# Bronx R6 1N

## 1

#### The roll of the ballot is to vote for the debater who best proves the truth or falsity of the resolution. To clarify, vote aff if I prove the resolution true and vote neg if they prove it false.

#### Text – Dictionary.com defines affirm as to maintain as true Dictionary.com, [https://www.dictionary.com/browse/affirm] And to negate as to deny the existence, evidence, or truth of Dictionary.com, [https://www.dictionary.com/browse/negate] Text first – Text comes first – a) Controls the internal link to fairness since it’s the basis of things like predictability and prep b) Key to jurisdiction since the judge can only endorse what is within their burden. Jurisdiction always comes first, anything else is intervention c) Even if another role of the ballot is better for debate, that is not a reason it ought to be the role of the ballot, just a reason we ought to discuss it.

#### The Meta Ethic is internalism - Morality only works if we are motivated to follow it. Any external or outside force fails as a way of looking to morality. People making rules to guide or force others to obey will never be a “moral” system, as individuals must have the desire to take an action in order for them to be motivated to take it. Every actual action has to be explained by a belief or desire that the agent has – else they wouldn’t take it

#### Next, every agent takes their ability to act on their ethical system as instrumentally valuable. Only self interest bridges relativism to provide a universal principle.

**Moore** Margaret Moore, Queens University professor in the Political Studies department, cross-appointed (as a courtesy) in Philosophy, Reviewed Work(s): Morals by Agreement. by David Gauthier, Noûs, Vol. 25, No. 5 (Dec., 1991), pp. 707-714 ///AHS PB /BHHS AK recut

On Gauthier's view, morality is a sub-set of self-interest (he calls it preference-fulfillment), which is instrumentally necessary, not absolutely, but given features of the human situation which are almost certain to ob- tain. By taking as his starting-point the agent's subjective motivational set, whatever its content, Gauthier can claim that the requirements of morality escape none who fall under its ambit, for each person necessarily acts on his or her desires and aims. If Gauthier's project is successful, he will have refuted the moral skeptic: by demonstrating that morality is self-interestedly rational, he can claim that the principles are justified and that they apply to everyone. He does not need to presuppose a feeling such as sympathy to explain moral action, or appeal to a process of moral education and socialization within communities which shape the individual's desires and beliefs in accordance with a specific moral conception. Gauthier's agents simply maximize their utility and in the process find that they need to co-operate with others and that the dynamics of co- operation make it rational in self-interested terms to constrain their utility- maximization. By considering in this way the principles and constraints which it would be rational for co-operating self-interested agents to adopt, Gautheir claims to be able to deduce a system of moral constraints and Principles.

#### This entails a system of mutual self restraint: moral principles can be only be the object of a hypothetical moral agreement that all agents have reason to implement. Contracts are the only standard capable of generating normativity since each agent rationally chooses to protect their self-interest by entering the contract.

**Gauthier** [David Gauthier, Canadian-American philosopher best known for his neo-Hobbesian social contract theory of morality, Why Contractarianism?, 1998], ///AHS PB /BHHS AK recut

I shall not rehearse at length an argument that is now familiar to at least some readers, and, in any event, can be found in that book. But let me sketch briefly those features of deliberative rationality that enable it to constrain maximizing choice. The key idea is that in many situations, if each person chooses what, given the choices of the others, would maximize her expected utility, then the outcome will be mutually disadvantageous in comparison with some alternative – everyone could do better**. 14 Equilibrium, which obtains when each person ’ s action is a best response to the others ’ actions, is incompatible with (Pareto-) optimality, which obtains when no one could do better without someone else doing worse. Given the ubiquity of such situations,** each person can see the benefit, to herself, of participating with her fellows in practices requiring each to refrain from the direct endeavor to maximize her own utility, when such mutual restraint is mutually advantageous. No one**,** of course**,** can have reason to accept any unilateral constraint on her maximizing behavior; each benefits from, and only from, the constraint accepted by her fellows. But if one benefits more from a constraint on others than one loses by being constrained oneself, one may have reason to accept a practice requiring everyone, including oneself, to exhibit such a constraint. We may representsuch a practiceas capable of gaining unanimous agreement among rational persons who were choosing the terms on which they would interact with each other. And this agreementis the basis of morality**.** Consider a simple example of a moral practice that would command rational agreement. Suppose each of us were to assist her fellows only when either she could expect to benefit herself from giving assistance, or she took a direct interest in their well-being. Then, in many situations, persons would not give assistance to others, even though the benefit to the recipient would greatly exceed the cost to the giver, because there would be no provision for the giver to share in the benefit. Everyone would then expect to do better were each to give assistance to her fellows, regardless of her own benefit or interest, whenever the cost of assisting was low and the benefit of receiving assistance considerable**.** Each would thereby accept a constraint on the direct pursuit of her own concerns, not unilaterally, but given a like acceptance by others. Reflection leads us to recognize that those who belong to groups whose members adhere to such a practice of mutual assistance enjoy benefits in interaction that are denied to others**.** We may then represent such a practice as rationally acceptable to everyone.This rationale for agreed constraint makes no reference to the content of anyone ’ s preferences**.** The argument depends simply on the structure of interaction, on the way in which each person ’ s endeavor to fulfill her own preferences affects the fulfillment of everyone else**.** Thus, each person ’ s reason to accept a mutually constraining practice is independent of her particular desires, aims and interests, although not, of course, of the fact that she has such concerns**. The idea of a purely rational agent, moved to act by reason alone, is not, I think, an intelligible one.** Morality is not to be understood as a constraint arising from reason alone on the fulfillment of nonrational preferences. Rather, a rational agent is one who acts to achieve the maximal fulfillment of her preferences, and morality is a constraint on the manner in which she acts, arising from the effects of interaction with other agents

