LEXMARK AND INTERNATIONAL PATENT EXHAUSTION ON SALE: ITS IMPLICATIONS ON AFFORDABLE MEDICINES IN THE US AND INDIA

— Raj S. Davé, Neil Davey†, Vignesh Ramachandran**, and Ron Somers††*

Abstract: *The role of intellectual property in the pharmaceutical industry has been controversial for decades. On one hand, evidence suggests that patents and monopolies on drug sales for*

* Dr. Raj S. Davé, a registered patent attorney in the United States, is the President & Founder of *Davé Law Group* (DLG), a full-service Intellectual Property law firm in Virginia. Dr. Davé is an Emeritus Resource Faculty, School of Law, Policy and Governance (SLPG), School of Maritime, Air and Space Studies (SMASS), Rashtriya Raksha University, National Security and Police University of India He is a Visiting Professor Southwest University of Political Science and Law, Chongqing, China. He is the Chairman of Indian Government's Patent Facilitation Committee whose objective is to oversee the working of Patent Facilitation Centers in different Indian states. Dr. Davé is recognized as an "IP Star" by Managing Intellectual Property and the Legal 500 US He has authored articles published in Duke Law & Technology Review, Yale Journal of Law and Technology, and Harvard Journal of Law and Technology, among others.

† Neil Davey is a law student at Harvard Law School, where he is Managing Editor of the Harvard Journal of Law & Technology. Mr Davey has co-authored 20+ publications at the intersection of healthcare policy, biotechnology, and intellectual property. His current academic interests involve the legal and regulatory frameworks that underlie access to medicines in the Global South. Mr Davey was previously a healthcare consultant at McKinsey & Co., prior to which he was a Gates Cambridge Scholar studying an MPhil in Technology Policy.

** Vignesh Ramachandran is an Intellectual Property (IP) Counsel at Lam Research. Prior to Lam Research, he was an IP Associate at Perkins Coie LLP. Mr. Ramachandran is a member of the Advisory Council at San Jose State University (SJSU), where he is helping develop an IP curriculum and advise engineering students regarding careers paths in IP. He is the first member of the Patent Council at SJSU, where he evaluates whether to get protection for inventions by SJSU faculty and students. Mr Ramachandran has also published an article entitled, "Cybersecurity and Patent Law – Let's Work Together", in the American University IP Journal.

†† Ron Somers is Founder and CEO of *India First Group, LLC*, a strategic consulting firm dedicated to helping U.S. companies succeed in investing in India and assisting Indian companies navigate the complex regulatory environment in the United States. Ron Somers is a passionate advocate for deeper US-India commercial relations, having served as president of the Washington-based US-India Business Council (USIBC) for a decade from 2004-2014. Ron Somers holds a bachelor's degree from Middlebury College as well as a master's degree from Middlebury's Bread Loaf Graduate School, where he studied at Lincoln College, Oxford University.

limited periods are necessary to fund costly R&D required to produce life-saving therapies. On the other, there is concern that patent rights have gone too far in favour of innovation, limiting access to lower-income populations who cannot afford exorbitant drug prices. This tension plays out at a grander scale in the international context, as drug prices can vary drastically between countries, as has happened in the COVID-19 pandemic.

In 2017, the United States Supreme Court held in Lexmark that a patentee's rights are exhausted after international sale. This decision has immense implications for the U.S. pharmaceutical industry and the affordability of medicines worldwide. Legislators such as Senator Bernie Sanders have proposed bills in light of the decision to lower American drug prices by permitting importation from countries like Canada. Though FDA and other regulatory barriers may still be present, American innovator companies can no longer sue reimports on the grounds of patent infringement.

However, while the results may be favourable to U.S. consumers, international impacts remain to be seen. Some suggest that prices in countries like India could increase to reduce opportunities for arbitrage. In this article, we suggest methods for branded pharmaceutical companies to address issues arising from Lexmark while simultaneously providing affordable access—from voluntary licensing to avoid the risk of compulsory licenses and creative forms of contracting. Finally, we conclude regarding India's newfound consumer protection laws to note that American pharmaceutical players may not simply be able to lower product standards to prevent parallel importation back to the US.

Keywords: Drugs, Lexmark Medicine, Patent Exhaustion, Pharmaceutical, Lexmark.

I. INTRODUCTION TO INTERNATIONAL PATENT EXHAUSTION IN THE PHARMACEUTICAL INDUSTRY

The foundation of patent protection was borne from a desire, per Alexander Hamilton in his Report on Manufactures, to encourage, "new inventions and discoveries at home, and of the introduction into the United States of such as may have been made in other countries; particularly, those which relate to machinery."[1] This desire drove the formation and development of the patent system.

However, over time, the patent system has gained detractors due to the negative consequences. For instance, Stephen Hawking has euphemistically said: "We think we have solved the mystery of creation. Maybe we should patent the universe and charge everyone royalties for their existence."[2] Hawking is satirically referencing the push toward a gold rush in the patent world.[3] In other words, Hawking's commentary highlights the shift in motivations from the Hamiltonian age to the present, where monetization and prevention are the main motivators.

A. Patents in the Pharmaceutical Industry and Societal Impacts

In the pharmaceutical industry, in particular, patents often hinder access to medicine to the developing parts of the world. Such a consequence is perhaps more acute in the pharmaceutical industry than others, due to the humanitarian nature of the industry. Patenting can limit access to medicine by contributing to the increased costs of development, that are then passed to the customer, while the patent holder also controls the distribution.[4]

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1 Robert P. Merges, 'The Hamiltonian Origins of the U.S. Patent System, and Why They Matter Today' (2019) 104 Iowa L Rev 2559 <https://ilr.law.uiowa.edu/print/volume-104-issue-5/the-hamiltonian-origins-of-the-u-s-patent-system-and-why-they-matter-today/> accessed April 2021.

