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The Double-Edged Sword of Medical Patents: How Monopolies on Healthcare Products Disparately Impact Certain American Populations

Introduction

The purpose of granting patents is to encourage innovation for the betterment of society. But do patents for healthcare products have a disparate impact on healthcare outcomes for certain racial, ethnic, and socio-economic groups or possibly public health in general?¹

The excessive costs associated with researching, developing, and patenting medical innovations lead inventors to charge consumers high prices to recoup their losses.² While it is vital that inventors be able to repay the costs of creating and patenting new healthcare products, the necessity for profits forces consumers to bear the burden of the high costs of those products. Additionally, the high costs of research and development only incentivize inventors to research and invent solutions to problems that are in high demand, where profits will be higher.³ The necessity of access to healthcare products, especially pharmaceuticals, vaccines, and biotechnology, heightens the unfair burden of high costs.⁴

The system of monopolies created by healthcare product patents has many impacts on the healthcare industry, inventors, and consumers. Because of the inherent competition among manufacturers and inventors, large research companies and manufacturers have created strategies to help each other, while discouraging smaller innovators and

¹ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

² *Id.*

³ *Id.*

⁴ *Id.*

eliminating competition.⁵ While the creation of patent law, which produces such competition, intends to encourage innovation among inventors, in reality patent law often encourages innovation only from industry giants.⁶

Advances in the healthcare industry have created countless successful treatments and cures for many health issues, but these advancements are not as easily accessible to certain populations. It is well documented that people with low socio-economic status, as well as racial and ethnic minorities, have health inequity in the United States.⁷ This inequity stems, in part, from the high cost of physician visits and medication, as well as lack of access to preventative medicine and health insurance.⁸

The deficiency of information and clarity surrounding the U.S. healthcare system creates further barriers to quality and affordable healthcare products and services.⁹ These systemic issues, the exceedingly high costs of many healthcare products and services, and the continual advancement of healthcare and technology allow for unequal access to healthcare for many populations and therefore creates problems for those populations, as well as the country as a whole. The issue of healthcare inequity, while a serious problem in

⁵ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

⁶ *Id.*

⁷ Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, Trans Am Clin Climatol Assoc. (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3540621/>.

⁸ David B. Nash, *Health Inequities in America*, Am Health Drug Benefits (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5620509/>.

⁹ Victor J. Dzau and Celynn A. Balatba, *Health and Societal Implications of Medical and Technological Advances*, Science Translational Medicine, (Oct. 28, 2017), <https://stm.sciencemag.org/content/10/463/eaau4778>.

the United States, is largely not a problem for many other developed countries but persists in many developing countries throughout the world.¹⁰

There are a large number of proposed solutions and alternatives to the current patent system, but critics of the current system have yet to establish meaningful reforms that adequately incentivize innovation.¹¹ Though many alternatives have been proposed, the flawed system that is currently in place is still more effective at serving the intent of patent policy than any proposed alternative.¹² Until the proposed reforms address the key issues with the current system while also balancing the purpose of promoting innovation for the betterment of society, no reform can succeed.

While many factors contribute to economic and healthcare inequity in the United States, the high prices of healthcare products and services created by medical patents are a significant contributor to this inequity.

Background

The history of the United States' governance of patents emerges directly from the Constitution. "Congress shall have power . . . [t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."¹³ The inspiration for the constitutional language comes from England's Statute of Monopolies, which regulated the Crown's ability to grant

¹⁰ Tara Leevy, *Intellectual Property and Access to Medicine for the Poor*, AMA Journal of Ethics (Dec. 2006), <https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12>.

¹¹ Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, Health and Human Rights Journal, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹¹ *Id.*

¹² *Id.*

¹³ U.S. Const. art. I, § 8.

limited monopolies.¹⁴ While the European patent regulation sought to gain revenue by regulating patents, the United States' approach seeks to grant patents for the benefit of society.¹⁵

In 1790, Congress codified patent regulations in the Patent Act.¹⁶ The Patent Act was the first American statute to denote innovation as property and granted patents for inventions that were "sufficiently useful and important," to "promote the progress of useful Arts."¹⁷

Since its amendments in 1793, the Patent Act has remained largely unchanged.¹⁸ The amendments sought to provide clearer designations for patent eligibility.¹⁹ To be granted a patent, the Patent Act requires that an invention be (1) novel, (2) useful, and (3) non-obvious.²⁰ Recognizing the increased complexity of the healthcare industry and the potential impact on the American people, Congress sought to provide an extra level of protection and oversight for regulating healthcare products.²¹ In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act, and in turn, created today's Food and Drug Administration (FDA).²² The newly created FDA became responsible for regulating and

¹⁴ A Brief History of Patent Law in the United States (May 7, 2014), <https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2/>.

¹⁵ *Id.*

¹⁶ 35 U.S.C. §§1-390.

¹⁷ A Brief History of Patent Law in the United States (May 7, 2014), <https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2/>.

¹⁸ Victor J. Dzau and Celynn A. Balatba, *Health and Societal Implications of Medical and Technological Advances*, *Science Translational Medicine*, (Oct. 28, 2017), <https://stm.sciencemag.org/content/10/463/eaau4778>.

¹⁹ *Id.*

²⁰ *Id.* §102.

