# Lay Neg Shell

### NC – FWK

#### I negate the resolution resolved: The Member Nations of The World Trade Organization ought to reduce intellectual property protections for medicine.

#### My Value is morality due to the term ought in the resolution implying a moral obligation in the resolution itself.

#### My criterion is consistency with libertarian ideals

#### Business Dictionary explains libertarian ideals as:

Philosophical principle that **[Libertarian ideals] suggest**s **that a government's involvement in** civil economical and social **matters should be limited, and** that the **issues should be settled amongst civilians.** Libertarianism seeks to provide free-will participants the ability to make decisive decisions without the government determining or influencing the outcome, as long as it does not harm other individuals. Libertarianism is based off the belief that **each individual owns** every aspect of **their lives and** thus **should** have the ability to **control it.**

#### Prefer my criterion for the following reasons:

#### As a society, we generally recognize that people need individual liberties and rights. Individuals control what they do and thus we must respect their rights.. Feser:[[1]](#footnote-1)

But if **individuals are** inviolable ends-in-themselves (as Kant describes them) and **self-owners**, it follows, Nozick says, **that** they **have certain rights**, in particular (and here again following Locke) rights to their lives, liberty, and the fruits of their labor. To own something, after all, just is to have a right to it, or, more accurately, to possess the bundle of rights - rights to possess something, to dispose of it, to determine what may be done with it, etc. - that constitute ownership; and thus **to own oneself is to have** such **rights to the** various **elements that make up one's self.** **These** rights function, Nozick says, as side-constraints on the actions of others; they set **limit**s **on how others may**, morally speaking, **treat a person**. So, for example, since you own yourself, and thus have a right to yourself, others are constrained morally not to kill or maim you (since this would involve destroying or damaging your property), or to kidnap you or forcibly remove one of your bodily organs for transplantation in someone else (since this would involve stealing your property). **They are** also constrained **not to force you against your will** to work for another's purposes, even if those purposes are good ones. For if you own yourself, it follows that **you** have a right to **determine** whether and **how you will use your** self-owned **body and its powers**, e.g. either to work or to refrain from working.

#### Individuals have rights, so people must respect your actions and cannot restrict you. This also means the government cannot restrict you unless it is to prevent harm of another person. In order to make sure these rights are protected, we have to restrict the government. Because of this, the government’s only obligation is to protect rights. Feser 2:[[2]](#footnote-2)

The various programs of the modern liberal welfare state are thus immoral, not only because they are inefficient and incompetently administered, but because they make slaves of the citizens of such a state. Indeed, **the only** sort of **state that can be moral**lyjustified **is** what Nozick calls a***minimal*** *state*or "night-watchman" state, a government **which protects individuals**, via police and military forces, from force, fraud, and theft, **and administers courts** of law, but does **nothing else**. In particular, such **a state cannot** regulate what citizens eat, drink, or smoke (since this would i**nterfere with their right to use their** self-owned **bodies** as they see fit), cannot control what they publish **or** read (since this would interfere with their right to use the **property** they've acquired with their self-owned labor- e.g. printing presses and paper - **as they wish**), cannot administer mandatory social insurance schemes or public education (since this would interfere with citizens' rights to use the fruits of their labor as they desire, in that some citizens might decide that they would rather put their money into private education and private retirement plans), and cannot regulate economic life in general via minimum wage and rent control laws and the like (since such actions are not only economically suspect - tending to produce bad unintended consequences like unemployment and housing shortages - but violate citizens' rights to charge whatever they want to for the use of their own property).

#### This implies that anything the government does that is not either for protection or administering the courts is not just. So we have to minimize the government in order for it to not overstep its authority.

#### Also, if a government has total control over society they can become corrupted easily. They have no one to be accountable to and thus can abuse their power. Thus, we have to restrict governmental authority

### Contention 1 – Property Rights

#### Locke's theory of property rights entails that patents for medicines are morally justified by individuals' property right in their own person and labor.