2 'An Inventor's Guide to Understanding Patent Eligibility' (*InQuartik*, 15 October 2020) <https://www.inquartik.com/blog/basic-inventors-guide-understanding-patent-eligibility/> accessed 5 April 2021.

3 ibid.

4 Michelle Chen, 'Patents Against People: How Drug Companies Price Patients out of Survival' (*Dissent Magazine*, 9 December 2013) <https://www.dissentmagazine.org/article/patents-against-people-how-drug-companies-price-patients-out-of-survival> accessed 6 April 2021.

Further, commentators have reasoned that not only do pharmaceutical patents promote a business model incentivizing high price points but that patents also prevent further innovation from occurring.[5] This is primarily because pharmaceutical companies have been incentivized, at least in part by the patent system, to only make drugs that are high market potential.[6] Further, critics contend that most innovation comes from academic centers and research institutions, while much of pharmaceutical spending is on marketing and advertising.[7]

While intellectual property protection is important in the pharmaceutical sector given the high costs of R&D, with widely cited studies showing that the median cost for bringing a drug to market is $985 million,[8] abuses such as the development of copycat drugs to extend patent life and abnormally high profit margins remain as top concerns for healthcare consumers.[9] The monetary and predatory consequences, therefore, of the patent system cannot be ignored in the pharmaceutical industry.

Perhaps the finest example of the confrontation between pushing innovation through patent law and its consequences is the situation in South Africa in the mid to late 1990s. At the time, South Africa was experiencing one of the fastest expanding HIV/AIDS epidemics in the world.[10] The patients, due to high prices, had no or very limited access to lifesaving antiretroviral therapy ("ART").[11] However, the ART medications were being sold at lower prices abroad, and thus, Nelson Mandela's South African Government passed the South African Medicines and Related Substances Control Act Amendments.[12] Of particular interest to the pharmaceutical industry and the patent industry, was Section 15(c), which indicated that the South African government believe

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5 'Should Patents on Pharmaceuticals Be Extended to Encourage Innovation?' (*The Wall Street Journal*, 23 January 2012) <https://www.wsj.com/articles/SB10001424052970204542404577156993191655000> accessed 6 April 2021.

6 ibid.

7 Michele Boldrin and David Levine, 'The Pharmaceutical Industry' in Michele Boldrin and David K. Levine (eds), *Against Intellectual Monopoly* (Cambridge University Press 2010).

8 Olivier Wouters, Martin McKee and Jeroen Luyten, 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018' (2020) 323 JAMA 844-853.

9 Chen (n 4).

10 Burcu Kilic and Peter Maybarduk, 'The Lexmark Litigation: Why Does Big Pharma Care So Much About Ink Cartridges?' (*Intellectual Property Watch*, 17 September 2015) <https://www.ip-watch.org/2015/09/17/the-lexmark-litigation-why-does-big-pharma-care-so-much-about-ink-cartridges/> accessed 8 April 2021.

11 ibid.

12 Debora Halbert, 'Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs' (2002) 1 Seattle Journal for Social Justice 257 <https://digitalcommons.law.seattleu.edu/cgi/viewcontent.cgi?article=1231&context=sjsj> accessed 8 April 2021.

it was permitted to engage in compulsory licensing and parallel importation of drugs to provide access at prices affordable to South Africans.[13]

At the time, the South African government believed it was acting in accordance with the Trade-Related Aspect of Intellectual Property Right ("TRIPS") agreement, which allowed each member of the World Trade Organization ("WTO") to design its regime concerning exhausting of patents.[14] In other words, this freedom, allowed countries to shop for the lowest price of a drug and import that drug at the lower price.[15] While the South African legislation took a human rights-based approach, it was not long before multinational – mainly, American – pharmaceutical companies began admonishing the South African legislation. Namely, the companies argued that the legislation was a violation of TRIPS, which resulted in an international dispute that was framed as a battle between commercial interests and human rights.[16]

TRIPS, in general terms, established minimum standards for the availability, scope, and use of seven forms of intellectual property: copyrights, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits, and undisclosed information (trade secrets).[17] It spells out permissible limitations and exceptions in order to balance the interests of intellectual property with interests in other areas, such as public health and economic development.[18] Notably, the 2001 Doha Declaration on the TRIPS agreement responded to concerns about access to affordable medicines in developing countries, allowing the use of compulsory licenses on a case-by-case basis.[19] The agreement was driven by worries about obstacles to access care for diseases of public health importance, including HIV, tuberculosis, and malaria.[20]

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13 ibid 269.

14 Burcu Kilic and Peter Maybarduk, 'The Lexmark Litigation: Why Does Big Pharma Care So Much About Ink Cartridges?' (*Intellectual Property Watch*, 17 September 2015) <https://www.ip-watch.org/2015/09/17/the-lexmark-litigation-why-does-big-pharma-care-so-much-about-ink-cartridges/> accessed 8 April 2021.

15 ibid.

16 Debora Halbert, 'Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs' (2002) 1 Seattle Journal for Social Justice 257 <https://digitalcommons.law.seattleu.edu/cgi/viewcontent.cgi?article=1231&context=sjsj> accessed 14 April 2021.

17 'Trade Related Aspects of IP Rights' (United States Patent and Trademark Office - An Agency of the Department of Commerce, 1 November 2019) <https://www.uspto.gov/ip-policy/trade-related-aspects-ip-rights> accessed 6 April 2021.

18 ibid.