²¹ Food and Drug Administration (2020), <https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states> (last visited Oct. 10, 2020).

²² *Id.*

overseeing the creation and production of medical products.²³ In 1962, the FDA enacted the Drug Amendments which required new safety tests, as well as a new requirement of substantial evidence of a drug's safety.²⁴ Congress then continued building and shaping patent law by instituting the 1976 Medical Device Amendments, which allows the FDA to evaluate the safety and effectiveness of medical devices.²⁵ Today, the FDA requires extensive pre-clinical and clinical trials before any drugs, vaccines, or medical devices can enter the market.²⁶

Discussion

Patents are essential for encouraging inventors and researchers to develop new and innovative creations for the betterment of society. Innovative ideas are especially critical in the healthcare field, partly because of their lifesaving potential. Modern medicine relies heavily on researchers who are committed to developing new vaccines, treatments, and medical technology in order to combat the ever-changing healthcare needs of patients.²⁷ In many cases, these innovations can be the difference between life and death.

However, an issue arises when the cost of developing and patenting these innovations allows the manufacturers to charge high prices for their inventions, resulting in costly medical products and services for consumers.²⁸ While the intent behind patents is

²³ Food and Drug Administration (2020), <https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states> (last visited Oct. 10, 2020).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ Victor J. Dzau and Celynne A. Balatba, *Health and Societal Implications of Medical and Technological Advances*, *Science Translational Medicine*, (Oct. 28, 2017), <https://stm.sciencemag.org/content/10/463/eaau4778>.

²⁸ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, *Global Policy*, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

to incentivize researchers and inventors to find solutions to problems and encourage innovation, the intent was likely to allow for society to have easier access to these innovations, not to make them so expensive that some people struggle to afford them. This unequal access to healthcare products and services almost ensures healthcare inequity among racial and ethnic minorities and low socio-economic populations and can lead to disparate impacts for those populations.

I. Unique challenges facing medical patents

While the United States' patent system is used to encourage innovation among inventors and artists to better society, when it comes to healthcare product patents, there are many considerations and unique challenges within the healthcare industry. One reason healthcare product patents are unique is their inherent impact on human life and well-being.

Because of the requirements of patentability, inventions with patents must serve novel and useful purposes and therefore lead to advances in society.²⁹ The essential nature of healthcare products coupled with the high cost to develop a patented healthcare invention can often lead to circumstances where such inventions become unaffordable to many Americans.³⁰

Consumers sometimes do not have the luxury of choosing whether or not to purchase a product, since their health will suffer without the product. Consequently, these

²⁹ U.S. Patent and Trademark Office (2020), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents> (last visited Sep. 20, 2020).

³⁰ Victor J. Dzau and Celynne A. Balatba, *Health and Societal Implications of Medical and Technological Advances*, *Science Translational Medicine*, (Oct. 28, 2017), <https://stm.sciencemag.org/content/10/463/eaau4778>.

consumers end up paying exorbitant prices for patented items, where their generic counterparts would be much less expensive.³¹ The high demand for healthcare products within the market often forces large manufacturers to choose between providing consumers affordable drugs, medical supplies, and other healthcare products or making higher profits from charging exceedingly high prices.³²

II. Monetary constraints of patent research & application process

Considering the costs associated with creating a patentable invention, obtaining and maintaining a patent with the United States Patent and Trademark Office (USPTO), and maintaining approval from the FDA, it is clear how patent monopolies force manufactures to charge high prices.^{33,34}

A. Costs of research and innovation

In 2017, the Pharmaceutical Research and Manufacturers of America (PhRMA) estimated that the average cost of research and development for a pharmaceutical company was \$71.4 billion, which made up approximately 21.4% of those companies' total sales.³⁵ These figures are likely so high due to the high failure rate of pharmaceuticals.³⁶ For example, between 2002 and 2012, the failure rate of drugs to treat Alzheimer's Disease was

³¹ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

³² Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, Trans Am Clin Climatol Assoc. (2012).

³³ U.S. Patent and Trademark Office (2020), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents> (last visited Sep. 20, 2020).

³⁴ U.S. Food and Drug Administration (2020), <https://www.fda.gov> (last visited Sep. 18, 2020).

³⁵ Andrew Dunn, *Drugmakers say R&D spending hit record in 2017*, (August 15, 2018), <https://www.biopharmadive.com/news/phrma-research-development-spending-industry-report/529943/>.

³⁶ Pharmaceutical Technology (2020), <https://www.pharmaceutical-technology.com/features/featurecounting-the-cost-of-failure-in-drug-development-5813046/> (last visited Oct. 10, 2020).

