# Stock NC

I negate the resolution, Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

## IPR DA

#### Reducing patents doesn’t aid in the accessibility of cheap, generic drugs

**Cullet 03** Philippe Cullet. “Patents and Medicine: The Relationship between TRIPS and the Human Right to Health.” *International Affairs*. 01/2003. https://www.jstor.org/stable/3095545

Access to drugs is one of the fundamental components of the human right to health. It is of specific importance in the context of the introduction of patents on drugs, because patents have the potential both to improve access, by providing incentives for the development of new drugs, and to restrict access, because of the comparatively higher prices of patented drugs. Accessibility generally refers to the idea that health policies should foster the availability of drugs, at affordable prices, to all those who need them. This implies a strong link between lack of access to drugs and poverty. About one-third of the world's population does not have access to basic drugs, a proportion which rises above one-half in the most affected regions of Africa and Asia. Furthermore, a large proportion of people in developing countries do not have access to medical insurance and more often than not pay for drugs themselves. Since price is a major issue in access, it is significant that patented drugs are more expensive than generics. However, patents are not the only factor influencing access, since even cheap generic drugs may not be affordable for people below the poverty line. In these situations access can be ensured only through further measures such as public subsidies or price control measures. The sheer scale of the problem of access to drugs is only too clear in the context of HIV/AIDS. A consortium of international organizations has estimated that fewer than 10 per cent of the people living with HIV/AIDS in developing countries have access to antiretroviral therapy. This proportion goes down to about 0.I percent in Africa. The links among patents, the price of medicines and access to drugs have been taken into consideration by various countries in developing their legal and policy framework in the health sector. India is particularly noteworthy in this respect. As noted above, India adopted patent legislation which prohibited product patents for medicines, and this constituted one of the major incentives for the development of a relatively strong pharmaceutical industry. In the first 25 years after independence, the domestic pharmaceutical industry remained relatively small, and by I970 (the year in which the Patents Act was passed) accounted for only about 25 per cent of the domestic market; but thereafter the restrictions on product patents, prices and foreign investment contributed to the rapid development of the industry, which now accounts for 70 per cent of bulk drugs and meets nearly all the demand for formulations. One of the most important impacts of the Indian Patents Act, prior to its recent TRIPS-related amendments, and the resulting development of a generic pharmaceutical industry has been significantly lower prices for drugs compared to other countries. Indeed, while drug prices in India were among the highest in the world in the initial stages of development, they are now among the lowest. This is not to say that access to drugs is universal-millions still cannot afford basic generic medicines- but the trend since 1970 has definitely been in the right direction. Apart from the exclusion of product patents, the Indian Patents Act introduced further measures to foster access to drugs. With regard to the duration of patent protection, the Act provided specific restrictions in the health sector. While normal patents were granted for 14 years, process patents on drugs or food were granted for only seven years. The Act also provided a strict compulsory licensing regime which included not only compulsory licences but also licences of right.

#### Reducing intellectual property rights results in counterfeit medicine

**Fifarma 21** “This is how we fight counterfeit medicine with Intellectual Property.” 4/22/2021. <https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/>

In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines that have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also,IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem. Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

## Innovation DA

**IP drives innovation**

Ezell and Cory 19 Stephen Ezell and Nigel Cory. 4-25-2019, "The Way Forward for Intellectual property Internationally," Information Technology and Innovation Foundation <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally>

The global economy, including developed and developing nations alike, is becoming more innovation-driven—powered by knowledge, creativity, and technology, each of which is fundamentally supported by intellectual property (IP) and intellectual property rights (IPR) protections. And yet, over the past two decades, the policy debate over IP’s role has come under an increasingly active and coordinated attack, driven by IPR skeptics and opponents hailing from a variety of academic and multilateral institutions, nongovernmental organizations (NGOs), and some developing nations and policymakers therein. They have done much to advance a false narrative that strong and effective IP is a win-lose, buy-sell proposition, which only helps the developed “North” (as opposed to the underdeveloped “South”). Yet if the international community is going to maximize global innovation—something that is critical if we are to make faster progress on commonly shared global challenges such as climate change, disease prevention and treatment, and economic growth—we will need a stronger and more wide-ranging consensus on the importance of IP to every country throughout the world. To maximize the role intellectual property can play in enabling innovation across the world, the countries that best recognize the essential link between the two—including the United States, Commonwealth nations, European Union members, Japan, Korea, Singapore, and others—need to revise and amplify efforts to build out and strengthen the international framework of intellectual property rules, norms, and cooperation.