19 World Health Organization, 'The Doha Declaration on the TRIPS Agreement and Public Health' <https://www.who.int/medicines/areas/policy/doha_declaration/en/> accessed 14 April 2021.

20 ibid.

In 2001, the pharmaceutical companies dropped all their litigation, primarily because it became a public relations disaster for them.[21] The events from the 1990s to the early 2000s highlight the conflict between the commercial interests and moral responsibilities that conflict in the pharmaceutical world, at least in part due to patent rights.

B. Patent Exhaustion

After the events of the 1990s and early 2000s, it was clear that the patent exhaustion doctrine needed further clarification as the world became increasingly intermingled. Further clarity was provided when the United States Supreme Court made a decision related to patent exhaustion in *Impression Products, Inc. v Lexmark International, Inc.*, No. 15-1189 (U.S. 30th May 2017).

Lexmark answered two issues: (1) whether a patentee can sue, under patent infringement, a downstream market participant who violates the restrictions on the right to reuse or resell that were imparted during the original sale; and (2) whether patent exhaustion applies irrespective of where the product was sold.[22] The U.S. Supreme Court held, unanimously, that patent exhaustion applies regardless of post-sale restrictions and held 7–1 (with Ginsberg J. dissenting) that patent exhaustion applies regardless of the country where the product is sold.[23]

The *Lexmark* decision provided a clear break where a patentee's rights are terminated. The decision aligned with public sentiment in that patent law should not be invoked to restrain downstream use and sale of that item.[24] In the pharmaceutical industry, the implications continue to be felt. However, some implications are clear: pharmaceutical companies may want to recoup investments in their first sale because they are not able to control the sale of their patented drugs through post-sale restrictions or prevent competition due to differential pricing models used abroad. As such, the *Lexmark* ruling, while mostly in line with the sentiment created in the 1990s, may financially burden

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[21] Burcu Kilic and Peter Maybarduk, 'The Lexmark Litigation: Why Does Big Pharma Care So Much About Ink Cartridges?' (*Intellectual Property Watch*, 17 September 2015) <https://www.ip-watch.org/2015/09/17/the-lexmark-litigation-why-does-big-pharma-care-so-much-about-ink-cartridges/> accessed 8 April 2021.

[22] *Impression Products Inc v Lexmark International Inc* No 15-1189 (US 30 May 2017) <https://www.supremecourt.gov/opinions/16pdf/15-1189_ebfj.pdf> accessed 8 April 2021.

[23] ibid.

[24] Dan Bagatell, Dana Hayter and Christopher Stanton, 'First Impressions: New Strategies in the New Era of Patent Exhaustion After Impression Products v. Lexmark International' (*JD Supra*, 14 June 2017) <https://www.jdsupra.com/legalnews/first-impressions-new-strategies-in-the-63488/> accessed 6 April 2021.

pharmaceutical companies. While the Supreme Court has made it near impossible for the pharmaceutical industry to return to the economics of a pre-HIV era, legislators are also doing their part to close the possibility of return even further.

C. Food and Drug Administration

In addition to the patent exhaustion doctrine, the Food and Drug Administration ("FDA") has sections that prohibit and allow certain international movement of drugs. First, under Section 505 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), any new drug that is not subject to an approved new drug application ("NDA") or abbreviated NDA ("ANDA") cannot be introduced into interstate commerce.[25] This section is obvious to most consumers; a drug needs to be approved before being imported. Second, per Section 801(d) of the FDCA – of Title 21 U.S.C. § 381(d) – it is illegal to import the foreign version of an FDA-approved drug.[26] The reasoning of this section is because the FDA approves a drug based on specific factors such as the label and where it was manufactured.[27]

The FDA's ordinances, in some ways, seem to contradict the sentiment behind *Lexmark*. Namely, *Lexmark* permits exhaustion after sale abroad and thereby allows a product that is sold at a cheaper price abroad, to be resold in America at a cheaper price. The FDA, conversely, does not permit foreign versions of FDA-approved drugs into the U.S. This conflict is part of the reason that Congress feels the need to rethink this issue.

II. PROPOSED LEGISLATION IN THE US

With the above context in mind, and with no intention to be advocating any political position, there are currently three bills that Vermont Senator Bernie Sanders (with others) has proposed to the Senate. Senator Sanders says that the bills are meant to, "drastically reduce prescription drug prices in the United States. The time is now to stand up to the pharmaceutical industry and say enough is enough. The greed of drug companies is out of control and the cost is human lives."[28]

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[25] Dennis Crouch, 'Demystifying Drug Importation after Impression v. Lexmark' (*Patently-O*, 6 June 2017) <https://patentlyo.com/patent/2017/06/demystifying-importation-impression.html> accessed 6 April 2021.

[26] ibid.

[27] Crouch (n 25).

[28] 'NEWS: Sanders, Khanna, Doggett, Welch, Bush Introduce Sweeping Legislation to Lower Drug Prices' (*Senator Bernie Sanders*, 23 March 2021) <https://www.sanders.senate.gov/press-releases/news-sanders-khanna-doggett-welch-bush-introduce-sweeping-legislation-to-lower-drug-prices/> accessed 6 April 2021.