99.6%.³⁷ While this statistic seems extreme, it is the reality for the majority of pharmaceutical researchers. Further, a successful approval rate of 0.4% does not mean that the approved drug is a cure or will even make a marked difference in the disease, it merely means that the drug gained approval.³⁸ The most common reason drugs face such high failure rates is not because of extreme and dangerous side effects, it can be because after so much time and effort in development, the drugs just not effective enough to make an impact on patient health and cannot survive in the market.³⁹ Further, when a large manufacturer determines that one of the drugs in development does not work, it can have detrimental implications for the company as a whole, such as drops in market shares.⁴⁰

Unlike pharmaceuticals, medical devices are much more diverse, some being very simple, such as a tongue depressor, and others very complex, such as a robotic surgery device. While these devices require the same rigorous research and development process as pharmaceuticals, the more complex devices often incur much higher operating costs.⁴¹ Consider Magnetic Resonance Imaging (MRI): just like a simple medical device, an MRI machine requires rigorous time and money-intensive research and development, and requires continual maintenance, user training, and skilled operation, all of which create

³⁷ Pharmaceutical Technology (2020), <https://www.pharmaceutical-technology.com/features/featurecounting-the-cost-of-failure-in-drug-development-5813046/> (last visited Oct. 10, 2020).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Marilyn J. Field and Thomas F. Boat, *Medical Devices: Research and Development for Rare Diseases*, The National Academies Press (2010), <https://www.ncbi.nlm.nih.gov/books/NBK56199/>.

increased expenses.⁴² Hospitals usually bear the costs of operation, training, and maintenance, which then passes to the consumer, likely at an even more inflated rate.⁴³

B. Costs of patent application and maintenance

Due to the increasing complexity of the patent application process, the more complex the invention, the more costly obtaining a patent becomes. Inventors typically pay attorney fees that are ten to fifteen times the cost of the application itself, which can cost upward of \$15,000, on top of fees to file the patent in other countries.⁴⁴ In addition to those costs, patent holders must pay maintenance and other fees, resulting in an estimated total cost of between \$160,000 and \$330,000 for the life of the patent.⁴⁵

C. Impact of research and patent costs on consumers

Once a patent product reaches the market, those costs associated with research and development, as well as patent expenses, pass directly to the consumer, which serves the purpose of patents and aligns with public policy.⁴⁶ However, once those costs are recouped by the manufacturers, they continue to charge the same prices, resulting in large profits, to the detriment of the consumer.⁴⁷ This overcharging is legal under current patent law in the

⁴² Pro Imaging Services (2020), <http://proimaging.com/wp-content/uploads/2014/10/How-Much-does-it-Cost-to-Operate-an-MRI.pdf> (last visited Oct. 24, 2020).

⁴³ Marilyn J. Field and Thomas F. Boat, *Medical Devices: Research and Development for Rare Diseases*, The National Academies Press (2010), <https://www.ncbi.nlm.nih.gov/books/NBK56199/>.

⁴⁴ Gene Quinn, *The Cost of Obtaining a Patent in the US*, (April 4, 2015), <https://www.ipwatchdog.com/2015/04/04/the-cost-of-obtaining-a-patent-in-the-us/id=56485/>.

⁴⁵ Joseph G. Hadzima, Jr., *Importance of Patents: It Pays to Know Patent Rules*, Boston Business Journal, (Dec. 7, 2006), <http://web.mit.edu/e-club/hadzima/the-importance-of-patents.html>.

⁴⁶ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

⁴⁷ *Id.*

United States, but many critics hope to reform policies by opting for price ceilings to create more affordable healthcare products for consumers.⁴⁸

III. Economic effects of monopolies created by healthcare product patents

The exorbitant costs of researching, developing, and patenting an invention causes companies to rely on the exclusive rights granted to them in order to charge such high prices for their product. A company can often manufacture a product at a high mark-up because of the relatively low cost of manufacturing.⁴⁹ The company benefits from these high costs especially within the healthcare field, as oftentimes, such products are necessary for consumers' health. The increasingly high demand for drugs, coupled with the vast inequality of access to healthcare in the United States, creates a platform for companies to charge extremely high prices and earn large profits.

A. 20-year monopoly on all patented healthcare products

A patent grants the patent holder the exclusive right to make, use, sell, offer to sell, keep the product, or import anything covered by the patent claims in any country where patent protection is granted.⁵⁰ This monopoly allows the patent holder to control the price at which he sells his invention, as well as excluding any competition within the market. Such impacts can have significant implications on healthcare product prices.

⁴⁸ Elle Mahdavi, *Patents and the Pharmaceutical Industry*, CA Review Management, <https://cmr.berkeley.edu/2017/05/patents-and-pharmaceuticals/#:~:text=Patents%20are%20a%20way%20to,would%20be%20accessible%20to%20all>.

⁴⁹ Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, Health and Human Rights Journal, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

⁵⁰ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

In addition to the exclusivity benefit that patent holders obtain, patents on pharmaceuticals face virtually no regulation on price once a healthcare product hits the market.⁵¹ This lack of restriction can lead to detrimental consequences for individuals who require medications to survive. For example, in 2015, Martin Shkreli was able to hike up the price of Daraprim, an AIDS medication, from \$13.50 to \$750 per pill.⁵² While this drastic price increase is completely legal, it could be regarded as immoral, and certainly leads to a disparate impact on healthcare access to vulnerable populations.⁵³ This failure of regulation is a substantial issue with the patent system and continually affects the racial and ethnic minorities as well as low socio-economic populations.⁵⁴

Another patent issue that arises in the healthcare industry is that while the intent behind patents is to encourage innovation, because of the necessity for exclusivity and the competition that it breeds, much of the research for innovations occurs in secret.⁵⁵ While this makes sense for companies to beat out other companies in the race to develop and patent, it actually discourages open-source innovation, where researchers and inventors from several institutions and companies collaborate with each other, rather than competing with one another.⁵⁶ Additionally, a large share of innovation is devoted to “me

