. KS adopt a consequentialist approach arguing that individual well-being is a desirable outcome.[87] Many studies have been published about KS's proposal, many of

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[81] *Id.* at 183.

[82] Return Mail, Inc. v. U.S. Postal Serv., 139 S. Ct. 1853, 1859 (2019) (citing 35 U.S.C. §§ 101, 102, 103).

[83] *See* Olson, *supra* note 79, at 191–92.

[84] *One-Year Rule*, NOLO, https://www.nolo.com/dictionary/one-year-rule-term.html (last visited July 28, 2020).

[85] *See* Olson, *supra* note 79, at 192–93.

[86] The Pareto principle determines that "if everyone is strictly better off under one policy than under another, the former should be deemed superior." Louis Kaplow & Steven Shavell, *Fairness Versus Welfare: Notes on the Pareto Principle, Preferences, and Distributive Justice*, 32 J. OF LEGAL STUD. 331, 336 n.5 (2003).

[87] *See id.* at 331–34.

them containing criticism.[88] This Article will not address the entire KS debate. However, it is noteworthy to provide a brief review of the main proposals of the KS position, as they also may contribute to the compulsory licensing debate.

KS attempted to establish a normative conclusion on law and economics scholarship, which proposed that all normative decisions adopted by judges and policy makers should be based on welfare considerations.[89] Thus, legal rules should be developed entirely with respect to their effects on the well-being of individuals within society.[90] So, following KS's idea, the analysis should focus on the existent compulsory licensing mechanism using no other criteria than *efficiency*. KS's welfare economic rule can be broken down into three characteristics: (1) adopting a consequentialist view of the decisions, (2) embracing a certain type of welfarism, and (3) adopting a utilitarian preference satisfaction view.[91]

As KS suggests, "[u]nder a welfarist approach to policy assessment, one first determines how a policy affects each individual's well-being and then makes an aggregate (distributive) judgment based exclusively on this information pertaining to individuals' welfare."[92] It should be noted that KS's conception on individual's well-being is comprehensive.[93] A key notion of KS's argument is the implementation of fairness across many forums, including in terms of justice, rights, and/or cognate concepts.[94] This notion is based on three assumptions: (1) most notions of fairness are non-consequentialist; (2) some notions of fairness are completely compatible with welfare views (KS's arguments have no objection with notions of fairness grounded on welfare terms); and (3) favoring fairness on other terms than welfare grounds will conflict with efficient distribution.[95] On an opposite view, a fairness criterion that might allow interpersonal comparison of well-being will not conflict with KS's point of view. So, KS's view likely does not conflict with the utilitarian view of fairness.[96]

The welfarist method proposed by KS consists of utilizing the theory

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[88] *See generally* Richard Craswell, *Kaplow and Shavell on the Substance of Fairness*, 32 J. OF LEGAL STUD. 245 (2003); Lewis A. Kornhauser, *Well-Being, and Morality in Social Decisions*, 32 J. OF LEGAL STUD. 303 (2003); Jeremy Waldron, *Locating Distribution*, 32 J. OF LEGAL STUD. 227 (2003).

[89] Kaplow & Shavell, *supra* note 86, at 341–42, 356–60.

[90] *See* KAPLOW & SHAVELL, *supra* note 20, at 18.

[91] For a discussion of those characteristics, see Christopher P. Taggart, *Fairness Versus Welfare: The Limits of Kaplow and Shavell's Pareto Argument*, 99 MARQ. L. REV. 661, 661–62 (2016). In very basic terms, a consequentialist view means that a moral outcome will be right or wrong just based on the consequences of the outcome; welfarism means that the measure of the consequences will be well-being; and finally, utilitarian means that following certain axioms you can obtain that will provide a rational measure of how to choose.

[92] Kaplow & Shavell, *supra* note 86, at 332.

[93] *See generally id.*

[94] *Id.* at 333.

[95] *Id.* at 334.

[96] *See id.* at 360–61.

of preference maximization.[97] Thus, this vision is comprised of everything of concern to the individual's well-being, including sentiments of fairness, justice, equality, and the like. KS should be seen in a narrow sense—their proposal is a warning to avoid creating inconsistent policy recommendations. It has been said that if the aim of KS is looking for consistency, then there might be a problem for completeness, as there may be an indefinite number of policy issues that the system is simply unable to decide.[98] This Article does not challenge the previous conclusion. Instead, the rule proposed by KS can serve as a guideline for better decision-making than the rules already used in a compulsory licensing framework, because the problem in compulsory licensing is one of consistency.

