#### “When ”

#### I affirm the resolution resolved, that the member nations of the WTO ought to reduce intelluctal property protecionss.

My value in today’s debate is morality because the vword ought in the resolution implies a moral obligation

The value criteria in today’s debate should be societal welfare. Prefer

1. Allows for a larger a variety of arguments. My opponeny’s value crieteria may only be good for a small sliver of affs – but societal welfare allows us to include different impacts.
2. Nations – they are responsible for choosing the best action for everyone. Only societal welfare gives them an option when deciding between two different decisions
3. How to choose

#### Contention 1 is Covid:

#### We got lucky with COVID – future pandemics will be much worse and existing provisions in TRIPs are not used --- the status quo can’t solve.

Nancy S. **Jecker &** Caesar A. **Atuire 21**. \*Department of Bioethics & Humanities, University of Washington School of Medicine, \*\*Department of Philosophy, University of Johannesburg, Auckland Park, Gauteng, South Africa, “What’s yours is ours: waiving intellectual property protections for COVID-19 vaccines,” Journal of Medical Ethics, July 6, 2021, <https://jme.bmj.com/content/medethics/early/2021/07/06/medethics-2021-107555.full.pdf>., RJP, **DebateDrills.**

A proponent of IP protections may insist TRIPS already includes built-in exceptions adequate to the task. Article 31 grants governments rights to issue licenses for using a patent during the patent term without a patent holder’s consent. This exception was used 144 times between 2001 and 2016 to create flexibilities for 89 countries.29 In 2017, it was extended to allow licensed countries to export products to countries that lack production capacity. Isn’t that enough?

In reply, Article 31 will not take us very far. While useful for some applications, it is cumbersome. For example, for pharmaceutical products, after applying for an exception, exporting countries must prove products go only to destination nations, are readily identifiable based on variations of colour or shape, and include only product necessary to meet requirements of an eligible country; importing nations must notify the TRIPS

council of receipt. Fulfilling these requirements would needlessly delay the vital task of vaccinating the world.

Finally, critics might point to the case of Moderna, which voluntarily pledged (in October 2020) not to enforce its patents during the pandemic. Since companies have not lined up to produce Moderna’s vaccine, doesn’t that show the ineptitude of temporary waivers? In reply, a single pledge by a single company is a start, but insufficient to catalyse the global changes needed. In conclusion, loosening the grip of IP protections is not a miracle fix, and there are many other barriers to a safer world. This paper filled a gap in current debates about IP protections for COVID-19 vaccines by focusing on ethics. In the final analysis, a temporary waiver of IP protections is the world’s best bet.

#### Developing countries need assistance – it’s time for the U.S. to step up to the plate and do its job

Stone 21 – Judy Stone is an Infectious Disease specialist; “Covid Vaccine Equity - Developing Countries Need Our Help”; Forbes, May 11, 2021; <https://www.forbes.com/sites/judystone/2021/05/11/vaccine-equitydeveloping-countries-need-our-help/?sh=10939a363ec8> //advay

A few months ago India was doing relatively well and the U.S. was getting crushed by a devastating second Covid-19 wave. Now it’s the reverse. Public health measures were implemented too sporadically (U.S.) and reversed too quickly (both), with predictable results. While the U.S. is beginning to focus attention on the growing catastrophe in India, not enough attention is being given to other areas in the region. Countries like Bangladesh, Nepal, Pakistan, Laos and others in the region may soon be matching the explosive growth of Covid in India. Nepal is one of the poorest countries. Although it has a population of 30 million people, there are only 1595 ICU beds and 480 ventilators throughout the entire country. (This is not much less than in India, at ~1 ICU bed/19,000, but the US has ~1/3800). There are only 80 physicians per 100,000 people, compared to 93 per 100,000 in India or 259 per 100,000 in the US. With a 50% positivity rate for Covid testing, how long do you think those few beds and limited healthcare will last before being completely overwhelmed. Cases in Nepal have increased by 1,645% in the past month. Thailand had a similar rate of increase, with most of their cases being the U.K. variant B.1.1.7, which is known to be more transmissible. Part of the problem in Nepal is that its Prime Minister, Oli, like India’s PM Modi, and Donald Trump had allowed religious festivals and large political gatherings to continue as politically expedient, at the expense of public health and safety. Heavily reliant on tourism to support its economy, Mount Everest has been opened to climbers; there have been outbreaks reported from the base camp although the government has denied this. And much as our former president recommended injecting bleach, PM Oli has reportedly suggested gargling with guava leaves, which is at least less immediately hazardous, although still as useless as treatment. This uncontrolled pandemic will endanger us all by increasing the likelihood of further mutations emerging and spreading globally. India has a new “variant of interest,” called B.1.617⁠, which is also spread more rapidly. The South African variant, B.1.351, is also circulating in India, along with the UK’s B.1.1.7⁠. This—and the huge number of cases—are what prompted the US to ban travel from India. One of the problems in the region is that India’s Serum Institute was to supply much of the area with vaccines. Instead, India is desperate, unable to meet its own country’s needs, and has banned the export of vaccines. Nepal has instead turned to China and Russia, who are engaging in vaccine diplomacy who are donating supplies while the US has been sitting on the sidelines.