⁵¹ Elle Mahdavi, *Patents and the Pharmaceutical Industry*, CA Review Management, <https://cmr.berkeley.edu/2017/05/patents-and-pharmaceuticals/#:~:text=Patents%20are%20a%20way%20to,would%20be%20accessible%20to%20all.>

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Fran Quigley, Making Medicines Accessible: Alternatives to the Flawed Patent System, *Health and Human Rights Journal*, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

⁵⁶ *Id.*

too” products, as in products that already have a high market value, rather than ones that offer new therapeutic benefits.⁵⁷

B. Effects of disease prevalence on market demand

One of the most important factors when considering a patent is the potential demand for a product.⁵⁸ While a monopoly on a medical invention allows a patent holder to have complete control over the market for that product, the patent holder can only make money if there is a demand for such a product within the market.⁵⁹ In the healthcare field, there is a high demand for many medical devices, vaccines, and pharmaceuticals due to the potentially life-saving properties of the products.⁶⁰ The high demand, however, deters innovators from researching health problems that are not as prevalent in society, which results in relatively few medical treatments or healthcare products.⁶¹ Because rare diseases affect only a small portion of the population, researchers are not as likely to recoup losses from costly research when the demand for the invention will likely have little earning potential.⁶²

If there is not a large market for a certain healthcare solution, such as a pill or vaccine for a rare disease, it likely will conjure much less attention from commercial inventors and researchers, as there will likely not be a large profit.⁶³ In this regard,

⁵⁷ Fran Quigley, Making Medicines Accessible: Alternatives to the Flawed Patent System, Health and Human Rights Journal, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ Amy Paturel, MS, MPH, *Too Rare for Research? How to Handle an Orphan Disease*, American Academy of Neurology (May 2012) <https://www.brainandlife.org/articles/too-rare-for-research-people-with-rare-diseases-often-experience/>.

⁶² *Id.*

⁶³ *Id.*

healthcare product patents only incentivize innovation if the product is in high demand or has the potential for a high market price.⁶⁴

To combat this conflict, Congress passed the Orphan Drug Act, as an amendment to the Federal Food, Drug, and Cosmetic Act in 1938.⁶⁵ Congress sought to incentivize researchers to investigate and develop treatments to rare diseases by providing up to 50 percent tax credits to developers, in addition to the benefits already obtained by patenting the inventions.⁶⁶ In actuality, the rare diseases which inspired the Orphan Drug Act affected between 20 and 25 million people.⁶⁷

While there remains a need for research and development for rare disorder treatments, the incentives provided by the Orphan Drug Act saw over 200 approved products to treat orphan disorders by the year 2009, which provided treatment to eleven million patients.⁶⁸ A potentially negative implication that results from the Orphan Drug Act is that many companies apply for Orphan Drug status once their original patent expires in an attempt to extend their patent for an extra seven years.⁶⁹ Clearly, the Orphan Drug Act has its flaws, but the U.S. has yet to develop a solution without significant loopholes for

⁶⁴ Amy Paturel, MS, MPH, *Too Rare for Research? How to Handle an Orphan Disease*, American Academy of Neurology (May 2012) <https://www.brainandlife.org/articles/too-rare-for-research-people-with-rare-diseases-often-experience/>.

⁶⁴ *Id.*

⁶⁵ Public Law 97 - 414.

⁶⁶ *Id.*

⁶⁷ John Swann, Ph.D. *The Story Behind the Orphan Drug Act* (Feb. 23, 2018), <https://www.fda.gov/industry/orphan-products-development-events/story-behind-orphan-drug-act>.

⁶⁸ Timothy Coté, M.D., M.P.H, *Breakthrough Business Models: Drug Development for Rare and Neglected Diseases and Individualized Therapies*, National Academies Press (2009), <https://www.ncbi.nlm.nih.gov/books/NBK50974/#:~:text=During%20the%2025%2Dyear%20history,see%20Figure%203%2D1>).

⁶⁹ Elle Mahdavi, *Patents and the Pharmaceutical Industry*, CA Review Management, <https://cmr.berkeley.edu/2017/05/patents-and-pharmaceuticals/#:~:text=Patents%20are%20a%20way%20to,would%20be%20accessible%20to%20all>.

⁶⁹ *Id.*

treating rare disorders. One potential solution would be to enact a price ceiling on pharmaceuticals.⁷⁰ A Kaiser Health News poll showed that 78 percent of the respondents supported the government creating a price ceiling on certain prescription drugs.⁷¹

C. How monopolies are used as a weapon against small-scale inventors

Large companies whose profits are dependent on the monopolies of healthcare products often employ cross-licensing of patents as a way to avoid interfering⁷² with other large companies' innovation.⁷³ While this allows large companies to have more freedom to innovate without worrying about infringing on existing patents, it can also result in the blocking of small-scale inventors from entering the market.⁷⁴ Allowing small-scale inventors to participate in such innovation could lower costs to consumers and provide improved services that would disrupt the market for the larger companies.⁷⁵ Excluding small inventors from entering the market benefits those large companies, but in turn, is a detriment to consumers and other small-scale inventors.⁷⁶

D. Competition once an original patent expires

⁷⁰ Elle Mahdavi, *Patents and the Pharmaceutical Industry*, CA Review Management, <https://cmr.berkeley.edu/2017/05/patents-and-pharmaceuticals/#:~:text=Patents%20are%20a%20way%20to,would%20be%20accessible%20to%20all>.