#### Thus, the standard is consistency with contractarianism. Prefer for regress – agents can always why a rule exists or how to interpret it – that requires a new rule which is regressive. Thus, only self-imposed contractual obligations can generate normative bindingness

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#### I negate –

#### 1] Patents are contracts with the government to protect exclusivity in return for disclosure, WIPO:

WIPO [World Intellectual Property Organization], Frequently Asked Questions: Patents, <https://www.wipo.int/patents/en/faq_patents.html> //LHP AV

What is a patent? **A patent is an exclusive right granted for an invention**. In other words, a patent is an exclusive right to a product or a process that generally provides a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application. **The patent owner may give permission to, or license, other parties to use the invention on mutually agreed terms. The owner may also sell the right to the invention to someone else, who will then become the new owner of the patent**. Once a patent expires, the protection ends, and an invention enters the public domain; that is, anyone can commercially exploit the invention without infringing the patent. What rights does a patent provide? **A patent owner has the right to decide who may – or may not – use the patented invention for the period in which the invention is protected**. In other words, patent protection means that the invention cannot be commercially made, used, distributed, imported, or sold by others without the patent owner's consent. What kinds of inventions can be protected? Patents may be granted for inventions in any field of technology, from an everyday kitchen utensil to a nanotechnology chip. An invention can be a product – such as a chemical compound, or a process, for example – or a process for producing a specific chemical compound. Many products in fact contain a number of inventions. For example, a laptop computer can involve hundreds of inventions, working together. How long does patent protection last? Patent protection is granted for a limited period, generally 20 years from the filing date of the application. Is a patent valid in every country? Patents are territorial rights. In general, the exclusive rights are only applicable in the country or region in which a patent has been filed and granted, in accordance with the law of that country or region. How are patent rights enforced? **Patent rights are usually enforced in a court on the initiative of the right owner**. In most systems a court of law has the authority to stop patent infringement. However the main responsibility for monitoring, identifying, and taking action against infringers of a patent lies with the patent owner. What does it mean to “license a patent” and why is it done? Licensing a patent simply means that the patent owner grants permission to another individual/organization to make, use, sell etc. his/her patented invention. This takes place according to agreed terms and conditions (for example, defining the amount and type of payment to be made by the licensee to the licensor), for a defined purpose, in a defined territory, and for an agreed period of time. A patent owner may grant a license to a third party for many reasons. The patent owner may not have the necessary manufacturing facilities, for example, and therefore opts to allow others to make and sell his/her patented invention in return for “royalty” payments. Alternatively, a patent owner may have manufacturing facilities, but they may not be large enough to cover market demand. In this case, he/she may be interested in licensing the patent to another manufacturer in order to benefit from another income stream. Another possible situation is one in which the patent owner wishes to concentrate on one geographic market; therefore the patent owner may choose to grant a license to another individual/organization, with interests in other geographical markets. Entering into a licensing agreement can help to build a mutually-beneficial business relationship. Unlike selling or transferring a patent to another party, the licensor continue to have property rights over the patented invention. Why are patents useful (to society, business, individuals etc.)? Patented inventions have, in fact, pervaded every aspect of human life, from electric lighting (patents held by Edison and Swan) and plastic (patents held by Baekeland), to ballpoint pens (patents held by Biro), and microprocessors (patents held by Intel, for example). Patents provide incentives to and protection for individuals by offering them recognition for their creativity and the possibility of material reward for their inventions. **At the same time, the obligatory publication of patents and patent applications facilitates the mutually-beneficial spread of new knowledge and accelerates innovation activities by, for example, avoiding the necessity to “re-invent the wheel”.** Once knowledge is publicly available, by its nature, it can be used simultaneously by an unlimited number of persons. While this is, without doubt, perfectly acceptable for public information, it causes a dilemma for the commercialization of technical knowledge. **In the absence of protection of such knowledge, “free-riders” could easily use technical knowledge embedded in inventions without any recognition of the creativity of the inventor or contribution to the investments made by the inventor. As a consequence, inventors would naturally be discouraged to bring new inventions to the market, and tend to keep their commercially valuable inventions secret.** A patent system intends to correct such under-provision of innovative activities by providing innovators with limited exclusive rights, thereby giving the innovators the possibility to receive appropriate returns on their innovative activities. In a wider sense, the public disclosure of the technical knowledge in the patent, and the exclusive right granted by the patent, provide incentives for competitors to search for alternative solutions and to “invent around” the first invention. These incentives and the dissemination of knowledge about new inventions encourage further innovation, which assures that the quality of human life and the well-being of society is continuously enhanced. Applying for patent protection What conditions must be met to obtain patent protection? There are numerous conditions that must be met in order to obtain a patent and it is not possible to compile an exhaustive, universally applicable list. However, some of the key conditions include the following: The invention must show an element of novelty; that is, some new characteristic which is not known in the body of existing knowledge in its technical field. This body of existing knowledge is called “prior art”. The invention must involve an “inventive step” or “non-obvious”, which means that it could not be obviously deduced by a person having ordinary skill in the relevant technical field. The invention must be capable of industrial application, meaning that it must be capable of being used for an industrial or business purpose beyond a mere theoretical phenomenon, or be useful. Its subject matter must be accepted as “patentable” under law. In many countries, scientific theories, aesthetic creations, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial methods, methods for medical treatment (as opposed to medical products) or computer programs are generally not patentable. The invention must be disclosed in an application in a manner sufficiently clear and complete to enable it to be replicated by a person with an ordinary level of skill in the relevant technical field. Who grants patents? **A patent is granted by a national patent office or by a regional office that carries out the task for a number of countries. Currently, the following regional patent offices are in operation:** African Intellectual Property Organization (OAPI) African Regional Intellectual Property Organization (ARIPO) Eurasian Patent Organization (EAPO) European Patent Office (EPO) Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC Patent Office) Under such regional systems, an applicant requests protection for an invention in one or more member states of the regional organization in question. The regional office accepts these patent applications, which have the same effect as national applications, or grants patents, if all the criteria for the grant of such a regional patent are met. There is currently, no universal, international system for the grant of patents.