#### It’s not too late---COVID will continue across the developing worlds for years to come.

Brink **Lindsey 21**. Vice President, Niskanen Center; Writes for Brookings, “Why Intellectual Property and Pandemics Don’t Mix,” Brookings, June 3, 2021, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>, RJP, **DebateDrills**.

Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is [currently raging in India and throughout South America](https://www.nytimes.com/interactive/2021/world/covid-cases.html), overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference.

Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time.

#### Future pandemics at 10x more deadly – thousands are going to die

Ceballos 5/27 Gerardo Ceballos [PhD, Dr Gerardo Ceballos is an ecologist and conservationist at the Universidad Nacional Autonoma de Mexico. He is particularly recognized for his influential work on global patterns of distribution of diversity, endemism, and extinction risk in vertebrates. He is also well-known for his contribution to understanding the magnitude and impacts of the sixth mass extinction.], 5/27/21, “THE SIXTH MASS EXTINCTION AND THE FUTURE OF HUMANITY”, Population Matters, <https://populationmatters.org/news/2021/05/sixth-mass-extinction-and-future-humanity> DD AG

Somewhere, sometime in late 2019, a coronavirus from a wild species, perhaps a bat or a pangolin, infected a human in China. This could have been an obscure event, lost without trace in the annals of history, as it is very likely this has occurred many times in the last centuries. But this particular event was somehow different. The coronavirus became an epidemic first and a pandemic later. Covid-19 became the worst pandemic since the Spanish flu in 1918. The horrific human suffering it has caused, and its economic, social and political impacts, are still unraveling.

The reason Covid-19 and more than forty other very dangerous viruses, such as Lassa fever, HIV and Ebola, have jumped from wild animals to humans in the last four decades is the destruction of natural environments and the trafficking and consumption of wild animals.

The wildlife trade is to satisfy the insatiable and extravagant demand for these species in the Asian market, in countries such as China, Vietnam and Indonesia. The illegal wildlife trade is a gigantic business. It is as lucrative as the drug trade, but without the legal implications. The immense appetite of China and other Asian societies for exotic animals has promoted exponential growth in trade and profits. Wild and domestic animals sold in “wet markets” are kept in unsanitary and unethical conditions. There, feces, urine and food waste from cages at the top spill into cages at the bottom, creating the perfect conditions for viruses to leap from wild animals to domestic animals and humans. Thousands of wildlife species or their products are traded annually.

Wildlife trade is one of several human impacts, including habitat loss and fragmentation, pollution, toxification and invasive species, that have caused the extinction of thousands of species and threaten many more. Indeed, most people are unaware that the current extinction crisis is unprecedented in human history. Extinction occurs when the last individual of a species dies. The UN recly estimated that one million species, such as the panda, the orangutan and the Sumatran rhino, are at risk of extinction.

The second finding is that population extinctions, which are the prelude to species extinctions, are occurring at very fast rates (Ceballos et al., 2017). Around 32 percent of a sample of 27,000 species have declining populations and have experienced massive geographic range contractions. Population extinctions are a very severe and widespread environmental problem which we have called “Biological Annihilation”.

Finally, our third finding indicates that the magnitude of the extinction crisis is underestimated because there are thousands of species on the brink of extinction (Ceballos et al., 2020). Those species will likely become extinct in the near future unless a massive conservation effort is launched soon.

Many times, people have asked me why we should care about the loss of a species. There are ethical, moral, philosophical, religious and other reasons to be concerned. But perhaps the one that is most tangible for most people is the loss of ecosystem services, which are the benefits that humans derive from the proper function of nature. Ecosystem services include the proper mix of gases in the atmosphere that support life on Earth, the quantity and quality of water, pollination of wild crops and plants, fertilization of the soil, and protection against emerging pests and diseases, among many others. Every time a species is lost, ecosystem services are likely to erode and human well-being is reduced.

The loss of so many ecosystems and species is pushing us towards the point of collapse of civilization. The good news is that there is still time to reduce the current extinction crisis. The species and ecosystems that we manage to save in the next 10 – 15 years will define the future of biodiversity and civilization. What it is at stake is the future of mankind.