⁷¹ *Id.*

⁷² *Id.*

⁷³ The Great IP Debate: Do Patents Do More Harm than Good?, (July 28, 2016), <https://sciencebusiness.net/news/79887/The-Great-IP-Debate%3A-Do-patents-do-more-harm-than-good%3F>.

⁷⁴ *Id.*

⁷⁵ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

⁷⁶ *Id.*

Once a patent expires, companies race to create new forms of essentially the same invention to obtain new patents and gain exclusivity in the market.⁷⁷ However, once the original patent expires, those rivals have to compete against the generic versions, which often is accessible at a much cheaper price.⁷⁸

Often, when a company's patent is set to expire, that company makes some minor changes to the drug, vaccine, or device to make it patent-eligible again, resulting in essentially an extension of the prior patent.⁷⁹ This process is referred to as strategic patenting.⁸⁰ Since the company already had the majority of the research and development done regarding the original product, a few tweaks to the existing product will take much less time and effort to make it patentable compared to other companies that are starting from scratch, thus creating an opportunity for the original patent-holder to have a perpetual patent on a product.⁸¹ This behavior weighs against public policy, as Congress's intent when writing the Patent Act was to encourage innovation, and strategic patenting essentially devalues innovation by attempting to retain control of the market.⁸²

IV. Disparate impact of medical patents on healthcare in America

The healthcare industry in the United States is a flawed but long-standing system. Even though all Americans routinely interact with the healthcare system, the interactions among different populations often lead to vastly different outcomes. There are many

⁷⁷ Denise L. Mayfield, JD, *Medical Patents and How New Instruments or Medications Might Be Patented*, MO. MED. (2016).

⁷⁸ *Id.*

⁷⁹ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

personal factors that contribute to an individual's overall healthcare experience, such as sex, geographic location, and socio-economic status, as well as external factors, like healthcare setting and broader environment.⁸³ However, there is a consistently disparate impact among racial and ethnic minorities, as well as low socio-economic populations in the United States.⁸⁴ This inequity, in part, stems from long-standing institutional racism as well as the politicization of healthcare as a privilege rather than a human right.⁸⁵

A. Racial, ethnic, and socio-economic inequality of healthcare access

Racial and ethnic minorities, as well as low socio-economic groups, face increased healthcare inequities when compared to other populations in the United States.⁸⁶ Because some Americans view healthcare as an economic issue, rather than a human rights issue, it is imperative that consumers treat shopping for healthcare products and services like shopping for other nonhealthcare products and services.⁸⁷ To get high-value healthcare, consumers should compare the prices of different providers, products, and services to ensure that they are getting the best value for their money.⁸⁸

While cost-comparison makes sense generally for Americans, racial and ethnic minorities as well as low socio-economic populations have less access to information,

⁸³ Ali Mohammad Mosadeghrad, *Factors Affecting Medical Service Quality*, Iranian Journal of Public Health (Feb. 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450689/>.

⁸⁴ Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, Trans Am Clin Climatol Assoc. (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3540621/>.

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ Jessica Greene, Ph.D. and Rebecca M. Sacks, M.P.H., *Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices*, Health Services Research (Feb 25, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056584/>.

resources, and education to be able to adequately make these decisions.⁸⁹ This lack of access is, in part, due to the vast complexity of the healthcare system and the heavy regulation of the industry.⁹⁰ Further, while economic inequity has an impact on the healthcare of racial and ethnic minorities as well as low socio-economic populations, the overall healthcare industry has a substantial impact on the economy of the entire country.⁹¹

In addition, while continual healthcare and technological advancement is a purpose of patent law and a benefit for society as a whole, such advancements can leave behind minorities and low-socioeconomic populations due to lack of education, information, and access to these advancements.⁹²

B. Patents disproportionately lessen access to healthcare/medicine based on racial, ethnic, and socio-economic variants

Racial and ethnic minorities as well as low socio-economic populations already suffer from healthcare inequity due to several previously stated societal issues.⁹³ The high prices of healthcare products and services resulting from patent monopolies only increase that inequity by creating unaffordable healthcare services, medications, and other healthcare products.⁹⁴

C. Healthcare as a political and economic issue, rather than a human rights issue

⁸⁹ Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, Trans Am Clin Climatol Assoc. (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3540621/>.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

Healthcare is one of many issues on which Americans cannot agree. While some believe that access to healthcare is a human right that everyone is entitled to, others feel that it is an issue best left up to private companies and individuals to decide. While this issue is not black and white, healthcare as a political issue has become much more radicalized in recent years.⁹⁵ While one might assume that divisions on healthcare beliefs exist across populations differing by race, sex, or socio-economic status, the starkest disagreements on healthcare are evident across political party lines.⁹⁶ This political divisiveness allows Americans to debate healthcare just like other political issues.