III. AN ARGUMENT FAVORING A WELFARE VIEW ON COMPULSORY LICENSING

The KS rule says that a good policy should pursue the total welfare of individuals.[99] Can this rule serve as a guideline for the application of the compulsory licensing regime? Under certain conditions, the KS rule might have a range of applications. KS proposes two types of cases: symmetric and asymmetric.[100] The first relates to the same structure of preference for all agents, thereby the rules should be designed so that one can maximize all preferences.[101] In asymmetric cases, the initial endowment of well-being might be different.[102]

In the KS scheme, a compulsory licensing problem would fit under the asymmetric structure. The classical scenario might be depicted as asymmetric because the legal rule does not affect both parties in the same way. In these situations, usually there are two players with different endowments of intellectual property rights and intellectual property capabilities. So, the compulsory license, understood as a distribution rule, tends to affect each player in a different way.

In most compulsory licensing literature, the bargaining situation is static with no consideration of future generations.[103] This implies that the focus is on north to south welfare transfer, or alternatively as a "signaling game" that measures the level of threat and its impact on R&D. Namely, the discussion is focused on the threat posed by a country using the compulsory licensing mechanism in technology transfer, as well as the externalities that

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[97] *See generally* KAPLOW & SHAVELL, *supra* note 20, at 413–36.

[98] Giuseppe Dari Mattiacci, *Gödel, Kaplow, Shavell: Consistency and Completeness in Social Decision-Making*, 79 CHI.-KENT L. REV. 497, 499 (2004).

[99] KAPLOW & SHAVELL, *supra* note 20, at 3–4.

[100] *Id.* at 52.

[101] *Id.* at 53 n.75.

[102] *Id.* at 112 n.68.

[103] *See, e.g.*, Pankaj Tandon, *Optimal Patents with Compulsory Licensing*, 90 J. OF POL. ECON. 470 (1982).

this mechanism creates.[104]

The conclusions of the existing literature may be correct. Regardless, the distribution of and access to drugs today might come at a high cost—a cost associated with the risk of not enough R&D for creating drugs in the future. Therefore, to decide the level of distribution between generations, a welfare efficient approach might be useful. Of course, the usefulness of this criteria is based on the utilitarian characteristic of the entire intellectual property regime.

Usually, arguments favoring compulsory licensing are based on some type of hierarchy of rights approach.[105] Some of the literature favoring access to healthcare justifies compulsory licensing on the basis that it is morally wrong to use patents rights to restrict access to healthcare, since the latter right might have a higher rank than the former right.[106]

KS's arguments about welfare could be used to determine whether, and to what extent, compulsory licensing is an efficient mechanism for distributing the human right of access to healthcare. Then, efficiency can serve to determine policy recommendations about when it is appropriate to impose a compulsory licensing scheme. This view might substitute some of the arguments based on fairness.[107]

Since patent law is based on the criteria that "exclusive rights" are granted only to those inventions that might have certain positive impact on society (positive utility), then any rent seeking behavior that might create incentive to decrease the level of welfare of society should be corrected.[108] Compulsory licensing seems to be a certain type of redistribution criteria that fits under the welfare efficiency criteria.

Now, since impact on drug development occurs over time, a proper welfare view of patents in the pharmaceutical industry must be understood only on an intertemporal basis. Most of the discussion of patent and healthcare considers only distributive effects on a temporal basis—distinguishing developed countries with production capacity from developing

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[104] *See generally id.*; F.M. Scherer, *First Mover Advantages and Optimal Patent Protection*, Faculty Research Working Paper Series, Harvard Kennedy School Mossavar-Rahmani Center for Business and Government (2015), https://research.hks.harvard.edu/publications/getFile.aspx?Id=1191.

[105] *See, e.g.*, Peter K. Yu, *International Rights Approaches to Intellectual Property: Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1096–02 (2007).

[106] *See, e.g.*, Uche Ewelukwa, *Patent Wards in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203 (2005).

[107] *See* Mark Heywood, *South Africa's Treatment Action Campaign: Combining Law and Social Mobilization to Realize the Right to Health*, 1 J. OF HUM. RTS. PRAC. 14 (2009).

[108] Rent seeking is "an economic concept that occurs when an entity seeks to gain added wealth without any reciprocal contribution of productivity." Christina Majaski, *Rent Seeking*, INVESTOPEDIA (Aug. 28, 2019), http://www.investopedia.com/terms/r/rentseeking.asp.

countries without production capacity.[109]

To achieve the above goal, it is necessary to construct a social welfare function in which: (1) a greater hierarchy is given to those with needs so as to grant them access to medicines; (2) compensation for the patent holder is established; (3) consideration is given to the impact of R&D for future generations; and (4) a certain weight is given to variables about the moral uncertainty imposed by the cost assumed by the actual generation in terms of granting enough R&D activities for future generations.