#### Impacts –

#### A] Violating contracts agreed to is intrinsically bad as per the framework

#### B] mutual advantage of the contract is undermined as inventors have no incentive to disclose their inventions, which also turns case because other companies can’t make it if they don’t know how to

#### C] Free riding – other agents can use the knowledge without contribution, which violates the framework because agents not involved in the contract unjustifiably exploit another person.

#### 2] Illegitimacy – the conditions that can create a legitimate new contract are not present – thus, the aff is illegitimate

#### A] imbalance of power – the international sphere has certain countries with more power over others, which means the aff can never be justified as a contract – rational parties would never need a contract in a space with power imbalance

#### B] Third Parties – the ones affected are the pharmaceutical companies and their rights, so making a contract absent their consent is illegitimate

#### 3] Secrets are good – they are essential parts of contracts formulated by the subject

## 2

#### CP: Member nations of the WTO should create a two-part hybrid scheme to protect clinical data as Gulatta describes. Gulatta 18:

Gulatta, Lea M. 2018 “Pharming Out Data: A Proposal for Promoting Innovation and Public Health through a Hybrid Clinical Data Protection Scheme.” https://eds.a.ebscohost.com/eds/detail/detail?vid=1&sid=db4adde5-9f42-4248-8469-6510e5a1cb52%40sdc-v-sessmgr02&bdata=JnNpdGU9ZWRzLWxpdmU%3d#AN=134133646&db=a9h