Gewertz, Nevin. "Intellectual Property And The Pharmaceutical Industry: A Moral Crossroads Between Health And Propert." Journal of Business Ethics 55:3. December, 2004. Web. August 18, 2021. <https://www.jstor.org/stable/25123392?seq=1#metadata\_info\_tab\_contents>.

**Intellectual property**, much like physical property, **is the product of labor**. According to Locke, "**every man has Property in his own Person'** (Locke, 1690, 11:27). **The individual labor belongs to that individual, and in turn this produces several conditions of origination for property:** (a) Locke argues that a person acquires ownership rights over a certain un claimed piece of property by "mixing his labor" with that property, thereby increases its value; (b) the right of property is conditional upon a person leaving in the commons enough (and as good) for the other commoners; (c) a person cannot take more out of the commons than he or she can use to advantage (Locke, 1690, 11:34-37). **The justification of intellectual property**, as a form of property in accordance with Locke, **depends on two factors**: **a conception of community, and the relation of that community to the intellectual com mons** (Drahos, 1996). **The notion of property means the right of exclusive possession to the objects which people take from the commons**. Commons can be defined as any sets of resources that a community recognizes as being accessible to any member of that community. **A person's inclusive right to the com mons does not include a right to everything in the commons, but merely the right to be included in the commons for the purpose of exercising the natural rights of survival** (Tully, 1980). **Even though intellectual property is by nature non-exclusionary, it functionally satisfies** a **Lockean** conception of **property** **because an individual both mixes his or her labor and increases the value of the original property.** In the context of drug development, one may argue that no synthetic chemical component magically appears as a figment of one's imagination. Instead, individuals mix labor in the form of time and money invested in research, education, and various resources, all of which are necessary to facilitate the creation of new ideas and novel medications. The **value of the finished prod uct, a novel idea to synthesize a medication capable of treating a specific disease, can be of greater worth than any of the individual component parts from which it is synthesized.** The value of the physical object is of greater worth, at least economically, than the idea itself. **Intellectual property provides an individual with an exclusive right to his or her own ideas. In practice, intellectual property is rewarded by the state in the form of a patent. A patent is a grant of a limited monopoly to an inventor in exchange for disclosing the invention to society** (Goldman, 1989). Once the patent has been awarded, the inventor can either control the product and set up its price in the market, or can sell his or her rights. In the U.S., a patent is legally defined as "the right to exclude others from making, using, offering for sale, or selling" a particular invention in the United States. **Additionaly, granting a patent rewards an inventor's creativity, labor, investment and accomplishments. Without proprietary protection of a patent, others could freely appropriate and put the invention to their own use** (Goldman, 1989).

#### The state has an obligation to protect property rights, and this must include intellectual property rights in medicines.

Gewertz, Nevin. "Intellectual Property And The Pharmaceutical Industry: A Moral Crossroads Between Health And Propert." Journal of Business Ethics 55:3. December, 2004. Web. August 18, 2021. <https://www.jstor.org/stable/25123392?seq=1#metadata\_info\_tab\_contents>.

**According to Nozick, the primary purpose of the state is to protect basic rights.** **One of these explicit rights is the right to intellectual property.** **The concept of intellectual property is not practical unless it is upheld by the state. A simple patent by itself holds no value. The value and rights granted within a patent are meaningful to the extent they are enforced.** Simplistically, the state is formed through an "invisible hands" process by which all individuals agree to a "monopoly over all use of force" (Nozick, 1974, p. 26). Each individual, regardless of his or her position within society, has agreed to accept this "monopoly over force" in order to protect his or her basic rights, such as property. Nozick holds that any infringement upon the basic rights of the individual by the state, such as redistribution of wealth or excessive taxation, is unjust. Such redistribution fundamentally violates the basic right of the individual to the products of his or her own labor. Nozick asserts that: A minimal state, limited to the narrow functions of protection against force, theft, fraud, enforcement of contract ... is justified. The state may not use its coercive apparatus for the purpose of getting some citizens to aid others (Nozick, 1974, p. ix). The purpose of the state is to protect individuals' basic rights, of which property is considered one of several. **Because intellectual property is a basic right, it would be unjust for the state to redistribute the profits** GlaxoSmithKlein receives from AZT or AZT itself, even if to provide better medical treatment for more individuals. **Instead, the state must ensure that the patent rights of the pharmaceutical company are upheld and not infringed upon by any possible substitute products.** Current domestic and international policies demonstrate an increasing trend towards the strict protection of intellectual property. The ideas behind such policies parallel the theoretical work of Nozick. As discussed, according to Nozick, **an individual is entitled to the market value of his or her "intellectual objects" over a given, non-infinite, time period**. **This market value, no matter how potentially extraneous, is not only acquired through just means but also distributed through just transfer.** In turn, within the minimalist state of Nozick's theory, no justification exists for state intervention and re-distribution of those goods or profits received by virtue of patent licensing. The states' obligation is to protect the intellectual property interests of an individual, as well as to protect the individual himself. \*Ellipsis from source