A. The Prescription Drug Price Relief Act

The bill requires the Department of Health and Human Services ("HHS") to review at least annually all brand-name drugs for excessive pricing and assess prices upon petition.[29] If any drugs are found to be excessively (defined below) priced, HHS must: (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs and biosimilar biological products.[30] HHS must also create a public database with its determinations for each drug.[31] Under this bill, the price of a drug is considered excessive if it is above the median prices of the drug in Canada, the United Kingdom (U.K.), Germany, France, and Japan.[32]

B. The Medicare Drug Price Negotiation Act

This bill makes a series of changes relating to the prices of prescription drugs under the Medicare prescription drug benefit and Medicare Advantage ("MA") prescription drug plans ("PDPs").[33] Under the *status quo*, the Centers for Medicare & Medicaid Services ("CMS") may not negotiate the prices of covered drugs or establish a formulary. This bill repeals these restrictions and requires the CMS to: (1) negotiate the prices of covered drugs; and (2) either establish a formulary for covered drugs or require changes to PDP formularies that take into account CMS negotiations.[34] If the CMS is unable to negotiate a reasonable price for a drug, the price must be the lowest of three specified options (eg, the average price in other countries).[35]

Such an approach would be modelled off the UK's National Institute for Health and Care Excellence ("NICE"). NICE makes economic evaluations of healthcare technologies by measuring cost-effectiveness of certain drugs relative to alternatives.[36] Based on these determinations, the National Health Service ("NHS") negotiates with pharmaceutical companies and makes purchasing decisions.[37] Since the NHS acts as a centralized gateway for drugs entering the U.K., it has the bargaining power to lower prices and increase the

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29 Prescription Drug Price Relief Act 2021.
30 ibid.
31 ibid.
32 ibid.
33 The Medicare Drug Price Negotiation Act 2021.
34 ibid.
35 ibid.
36 Christopher McCabe, Karl Claxton, and Anthony Culyer, 'The NICE Cost-Effectiveness Threshold: What it is and What that Means' (2008) 26(9) Pharmacoeconomics 733.
37 House of Parliament, 'Drug Pricing' https://www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf> accessed 14 April 2021.

accessibility of care to patients. Sanders's Medicare Drug Price Negotiation bill would allow CMS to similarly negotiate for lower drug prices as a centralized body, overcoming the existing fragmentation in the US healthcare industry that contributes to higher-than-average medicine prices.[38]

Additionally, Senator Sanders's plan requires drug manufacturers to issue rebates to the CMS for drugs dispensed to eligible low-income individuals.[39] Subject to civil monetary penalties, a Medicare or MA PDP sponsor must report, both to drug manufacturers and the CMS, specified information related to the determination and payment of such rebates.[40]

C. The Affordable and Safe Prescription Drug Importation Act

This bill addresses the importation of qualifying drugs that are manufactured at FDA-inspected facilities in Canada.[41] The bill requires the FDA to promulgate regulations within 180 days permitting wholesalers, pharmacies, and individuals to import certain prescription drugs from Canada.[42] After two years, the FDA may permit the importation of prescription drugs from other countries.[43]

D. Constitutional Questions

In practice, these bills would allow government entities (eg, HHS), if the companies do not lower drug prices, to expedite the approval of generics and/or control pricing, regardless of any patents or government-granted exclusivities that are in place. The question arises, then, whether patents grant complete freedom to do as a patentee would like or whether a patent grants limited freedom that can be curtailed based on perceived morally questionable actions. Perhaps, the broader question then would be whether the proposed legislation constitutes a taking, per the United States Constitution.

The Takings Clause of the Fifth Amendment of the U.S. Constitution reads: "Nor shall private property be taken for public use, without just

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[38] Allie Nawrat, 'Comparing the US's Ten Most Expensive Drugs with Prices in the UK' (*Pharmaceutical Technology*, 27 January 2020) <https://www.pharmaceutical-technology.com/features/us-most-expensive-drugs-uk-prices/> accessed 14 April 2021.

[39] The Medicare Drug Price Negotiation Act 2021.

[40] ibid.

[41] Summary of the Affordable and Safe Prescription Drug Importation Act 2019 <https://www.sanders.senate.gov/wp-content/uploads/Summary-The-Affordable-and-Safe-Prescription-Drug-Importation-Act.pdf> accessed 14 April 2021, wherein it is noted: 'The bill would not permit … until there is a material change in circumstances.'

[42] ibid.

[43] ibid.

compensation."[44] This Clause was intended to endorse the principle that the government should not be able to place burdens on property owners, without just compensation for causing that burden.[45] The Clause has been interpreted over the years to mean that, at the very least, when the government outright confiscated property, just compensation should be paid to the owner.[46] With regards to what constitutes property under the Fifth Amendment, it is generally agreed that all forms of private property, animals, corporate stock, leases, mortgages, and others qualify.[47] Intangible property, such as intellectual property rights, including patents, copyrights, trademarks, and trade secrets have also been accepted as belonging in this category.[48] In fact, the Supreme Court has for more than 100 years recognized that patents are private property (See *United States v Am. Bell Tell Co*).[49]

Further to determine whether patents are property under the Fifth Amendment, the natural next question is what is just compensation. Again, it has been widely accepted that just compensation is determined based on the fair market value of the property.[50] In the case of a patent, the fair market value can be determined, for example, based on royalties that are paid for similar technology (eg, ART unit) patents during their lifetimes.

Patents, therefore, are considered property under the Fifth Amendment and have viable ways to determine just compensation. Why, then, does Senator Bernie Sanders believe the proposed legislation is not a violation of the Constitution? It may be because of the increasing grey area in which governments are allowed to not compensate private property owners, in what is known as a regulatory taking derived from the state's police power to secure the general welfare in areas of health and safety.

For example, the government is not required to compensate private property owners when it requires them to take reasonable steps to avoid pollution or other releases that harm either public or private property in land, air, and water.[51] Further, the government can also impose fines and court orders, with-

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44 Richard A. Epstein and Eduardo M. Peñalver, 'The Fifth Amendment Takings Clause' (*The National Constitution Center*) <https://constitutioncenter.org/interactive-constitution/interpretation/amendment-v/clauses/634> accessed 7 April 2021.