**IP incentives innovation**

Ezell and Cory 19 Stephen Ezell and Nigel Cory. 4-25-2019, "The Way Forward for Intellectual property Internationally," Information Technology and Innovation Foundation <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally>

Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). **IP** also **plays** an especially **important role for R&D-intensive industries**. To take the example of the **biopharmaceutical industry**, it is characterized by **high-risk, time-consuming,** and **expensive processes** including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The **drug development process spans** an average of 11.5 to **15 years**. For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, **0.05 to 0.1 percent of drugs make it** from basic research **into clinical trials**. **Of those** rare few which make it to clinical testing, **less than 12 percent** are ultimately **approved** for use **by the** U.S. Food and Drug Administration (**FDA**). In addition to **high risks**, drug development is **costly**, and the **expenses** associated with it are **increasing**. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent. Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in **new drug development requires** $1.7 billion to **$3.2 billion up front** on average. A 2018 **study by the Coalition for Epidemic Preparedness** found similar risks and figures for vaccines, stating, “In general, **vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure**.” Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs. Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry. To say the least, **biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns**. **Without IP protection**, biopharmaceutical **manufacturers have little incentive to take** the **risks necessary to engage** in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. **IP rights give** life-sciences enterprises **the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation** secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.

#### IP Protections for biopharmaceuticals are essential to encouraging innovation and ensuring that firms will continue to invest in them

Grabowski and DiMasi, 15 Henry G. Grabowski (grabow@ econ.duke.edu) is a professor of economics at Duke University, in Durham, North Carolina. Joseph A. DiMasi is director of economic analysis at the Tufts Center for the Study of Drug Development, Tufts University, in Boston, Massachusetts. Genia Long is a senior advisor at the Analysis Group, in Boston, Massachusetts. “The Role of Patents and Research and Development Incentives in Biopharmaceutical Innovation” Health Affairs, 34, no.2 (2015):302-310

Technological innovation is widely recognized as a key determinant of economic and public health progress.1,2 Patents and other forms of intellectual property protection are generally thought to play essential roles in encouraging innovation in biopharmaceuticals. This is because the process of developing a new drug and bringing it to market is long, costly, and risky, and the costs of imitation are low. After a new drug has been approved and is being marketed, its patents protect it from competition from chemically identical entrants (or entrants infringing on other patents) for a period of time. For firms to have an incentive to continue to invest in innovative development efforts, they must have an expectation that they can charge enough during this period to recoup costs and make a profit. After a drug’s patent or patents expire, generic rivals can enter the market at greatly reduced development cost and prices, providing added consumer benefit but eroding the innovator drug company’s revenues. The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) was designed to balance innovation incentives and generic price competition for new drugs (generally small-molecule chemical drugs, with some large-molecule biologic exceptions) by extending the period of a drug’s marketing exclusivity while providing a regulatory framework for generic drug approval.

## Covid DA

#### Covid vaccines were built on intellectual property rights

**Stevens and Schultz 21** Philip Stevens and Mark Schultz, the executive director of Geneva Network and Director of the Intellectual Property and Technology Law Program at the University of Akron School of Law. “Why intellectual property rights matter for COVID-19” 1/14/2021. <https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/>

