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

**My value is morality for two reasons:**

1. **The resolution’s use of the word “ought” implies a moral obligation**
2. **Morality allows us to perceive what is inherently good or bad. It is the value upon which we can conceptualize all other values, thus it must be prioritized.**

## **My criterion is Protecting public health**

**Christoph J. Crützen, Maximilian Kücking**

**Several Percentage, 5-5-2021, "The Waiver of Patent Protection for COVID-19 Vaccines — On Practicability and Purpose of Such Measure," No Publication, https://www.mayerbrown.com/en/perspectives-events/publications/2021/07/ger-the-waiver-of-patent-protection**

A waiver or limitation of patent protection initiated by the government could discourage pharmaceutical companies from taking on the costly research and development work required to provide critical medicines in the future, as they would have to fear that they would not be able to recoup their risky investment. Against this background, German Chancellor Angela Merkel’s rejection of the U.S. initiative should be seen as a strong signal. After all, Germany had long been considered one of the most important patent applications in Europe came from Germany, and Germany is also extremely popular as a location for patent infringement proceedings in Europe due to its specialized court locations in Düsseldorf, Mannheim, and Munich

## **Contention 1 is Patent importance**

#### Patents encourage research

**Henry G. Grabowski, Joseph A. DiMasi, and Genia Long 2015"The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation," No Publication, https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047**

Patents and other forms of intellectual property protection play essential roles in encouraging innovation in biopharmaceuticals. As part of the “21st Century Cures” initiative, Congress is reviewing the policy mechanisms designed to accelerate the discovery, development, and delivery of new treatments. **Debate continues about how best to balance patent and intellectual property incentives to encourage innovation, on the one hand, and generic utilization and price competition, on the other hand.** We review the current framework for accomplishing these dual objectives and the important role of patents and regulatory exclusivity (together, the patent-based system), given the lengthy, costly, and risky biopharmaceutical research and development process. **We summarize existing targeted incentives, such as for orphan drugs and neglected diseases, and we consider the pros and cons of proposed voluntary or mandatory alternatives to the patent-based system, such as prizes and government research and development contracting.** We conclude that patents and regulatory exclusivity provisions are likely to remain the core approach to providing incentives for biopharmaceutical research and development. However, prizes and other voluntary supplements could play a useful role in addressing unmet needs and gaps in specific circumstances. TOPICS PATENTS PHARMACEUTICALS PRESCRIPTION DRUGS MARKETS DISEASES INTELLECTUAL PROPERTY RESEARCH AND DEVELOPMENT PRESCRIPTION DRUG COSTS FDA APPROVALS PROCESS BIOLOGICS PRICE COMPETITION AND INNOVATION ACT Technological innovation is widely recognized as a key determinant of economic and public health progress. [1](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B1),[2](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B2) 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. This framework was later changed to encompass so-called biosimilars for large-molecule (biologic) drugs through the separate Biologics Price Competition and Innovation Act of 2009. Other **measures have been enacted to provide research and development (R&D) incentives for antibiotics and drugs to treat orphan diseases and neglected tropical diseases.**

Discussion continues about whether current innovation incentives are optimal or even adequate, given evolving public health needs and scientific knowledge. For instance, the House Energy and Commerce Committee recently embarked on the “21st Century Cures” initiative, [3](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B3) following earlier recommendations by the President’s Council of Advisors on Science and Technology on responding to challenges in “propelling innovation in drug discovery, development, and evaluation.” [4](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B4)

In this context, we discuss the importance of patents and other forms of intellectual property protection to biopharmaceutical innovation, given the unique economic characteristics of drug research and development. **We also review the R&D incentives that complement patents in certain circumstances.** Finally, we consider the pros and cons of selected voluntary (“opt-in”) or mandatory alternatives to the current patent- and regulatory exclusivity–based system (such as prizes or government-contracted drug development) and whether they could better achieve the dual goals of innovation incentives and price competition.