45 ibid.

46 Epstein and Peñalver (n 44).

47 Epstein and Peñalver (n 44).

48 Epstein and Peñalver (n 44).

49 Steve Brachmann and Gene Quinn, 'Patents as Property Rights: What Will It Take to Restore Sanity to the Narrative Surrounding US Patents?' (*IPWatchdog*, 10 May 2017) <https://www.ipwatchdog.com/2017/05/10/patents-property-rights/id=83074/> accessed 6 April 2021.

50 Epstein and Peñalver (n 44).

51 Epstein and Peñalver (n 44).

out a duty to compensate, to force a private property owner to stop harmful activities.[52] By expanding the grey area in which the state can regulate harms in the name of the public good, the government has been able to burden the individual property owner without triggering just compensation.

Due to expanding gray areas, it is not far-fetched to believe that legislation such as the ones discussed above, may not trigger just compensation. Namely, if taking for prevention of "harmful activities" such as pollution is permitted without just compensation, it may not be a huge leap to consider high drug prices in a similar category. High drug prices do cause harmful consequences such as decreased access to drugs, which in the most literal sense, harm lives.

In a recent Supreme Court case, *Oil States Energy Services LLC v Greene's Energy Group LLC*, the Court adjudicated, among other things, whether *inter partes* review ("IPR") violates the Constitution by terminating private property rights through a non-Article-III forum without a jury.[53] One of the pillars of this issue is whether a patent is private property. To which, the Court said that three decisions—*United States v American Bell Telephone, McCormick Harvesting Machine Co v Aultman, and Brown v Duchesne*—recognize patent rights as the "private property of the patentee."[54] The Court decided that IPRs are constitutional because an IPR is a "second look at an earlier … grant," and it involves the same interests as the earlier grant.[55] The fact that IPRs occur after the grant does not make a difference.

Further, the Court classified a patent as a "public franchise" because the grant of a patent falls with the public-rights doctrine.[56] In other words, because granting a patent involves a matter between the government and others and because granting a patent is a constitutional function carried out by the executive and legislative branches, it is considered a public franchise.[57] The Court used an example of a bridge to further illustrate the analogy.[58] A bridge, after it is built, can be subject to certain authority by the government, such as tolling.[59] Such an authority is permitted under the public-rights doctrine.[60]

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52 Epstein and Peñalver (n 44).

53 *Oil States Energy Services LLC v Greene's Energy Group LLC* 2018 SCC OnLine US SC 24 : 200 L Ed 2d 671 584 US (2018) (U.S. 27 November 2017) <https://www.supremecourt.gov/opinions/17pdf/16-712_87ad.pdf> accessed 6 April 2021.

54 ibid.

55 ibid.

56 ibid.

57 ibid.

58 'Oil States Energy Services v. Greene's Energy Group' (*Banner Witcoff*) <https://bannerwitcoff.com/issue/oil-states-energy-services-v-greenes-energy-group/> accessed 6 April 2021.

59 ibid.

60 ibid.

Although the decision in *Oil States Energy Services* seems to further bolster that patent are private property under the Constitution and in particular, the Takings Clause, further inspection indicates otherwise. Namely, the Court recognizes that patents are property but endorses the caveat that patents are considered public franchises. In doing so, the Court has left open the door for government intrusions. Further, the Court made it clear that an IPR is a second look at an earlier grant of a patent. By making this clear, the Court allows a non-Art III court to void a previously granted patent. The basis for doing so is in patent law; however, the principle of voiding a granted application is getting more prevalent.

This decision, in parallel with recent trends regarding the Takings Clause and public sentiment towards pharmaceutical patents, indicates that the grey area in which government can take without triggering just compensation is growing. Senator Sanders may have an uphill battle if his legislation is litigated under a Takings Clause cause of action. However, it seems that the pharmaceutical industry may also have a similar challenge in this situation. History is against the pharmaceutical companies and another public relations disaster such as the one in the late 1990s is an ill-advised path.

E. Legitimacy of the Legislation

As it stands, patents are private property under the Takings Clause. Senator Sanders' legislation, at least The Prescription Drug Price Relief Act, may be a violation of the Takings Clause. Given the unambiguous language – the HHS *must* void any government-granted exclusivity – a taking is likely to result if this legislation is passed. And, as it stands, the government would need to pay just compensation.

However, a public health emergency such as the lack of access to medicine and price gouging in America may be considered a harmful act that does not trigger just compensation. Seemingly, the legislation has laid the foundation for making this argument because of the numerous statistics that are cited as justification. For example, Americans have seen the price of drugs skyrocket as much as 5,000% overnight and in midst of the COVID-19 pandemic, pharmaceutical companies raised prices on over 860 drugs in 2020.[61] Moreover, nearly 1 in 4 adults in the U.S. say it's difficult to afford their medicines and three in ten adults did not take their prescribed medicine due to the costs.[62]

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[61] The Affordable and Safe Prescription Drug Importation Act 2019 (Summary) <https://www.sanders.senate.gov/wp-content/uploads/Summary-The-Affordable-and-Safe-Prescription-Drug-Importation-Act.pdf> accessed 13 April 2021. See also Sanders (n 28).

[62] ibid.

It remains to be seen whether the proposed legislation will become law. Irrespective of the legislation, it is clear that the pharmaceutical industry and how they use their patents are under attack.