D. How lack of insurance heightens healthcare inequity

The debate over healthcare reached a peak in 2010 when President Obama signed the Patient Protection and Affordable Care Act into law.⁹⁷ The Affordable Care Act sought to provide insurance coverage to over 30 million uninsured Americans.⁹⁸

The uninsured in America tend to be disproportionately poor, young, and from racial or ethnic minority groups.⁹⁹ Data from the American Community Survey between 2008 and 2014 shows that prior to the enactment of the Affordable Care Act, 40.5 percent of Hispanic adults and 25.8 percent of Black adults in America were uninsured, as compared to 14.8 percent of white adults.¹⁰⁰ There are many consequences that uninsured

⁹⁵ Amy Wolf, *Political divide: Why Health Care is the Issue on Which Americans May Never Agree*, Vanderbilt University, (April 10, 2012), <https://news.vanderbilt.edu/2012/04/10/health-care-politics/>.

⁹⁶ *Id.*

⁹⁷ Sara Rosenbaum, JD, *The Patient Protection and Affordable Care Act: Implications for Public Health Policy and Practice*, Public Health Rep., (Feb. 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001814/>.

⁹⁸ *Id.*

⁹⁹ Thomas C. Buchmueller, *Effect of the Affordable Care Act on Racial and Ethnic Disparities in Health Insurance Coverage*, Am J Public Health, (Aug. 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4940635/>.

¹⁰⁰ *Id.*

people deal with, such as less access to preventive services, poorer health outcomes, higher disability rates, and lower earnings due to illness.¹⁰¹ A significant effect of being uninsured is the amount that uninsured individuals pay out of pocket for healthcare products and medications.¹⁰²

E. Impact of the U.S. as a high-income market

Because a majority of healthcare products, especially pharmaceuticals, are typically inexpensive to manufacture, once a product is has a patent, it takes relatively little time to recoup losses from research, development, and patenting, and then companies can start to make large profits.¹⁰³ As a result of patent monopolies, coupled with the essential nature of healthcare products and medicines, today's pharmaceutical industry is one of the most profitable sectors in history.¹⁰⁴ Because the U.S. is a high-income market, pharmaceutical companies can get away with charging exorbitant prices for drugs, and while many Americans struggle to afford these treatments, the high-income market dictates treatment rates.¹⁰⁵

V. Ripple effects outside the U.S.

¹⁰¹ Wayne J. Riley, *Health Disparities: Gaps in Access, Quality and Affordability of Medical Care*, Trans Am Clin Climatol Assoc. (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3540621/>.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, Health and Human Rights Journal, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

The consequences facing indigent communities in the United States are also issues existing in many indigent countries, where people die of illness at high rates, even when effective treatments exist for those illnesses.¹⁰⁶

A. International patent regulation

For a United States patent holder to obtain patent rights outside the United States, the patent holder must file an international patent application under the Patent Cooperation Treaty (PCT), which was established by the World Intellectual Property Organization.¹⁰⁷ Upon approval, the patent holder will have a patent right with all countries that have ratified the PCT.¹⁰⁸ The World Trade Organization (WTO) has established the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which seeks to establish a set of standard international rules regarding intellectual property.¹⁰⁹

Article 27 of the TRIPS Agreement allows governments to deny patents if its commercial exploitation could have a negative effect on human life or health.¹¹⁰ While the intent behind the TRIPS Agreement was to create a uniform system of regulation for intellectual property, it still had substantial issues, especially regarding developing countries and least developed countries (LDCs).¹¹¹ Between 1995, when the TRIPS Agreement went into effect, and 2001, LDCs were exempt from TRIPS, but due to the lack of

¹⁰⁶ Tara Leevy, *Intellectual Property and Access to Medicine for the Poor*, AMA Journal of Ethics (Dec. 2006), <https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12>.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ World Trade Organization (2020), https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Sep. 21, 2020).

¹¹⁰ Tara Leevy, *Intellectual Property and Access to Medicine for the Poor*, AMA Journal of Ethics (Dec. 2006), <https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12>.

¹¹¹ *Id.*

production in LCDs, they often relied on importation from supplier countries, or they relied on compulsory patents.¹¹² The importation of drugs often resulted in unaffordable drug prices and led to drug unavailability.¹¹³ Powerful interest also often pressured LCDs against engaging in compulsory patents.¹¹⁴

Recognizing that they needed to do more to aid poor countries, especially with regard to HIV/AIDS, malaria, and tuberculosis epidemics, the WTO amended TRIPS in 2001 with the Doha Declaration on Public Health (Doha).¹¹⁵ Doha's goal was to allow member countries to alter their domestic patent laws so that compulsory license exports can help any country that might lack sufficient manufacturing ability.¹¹⁶

Still, the Doha amendment only permitted those supplier countries with a compulsory patent to sell the more affordable pharmaceuticals domestically, which did almost nothing to help LCDs who lack manufacturing capacity.¹¹⁷ In 2005, WTO finally amended the Doha Declaration on Public Health to allow countries with compulsory patents to alter their domestic patent law in order to provide other LCDs pharmaceuticals at a much lower cost.¹¹⁸

B. US implications of international patent policy

¹¹² Tara Leevy, *Intellectual Property and Access to Medicine for the Poor*, AMA Journal of Ethics (Dec. 2006), <https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12>.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

In early 2020, both of the major political parties in the United States proposed and supported the U.S.'s withdrawal from WTO, with both parties stating that the WTO no longer represents the interests of the United States.¹¹⁹ There is no way to know what lasting effects the pending U.S. withdrawal from the WTO might have on international intellectual property protections, especially with regard to medical and pharmaceutical patents.