IP is the bedrock upon which today’s COVID-19 vaccines have been built. The technologies they are based on did not come out of thin air at the beginning of the pandemic, but had been under development for decades, with substantial research in academic labs followed by years of risky investment by commercial start-ups. Consider the messenger RNA (mRNA) technology that is the basis for two of the first vaccines approved in Western countries. Scientists discovered in 1961 that mRNA could be used to “reprogram” cells to battle disease. It took decades of lab research and private sector-funded development by startups BioNTech and Moderna to overcome major difficulties and turn the technology into an effective vaccine that can be safely given to patients. Both companies and their investors have [spent](https://www.wsj.com/articles/how-pfizer-delivered-a-covid-vaccine-in-record-time-crazy-deadlines-a-pushy-ceo-11607740483)[billions of dollars](https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19) on mRNA research prior to the pandemic. While academic research is fundamental, the end result would not have been possible without the private sector, which depends on intellectual property rights. Shortly before the pandemic started, we spoke to Dr. Derrick Rossi, the academic founder of Moderna. When asked whether the treatments could be brought from the academic lab to patients without the help of the private sector, Dr. Rossi’s reply was categorical: “Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients.” Dr. Rossi explains that bringing a drug to market takes many professionals, sharing their labour and diverse expertise. “This industry of professionals is out there… The more people that are involved in the chain, post-academic discovery, the more you have pros involved — all the way from IP filings to VCs to due diligence to assembling a team,” the more likely you are to develop a viable treatment. Developing a practical application for a great academic insight takes vast sums, and investors need some prospect of a return on that investment. As Dr. Rossi explains, “you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple.” The other claim [frequently heard](https://www.science.org.au/curious/policy-features/humanity-cannot-afford-covid-19-patent-battle) at the beginning of the pandemic was that IP poses a barrier to collaboration and knowledge-sharing, so in a time of emergency any related IP should be open licensed or pooled. In reality, the IP system encouraged the rapid establishment of dozens of partnerships around COVID-19-19, with even [commercial rivals](https://cen.acs.org/biological-chemistry/infectious-disease/How-big-pharma-firms-quietly-collaborating-on-new-coronavirus-antivirals/98/i18) prepared to cooperate and share capital and proprietary intellectual resources such as compound libraries. Examples of consortia between the private sector and research centres include the [COVID-19-19 Therapeutics Accelerator](https://www.therapeuticsaccelerator.org/) to evaluate new and repurposed drugs and biologics, the EU-backed [Swift COronavirus therapeutics REsponse](https://cordis.europa.eu/project/id/101003627), [Corona Accelerated R&D in Europe](https://cordis.europa.eu/project/id/101005077) (CARE) as well as dozens of bilateral agreements between companies. Indeed, the Pfizer vaccine is the result of its collaboration with BioNtech, where partners shared and combined know-how and proprietary knowledge to create the first vaccine authorized in the U.S. Far from being a barrier to such collaborations, IP is fundamental. Because patent rights require public disclosure, they enable drug developers to identify partners with the right intellectual assets such as know-how, platforms, compounds and technical expertise. Without patents most of this valuable proprietary knowledge would be kept hidden as trade secrets, making it impossible for researchers to know what is out there. Second, the existence of laws protecting intellectual property helps rights-holders make the decision to collaborate in the first place. By allaying concerns about confidentiality, IP enables companies to open up their compound libraries, and to share platform technology and know-how without worrying they are going to sacrifice their wider business objectives or lose control of their valuable assets. For instance, rights holders might contribute IP that is useful for entirely different diseases to COVID-19 collaborations. IP rights and licensing ensure those rights can only be used for the agreed reason, preventing competitors freeriding to gain an unfair advantage in other areas. As the former Director General of WIPO noted in June 2020, the main challenge at the time was “not access to vaccines, treatments or cures for COVID-19-19, but the absence of any approved vaccines, treatments or cures to have access to. The policy focus of governments at this stage should therefore be on supporting science and innovation”. During this initial phase of the pandemic, the majority of governments followed this advice, especially by not threatening to remove IP of products yet to be invented. [No government](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action) from a country with a significant life-science R&D industry, for instance, backed the WHO’s “[Solidarity Call to Action](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action)” in which companies were asked to unilaterally cede IP and data related to COVID-19 to its new technology and IP pool, C-TAP.  The WHO embarked on this initiative with no evidence that IP would stand in the way of R&D and access efforts, distracting efforts away from more practical initiatives that stood greater chance of success.