III. POTENTIAL IMPACTS OF LEXMARK ON AFFORDABLE MEDICINES IN INDIA

Prior to *Lexmark*, pharmaceutical companies were able to block their own FDA-approved drugs sold in foreign jurisdictions like India (typically at a lower price) from being resold in the U.S.. Notwithstanding the aforementioned FDA import restrictions on foreign versions of FDA-approved drugs, pharmaceutical players were able to engage in a double-dipping "sell and sue" strategy. Now, given international patent exhaustion due to *Lexmark*, pharmaceutical companies are no longer able to restrict reimports through patent infringement suits. To avoid blurring the line between highly-priced domestic drugs and cheaper versions of the same drug abroad, pharmaceutical companies will need to resort to novel pricing and licensing approaches.

A. Impact of Lexmark on Increasing Branded Drug Prices in India

Some experts contend that while *Lexmark* could have consumer-friendly effects in the U.S., as demonstrated by the various Bernie Sanders proposals, an unintended consequence could be higher prices abroad.[63] Namely, given that *Lexmark* prevents pharmaceutical players from prohibiting the resale of goods in the U.S. on patent infringement grounds, the cost of drugs will likely be increased in foreign jurisdictions to limit the opportunities for arbitrage. Thus, while overall welfare for Americans may increase, relative welfare for those in India may be reduced.[64]

However, given the availability of mechanisms like compulsory licensing as allowed by the Doha Declaration to the TRIPS agreement, pharmaceutical companies must be cautious to not increase prices so much as to trigger patent circumvention entirely. Thereby, given these constraints, the burdens of *Lexmark* will likely fall primarily on the pharmaceutical industry. In a universe wherein the branded pharmaceutical industry is overcharging relative to R&D spend (given significant advertising expenses and frequent licensing from academic/governmental institutions at a low cost), this should not greatly affect innovation, and the companies could just internalize the costs.

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[63] Daniel Hemel and Lisa Ouellette, 'Trade and Tradeoffs: The Case of International Patent Exhaustion' (2016) 116 Columbia Law Review Sidebar 17-31.

[64] ibid.

Further, if the prior narratives around me-too drugs and the development of solely high market-potential drugs – as mentioned above – are true, consumers should have limited concern. But in another universe with slim margins and exorbitant R&D costs, as portrayed by Big Pharma, the changes due to *Lexmark* could result in reduced incentives to innovate. Thus, while domestic pricing may be lowered, the "costs" of fewer lifesaving treatments could be borne worldwide. Nonetheless, it is possible that the U.S. and countries like India may see price decreases and increases, respectively, so as to limit arbitrage opportunities.

Namely, *Lexmark* encourages innovator pharmaceuticals to recover as much profit from the first sale, as downstream control over pricing and royalties has now disappeared. But given the possibility of the Indian government issuing a compulsory license – as was done against Bayer in favour of Indian generic company Natco for the anticancer drug Sorafenib/Nexavar – pharmaceutical companies are likely wary of this approach.[65] In the case, *Bayer Corporation v Union of India*, the Indian Intellectual Property Appellate Board ("IPAB") upheld the Controller's decision to grant Natco a non-exclusive license on the grounds of lacking affordability and resulting limited access.[66]

Bayer was charging almost 10x the price compared to generic company CIPLA for the same drug (INR 2,80,000 v INR 28,000).[67] The compulsory license was legally justified with reference to Section 84(1) of the Indian Patent Act of 1970 (amended in 2005), which is consistent with TRIPS in permitting a compulsory license when the patented invention "is not available to the public at a reasonably affordable price."[68] While IPAB ultimately mandated that a 7% royalty be paid to Bayer, this minimal allowance and a severely depressed price point was effectively a complete loss for Bayer in the Indian market.

Though India has been stereotyped as being lenient in granting compulsory licenses, a number of other countries – namely Brazil, Thailand, and various African nations – have invoked this provision more frequently.[69] To note, compulsory licensing is more likely for small molecule treatments with limited manufacturing complexity that local generic companies can easily replicate (and less likely for complicated large molecules). Regardless, the threat of

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[65] Anu Singhai and Manu Singhai, 'A Study of Natco v Bayer Case: Its Effect and Current Situation' (2016) 2 MIT International Journal of Pharmaceutical Sciences 21-23.

[66] ibid.

[67] Mansi Sood, 'Natco Pharma Ltd v Bayer Corporation and the Compulsory Licensing Regime in India' (2013) 6 NUJS Law Review 99.

[68] ibid.

[69] Reed Beall and Randall Kuhn, 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' (2012) 9 PLOS Medicine 1.

a possible compulsory license in India will ultimately curb any dramatic price increase by U.S. pharmacos in India.

Furthermore, in cases of direct sales from U.S. manufacturers to Indian consumers, there is a greater fear of reimportation to the U.S.. Since the product is of course FDA-approved and was also manufactured within the U.S., neither Sections 505 nor 801 of the FDCA would prevent reimportation. Thus, there is a tension between charging high prices abroad to avoid the risks of reimportation/arbitrage while not increasing prices so much as to increase the chance of a compulsory license. But there is one way out of this dilemma: voluntary licensing.

B. Voluntary Licensing between American Innovator Companies and Indian Generics

One now-proven, effective strategy that innovator pharmaceutical companies can take to simultaneously avoid the risks of patent exhaustion and compulsory licensing is voluntary licensing. For example, Gilead experimented and pioneered this approach with its one-pill-a-day regimen HIV therapies in more than one hundred countries by voluntarily licensing its innovation with reputable pharmaceutical companies in India, including with the Medicines Patent Pool. In 2014, just months after the U.S. FDA approved Sovaldi as an effective treatment/cure for Hepatitis C, Gilead built on its earlier successful HIV therapy Voluntary Licensing experience with a focus on increasing access to care for hepatitis in developing countries, including in India.[70]

Gilead issued Voluntary Licenses to 11 Indian generic companies, notably Aurobindo, Mylan, Hetero, Cadila, Cipla, Ranbaxy (Sun), Strides, NATCO, Ferozsons, Laurus and Biocon to manufacture the product and distribute finished product to ultimately 105 developing countries, in addition to India. Moreover, this Voluntary License also included therapies that had not yet been cleared by the FDA such as the pan-genotypic Epclusa which treats multiple genotypes of HCV, with an effective cure rate of >95%.