### Contention 2 – Innovation

#### IP protections are necessary for medical innovation. Bacchus 20

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With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long‐standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be ex‐ tended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID‐19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

#### Innovation cannot happen without protections—multiple warrants. McDole and Ezell 21

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In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non‐regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID‐19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID‐19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP‐related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP‐owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP‐intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP‐intensive industries, and IP generates higher wages and greater revenue per employee, especially for small‐to‐medium‐sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP‐intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top‐four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID‐19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.

# XT/FL

#### FRAMEWORK WEIGHING

#### There are two primary errors in the premises of their framework:

#### First, freedom is a primary side constraint on anything else because even if we care about well-being we must be free in order to act

#### Second, life without freedom isn’t worth living, which means there is more value in protecting our freedoms.

#### Now on their social contract argument – it collapses into my framework, the social contract is about the government protecting our rights, not maximizing our well being

#### Next, on their Goodin argument about governments – this is a logical fallacy because they have just made a claim about what some governments do, but that doesn’t mean its an ethically good thing. My framework resolves this because I best explain what a good government looks like. Additionally, this is empirically disproven in the real world as the German government uses freedom as a primary value in their constitution.

#### Finally, the lexical pre-requisite argument is wrong because their framework cannot solve for all deaths meaning it doesn’t actually come prior. Freedom is what enables us to act in the first place which means my arguments o/w my opponents arguments.

#### Extend My 1st Contention- Johns Lockes philosophy of property rights means that you have the rights to your own ideas, this means that we cannot reduce IP rights because then people that worked hard to formulate ideas of their own would no longer

#### Extend my

## Blocks

## At Accessibility

**Reductions in IP do not improve accessibility, and some protections are necessary for balancing public and private interests.**

**Krattiger 13**

Anatole Krattiger,; Adjunct Professor, School of Integrative Plant Science Plant Breed‐ ing and Genetics Section ; September 2013; ”Promoting access to medical innovation”; https://www.wipo.int/wipo\_magazine/en/2013/05/article\_0002.html, WIP Magazine, accessed 7‐29‐2021; JPark

The rationale of the intellectual property (IP) system in general, and the patent system in particular, is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in patent applications is accessible to soci‐ ety. In this way, it seeks to balance competing private and public interests. Anyone applying for a patent is required to disclose the details of their technology so that the pub‐ lic is aware of, and can eventually use, the knowledge contained in patent documents. Patent information available through public databases, such as WIPO′s PATENTSCOPE, offers useful insights about innovation trends and freedom‐to‐operate, and can help shape patenting and licensing strategies. Data indicate overall long‐term growth in patenting of medical technologies (a sign of renewed investment in this area) and that an increasingly diverse range of public and private users (see Figures 2 and 3), including from emerging economies, are using the international patent system. While the patent system is designed to promote innovation by providing an incentive to invest in R&D, the impact of patents on access to medical technologies is complex and much debated. Just as the existence of a patent need not be a barrier to access, the absence of a patent right does not guarantee effective access. As noted in the WHO′s Framework for Access to Medicines, access to medicines is rarely dependent on a single factor; it also includes rational selection and use of medicines, affordable prices, sustainable financing and reli‐ able health and supply systems, among others. Striking an appropriate balance Striking an appropriate balance between encouraging medical innovation and enabling access to it has been a major preoccupation of policymakers, health activists and the private sector, since the 1990s when concerns about access came to the fore in relation to the treatment of HIV/AIDS in many African countries. The WTO′s Doha Declaration on the TRIPs Agreement and Public Health of 2001, clarified a number of rules specific to IP and helped reassure the global community that IP should not prevent access to the medicines needed in developing countries. Medical technologies are usually very expensive to develop but relatively cheap to reproduce. Without the protection conferred by a patent it would not be financially viable for companies to continue investing in re‐ search, product development and regulatory approval. If competitors could “free ride” on the cost of developing a product and were able to immediately introduce their own versions, the inventor would not get the expected financial returns thereby weakening any incentive to develop new products.