As such, this Note proposes a two-part, hybrid scheme to protect clinical data. **First, the originator company receives one year of traditional data exclusivity after obtaining marketing approval, during which no generic manufacturer may rely on the originator’s data. After the year is up, a cost-sharing system takes over, allowing generic competitors to rely on the originator’s data for a price proportionate to the actual cost of generating the data.274 The cost-sharing system endures for an additional four years, at which point the data become publicly available to anyone.** The first stage functions much as data exclusivity currently functions under TRIPS and other similar agreements. The beneficiary of the exclusivity does not need to take any affirmative action in order to receive protection. Rather, exclusivity attaches automatically, with each country’s regulatory agency prohibited from giving approval to a competitor drug that relies on the originator data for a period of one year. **The benefits of this are** twofold—**first**, **it is a system with which developed countries are already familiar, and to which they are partial. Second, providing a standard, nonnegotiable period of protection would assure pharmaceutical companies that they would have at least a year to recoup costs without significant competition on the market. Given that most pharmaceutical companies are located in powerful, industrialized nations, it is important to have them on board to implement any new global sch**eme. The second phase, cost sharing, requires a generic company to fairly compensate the originator company for the right to rely on its data**. In order to accomplish “fair” compensation, the originator company must document its actual costs incurred to generate the data, and disclose those costs to the national regulatory agency**. To best facilitate the process, originator companies must provide these disclosures with their materials for initial market approval. In that way, any disputes over expenditures may be able to be resolved before the cost-sharing period begins, allowing efficient entry of generic products into the market. Once the cost is disclosed and the cost-sharing period commences, any generic company wishing to rely on the originator data must pay a portion of that cost. The cost to share in the data depends on the size of the market the generic company plans to enter, and the number of generic competitors relying on the data. To illustrate, assume a company obtains approval to market a drug.275 It discloses that it spent $100 million to generate the data needed to bring the drug to market. If a generic competitor wanted to rely on that data to market a drug in Saudi Arabia, which represents 1 percent of the global pharmaceutical market,276 it must pay 1 percent of the originator company’s costs spread out over the four-year costsharing period—$1 million in total, or $250,000 per year. Now assume the same generic company wanted to market the drug in China, a country that comprises 10 percent of the global market. The generic manufacturer would be responsible for paying 10 percent of the originator’s costs, amounting to $10 million in total, or $2.5 million each year. These costs would be defrayed both by additional generic competitors entering the market around the same time as the originator company, and by generic companies entering the market later in the four-year cost-sharing period. If a second generic manufacturer also enters the Saudi Arabian market relying on the originator company’s data, the annual costs for both generic companies are cut in half, because there is another actor to share the costs. Additionally, generic companies are only responsible for the annual payments: if a generic manufacturer entered the Saudi Arabian market two years into the cost-sharing period, it would only have to pay $500,000—for the remaining two years of the cost-sharing period at $250,000 annually—rather than the $1 million total fee. In order to ensure that originator companies are not needlessly overcompensated, there are additional caps on how much the originator may recoup. This Note proposes that once the originator company has recovered fifteen times what it cost to develop the drug, the cost-sharing period ends, even if that occurs before the typical fouryear term. A fifteen-fold return on investment is more than even the most successful pharmaceutical companies can boast currently—for example, in 2013, Pfizer, a large, US-based drug company, spent $6.6 billion on research and development, while its total revenue was $51.6 billion, less than an eight-fold return. 277 Such a cap would allow pharmaceutical companies to adequately compensate for research costs for products that did not make it to market. This hybrid system may seem novel, but it is not wholly unheard of. The United States uses a combination of data exclusivity and cost sharing for approval of agricultural chemicals in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).278 Under FIFRA, covered chemicals receive ten years of exclusivity, during which the underlying data may not be relied on by other parties who want to register the same chemical with the Environmental Protection Agency.279 For the next ten years, generic competitors may rely on the originator’s data for a fee.280 This system has successfully been in place since 1975, and has generally run smoothly.281 **This proposed hybrid scheme has several benefits and resolves many outstanding issues with clinical data protection. Currently, clinical data is often protected longer than is truly necessary to recover costs and incentivize innovation.** Regardless of exactly how long it takes for a pharmaceutical company to begin to profit on a particular product, it is obvious that indiscriminately offering the same amount of protection to all clinical data necessarily means sometimes offering too much protection. **By offering a set period of pure data exclusivity followed by a tailored cost-sharing system, originator companies are only compensated as much as they need to be. Further, the burden of fairly compensating the originator is shared between multiple generic companies, eliminating monopolies and passing fewer costs to the consumer.** The cost to generic manufacturers to rely on the originators’ data is relatively modest when compared to the cost of developing a drug from start to finish, which can be as high as $53 million.282 Allowing generic companies affordable access to originator data after one year means generic drugs will make it to market much sooner and much more affordably than under the current system, increasing access to affordable and necessary medications in developing countries. And importantly, this scheme accomplishes all this with an easy-to-administer system through which the beneficiary need take no action other than properly disclosing its costs when applying for market approval. Some may argue that this system would lead to bad incentives for pharmaceutical companies. Just like lawyers may be tempted to run up legal costs if they get paid by the hour, drug developers may see a benefit to delaying drug development or spending more money than necessary in order to receive higher compensation from generic competitors for their clinical data. However, under the cost-sharing scheme, there is no real incentive to artificially inflate costs, because the originator company can only recoup up to fifteen times what it spent. The one-year data exclusivity period might allow the originator to recover some of the artificially high costs, but not enough to encourage companies to intentionally spend more money. There is also the additional pressure of the economic market—if a company spends an exorbitant amount during drug development, it will need to charge more for its product to ensure it will recover its costs. The originator company cannot rely entirely on the cost-sharing mechanism, because there is no guarantee that any generic company will want to rely on its data. Should a competitor enter the market without having to rely on the originator’s data, and the competitor is able to price its product more affordably, the free market will punish the higher-priced medicine. Additionally, clinical data protection essentially only applies to products that are successful. There is significantly reduced need to shield data that stemmed from a product that was ultimately never approved. Because so few compounds actually make it to market, pharmaceutical companies would be playing a very dangerous game if they chose to artificially inflate costs of developing all their drugs in the hopes of longer protection for the data generated in creating the rare successful drug.

## 3

#### Orphan drug legislation is specifically key to stimulate research into rare diseases

Horgan et. al 20 D, Moss B, Boccia S, Genuardi M, Gajewski M, Capurso G, Fenaux P, Gulbis B, Pellegrini M, Mañú Pereira M, M, Gutiérrez Valle V, Gutiérrez Ibarluzea I, Kent A, Cattaneo I, Jagielska B, Belina I, Tumiene B, Ward A, Papaluca M: Time for Change? The Why, What and How of Promoting Innovation to Tackle Rare Diseases – Is It Time to Update the EU’s Orphan Regulation? And if so, What Should be Changed? Biomed Hub 2020;5:1-11. doi: 10.1159/000509272 [https://www.karger.com/Article/Fulltext/509272#](https://www.karger.com/Article/Fulltext/509272) //sid