Not only does this Voluntary Licensing approach render moot the need for any country to issue a compulsory license, as the drugs distributed by the generic companies *en masse* for the Indian population and for the 105 other markets included in the Voluntary License, but the cost of the therapy will also be far less expensive than the equivalent product sold by Gilead and offers the

[70] Gilead Press Release (15 September 2014) <https://www.gilead.com/news-and-press/press-room/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries> accessed 14 April 2021.

added bonus of building indigenous technical capability among the cohort of Voluntary Licensees in that a full technical package is provided by Gilead as part of the Voluntary License.

This allows the local Voluntary Licensees the ability to deliver at scale the highest quality therapies to a maximum number of patients at the lowest possible cost. As part of the Voluntary License, the pharmaceutical innovator recoups some nominal royalty payments from the Voluntary Licensees, which in the case of Gilead is reinvested back into its patient access program, with the end-goal of reaching a maximum number of patients in need of these treatment therapies. The result is that the drug price is significantly reduced, owing to the specific innovativeness of the Licensee and their manufacturing prowess, and the ability of the Licensees to scale. Further, the Indian Licensees enjoy logistical access to many of these far-away markets, enabling them to compete with one another in these markets, which further drives down pricing.

The result is that the beneficiary is the patient, the end-consumer, while the Licensees also benefit given the massive population offered in the License territories, providing the Indian generic companies a revenue stream that is certainly more favourable than what would be derived by a simple compulsory license (ie, through sheer volume). Further, some studies have shown that voluntary licensing is preferable to foreign countries relative to a compulsory license as it enables cooperation in technology transfer, which is especially important in cases where manufacturing is particularly complex and there is an emergency, like for the COVID-19 therapies and vaccines.[71]

Former Gilead Sciences' CEO, John C. Martin, who helped pioneer the Voluntary Licensing model for these life-saving therapies, believed that with such innovation comes a serious responsibility. To a 2019 graduating class of India Institute of Management Ahmedabad students, Dr. Martin said: "Finding an effective treatment or a cure for a deadly virus as devastating as Hepatitis C comes around in science - at best - once every 30 years. When you find a cure for a deadly disease, you should have only one focus: getting that cure or treatment to the patients who need it most. Voluntary Licensing is an enabler of patient access."

When challenged by a curious student from this same audience, asking 'Then how does your company recoup costs and make a profit if you give away licenses and markets for half the world's countries for your most prized products?' John Martin replied, "You worry about lives and not money if you are a

[71] Daniel Kim, 'Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing' (2016) 8 American University Intellectual Property Brief 63.

serious scientist. You will make your money another day, by inventing another drug." For the late John C. Martin, science and patients always came first.

Gilead Sciences' pioneering Voluntary License model is now a proven concept. Case-in-point: Gilead's licensing of its HIV therapies presently reaches and treats as many as 20 million patients each day, allowing these HIV-infected individuals to live a normal life. For its Hepatitis therapies, Gilead's Voluntary Licensees have reached and have cured as many as 1 million patients in India. And with 9 Voluntary Licenses (7 in India, 1 in Pakistan, and 1 in Egypt), Gilead's remdesivir is available on the front lines in the fight against COVID-19, in 127 countries, including India. Namely, the Voluntary Licensees are Hetero, Mylan, Jubilant, Cipla, Biocon, Dr. Reddy's Labs, Cadila, Ferozsons and Eva Pharma.

Regarding exhaustion, it is unclear whether such a voluntary licensing agreement alone would qualify under the *Lexmark* regime. More specifically, exhaustion applies only to the "initial *authorized sale* of a *patented* item."[72] The question remains, does such a license really count as a *sale?* Regardless, even if we assume that the product in question is FDA-approved, but it is manufactured at a generic facility not approved by the FDA, 21 U.S.C. § 381 would likely block reimportation.

But for the sake of argument, if we assume that the product is manufactured at an FDA-approved global facility (thereby, Sections 505 and 801 of the FDCA do not present regulatory barriers), regulation alone will not prevent the newfound arbitrage problem of international patent exhaustion. And given that a significant number of drugs prescribed in the U.S. are manufactured in India (1/3 of all generics, which make up 90% of the medicines prescribed), it is reasonable to assume that these facilities like at Dr. Reddy's Labs are FDA-approved.[73] Thus, without regulatory obstacles overcoming the problems resulting from international exhaustion, pharmaceutical players will have to creatively indicate in *contracts* to which countries the generic players are *authorized* to sell the cheaper version of the product.

C. Creative Contracting to Avoid Arbitrage Effects

As Gilead has done with the various Indian generic companies, branded pharmaceutical players can explicitly limit the ability of generic players to sell in certain countries, like the U.S.. For example, a branded innovator company

[72] Hemel and Ouellette (n 63) 21-22.

[73] Radha Iyer, 'Making the Case of Indian Generic Manufacturing' (*Drug Store News*, 29 October 2019) <https://drugstorenews.com/making-case-indian-generic-manufacturing> accessed 14 April 2021.

like Pfizer could choose to license Dr. Reddy's in India on the condition that it only sell the product in India, or maybe India and China. Thus, any subsequent sale into the U.S. (or to any country other than India and China) would be considered *unauthorized* and thereby not fall under the exhaustion doctrine. But what if the initial sale from a generic company to a domestic intermediary in India is *authorized*, and then a subsequent sale to the U.S. occurs? In these cases, where the licensee lacks privity with the end user, it is unclear how the exhaustion doctrine would play out.