Considering the previous statement as a starting point, we can propose the following principles based on welfare grounds:

(1) If we accept property rights from the utilitarian perspective, it can be said that patents (as a type of property right) make sense only to the extent that they promote the total welfare of a society. Thus, patent length and protection should equal compensation for R&D, plus a premium for the risks involved in investment.

(2) Because drugs are basic elements that promote healthcare, and healthcare creates positive utility for societies, R&D activities that promote health should be maximized. And by extension, compulsory licensing should be granted only to the extent that it will not affect such advances to the present generation, but also includes an equivalent level of incentive for R&D for the next generation.

(3) Welfare should be considered as not only weighing the costs and benefits of the actual distribution of access to drugs, but it also should take into account the probability of leaving enough incentives so that future generations might have an equal chance of getting valuable drugs for their generation, whose research must be started during this generation.

This does not lead to the conclusion that compulsory licenses should never be applied, nor that they must always be used. Rather, it only implies that if the situation is not analyzed through the lens of well-being, the resulting distribution can lead to detriments for everyone as a whole, making everybody worse off.

The principles previously stated might lead to shift rights that are typically in conflict in this type of scenario: property rights (intellectual property and patents) versus access to drugs. If it is assumed that a patent holder's rights are completely instrumental to maximizing healthcare in present and future generations, then the tradeoff when applying compulsory licensing would be the present generation's access to drugs versus the future generation's potential access to drugs. Change implies an important shift in

[109] *See, e.g.*, Ewelukwa, *supra* note 106.

the rhetoric used for policy analysis in this type of situation.

An instrumental view of patents might allow for a determination of an optimal number of compulsory licenses that can be issued without affecting an optimal level of R&D which—as previously stated—is the main reason for granting patents in the healthcare industry.

(a) If the total compulsory licenses issued at moment x is less than the expected value of investing in future R&D, then compulsory licensing is creating a Pareto improvement. The present generation is doing better, and future generations continue to have an equal chance of getting the same R&D level.

(b) If the total compulsory licenses issued at moment x is equal to the expected value of investing in future R&D, then compulsory licensing is a Pareto optimal *vis-a-vis* the scope of protection of patent rights at moment x.

(c) If the total compulsory licenses issued at moment x (Time0 or T0) is higher than the expected value of investing in future R&D (T1), then compulsory licensing might be hurting innovation of future generations; thus, decreasing the chance of creating necessary drugs in T1.[110] Then, we have reached an inefficient level of compulsory licensing since the intertemporal marginal benefit (MBg) is lower than the intertemporal marginal cost (CMg)—MBg < MCg.

The previous statement contributes to clarifying the rhetoric of the discussion in the pharmaceutical compulsory licensing debate and might level the playing field when comparing the goods in the tradeoff. Even if SPR supporters claim that the reason for protecting intellectual property rights would be utilitarian, strong patents are good because they promote more R&D.[111] Extreme WPR supporters usually claim that healthcare has priority over property rights based on certain hierarchy structure of rights. In this way, the latter usually have a winning card, since most of the time our moral intuition says that healthcare is more important than making profit from property rights.

A way to overcome this debate is to level the playing field by putting

[110] Expected value is defined as "an anticipated value for an investment at some point in the future. In statistics and probability analysis, the expected value is calculated by multiplying each of the possible outcomes by the likelihood each outcome will occur and then summing all of those values. . . . $EV = \sum P(X_i) \times X_i$." Will Kenton, *Expected Value*, INVESTOPEDIA (June 27, 2020), https://www.investopedia.com/terms/e/expected-value.asp.

[111] *See* Marshall Phelps, *Do Patents Really Promote Innovation? A Response to the Economist*, FORBES, (Sept. 16, 2015, 2:42 PM), https://www.forbes.com/sites/marshallphelps/2015/09/16/do-patents-really-promote-innovation-a-response-to-the-economist/#1c4abd371921; Gene Quinn, *The Theory of Patents and Why Strong Patents Benefit Customers*, IPWATCHDOG (Nov. 24, 2015), https://www.ipwatchdog.com/2015/11/24/theory-patents-strong-patents-benefit-consumers/id=61341/.

the two opposite views of patents rights—SPR and WPR—together to discuss the same good: healthcare. Thus, the debate should be about to what extent limiting intellectual property on patents for the present generation affects R&D for new drugs, especially considering the effect that this may have on access to drugs for future generations. This statement is consistent with KS's argument as the fairness criteria that might be applied to a compulsory licensing scheme is a welfarist one.

So, while all arguments about compulsory licensing are based on a certain hierarchy of rights, in general terms, these arguments are based on concepts other than that of well-being and cannot lead to a consistent application of the patent exception regime. Yet, an argument based on the theory of utilitarianism of goodness and well-being (as a distributive claim and efficiency as a pattern of distribution) could lead to a more coherent explanation of the existing rules as well as the praxis.