The European Union’s (EU) Regulation (EC) No. 141/2000 on orphan medicinal products (OMPs) (referred to as “the regulation” in this paper) states that “patients suffering from rare conditions should be entitled to the same quality of treatment as other patients,” and concludes that “it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry” [[1](https://www.karger.com/Article/Fulltext/509272#ref1)]. Rare diseases had already been identified as a priority area for Community action within the framework for action in the field of public health [[2](https://www.karger.com/Article/Fulltext/509272#ref2)], and the regulation’s stated aim is – “to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” It set up a mechanism to ensure that “orphan medicinal products eligible for incentives should be easily and unequivocally identified,” with the condition that “objective criteria for designation should be established” [[3](https://www.karger.com/Article/Fulltext/509272#ref3)]. The core incentive of the regulation is the granting of 10 years (+2 years for paediatric orphan medicines) of marketing exclusivity and a range of financial and scientific provisions granted via the European Medicines Agency to support product development and application for Marketing Authorisation. Nearly two decades later, the success of the measure has been demonstrated. Investment both from public research funders and from companies of all sizes in rare disease research has resulted in the approval of more than 150 orphan drugs – compared with just eight therapies for rare diseases available before the adoption of the regulation. That translates into a lot of patient benefit. With clinical research stimulated by the legislation, the EU sees some 2,000 clinical trials providing still more innovation or hope for treatments in the current R&D pipeline [[4](https://www.karger.com/Article/Fulltext/509272#ref4)]. But over the intervening years, the limitations in the functioning of the legislation have become apparent too, and these merit attention if the beneficial effects for patients and caregivers are to be maximised [[5](https://www.karger.com/Article/Fulltext/509272#ref5)]. This paper explores the successes and limitation of both the regulation and its implementation mechanisms in the current regulatory context, and suggests some improvements that could maximise its benefits and boost rare disease research even further. The discussion needs to be precise if it is to be effective. Review of the functioning of the regulation may coincide with a period of more intense scrutiny and concerns over containing the rise of expenditure to ensure sustainability of healthcare systems, with a particular focus on expensive innovation which are often developed within the orphan conditions. While there is undoubted importance in the wider but distinct debate over healthcare costs, it does not bear directly on reviewing the orphan medicines regulation [[6](https://www.karger.com/Article/Fulltext/509272#ref6)]. At the same time, economic questions do, however, have relevance to the debate on orphans, since patients’ access to the medicines that become available is conditioned by the national arrangements for reimbursement or listing of products: there is an increasing tension between the potential access to agents that can modify or even cure rare diseases, and the models for reimbursement available to European payers. Part of this hesitancy can be ascribed to the novelty of the challenges presented by many innovative treatments, which by their nature present unknowns to payers. Clearly, there is also a need to deal with uncertainty with regard to value demonstration, especially when value or values are perceived not to be sufficiently demonstrated. The risk is that such powerful economic reservations can have a cumulative negative impact on the motivation for pursuing research into rare disease treatments – thus running counter to the guiding principle of the legislation itself [[7](https://www.karger.com/Article/Fulltext/509272#ref7)]. Current value assessment rules across Europe for orphan drugs remain largely inadequate and can become a real fourth hurdle to effective patient access to those treatments [[8](https://www.karger.com/Article/Fulltext/509272#ref8)]. The regulation’s stimulation of new product development has also helped promote the development of EU biotech companies. The last two decades have witnessed the emergence of more than 150 small and medium enterprises (SMEs) focusing on rare diseases. No wonder that one of the prominent Members of the European Parliament over this period, Francoise Grossetête, emphasised the importance of the regulation in addressing “real medical needs” and generating “therapeutic breakthroughs” [[9](https://www.karger.com/Article/Fulltext/509272#ref9)]. The underlying strength of the concept of providing incentives for R&D in areas of unmet need is confirmed by the fact that Germany and other Member States are now exploring whether OMP-type incentives could contribute to solving the major risks of antimicrobial resistance (AMR), through promoting development of new anti-bacterials even where simple market economics do not provide sufficient motivation for investment [[10](https://www.karger.com/Article/Fulltext/509272#ref10)]. Thanks to increased investments and the associated efforts thus made possible, some rare diseases now benefit from effective treatments. There are leading examples in the area of haemophilia, paroxysmal nocturnal haemoglobinuria (PNH), and some lysosomal storage diseases such as Gaucher. The full list of conditions for which “orphans medicines” have been launched in Europe is too extensive to reproduce here, but by way of illustration it ranges from rare cancers to rare variants of common diseases (pulmonary hypertension, neonatal diabetes) and to rare congenital, mostly childhood-onset disorders (Gaucher, cystinosis, inherited hyperammonaemias) [[11](https://www.karger.com/Article/Fulltext/509272#ref11)]. However, these tales of success should not lead to any delusions that the process has been – or is becoming – easy. Successes in developing innovative treatments are hard-won. Without consistent and determined effort, innovation does not happen – and innovation in rare diseases is all the more challenging. The key elements of the innovation process are well documented, but the nature of the challenges is perhaps not always fully appreciated by those outside the healthcare sector, being seen as costs and not as investments. Rare diseases are categorized as “orphan diseases” because their occurrence in a small number of patients means that, despite apparent high unmet medical need, there is limited scientific understanding, making it difficult to justify the development risk and investment to develop new treatments. The OMP regulation was developed explicitly to support efforts in this field of innovation [[12](https://www.karger.com/Article/Fulltext/509272#ref12)].