Nonetheless, if pharmaceutical companies are explicit enough in their contracting terms, they could force the generic players to indemnify them for any product diversion back into the U.S. market. By this standard, both international manufacturers and downstream distributors would be liable for any breach of contract. Therefore, given the change in exhaustion law and the inability of pharmaceutical players to restrict entry on grounds of patent infringement, the innovator companies may be able to sue on breach of contract grounds, though this may be more complicated given privity issues. And if contractual territorial export restrictions are unsuccessful, there is one final possibility – to create products that simply could not be imported back into the U.S. given FDA approval restrictions.

D. Reducing Product Standards for the Indian Market

As noted above, finding generic players who manufacture drugs in unapproved facilities could be a simple fix to the reimportation issue given Section 801(d) of the FDCA. But due to the plethora of Indian-manufactured generics in the U.S., this may not be a reasonable approach. An alternative – beyond raising prices, voluntary licensing, and creative contracting—would be to sell products in India that simply cannot be resold to the U.S. given FDA approval restrictions, in particular, that are blocked by Section 505 of the FDCA.

To be specific, while U.S. pharmacos may not be able to control how licensed products are manufactured or whether they will have a "not made in an FDA-approved facility" stamp, they could sell lower quality drugs that would not be approved at home. This would certainly raise ethical issues, and may even result in reputational damage, but might be the only way out of the patent dilemma caused by *Lexmark*'s international exhaustion if unique contracting approaches fail. This begs the question: would the Indian FDA-equivalent even accept such products?

In the case of remdesivir, India's Drug Controller issued 'emergency use authorization' to Gilead's Voluntary Licensees only after U.S. FDA

authorization had been granted to Gilead in the U.S., and after Japan's drug controller and Europe's drug controller followed suit. Further, DCGI only granted marketing approval to the Indian Voluntary Licensees of remdesivir after laboratory and science-based testing and confirmation by India's regulator that the purity and quality of the remdesivir being manufactured in India by the Voluntary Licensees is equivalent to the innovator's original product.

While safety and manufacturing standards may sometimes be less stringent in India relative to the US for pharmaceutical products, voluntary licensing can actually up the ante in terms of ensuring equivalent quality and, in doing so, mitigates the possibility of arbitrage from exhaustion by effectively forcing a "not FDA approved" stamp on the drug which raises consumer protection issues from the Indian standpoint as well.

E. Indian Consumer Protection Act 2019

The Central Drugs Standard Control Organization ("CDSCO") within the Indian government is analogous to the US FDA, as defined by the Drugs and Cosmetics Act 1940.[74] In particular, the Drugs Controller General of Indian ("DCGI") within CDSCO approves drugs and sets manufacturing, sales, import, and distribution standards within the country. Importantly, India's 2019 Consumer Protection Act ("CPA"), repealing and replacing the 1986 version of the Act, has the effect of expanding existing regulatory/consumer protection law that outlines medical product liability.[75]

The Act allows for consumers to institute class action suits before a consumer-centric forum, with remedies ranging from money damages to compensate the consumer for any injury suffered due to manufacturer negligence or fraud (including punitive damages) in addition to a full refund, as well as injunctive relief to remove defects from the goods or withdraw the hazardous goods entirely from the market.[76] Importantly, such expansive consumer protections move India away from the stereotypical image of a country lacking critical regulatory oversight. Assuming the provisions of the Act are adequately enforced, pharmaceutical companies will not be able to play the game of simply producing lower quality drugs for the Indian market to avoid parallel

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[74] Darren Punnen, Shreya Shenolikar and Milind Antani, 'Medicinal Product Regulation and Product Liability in India: Overview' (*Practical Law UK*, 1 November 2020) <https://content.next.westlaw.com/9-504-6786?__lrTS=20210212143303707&transitionType=Default&contextData=(sc.Default)&firstPage=true#:~:text=Drugs%20and%20medical%20devices%20are,of%20drugs%20and%20medical%20devices.> accessed 14 April 2021.

[75] ibid.

[76] The Consumer Protection Act 2019.

importation. Not only is this ostensibly unethical, but the CDSCO may also have a newfound mandate through the CPA to limit such approvals.

IV. CONCLUSION

To conclude, this puts US pharmaceutical companies in a tough spot. While *Lexmark* could have beneficial effects on drug prices in the US, as witnessed by the various Bernie Sanders' proposals, the impact in international markets like India is yet to be seen. Though pharmaceutical players could try to increase foreign prices to reduce arbitrage opportunities resulting from reimportation, there is a risk of compulsory licensing. Voluntary licensing, especially when combined with creative contracting terms, could present a solution. This is especially the case if there are contractual limitations as to which geographies the Voluntary License applies.

Without such contractual fine-tuning, licensing to well-established Indian generics with FDA-approved facilities could allow them to circumvent FDA import law, Section 801. Therefore, *Lexmark* has the effect of shifting burdens from patent infringement lawsuits to rest on breach of contract cases. Finally, PharmaCos could take the approach of lowering drug quality standards altogether in foreign countries like India, such that reimportation to the US would be decisively restricted by the FDA's Section 505. But with strengthened regulation in global markets – such as through the Indian Consumer Protection Act 2019—it remains to be seen whether such a strategy would hold up. Thus, regardless of the approach taken, it is clear that US drug manufacturers will need to adjust their distribution strategy in developing countries like India due to *Lexmark*'s international patent exhaustion on sale.