#### Turn- Waiving patents can’t resolve drug access issues but instead create a more dangerous scenario for developing countries. Garde 21

Damian Garde (national biotech reporter for STAT), Helen Branswell (senior writer at STAT covering infectious diseases and global health; former CDC Knight Fellow and Nieman Global Health Fellow at Harvard; recipient of the 2020 George Polk Award for coverage of the Covid pandemic), and Matthew Herper (senior writer at STAT covering medicine). “Waiver of patent rights on Covid‐19 vaccines, in near term, may be more symbolic than substantive.” Stat News. 6 May 2021. JDN. https://www.statnews.com/2021/05/06/waiver‐of‐patent‐rights‐on‐covid‐19‐vaccines‐ in‐near‐term‐may‐be‐more‐symbolic‐than‐substantive/

In October, Moderna vowed not to enforce its Covid‐19‐related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of pro‐ cess steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in‐demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry‐wide ... looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the peo‐ ple who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry‐Heath, CEO of the trade group BIO, put it in a statement, “hand‐ ing needy countries a recipe book without the ingredients, safeguards, and sizable work‐ force needed will not help people waiting for the vaccine.”

## At Developing Countries

**Flexibilites exist in the status quo.**

**Crosby et al. 21**

Daniel Crosby, Evan Diamond, Isabel Fernandez De La Cuesta, Jamieson Greer, Jef‐ frey Telep, Brian White; Crosby specializes in international trade, investment and mat‐ ters related to public international law. Diamond is a partner on our Intellectual Prop‐ erty, Patent, Trademark and Copyright Litigation team.; 3‐5‐2021; ”Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID‐related Medical Products”; https://www.jdsupra.com/legalnews/group‐of‐ nearly‐60‐wto‐members‐seek‐2523821/, JD Supra, accessed 7‐21‐2021; JPark

Existing flexibilities for developing countries. The WTO Agreement on Trade‐Related Aspects of Intellectual Property Rights (TRIPS Agreement) protects intellectual property, and recognizes that patents can be licensed either voluntarily on commercial terms, or without the authorization of the rights holder under “compulsory licenses” where “the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.” (TRIPS Agreement, Article 31(b).) Countries are not required to request authorization “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non‐commercial use,” but must notify rights holders “as soon as reasonably practicable;” and in any case must pay “adequate remuneration” to the right holder. Notably, intellectual property rights may be protected pursuant to bilateral investment treaties or free trade agreements that protect covered investments in certain circumstances. Some such treaties reference the TRIPS Agreement while others do not.

## AT Patent Trolling

**Patent trolling risk is exclusively a problem for non medical patents, while pharma and biotech patents have little risk of patent trolling, do not let the aff gain offense under this argument unless they can prove uniquely medical patents have high probability of trolling**

**Thomas 6**

Robert E. Thomas (Associate Professor of Legal Studies and Huber Hurst Fellow, Warrington College of Business, University of Florida). “Vanquishing Copyright Pirates and Patent Trolls: The Divergent Evolution of Copyright and Patent Laws.” American Business Law Journal Volume 43, Issue 4, 689–739, Winter 2006. JDN. https://heinonline.org/HOL/LandingPage?handle=hein.journals/ambuslj43&div=25