**IPPs were crucial to the medicine effort against Covid.****EFPIA 21’** (The European Federation of Pharmaceutical Industries and Associations) <https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/>

**Intellectual property has the power to bring about vital medical innovation. It creates access to new treatments which in turn creates healthy populations. It can support people’s lives and their livelihoods.**

**IP** is the **key driver of innovation**. It has **enabled unprecedented collaborations between** biopharmaceutical **innovators** and **governments, universities** and other **research partners to speed up progress on** hundreds of potential **COVID-19 treatments**, diagnostics **and vaccines** for patients**.** It is only **because of IPP** that we have **over 300 treatments and more than 200 vaccines** currently being explored **for use against COVID-19.** Fostering a research eco-system that can deliver that innovation rather than undermining it through challenges to IP, is the **best way to protect citizens across** Europe and **around the world.** Every **new treatment or cure starts with the spark** of an idea. **Protecting that spark** can involve ensuring funding for early-stage development of a new therapy, it can be creating the right environment for collaboration between research partners, it **can be evolving the regulatory framework to keep pace with rapidly advancing science and protecting the spark means having a strong and effective intellectual property framework.** Pharmaceutical intellectual property (**IP) – incentives** and rewards are the foundation on which innovation is built: they **encourage and protect innovation**, driving research and development investments into areas of unmet medical need.

#### Direct government support would be more effective than IPR in battling public health crises

**Lindsey 21** Brink Lindsey, vice president at the Niskanen Center. “Why intellectual property and pandemics don’t mix.” *The Brookings Institution*. 6/3/2021. <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>

What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? The most effective approach during a public health crisis is direct government support: public funding of R&D, advance purchase commitments by the government to buy large numbers of doses at set prices, and other, related payouts. And when we pay drug makers, we should not hesitate to pay generously, even extravagantly: we want to offer drug companies big profits so that they prioritize this work above everything else, and so that they are ready and eager to come to the rescue again the next time there’s a crisis. It was direct support via Operation Warp Speed that made possible the astonishingly rapid development of COVID-19 vaccines and then facilitated a relatively rapid rollout of vaccine distribution (relative, that is, to most of the rest of the world). And it’s worth noting that a major reason for the faster rollout here and in the United Kingdom compared to the European Union was the latter’s misguided penny-pinching. The EU bargained hard with firms to keep vaccine prices low, and as a result their citizens ended up in the back of the queue as various supply line kinks were being ironed out. This is particularly ironic since the Pfizer-BioNTech vaccine was developed in Germany. As this fact underscores, the chief advantage of direct support isn’t to “get tough” with drug firms and keep a lid on their profits. Instead, it is to accelerate the end of the public health emergency by making sure drug makers profit handsomely from doing the right thing. Patent law and direct support should be seen not as either-or alternatives but as complements that apply different incentives to different circumstances and time horizons. Patent law provides a decentralized system for encouraging innovation. The government doesn’t presume to tell the industry which new drugs are needed; it simply incentivizes the development of whatever new drugs that pharmaceutical firms can come up with by offering them a temporary monopoly. It is important to note that patent law’s incentives offer no commercial guarantees. Yes, you can block other competitors for a number of years, but that still doesn’t ensure enough consumer demand for the new product to make it profitable. The situation is different in a pandemic. Here the government knows exactly what it wants to incentivize: the creation of vaccines to prevent the spread of a specific virus and other drugs to treat that virus. Under these circumstances, the decentralized approach isn’t good enough. There is no time to sit back and let drug makers take the initiative on their own timeline. Instead, the government needs to be more involved to incentivize specific innovations now. As recompense for letting it call the shots (pardon the pun), the government sweetens the deal for drug companies by insulating them from commercial risk. If pharmaceutical firms develop effective vaccines and therapies, the government will buy large, predetermined quantities at prices set high enough to guarantee a healthy return. For the pharmaceutical industry, it is useful to conceive of patent law as the default regime for innovation promotion. It improves pharmaceutical companies’ incentives to develop new drugs while leaving them free to decide which new drugs to pursue – and also leaving them to bear all commercial risk. In a pandemic or other emergency, however, it is appropriate to shift to the direct support regime, in which the government focuses efforts on one disease. In this regime, it is important to note, the government provides qualitatively superior incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return. It should therefore be clear that the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver. Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support. Arguments that a TRIPS waiver would deprive drug makers of the incentives they need to keep developing new drugs, when they are presently receiving the most favorable incentives available, can be dismissed as the worst sort of special pleading. That said, it is a serious mistake to try to cast the current crisis as a morality play in which drug makers wear the black hats and the choice at hand is between private profits and public health. We would have no chance of beating this virus without the formidable organizational capabilities of the pharmaceutical industry, and providing the appropriate incentives is essential to ensure that the industry plays its necessary and vital role. It is misguided to lament that private companies are profiting in the current crisis: those profits are a drop in the bucket compared to the staggering cost of this pandemic in lives and economic damage.