#### **Getting rid of patents will reduce funding for R&D**

**Henry G. Grabowski, Joseph A. DiMasi, and Genia Long 2015"The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation," No Publication, https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047**

**The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity**. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. [5](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B5) The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. [6](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B6) Only approximately one in eight drug candidates survive clinical testing. [6](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B6) As a result of the **high risks of failure and the** high costs, research and development must be funded by the few successful, on-market products **(the top quintile of marketed products provide the dominant share of R&D returns).** [**7**](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B7)**,**[**8**](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B8) **Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success.** Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). [9](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B9) **Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s.** [10](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B10) Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. [11](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B11) The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms. **Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research.** This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. **Universities received only 390 patents for their discoveries in 1980,** [**12**](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B12) **compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012)**. [13](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B13) University licensing trends have generated debate. For instance, there have been recent proposals to encourage the federal government to “march in” and require a university to license a patent or enforce reduced pricing or other terms. [14](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B14) The percentage of approved drugs with public-sector patents is relatively small. [15](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B15) Nevertheless, if the government exercised its march-in rights in this way, that action could have adverse effects on technology transfer activities and early-stage company investment, particularly if it were to disrupt existing expectations of grantees, licensees, and investors. [12](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B12) There have been four petitions to the NIH requesting it to exercise march-in rights on behalf of the federal government; none has been granted. [16](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B16)

#### **Medicines are expensive to make**

**Linda A. Johnson, 5-6-2021, "EXPLAINER: Why patents on COVID vaccines are so contentious," AP NEWS, https://apnews.com/article/patents-coronavirus-pandemic-business-health-1e39ca2f2d67bf1574c13e9a924e8468**

**The Biden administration’s call to lift patent protections on COVID-19 vaccines to help poor parts of the world get more doses has drawn praise from some countries and health advocates. But it has run into resistance from the pharmaceutical industry and others, who say it won’t help curb the outbreak any time soon and will hurt innovation.** Here’s a look at what patents do and why they matter: HOW DO DRUG PATENTS WORK? ADVERTISEMENT Patents reward innovation by preventing competitors from simply copying a company’s discovery and launching a rival product. In the U.S., patents on medicines typically last 20 years from when they are filed, which usually happens once a drugmaker thinks it has an important or lucrative drug. **Because it often takes a decade to get a drug approved, companies typically enjoy about a dozen years of competition-free sales.** But drugmakers usually find ways to improve their product or widen its use, and they secure additional patents that can extend their monopoly for many more years. **WHY IS PATENT PROTECTION SO IMPORTANT TO DRUGMAKERS?** Medicines are incredibly expensive to develop. Most experimental drugs fail at some point during the years of laboratory, animal and finally human testing. Averaging in the cost of those flops, it typically costs over $1 billion to bring a drug from discovery to regulatory approval. Without the prospect of years of sales without competition, there’s far less incentive to take that risk.

## **Contention 2 is IP’s aren’t a problem**

#### **IP relief won’t be beneficial**

**India And, 5-25-2021, "A patent waiver on COVID vaccines is right and fair," No Publication, https://www.nature.com/articles/d41586-021-01242-1**

**One of the biggest concerns about IP waivers is that they provide a short-cut to competitors looking to acquire expensive technology.** Companies **also** say that IP relief will not accelerate vaccine manufacturing, because materials are in short supply and it can take several years to build up capacity from scratch. Moreover, the governments opposing the waiver argue that current WTO rules already allow countries to apply for ‘compulsory licensing’ to override IP during emergencies. Right now, for example, Bolivia is applying to the WTO to use this process to allow it to manufacture Johnson & Johnson’s COVID vaccine. **However**, a group of researchers in the United Kingdom who study patent law point out in a draft paper on the waiver proposal that compulsory licences are extremely complex and time-consuming to apply for (S. Thambisetty et al. Preprint at https://ssrn.com/abstract=3851737; 2021). The EU has also pointed out that the United States has been blocking exports of COVID-19 vaccines and their components. It is right that this be called out.