While the growth of patent infringement claims is a significant problem, not all technology companies share the resolve to curtail the patent troll problem. Biotech/pharma companies are likely less concerned about infringement claims.158 The high cost of pro‐ ducing biotechnology and pharmaceuticals substantially reduces the number of com‐ panies with sufficient resources to engage in innovation‐producing research in biotech/ pharma.159 While it is unclear whether these high entry costs lead to fewer patents, they do limit the universe of companies that can produce innovations and bring patent infringement claims. Moreover, biotech/pharma patents are likely to cover the entire drug, whereas info‐tech products may consist of thousands of inventions. Thus, there are almost certainly fewer innovations in biotech/pharma that can trigger patent litiga‐ tion.160

#### First, “incremental” innovations are a key aspect of R&D, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

As already mentioned, **the costs and time necessary to bring a drug to the market are considerable**. While the initial patents covering the basic chemical or protein entity are important to encourage the further investment to bring the drug to the market, **the length of time afforded protection** by such patents ‐ due to the considerable amount of time necessary to develop a suitable formulation and presentation of the drug, and the time to conduct clinical trials ‐ **usually does not provide sufficient protection to balance the overall financial investment.** Further, **many inventions** made during the develop‐ ment of the drug formulation or presentation, while possibly **viewed as ’incremental inventions’ by some, are actually critical to bringing the drug to the market**. Indeed, as a proportion of all patents granted worldwide, very few relate to what may be termed “breakthroughs”. **The vast majority cover innovations which build on inventions of others, with the benefit of full disclosure of those inventions in patent specifications**. That is what the patent system was designed to encourage. **By its very nature**, there‐ fore**, it encourages inventors to adapt and modify the developments** patented by others **incrementally** or in any other way. It would therefore, in ICC’s view, be wholly in‐ appropriate not to allow patents for such forms of innovation; and any such change would adversely affect the ability to finance future drug research. **The innovation process in the pharmaceutical sector, as for all other scientific sectors, is one of evolution**. The criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. **If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. Of these criteria, the most relevant here is inventive step**. The invention must not have been obvious to a person skilled in the relevant art at the time the application for a patent was first filed, taking into account the state of the art at that time. There is no common understand‐ 192 7 Negative Evidence ing around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied differs from country to country. It even differs over time within the same country. Significant progress has, however, been made in harmonizing the standard, particularly in the US, Japan and Europe. This harmonized standard should, in ICC’s view, in time become the “gold standard” for patents globally. In the meantime, it may be necessary and appropriate, to encourage investment in local research and manufacturing, for developing countries to adopt a lower threshold to provide easy access to patents for local entrepreneurs. But in ICC’s view, it cannot be right to require such countries to adopt a higher standard of inventive step. In any event, neither the inventive step requirement, nor the other basic criteria, make any distinction between different types of innovation œ for example between “in‐ cremental” and “discrete”, or between “me too” and “breakthrough” innovations. As with any innovation, all of these have to be judged against the same basic rules, and that, in ICC’s view, is entirely appropriate. To the extent that genuine concerns about patent quality exist, they relate to the whole range of patents**. They are not specific to patents for healthcare products, nor to patents for so‐called incremental innovations. If such inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have wrongly been granted, courts should (and have) corrected those errors** œ all as part of the international efforts referred to above to ensure that an appropriate balance is achieved between all entities affected by patents. **However, the fact that there have been some examples of patent‐granting authorities ap‐ plying the criteria incorrectly does not justify fundamental change to those underlying principles.**

**Other strategies exist for tackling patent trolling, IPR reductions would solve, empirics prove**

**Magliocca 13**

Gerard N. Magliocca (Associate Professor, Indiana University School of Law). “Black‐ berries and Barnyards: Patent Trolls and the Perils of Innovation.” 82 Notre Dame L. Rev. 1809 (2013). JDN. https://scholarship.law.nd.edu/ndlr/vol82/iss5/2