#### Waiving IP protections for medicines such as the Covid-19 vaccine undermines responses to combat the disease

Ubl, 21 Stephen J. Ubl is president and chief executive officer of the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents America’s leading biopharmaceutical research companies. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.“PhRMA Statement on WTO TRIPS Intellectual Property Waiver” [https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver May 5](https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver%20May%205), 2021

“In the midst of a deadly pandemic, the Biden Administration has taken an unprecedented step that will undermine our global response to the pandemic and compromise safety. This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines.

“This change in longstanding American policy will not save lives. It also flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery. This decision does nothing to address the real challenges to getting more shots in arms, including last-mile distribution and limited availability of raw materials. These are the real challenges we face that this empty promise ignores.

“In the past few days alone, we’ve seen more American vaccine exports, increased production targets from manufacturers, new commitments to COVAX and unprecedented aid for India during its devastating COVID-19 surge. Biopharmaceutical manufacturers are fully committed to providing global access to COVID-19 vaccines, and they are collaborating at a scale that was previously unimaginable, including more than 200 manufacturing and other partnerships to date. The biopharmaceutical industry shares the goal to get as many people vaccinated as quickly as possible, and we hope we can all re-focus on that shared objective.”

## Compulsory Licenses DA

#### Compulsory licenses present a viable alternative to intellectual property rights

**Wise 14** Jacqui Wise. “Patent wars: affordable medicines versus intellectual property rights.” *British Medical Journal*. 2/17/2014-2/23/2014. https://www.jstor.org/stable/10.2307/26514007

The pharmaceutical industry is increasingly looking towards emerging markets, where demand for new drugs is rising rapidly alongside rates of chronic disease. But in recent years India, known as the “pharmacy of the developing world,” has led the battle for affordable drugs, using legal mechanisms to overturn patents so that its generic drug companies (which produce a fifth of the world’s generic drugs) can undercut the Western giants. Developing countries have followed India’s example, and battles over patent protection and prices have broken out from Indonesia to Brazil. The fight echoes the one over access to treatments for HIV infection a decade or two ago, but it is now being fought over a far wider range of drugs with greater financial implications for Western drug companies. In a series of high profile court cases, India has rejected several patent claims for cancer drugs and Roche decided in August not to pursue a patent application for its breast cancer drug trastuzumab (Herceptin) because it viewed it as a losing battle in India’s current intellectual property environment. A key decision came in 2012, when India issued a compulsory licence for Bayer’s cancer drug sorafenib (Nexavar), allowing a local company Natco to produce a generic version. A compulsory licence allows a company to produce a patented product without the consent of the patent owner. Under the World Trade Organization’s trade related aspects of intellectual property rights (TRIPS) agreement countries are free to grant compulsory licences in the interest of public health; however, there is much argument about how this is defined. The Indian courts ruled that the costs of $4500 (£2700; €3300) a month for sorafenib were unaffordable to the Indian government. A generic version of the drug is now available for $175 a month. Since that decision a further two applications for compulsory licences have been rejected. But the Indian government has set up an expert committee to review drug patents and identify whether any additional compulsory licences should be issued. The drug industry fears that the floodgates will open and that this will create an “innovation crisis.” Andrew Jenner, executive director of the International Federation of Pharmaceutical Manufacturers and Associations, said: “Increased use of compulsory licensing provisions will reduce the incentive to invest in the research and development of new medicines in India and should be seen as a last resort as open discussions with patent holders often lead to successful outcomes.”