#### **Why IPs aren’t a problem**

**Andrei Iancu April 13, 2021, 4-13-2021, "No evidence that patents slow vaccine access," STAT, https://www.statnews.com/2021/04/13/no-evidence-patents-slow-vaccine-access/**

So before rushing to disrupt the world’s intellectual property systems, governments need to identify specific evidence that intellectual property protection is actually a problem. Adar Poonawalla, CEO of the Serum Institute of India, told The Guardian that insufficient license-granting by patent holders is not an impediment to speedy vaccine rollout and that “it just takes time to scale up,” pointing to the complexity of the manufacturing process. And Bill Gates, the mega-philanthropist whose foundation spearheads many global vaccination efforts, recently told the [“Sway” podcast](https://podcasts.apple.com/us/podcast/innovation-not-trees-how-bill-gates-plans-to-save-the-planet/id1528594034?i=1000509080772), “Believe me, IP did not limit anything.” On the contrary, intellectual property rights made it possible for research scientists to make the decades of investments required to develop and deliver safe and effective Covid-19 vaccines in record time. **Companies would not share such critical technology with competitors if the law didn’t protect their investments.** Some of those advocating for patent waivers have their hearts in the right place: They want to end the pandemic. **But** the evidence that setting aside patent protection will do anything to boost access or expand supply just isn’t there. Removing intellectual property protections on medicines will only ensure that we have fewer of them in the future. This is not a risk worth taking, especially when the evidence suggests we don’t need to.

#### **IPs aren’t in the way production**

**Andrei Iancu April 13, 2021, 4-13-2021, "No evidence that patents slow vaccine access," STAT, https://www.statnews.com/2021/04/13/no-evidence-patents-slow-vaccine-access/**

So before governments take the risk of waiving patents, they should evaluate whether intellectual property rights are really standing in the way of vaccine manufacturing and distribution. **To do that, they need to answer two questions: Is there evidence that a broad range of Covid-19 vaccine developers have been asked for, and unreasonably refused, licenses to their IP?** Are there more facilities that could manufacture a vaccine in short order if they just had the intellectual property? **The answers are no and no.** The issues about making more vaccines and distributing them to every country are far more complex than those proposing to waive intellectual property rights on these vaccines would have us believe. Manufacturing and distributing these vaccines is extremely complicated, posing issues well beyond patents. Almost every factory on the planet that can make these vaccines is already doing so. One of the biggest, the Serum Institute in India, has contracts with AstraZeneca and others to make millions of doses. Under deals like these, manufacturing plants in India will produce [3.6 billion doses](https://timesofindia.indiatimes.com/india/at-3-6-billion-india-pegged-to-produce-most-covid-19-vaccine-doses-after-us-in-2021/articleshow/80254075.cms) of vaccine this year, second only to the United States. Other companies have licensed their manufacturing process to subcontractors, and even to competitors. [Johnson & Johnson and Merck](https://www.washingtonpost.com/health/2021/03/02/merck-johnson-and-johnson-covid-vaccine-partnership/) are teaming up to expand manufacturing capacity of the J&J vaccine. [Novartis and Sanofi](https://www.biopharmadive.com/news/novartis-pfizer-biontech-cororonavirus-vaccine-supply-deal/594215/) are using their facilities to help increase the production of the Pfizer/BioNTech vaccine. **In short, there’s robust collaboration and cooperation within the industry to ensure that vaccines are made quickly and safely.** And patents actually facilitate such cooperation, because each entity can rest assured that its proprietary technology is protected in the long run.