#### Orphan diseases require time intensive care and affect millions.

**Lancet 19** [Lancet, 2-1-2019, accessed on 9-6-2021, The Lancet Diabetes & Endocrinology, "Spotlight on rare diseases", https://www.thelancet.com/journals/landia/article/PIIS2213-8587(19)30006-3/fulltext]//sid

Feb 28 is Rare Disease Day, the theme of which this year is “bridging health and social care”. This 12th annual [Rare Disease Day](https://www.rarediseaseday.org/page/news/theme-2019)highlights the need for better coordination of medical, social, and support services to lessen the burden that rare diseases—often complex, chronic, and disabling—have on the everyday lives of patients, their families, and carers. As a recent [Europe-wide survey](http://download2.eurordis.org.s3.amazonaws.com/rbv/2017_05_09_Social%20survey%20leaflet%20final.pdf)found that 80% of patients and carers had difficulty completing daily tasks, 70% found organising care time-consuming (with 60% finding it hard to manage), and 67% felt that health, social, and local services communicated poorly with each other, the theme of Rare Disease Day 2019 is timely. More than 6000 [rare diseases](https://globalgenes.org/rare-diseases-facts-statistics/) (80% with a genetic component) affect more than 300 million people worldwide. While an individual disease might be classed as rare (defined as affecting less than 1 in 2000 of the general population in the European Union or fewer than 200 000 people in the USA), the sheer number of rare diseases means that the overall numbers quickly stack up: 3·5 million people in the UK, 30 million across Europe, and 30 million in the USA are affected. Whether a single rare disease affects thousands or just one person, the impact on the affected individual and those around them can be devastating: 50% of rare diseases affect children, 30% of whom will die before age 5 years. Rare diseases present myriad challenges for patients, their families, and caregivers, including the time it takes to obtain a correct diagnosis for many patients. In a [survey](https://globalgenes.org/wp-content/uploads/2013/04/ShireReport-1.pdf) of patients and caregivers in the USA and UK, patients reported that it took on average 7·6 years in the USA and 5·6 years in the UK to get a proper diagnosis, during which time patients typically visited eight physicians (four primary care and four specialist) and received two to three misdiagnoses. As there is no approved treatment for 95% of rare diseases, a diagnosis can be a crushing reality check for patients and their families, rather than bringing hope and reassurance. As such, rare diseases impose a considerable emotional toll on patients and their caregivers. Other challenges include a lack of information and resources, the financial cost of care, and difficulty in accessing appropriate medical expertise, which is compounded by a lack of specialist training programmes for medical professionals. In this issue of The Lancet Diabetes & Endocrinology, we publish a call-to-action to address the [unmet need for subspecialty training](http://dx.doi.org/10.1016/S2213-8587(18)30369-3) in adult rare (inherited metabolic) diseases, which is crucial given that 50% of rare diseases present in adulthood and children surviving rare diseases eventually transition to adult care.

#### Rare diseases disproportionately affect people of color

**RDDC, No Date** (RDDC, No Date, accessed on 9-6-2021, Rare Disease Diversity Coalition, "Charting thePath Forwardfor Equity inRare Diseases", <https://3hqwxl1mqiah5r73r2q7zll1-wpengine.netdna-ssl.com/wp-content/uploads/2021/03/RDDC_Path_Forward_Final.pdf>)//sid

While the rare disease community continues to face hurdles generally, people of color face additional hurdles in their quest for care . Barriers to diagnosis and treatment for people of color often have deadly consequences . Flaws across the entire system have a compounding effect on the care that Black, Native American, Hispanic, Asian, and Pacific Islander Americans with rare diseases receive . Americans of color continue to be underrepresented in genome-wide association studies and clinical research trials, leading to a lack of understanding about effective treatments, particularly in diverse populations . Despite making up more than 38 percent of the U .S . population, people of color comprise only 16 percent of research study participants .20 On the patient side, people of color are less likely to have affordable access to health care and rare disease experts .21 To make matters worse, some rare diseases disproportionately impact people of color . For instance, sarcoidosis, sickle cell anemia, thalassemia, and some forms of lupus are known to affect minority populations at higher rates than the general population .22 And implicit bias particularly harms people of color with rare diseases .23

## 4

#### Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:

David Austin, [an Analyst in CBO’s Microeconomics Studies Division] and Tamara Hayford, [a principal analyst in the Health, Retirement, and Long-Term Analysis Division, Congressional Budget Office] prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis., April 2021, “Research and Development in the Pharmaceutical Industry” <https://www.cbo.gov/publication/57126> //LHP AV DOA: 9/8/21

At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

#### Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:

Stephen Ezell, [vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] and Nigel Cory, [an associate director covering trade policy at the Information Technology and Innovation Foundation. He focuses on cross-border data flows, data governance, intellectual property, and how they each relate to digital trade and the broader digital economy. Cory has provided in-person testimony and written submissions and has published reports and op-eds relating to these issues in the United States, the European Union, Australia, China, India, and New Zealand, among other countries and regions, and he has completed research projects for international bodies such as the Asia Pacific Economic Cooperation and the World Trade Organization.] “The Way Forward for Intellectual Property Internationally” April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> //LHP AV

INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **IPRs Strengthen Innovation** Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that **counties with stronger IP protection have more creative outputs** (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), **even at varying levels of development**.46 **IPR reforms also introduce strong incentives for domestic innovation**. **Sherwood**, using case studies from 18 developing countries, **concluded that poor provision of intellectual property rights deters local innovation and risk-taking**.47 In contrast, **IPR reform has been associated with increased innovative activity, as measured by domestic patent filings**, albeit with some variation across countries and sectors.48 For example, **Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets**.49 **Park** **and Lippoldt also observed that** the provision of adequate protection for **IPRs can help to stimulate local innovation**, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, **local innovators are introduced to technologies** first **through** the technology transfer that takes place in an environment wherein **protection** of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.**52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts**. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

#### Pharma Innovation checks new diseases.

**Engelhardt 8**, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for **r**esearch and **d**evelopment **spurs innovation** in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such **innovation is** both **necessary to maintain the human species** in an ever-changing and always dangerous environment in which **new microbial** and other threats may at any time emerge to threaten **human well-being, if not survival** (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

## Case

### FWK

### FWK – Hijack

#### Permissibility Negates –

#### 1] Semantics – Ought is defined as expressing obligation which means absent a proactive obligation you vote neg since there’s a trichotomy between prohibition, obligation, and permissibility and proving one disproves the other two.