The other lesson that can be drawn from the Gilded Age experience is that the flood of opportunistic litigation cannot be stemmed through substantive changes in patent rights. 16 First, industries unaffected by trolls view these proposals as harmful to their interests and lobby hard against them. As a result, every effort to address the issue through a comprehensive solution has failed in Congress.1 7 Second, since trolls and sharks succeed as long as they reach settlements, a substantive solution will be ineffec‐ tive because most of these cases never get to court. So long as there is significant uncertainty about whether an infringement suit will succeed, defendants will tend to settle. In the nineteenth century, Congress eliminated this risk by wiping out the patents that were fueling opportunistic litigation.18 This suggests that abolition may be the only solution for modern trolls, at least with respect to patents for business methods and software.’ 9 If that medicine seems too strong, then the Patent Office should escalate the fees that firms must pay to maintain their patents, which would make speculation in dormant ones more costly.

**A dormancy tax on patents can reduce patent trolling without reducing substantive rights**

**Magliocca 13**

Gerard N. Magliocca (Associate Professor, Indiana University School of Law). “Black‐ berries and Barnyards: Patent Trolls and the Perils of Innovation.” 82 Notre Dame L. Rev. 1809 (2013). JDN. https://scholarship.law.nd.edu/ndlr/vol82/iss5/2

If eliminating an entire patent class is too hard to stomach, then the focus should turn to administrative solutions. Improving patent quality by reforming the examination pro‐ cess can help matters, but the application process is not the only point where trolls are vulnerable.116 If there are too many dormant patents that can be used to snare the un‐ wary, then one way that can be resolved is by taxing patents at a higher rate to increase the costs of engaging in opportunistic behavior. This proposal to raise the maintenance fees for patents builds on the existing system. To retain ownership of a patent, the rights holder must pay a $900 maintenance fee in the fourth year.1 17 In the eighth year, the fee goes to $2300, and in the twelfth year it jumps to $3800.118 Now imagine a scheme in which these fees are sharply increased and assessed more frequently. The cost of ac‐ quiring and holding patents would skyrocket. As a result, firms would have a strong incentive to either use their dormant patents or allow them to lapse and enter the public domain. This would starve trolls of their sustenance. Furthermore, opportunistic li‐ censers that obtain patents with the intent of holding them back until others start using the same technology will pay dearly for their sandbagging. 19 A tax on patents would not eliminate opportunistic litigation, but it might go a long way toward bringing the problem under control. A significant objection to this proposal, of course, is that hiking the maintenance fees on patents raises the costs of innovation. This is certainly true, even though the cost of a patent application would not go up. 120 One response is that trolls already impose a tax on innovation, but one that is unpredictable and concentrated on a handful of unlucky victims. Changing the fee structure, by contrast, would spread this burden more evenly and rationally. Moreover, while a fee increase is not going to please the industries unaffected by trolls, they may be more likely to accept a reform that does not affect their patent rights and remedies as the current proposals do. This may be a case where we need to seek a ”second‐best” solution that accepts a suboptimal outcome because it can actually be implemented. Reforming the fee assessment in lieu of abolishing technology patents could be just what the doctor ordered in this respect. In sum, the failure of many thoughtful reforms during the nineteenth‐century debate on patent sharks shows that a solution focused on altering substantive rights or remedies cannot succeed. Policymakers should instead direct their efforts at an outright repeal or at administrative solutions that reduce the number of dormant patents and their ability to disrupt settled expectations.

**Evergreening only proves flaws in the application process, not the legitimacy of patents themselves**

**Jones 6**

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

In the context of pharmaceuticals, it has been suggested that patent protection should not be given to inventions comprising different salts, esters or other derivatives of known drugs, different dosage forms or means of administration of existing products, combinations of known products (including fixed dose combinations), nor “mere” new uses of known compounds, (all of which might qualify for the misnomer “incrementally modified drugs”); nor for modifications to medical devices (such as a single‐, rather than multiple‐dose, syringe). These suggestions are, in ICC’s view, misconceived. As stated above, if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them; and if patents are found wrongly to have been granted, courts and patents offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or “evergreening”. There is no need for separate, or new, legislation to deal with this issue. Further, the suggestion that such inventions do not benefit society is wrong. These types of so‐called “incremental” innovation generally result in better health outcomes2, for example by increasing efficacy, reducing side effects and/or making administration easier, resulting in improved compliance and greater effectiveness