The main objection to this previous argument is that the right of the patent holder is being neglected. This objection can be rebutted with the confirmation that our current patent system is grounded in utilitarian terms. So, the only reason why the state might grant the patent holder an exclusive right is that the invention might contribute to social well-being. In particular, the benefit of getting the drug must be higher than the cost associated with the exclusion right granted by the patent.

Of course, the traditional criticism of the utilitarian view, which can be applied against individual rights, may also affect IP rights in the same manner. However, the point of this Article is not to claim that this way of reasoning could be applied to all rights. Rather, this Article is simply asserting that given a certain bundle of rights based on utilitarian views (patents), their exceptions (such as compulsory licensing) must be also considered within the utilitarian view, and the way of measuring that exception within this framework is through efficiency, as KS argued.

It can be argued in response that some people are in more urgent need than others as far as access to healthcare is concerned. In this sense, there is no need to abandon the utilitarian perspective. A prioritarian view might be adopted in this matter, although applying the prioritarian view is beyond the scope of this Article.[112]

This line of reasoning leads to the acceptance of a view that IP rights are instrumental and not natural. The teleology of recognizing property rights in the case of patents on essential medicines is to raise total welfare in terms of access to new drugs. So, patents are beneficial instruments, but only if they

[112] A prioritarian view is a type of welfarist view that "for any given set of outcomes, [prioritarianism] generates a moral ranking of the outcomes, comparing them to each other as morally better, worse, or equally good." Matthew D. Adler & Nils Holtug, *Prioritarianism: A Response to Critics*, 18 POL., PHIL. & ECON. 101, 102 (2019).

maximize total welfare. Redistribution for patents is a necessary condition to allow R&D expenditure to continue growing and thriving so that future generations can enjoy their benefits.

It is clear that the proposal laid out in this Article is more consistent with a theory of fairness than with a theory of goodness.[113] However, there is an axiology associated with this normative proposal, which is to promote maximum welfare for the present and future generations. From a normative perspective, this theory is teleological, since the validity of a compulsory licensing depends on the aim upon which the compulsory licensing is imposed.

IV. CONCLUSION

This Article has argued that the existing legal framework for patents in medicines can be better understood from a utilitarian perspective. Although other theories—like those of Locke and Rawls—contain useful normative tools, they cannot be fully applied to the existing legal structure of patents because of its utilitarian characteristic.

Compulsory licensing is part of the existing regime. Therefore, any theory that tries to provide an efficient use of this legal tool should be expressed in utilitarian, welfarist terminology. This line of reasoning leads to the acceptance of a view that intellectual property rights are instrumental and not natural. The teleology of recognizing property rights in the case of patents on essential medicines is to raise total welfare in terms of access to new medicines.

Usually, compulsory licensing rhetoric is split between strong supporters of intellectual property rights and extreme weak supporters of intellectual property rights. The former base their claim on the importance of property rights for R&D, and the latter base their claim on certain hierarchy of rights criteria. A way to overcome this debate is to level the playing field and equalize the two opposite views so that they discuss the same good: healthcare. The debate should be about to what extent limiting IP rights on patents affects R&D on new drugs, and to what extent it affects healthcare for future generations.

This is also consistent with KS's argument since the fairness criteria according to which a compulsory licensing is applied is a welfarist one. So, basing arguments on something other than well-being cannot lead to a consistent application of the patent exception regime, while an argument

[113] A theory of the goodness discusses what it is good and the way you can reach that conclusion. A theory of fairness is concerned with the distributions of the goods. For a detailed discussion of those concepts, see John Broome, *Fairness*, *in* 91 PROCEEDINGS OF THE ARISTOTELIAN SOC'Y 87–01 (Oxford Univ. Press 1990).

based on total welfare provides a coherent explanation.

There are many issues not addressed in this Article, leaving room for further research and scholarship. Among the future research topics is the possibility of applying a priority view for determining the use of compulsory licensing. Also, in a similar vein, it is necessary to review the moral uncertainty that a decision of whether or not to impose a compulsory licensing may carry. Another topic lies in the construction of the social welfare function, which although mentioned in this Article, has not been properly developed. Additionally, further research could be conducted to incorporate the literature on intergenerational equity and explore its consequences on this proposal.

There are many implementation problems that need to be addressed as well. One of the most troublesome is that, even by accepting a utilitarian perspective, only in an ex-post scenario can it be verified that the usage of the compulsory licensing mechanism is higher than the optimum. So, there are uncertainty issues, especially due to the lack of information about the level of R&D and return of laboratories, that need to be considered from a policymaking point of view. The goal in this Article was to contribute to the distributive justice debate on patents with a utilitarian perspective. It is perfectly possible that in the near future the entire patent system might undergo deep revision. In that case, a bigger discussion about the justice of the entire system will be required.