## **Contention 3 is waivers are a bad idea**

#### **Pharmaceutical companies say we shouldn’t get a waiver**

**Joanne S.,May 6, 2021, "Pharma groups slam US decision to support COVID-19 vaccine patent waivers," No Publication, https://www.raps.org/news-and-articles/news-articles/2021/5/pharma-groups-slam-us-decision-to-support-covid-19**

WHO announced its support of the move. “I commend the United States on its historical decision for vaccine equity and prioritizing the well-being of all people everywhere at a critical time. Now let’s all move together swiftly, in solidarity, building on the ingenuity and commitment of scientists who produced life-saving COVID-19 vaccines,” said WHO Director-General Tedros Adhanom Ghebreyesus, the head of the World Health Organization. He added that “this is a monumental moment in the fight against COVID-19.” Doctors Without Borders/Medecins Sans Frontieres (MSF) also said that the decision will “increase sufficient and timely access” to these vaccines; the group asserts that many of the low-income countries in which MSF operates have only received .3% of global vaccine supply while the US has secured enough doses for its entire population. Knowledge Ecology International, a non-profit non-governmental organization, also “applauded” the decision. The group said that “it is a good time to brush up on potential for the Biden administration to use the Defense Production Act to loosen up access to manufacturing know-how and access to working cell lines and ask the WHO what its procedures are for evaluating quality of generic/biosimilar vaccines.” Yet major pharmaceutical industry groups in the US and the EU expressed disappointment in the decision.  **Stephen Ubl, the CEO of the Pharmaceutical Research and Manufacturers of America, said the decision will “sow confusion between public and private partners, further weaken already strained supply chain and foster the proliferation of counterfeit vaccines. …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.” Michelle McMurry-Heath, president and CEO of the Biotechnology Innovation Organization, concurred that it was a bad move. “Handing needy countries a recipe book without the ingredients, safeguards, and sizeable workforce needed will not help people waiting for the vaccine. Handing them the blueprint to construct a kitchen that, in optimal conditions, can take a year to build will not help us stop the emergence of dangerous new COVID variants.”**  The decision was **also** blasted by Nathalie Moll, director general of the European Federation of Pharmaceutical Industries and Associations, who called the proposal “short sighted” **in a 6 May statement.** She said “increasing capacity to deliver doses to citizens around the world requires the skills and technical know-how of the vaccine developer to bring on-board partner manufacturing organizations. You simply cannot achieve this kind of capacity expansion by waiving patents and hoping that hitherto unknown factories around the world will turn their hand to the complex process of vaccine manufacture.” In response to the US decision to back the waiver proposal, European Commission President Ursula von der Leyen said the EU was [open to discussions](https://www.nytimes.com/2021/05/06/world/europe/coronavirus-vaccine-patent-eu.html) on the proposal. A week earlier the European Parliament [voted down](https://www.euractiv.com/section/coronavirus/news/meps-vote-down-call-for-covid-vaccine-ip-waiver/) an amendment to back the IP waiver.

#### **The waiver won’t make vaccines more accessible**

**Linda A. Johnson, 5-6-2021, "EXPLAINER: Why patents on COVID vaccines are so contentious," AP NEWS, https://apnews.com/article/patents-coronavirus-pandemic-business-health-1e39ca2f2d67bf1574c13e9a924e8468**

WHAT IS THE PROCEDURE FOR LIFTING PATENT PROTECTIONS? **The decision is up to the 164-member World Trade Organization, which administers complex trade rules among nations. And all of them would have to agree for it to happen.** If waivers are approved, vaccine developers would then have to share their know-how for the very complex manufacturing. HAS THIS EVER HAPPENED BEFORE? There’s no precedent for vaccines, **but two decades ago WTO members passed a temporary waiver allowing poor countries to import cheap generic drugs for HIV, tuberculosis and malaria amid health crises. That temporary waiver eventually was made permanent.** WHAT WOULD LIFTING PROTECTIONS ON COVID-19 VACCINES ACCOMPLISH? That’s not entirely clear, but drugmakers and analysts say waiving patent rights won’t do much to get COVID-19 vaccines to developing countries faster. That’s because making them is far more complex than following a recipe, requiring factories with specialized equipment, highly trained workers and stringent quality control. There is also little available factory capacity. In addition, many raw materials to make the vaccines, along with vials, stoppers and other components, are in very short supply, **which won’t change soon.**

#### **Waiving patents can have severe long-term consequences**

**Damian Garde , Helen Branswell and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/**

**Conversely,** the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “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.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. **But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave.** Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.