## AT COVID

**Investing in manufacturing and distribution is a better anti‐COVID strategy than breaking patents**

**Rogin 21**

Josh Rogin (political analyst for CNN; foreign policy columnist at the Washington Post; B.A. in international affairs from the George Washington University’s Elliott School of International Affairs). “The wrong way to fight vaccine nationalism.” Wash‐ ington Post. 8 April 2021. JDN. https://www.washingtonpost.com/opinions/global‐ opinions/the‐wrong‐way‐to‐fight‐vaccine‐nationalism/2021/04/08/9a65e15e‐98a8‐11eb‐ 962b‐78c1d8228819\_story.html

A preferable approach would be to build more vaccine‐manufacturing capacity in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but that’s preferable to being dependent on other countries when the next pandemic hits. “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licens‐ ing agreements are already successfully facilitating cooperation between patent‐holding vaccine‐makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. That means helping the world and thinking about our strategic interests at the same time.

**The affirmative can’t solve the root cause of the problems developing nations face. WTO News Briefing 20**

WTO News Briefing; ; 10‐16‐2020; ”Members discuss intellectual property response to the COVID‐19 pandemic”; https://www.wto.org/english/news\_e/news20\_e/trip\_20 oct20\_e.htm, World Trade Organization News, accessed 7‐21‐2021; JPark

While a number of developing and least developed country members welcomed the proposal as a contribution to the discussion, many were still studying it in their capitals and asked for clarification on certain points, particularly regarding its practical imple‐ mentation and the possible economic and legal impact of the waiver at national level. A number of developing and developed country members opposed the waiver proposal, noting that there is no indication that intellectual property rights (IPRs) have been a gen‐ uine barrier to accessing COVID‐19 related medicines and technologies. While acknowl‐ edging that the sustained and continued supply of such medicines and technologies is a difficult task, they observed that non‐efficient and underfunded health care and pro‐ curement systems, spiking demand and lack of manufacturing capacity are much more likely to impede access to these materials. In the view of these members, solutions can be legitimately sought within the existing IP system as the TRIPS Agreement provides enough tools and sufficient policy space for members to take measures to protect public health. The suspension of IPRs, even for a limited period of time, was not only unnec‐ essary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.

## AT Generic Drug Manufacturers Solve

#### Generic medicine is dangerous—contamination and unsanitary manufacturing conditions.

White 19 [(C. Micheal, Professor and Head of the Department of Pharmacy Practice, University of Connecticut) “Why your generic drugs may not be safe and the FDA may be too lax” The Conversation, 12/4/19. <https://theconversation.com/why-your-generic-drugs-may-not-be-safe-and-the-fda-may-be-too-lax-125529>] RR