VI. Pharmaceutical industry impact on healthcare inequity

The pharmaceutical industry has a reputation for charging high prices, to the detriment of consumers.¹²⁰ Pharmaceutical companies recoup losses related to research and development from charging high prices for drugs. But because of the relatively low cost of manufacturing these drugs on a large scale, these companies are able to recoup losses fairly quickly and then make consistent profits by keeping drug costs high and overcharging consumers.¹²¹ This issue is a contributor to inadequate healthcare access in the U.S. among racial and ethnic minorities and low socio-economic populations.¹²²

The FDA can grant exclusivity to approved drugs in addition to the exclusivity that a patent grants, which means that the FDA will delay or prohibit approval of competitor drugs for a certain period of time.¹²³ The policy behind exclusivity seeks to allow a balance

¹¹⁹ Keith Johnson, *U.S. Effort to Depart WTO Gathers Momentum*, Foreign Policy (2020), <https://foreignpolicy.com/2020/05/27/world-trade-organization-united-states-departure-china/> (last visited Sep. 21, 2020).

¹²⁰ Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, Health and Human Rights Journal, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹²¹ *Id.*

¹²² *Id.*

¹²³ U.S. Food and Drug Administration, U.S. Food and Drug Administration (2020), <https://www.fda.gov> (last visited Sep. 18, 2020).

between pharmaceutical innovation and public access to drugs resulting from competition of generic drugs.¹²⁴ While generic drugs promote public policy and force manufacturers to reduce drug costs to compete with any generic counterparts, one lasting issue is that companies use strategic patenting to extend their patents and create perpetual patents.¹²⁵

VII. How to reconcile the healthcare product patent issues

The current U.S. patent system, although not perfect, does serve the Congressional purpose of encouraging innovation, but the innovation often comes from large manufacturers, to the detriment of small-scale inventors. Many ideas exist for how to better encourage innovation without many of the negative consequences of the current system, but none of the alternatives have been tested to see if they will result in better outcomes.¹²⁶

Until the day comes when a perfect patent system exists, our current patent system will have to suffice. Despite the inherent faults and consequences, the current system has unique benefits, such as forcing researchers to get creative with solutions so they can obtain their own patents.¹²⁷

A. Possible alternatives to the current patent system

To be worthwhile, any legitimate alternative or reform to the current patent system must be able to provide comparable incentives to researchers and inventors. Designers of

¹²⁴ U.S. Food and Drug Administration, U.S. Food and Drug Administration (2020), <https://www.fda.gov> (last visited Sep. 18, 2020).

¹²⁵ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, *Global Policy*, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

¹²⁶ Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, *Health and Human Rights Journal*, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹²⁷ *Id.*

an alternative solution would be required to better balance the need for incentives for companies to put in the time and money for research, development, and patenting, with the need for affordable access to healthcare products and services for racial and ethnic minorities and low socio-economic populations throughout the U.S.

One potential change to the current patent system is implementation of a price ceiling for healthcare products.¹²⁸ An issue that could arise, however, is that manufacturers might fear that they could not recoup their initial investments and incurred losses. A potential solution to this problem would be to allow companies to charge any price up until they earn enough money to recoup inherent losses and investments, and then institute a price ceiling to ensure more affordable and manageable prices for consumers.

Another change that the USPTO could implement is to reduce the incidence of strategic patenting, often used by large manufacturers to perpetuate existing patents and maintain exclusivity within the market.¹²⁹ Under current law, strategic patenting is completely legal, but it does nothing to benefit society and acts against the public interest.¹³⁰ Interestingly, China has recently considered instituting a policy granting a one-year exclusivity period for generic drugs to incentivize generic drug manufacturers.¹³¹ This would allow first-to-file generic drug patent applications to gain exclusivity in the market

¹²⁸ Fran Quigley, Making Medicines Accessible: Alternatives to the Flawed Patent System, *Health and Human Rights Journal*, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹²⁹ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, *Global Policy*, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

¹³⁰ *Id.*

¹³¹ Hongjiang Li, One year market exclusivity for generic drugs under China's patent linkage plan, *Biocentury*, (Sep. 15, 2020), <https://www.biocentury.com/article/630396/one-year-market-exclusivity-for-generic-drugs-under-china-s-patent-linkage-plan>.

for one year.¹³² While this could be a way to incentivize generic drug manufacturers, it is possible that the policy would encourage generic drug manufacturers to hike prices similar to their name-brand counterparts.

Most proposed reforms focus on providing various “push” and “pull” incentives.¹³³ Push incentives focus on providing funding through grants and subsidies in the early stages of research and development.¹³⁴ One of the most notable examples of this type of incentive is through the National Institutes of Health (NIH).¹³⁵ The NIH provides approximately \$30 billion in funding annually for medical research and development.¹³⁶ While government subsidies and philanthropy make up approximately 40 percent of all medical research funding, there are many other smaller push incentives out there for companies, from the private sector, academia, for-profit companies, and elsewhere.¹³⁷ In addition to grants and other subsidies, another push incentive consists of tax credits for companies performing medical research and development.¹³⁸

While push incentives consist of providing funding and tax credits in the initial stages of research and development, pull incentives focus on the later stages.¹³⁹ Pull incentives often take the form of monetary prizes or awards for the development of

¹³² Hongjiang Li, One year market exclusivity for generic drugs under China’s patent linkage plan, *Biocentury*, (Sep. 15, 2020), <https://www.biocentury.com/article/630396/one-year-market-exclusivity-for-generic-drugs-under-china-s-patent-linkage-plan>.