#### Presume neg- A. We assume statements to be false until proven true. That is why we don’t believe in alternate realities or conspiracy theories. The lack of a reason something is false does not me it is assumed to be true.

#### Util collapses to egoism – Solipsism is true – one can only verify self-consciousness since verification relies on our experience of consciousness which we can only do from our own consciousness because we inherently know it exists. However, I cannot verify the existence of others since I cannot go inside or explore their consciousness. Thus, util can only account for my own pleasure and cannot generate a normative reason to care about anyone else’s, which means the only obligation is to maximize my own pleasure.

#### That negates – a) aggregation is impossible by states since it assumes the ability to verify another agent exists b) there’s no obligation under util since there’s no reason care about anyone else’s pain or pleasure and the subject can do whatever it wants.

## Evergreening

### Plan/Solvency

#### The only way to fix evergreening is to fix the standards for what is patentable. The plan does not do that.

#### The one and done approach enables you to choose between patents, data exclusivity, and orphan drugs. It says nothing about evergreening or about whether or not you can repeatedly renew patents, or how long these patents take. It also does not make a claim about whether you can renew data exclusivity and –

#### Data exclusivity can be repeated, means no impact on innovation WHO 17

“Data Exclusivity and Other ‘Trips-plus’ Measures.” *UHC Technical Brief*, WHO, 2017, apps.who.int/iris/rest/bitstreams/1140151/retrieve. // LHP AB

Yet, there are some questions as to whether **data exclusivity could prevent the registration of medicines produced under a compulsory license** (Fig. 1b). If so, data exclusivity would **effectively render the compulsory license inoperative**. Second, **if** a period of data exclusivity is also **granted when an existing medicine obtains** marketing **authorization (or registration) for a second or new indication or for a new form, as in the case of paediatric versions of already approved drugs, data exclusivity could (be used to) extend** the **period of exclusivity** of the originator product (Fig. 2). Fig. 2: Extension of data exclusivity for second indication Patent granted Registration market entry End patent term Data exclusitvity Data exclusitvity Registration 2nd indication Finally, data exclusivity **could prevent** the **registration of generic** versions of **medicines even when** there is no patenton a medicine, e.g. **when a pharmaceutical product does not meet the standards for patentability** (e.g. **because it is not new or an inventive step),** **the patent lapses, when a country has no patent law,** or **when patents are not being granted for pharmaceuticals**. The **latter** situation **can arise in least-developed countries that are World Trade Organization (WTO) Members**, which do not have to grant or enforce patents for pharmaceuticals until 2033.b

#### Forces people to choose between orphan drug designation and patents, read the card, means they link.

#### And – evergreening doesn’t exist – most secondary patents are from other drug companies – nowhere does the plan make a claim about other drug companies patenting drugs – Christie 21:

Christie, A.F., Dent, C.H.R.I.S. and Studdert, D.M., 2021. Evidence of'Evergreening'in secondary patenting of blockbuster drugs. *Melbourne University Law Review*, *44*(2), pp.537-564.

It is reassuring that **the majority of follow-on innovation associated with blockbuster drugs is undertaken by entities other than the drug’s originator, and occurs both before and aer expiry of the patent over the drug’s API and the expiry of associated secondary patents held by the originator of the API**. **is shows that patents** — both primary and secondary — **which are owned by the originators of blockbuster drugs do not give them a monopoly over further innovation in relation to the drug**. us, it appears that **policymakers do not need to be concerned that drug originators’ secondary patents stifle welfare-enhancing innovation by others**. **e fact that most of the follow-on innovation by others occurs aer the granting of regulatory approval to market the drug provides policymakers with a potentially valuable lever.** It seems likely that any regulatory reforms which expedite the granting of drug approval will also expedite the commencement — and thus potentially increase the amount — of follow-on innovation that is undertaken by third parties. **Since such follow-on innovation is generally regarded as socially desirable, policymakers should seek to identify mechanisms that speed up the assessment of drug approval without compromising the effectiveness of that assessment**. Although the majority of blockbuster drug follow-on innovation is undertaken by third parties, a substantial amount (27%) is undertaken by the originator of the drug — resulting in an average of 13 secondary patents per drug. ese secondary patents have greater private value than those held by others, and their typology is consistent with the theorised evergreening behaviour of drug originators. Considered together with our earlier study’s findings, these findings provide support for the view that secondary patenting by drug originators can have adverse welfare effects through extending the originator’s marketplace exclusivity over the drug. Policymakers must be alert to this possibility, and need to consider how to reduce its likelihood. We consider that those responsible for implementing, reviewing, validating and correcting patent examination practices — patent offices and, ultimately, courts — should ensure that the patentability requirements, especially those of inventive step (non-obviousness) and industrial application (utility), are applied rigorously to the types of follow-on innovation with the greatest potential to have an evergreening effect — namely, delivery mechanisms for, and formulations of, APIs.