This leads to a vital question: Are generics safe? If drug manufacturers followed the FDA’s strict regulations, the answer would be a resounding yes. Unfortunately for those who turn to generics to save money, the FDA relies heavily on the honor system with foreign manufacturers, and U.S. consumers get burned. Eighty percent of the active ingredients and 40% of the finished generic drugs used in the U.S. are manufactured overseas. As a pharmacist, I know that the safety of prescription medications is vital. My research, recently published in the “Annals of Pharmacotherapy,” raises alarming concerns about our vulnerabilities. Do experts have something to add to public debate? Where are your drugs being made? A pharmacist at a drug plant outside Mumbai in 2012, shortly after a change in patent law allowed production of a generic cancer drug. Rafiq Mugbool/AP Photo Generic drug manufacturers either make bulk powders with the active ingredient in them or buy those active ingredients from other companies and turn them into pills, ointments or injectable products. In 2010, 64% of foreign manufacturing plants, predominantly in India and China, had never been inspected by the FDA. By 2015, 33% remained uninspected. In addition, companies in other countries are informed before an inspection, giving them time to clean up a mess. Domestic inspections are unannounced. Faking results The FDA informs manufacturing plants in other countries when it plans to inspect their plants. Andrew Harnik/AP Photo As I detail in my paper, when announced foreign FDA inspections began to occur in earnest between 2010 and 2015, numerous manufacturing plants were subsequently barred from shipping drugs to the U.S. after the inspections uncovered shady activities or serious quality defects. Unscrupulous foreign producers shredded documents shortly before FDA visits, hid documents offsite, altered or manipulated safety or quality data or utilized unsanitary manufacturing conditions. Ranbaxy Corporation pleaded guilty in 2013 to shipping substandard drugs to the U.S. and making intentionally false statements. The company had to withdraw 73 million pills from circulation, and the company paid a $500 million fine. These quality and safety issues can be deadly. In 2008, 100 patients in the U.S. died after receiving generic heparin products from foreign manufacturers. Heparin is an anticoagulant used to prevent or treat blood clots in about 10 million hospitalized patients a year and is extracted from pig intestines. Some of the heparin was fraudulently replaced with chondroitin, a dietary supplement for joint aches, that had sulphur groups added to the molecule to make it look like heparin. One of the heparin manufacturers inspected by the FDA received a warning letter after it was found to have used raw material from uncertified farms, used storage equipment with unidentified material adhering to it and had insufficient testing for impurities. These issues continue to this day. Dozens of blood-pressure and anti-ulcer drugs were recalled in 2018 and 2019 due to contamination with the potentially carcinogenic compounds N-nitrosodimethylamine or N-nitrosodiethylamine. One of the major producers of these active ingredient powders used by multiple generic manufacturers was inspected in 2017. The FDA found that the company fraudulently omitted failing test results and replaced them with passing scores. This raises a critical question: How many more violations would occur with inspections occurring as frequently as they do in the U.S., and more importantly, if they were unannounced? Relatively speaking, the number of drugs proved to be tainted or substandard has been small, and the FDA has made some progress since 2010. But the potential for harm is still great.

## General Turns

#### 1] With weaker IP protections, pharmaceutical companies will resort to trade secrets over patents---that undermines the public scientific collaboration that informs global public health response.

Gewertz, Nevin. "Intellectual Property And The Pharmaceutical Industry: A Moral Crossroads Between Health And Propert." Journal of Business Ethics 55:3. December, 2004. Web. August 18, 2021. <https://www.jstor.org/stable/25123392?seq=1#metadata\_info\_tab\_contents>.

The granting of a United States patent establishes a form of monopoly rights to specific creative works. The granting of exclusive monopoly rights prevents others from enjoying any positive externalities de rived from the idea itself. Yet, does the right to intellectual property include the right to exclude and limit the actions of others? A simple utilitarian analysis of the potential consequences of non exclusive intellectual property elucidates the need for patent rights to incorporate exclusive monopoly rights. **Without exclusive monopoly rights granted to their products, pharma**ceutical **companies would be forced to keep product information a secret**. **The usage of public forums for intellectual dialogue such as academic journals and conferences would give way to trade secrets** (Mansfield, 1993). **This type of secretive behavior would have nefarious effects both the scientific community and the collaborative principles upon which it thrives**. The exclusive monopoly rights rewarded by the state in the form of a patent are necessary to promote intellectual dialogue and to avoid the usage of trade secrets.

#### 2] Unpatented medicine cause counterfeits—

Lynbecker 16 [(Kristina M. L. Acri née, an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker’s research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically special problems facing the pharmaceutical industry.) “Counterfeit Medicines and the Role of IP in Patient Safety,” IPWatchDog, 7/27/16. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/>] RR

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated: “The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade, or $461 billion, in 2013. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3] [Kristina] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless. Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a s

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1. Feser, Edward, (Professor of Philosophy at Pasadena City College), IEP, <https://www.iep.utm.edu/nozick/>. [ajv]. [↑](#footnote-ref-1)
2. Feser, Edward, (Professor of Philosophy at Pasadena City College), IEP, <https://www.iep.utm.edu/nozick/>. [ajv]. [↑](#footnote-ref-2)