¹³³ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, *Global Policy*, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Fran Quigley, Making Medicines Accessible: Alternatives to the Flawed Patent System, *Health and Human Rights Journal*, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹³⁸ *Id.*

¹³⁹ *Id.*

treatments and other valuable healthcare products.¹⁴⁰ While these push and pull incentives exist currently, they are mostly funded by private philanthropy.¹⁴¹ If pull incentives have hope to create meaningful reform to the current patent system, government investment in these prizes will be necessary to provide sufficient incentive to innovators.¹⁴²

Conclusion

The patent system is an essential part of American medical and technological innovation, with its roots stemming from the text of the U.S. Constitution.¹⁴³ While the patent system has evolved and improved regularly since its original codification in 1790, there is still much to be done to create a well-functioning patent system that not only promotes innovation for the betterment of society but also works for the American people.¹⁴⁴ The various existing flaws within the current patent system, while perhaps not negatively affecting other industries, have the ability to have detrimental consequences for American consumers.

One of the main issues with the current system is that the exorbitant costs associated with research, development, and patenting of healthcare products force many manufacturers to charge high prices to recoup losses.¹⁴⁵ Further, even once those companies recoup their losses, they can continue to charge the same high prices to the

¹⁴⁰ Fran Quigley, Making Medicines Accessible: Alternatives to the Flawed Patent System, *Health and Human Rights Journal*, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ U.S. Const. art. I, § 8.

¹⁴⁴ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, *Global Policy*, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

¹⁴⁵ *Id.*

detriment of consumers.¹⁴⁶ This price gouging likely happens in many other industries, but due to the essential nature of the healthcare field, many consumers do not have a choice and must pay for these healthcare products that affect the consumer's health and wellbeing.¹⁴⁷ While some American healthcare consumers can afford to pay the high prices of patented healthcare products, many cannot. For racial and ethnic minorities, as well as low socio-economic populations in the U.S., there exists a consistent inequity of healthcare access in general. The lack of affordability of patented healthcare products further exacerbates such disparities.¹⁴⁸

Monopolies created by patents are meant to provide exclusivity to the patent holder, helping to recoup initial investments for research and development, as well as to cover the costs of obtaining and maintaining the patent with the USPTO.¹⁴⁹ While researchers need these incentives to make research and development worthwhile, the strategies employed by many companies actually discourage innovation by smaller inventors and leads to perpetual patents.¹⁵⁰ Although patent laws are different for every country, one benefit many countries enjoy is being able to apply for patent rights in other countries. The WTO established the TRIPS Agreement, which created a standard set of rules for governing international patents.¹⁵¹ The WTO has reformed the TRIPS Agreement many times, in

¹⁴⁶ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

¹⁴⁷ *Id.*

¹⁴⁸ Fran Quigley, Making Medicines Accessible: Alternatives to the Flawed Patent System, *Health and Human Rights Journal*, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.

¹⁴⁹ Helen Gubby, *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective*, Global Policy, (Sept. 6, 2019), <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730>.

¹⁵⁰ *Id.*

¹⁵¹ Tara Leevy, *Intellectual Property and Access to Medicine for the Poor*, *AMA Journal of Ethics* (Dec. 2006), <https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12>.

hopes of improving the patent system and creating more equity of healthcare access for developing countries and LCDs.¹⁵²

The detrimental effects that the patent system has on vulnerable American populations is apparent in many developing countries that have little access to affordable healthcare products in addition to a lack of manufacturing capabilities. Interestingly, most other developed countries do not have many of the affordability problems that exist in the U.S. This issue, in part, is due to the healthcare system in the U.S., as opposed to the universal healthcare systems that exist in many other developed countries.¹⁵³ There are many proposed changes surrounding the current patent system, ranging from price ceilings for healthcare products, reducing the prevalence of strategic patenting and perpetual patents, and providing further incentives to deter companies from charging excessive and unreasonable prices to the detriment of American consumers.¹⁵⁴

While there are many proposed alternatives to the current system, much more work is necessary to create meaningful reform. However, given the United States healthcare system's dynamic nature, it is possible that the U.S. will begin to see reforms in many facets of the healthcare system, as the U.S. seeks to correct the inequity throughout the country. Because affordability of healthcare products and medicines is a highly contested issue among political parties, the topic is up for debate and hopefully this discussion will lead to reform and meaningful change for healthcare product patents.

¹⁵² Tara Leevy, *Intellectual Property and Access to Medicine for the Poor*, AMA Journal of Ethics (Dec. 2006), <https://journalofethics.ama-assn.org/article/intellectual-property-and-access-medicine-poor/2006-12>.

¹⁵³ *Id.*

¹⁵⁴ Fran Quigley, *Making Medicines Accessible: Alternatives to the Flawed Patent System*, Health and Human Rights Journal, (Nov. 23, 2015), <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/>.