### Offense

### Turn

#### 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.**

#### Second, 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

#### 3] 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 21:

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 te usage of trade secrets.

#### 4] 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 shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.

#### 5] Drug competition slashes prices so fast that generic competitors also plummet – some go bankrupt, Sun 20:

Zhiyuan Sun, [Zhiyuan Sun is a statistician with a knack for analyzing clinical trials and company financials. Investing in healthcare and cannabis is his passion, as well as looking out for new, actionable stock investment ideas in these sectors. Lately expanding into innovations in cryptocurrency alongside biotech/cannabis content. Fool since April 2020.] “Why the FDA's **Drug Competition Action Plan** **Is Bad News for Generic Pharma**ceutical Stocks,” Jun 3, 2020, <https://www.fool.com/investing/2020/06/03/why-the-fdas-new-initiative-is-bad-news-for-generi.aspx> //LHP AV

#### It is no secret that prescription drug prices in America are the highest among all developed nations. A variety of factors have contributed to the issue, such as a lack of universal healthcare coverage, the staggering cost of conducting clinical trials to get drugs to approval, and price gouging by sector players with questionable motives. The problem has not gone unnoticed. Since 2017, the U.S. Food and Drug Administration (FDA) has been conducting an initiative called the Drug Competition Action Plan to make prescription drugs more affordable. The campaign is working well, but it comes at the expense of lower revenue and profits for many sector players. What does this mean for investors? Let's find out together. What the FDA is doing To put it simply, the FDA is devoting significant resources to expedite the approval of copycat drugs. Last year, the administrative body approved a record 1,171 generic drugs, a 21% increase from 2018 -- itself a year of record approvals. That's more than three generic drugs approved every day! Typically, branded drugs derive their revenue from the patent protection and market exclusivity they receive, allowing their makers a legal monopoly until the drugs lose their intellectual property protection. After their patents expire or generic manufacturers successfully challenge them in court, branded drugs can see their revenue decline by 80% to 90% in as little as 12 months due to fierce competition from copycat drugs. For example, Pfizer's (NYSE:PFE) once-blockbuster cholesterol reduction drug, Lipitor, saw its annual revenue plummet from $5 billion in 2011 to about $932,000 just a year later. The more copycat drugs the FDA approves, the more options patients have, which in turn reduces the prices of all drugs targeting an indication. How sector players are doing For generic manufacturers with a significant portion of their revenue coming from the U.S., the new initiative has done nothing less than wreak havoc on the bottom line. Take the case of Lannett Company (NYSE:LCI), which conducts more than 90% of its business operations in America. Revenue at Lannett declined by 16.4% year over year in the past quarter. Worse, its non-GAAP (adjusted) earnings per share declined further -- by more than 60% year over year. These developments spell out a lot of trouble for a company with a debt-to-equity ratio of more than 200%. Meanwhile, sector players that are profitable with little to no debt are seeing their margins shrink. For example, gross margins at ANI Pharmaceuticals (NASDAQ:ANIP) were slashed by 1,450 basis points year over year to 58%; at Taro Pharmaceutical Industries (NYSE:TARO), that number was 790. Both companies also saw their revenue decline by about 3% to 6% compared to last year. To put it mildly, the FDA wants to make changes, and it seems to have little concern over how this affects companies. Recently, Akorn, a generic drug company with 100% of its business coming from the U.S., filed for bankruptcy protection. Back in 2017, the company was valued at $4.3 billion. Is there hope? Luckily, not all generic pharmaceutical companies conduct all their operations in the U.S. Those with healthy international segments are in luck, because the FDA's new initiative does not affect other areas of the world. For example, Teva and Mylan (NASDAQ:MYL) are seeing their revenue and earnings per share grow, primarily because 52% and 63% of their revenue, respectively, comes from outside North America. Ample money can be made by investors wishing to ride these companies' rebound. But for the others named in this article, it's probably

### LBL

#### Feldman – he assumes the alternative to evergreening is new drug innovation – but there’s no warrant for that – the reason companies prioritize minor tweaks is because it’s what makes them money to allow for more substantive innovation. The alternative to evergreening is a) other forms of market differentiation like branding and b) other forms of patent avoidance. Getting rid of evergreening doesn’t make profitable things unprofitable.

#### Feldman 2 – extent of uniqueness means you kill your solvency.

#### The internal link in stanbrook says that limits on evergreening will reduce patent litigation – that’s just empirically false – what would happen is someone will try to patent something, the patent office will say no this is evergreening, and then they’ll get sued. In the world of the aff, there will be intense litigation about what is or what is not a new drug and what constitutes evergreening.

#### Arnold Ventures – there’s no impact to monopolies and no internal link to innovation at all. At best their impact is drug prices, but without an internal link to innovation, it doesn’t matter. Also, the card itself demonstrates why ocmpanies need to evergreen. The truveda example shows how the 20 year patent they should’ve had was only going to be two years because of how long it takes drugs to be approved. Two years is not enough to make money for someone to develop a new drug.

#### Superbugs – solving pandemic extinction uniquely demands massive pharmaceutical monopolies, because only when you can throw trillions of dollars at a short amount of time is when you can solve extinction fast enough. If we have a competition of hundreds of little non monopolized drug companies, there would be no one of them to solve. That impact turns monopolies.