## Contention 2: Insulin

#### Insulin is prohibitively expensive – new insulin analogues move the needle from human insulin to a lower quality, more expensive drug

Peccoud et al 18 Jenna E. Gallegos [],1 Christopher Boyer,2 Eleanore Pauwels,3 Warren A. Kaplan,4 and Jean Peccoud [Prof. Jean Peccoud joined the department in January 2016 as the Abell chair in synthetic biology]1,\*, December 18, “The Open Insulin Project: A Case Study for ‘Biohacked’ Medicines””, Trends in Biotechnology Vol 36 No. 12, <https://www.cell.com/trends/biotechnology/pdf/S0167-7799(18)30200-2.pdf> DD AG

Since its discovery in 1921, insulin has revolutionized the quality and quantity of life for persons with diabetes. Yet, despite its long market history, the cost of insulin has continued to rise. For example, insulin prices tripled between 2002 and 2013 [9], costing uninsured patients as much as US$400 per month [10]. In inner cities, the leading cause of diabetic ketoacidosis – a potentially fatal condition – is stopping or inconsistent insulin treatment, and cost is a major reason reported for this [11]. Cited examples of health risks from high insulin costs include rationing treatments, using expired products, fasting, and even intentionally inducing diabetic ketoacidosis in order to obtain insulin from hospital emergency rooms [12,13]. While many other lifesaving medications have become available as less expensive generics, the high price of insulin is maintained in part by the small number of multinational corporations that dominate the insulin market and the complex and opaque pricing and supply chain [14].

The structure of human insulin is not patent protected, but the market has shifted to the production of genetically modified insulin analogues, in large part because the pharmaceutical industry has seen fit to incrementally innovate, raise the price, and phase out the old forms of insulin [10,14]. Insulin analogues are marketed as having additional benefits such as fast or long-acting properties and labeling for pediatric or pregnant patients. However, many experts argue that the originally approved human insulin is just as effective for most patients [15,16], so it is difficult to say whether patients who, because of lack of insurance and/or socio-economic inequalities [17,18], should be literally paying the price for insulin analogues when human insulin may well be as effective.

Only now, with intellectual property (i.e., patents) for many insulin analogues having recently expired or expiring soon [19], have biosimilar insulin analogues been marketed. However, there is still no inexpensive supply of insulin biosimilars for people living with diabetes in North America, and Americans are paying a steep price for the ‘continued rejuvenation’ of this medicine [10]. Meanwhile, at least 11 insulin biosimilars are marketed (under less stringent regulatory frameworks) at considerably lower price points in China, India, Mexico, Pakistan, Peru, and Thailand [20]. Studies comparing a handful of these biosimilars to innovator insulins showed no meaningful differences [19,20].

It is difficult for potential biosimilar manufacturers to compete in the US because the regulatory system explicitly favors existing manufacturers. First, the main purpose of clinical trials is to establish similarity to an innovator biologic, not clinical benefit per se [21,22]. This emphasis on proof-of-similarity strongly favors the pharmaceutical companies that produced the original as only they have access to the confidential manufacturing protocols.

Additionally, while competitors wishing to manufacture a biosimilar are subject to strict regulatory oversight, changes by existing manufacturers rarely require clinical trials, and the resulting biosimilar is treated as interchangeable [23]. This discrepancy is deemed excusable because a manufacturer that modifies its own processes is supposed to have extensive knowledge and information about the product. It is thus no surprise that the first insulin biosimilar approved in the US, Basaglar1 (Box 2), was produced by Eli Lilly, which already owned 20% of the market share for insulin [24].

While generic drugs are typically 80% less expensive than the equivalent name-brand medications, Basaglar1 is only 15% cheaper than the innovator biologic Lantus1 [25]. The minimal cost saving associated with biosimilar insulins likely has little to do with manufacturing cost; the market value of pharmaceutical insulin is over $1000 per gram [9], while insulin costs roughly $50–75 per gram to manufacture [24]. Instead, costs are largely set by the intellectual property holders in response to the complex regulatory environment surrounding biologic drugs. Developers of biohacked insulin will thus have to navigate both intellectual property and regulatory hurdles in order to develop a more affordable model for insulin production.

#### IP – that prevents the creation of cheap, generic medicine

Greene 15 Jeremy A. Greene, M.D., Ph.D [I received an MA in medical anthropology from Harvard in 2004, the MD and PhD degrees in the history of science from Harvard in 2005]., and Kevin R. Riggs, M.D., M.P.H., March 19, 2015, “Why Is There No Generic Insulin? Historical Origins of a Modern Problem”, New England Journal of Medicine 372:1171-1175, <https://www.nejm.org/doi/full/10.1056/NEJMms1411398> DD AG

Reducing the problem of generic insulin to the contemporary debate over biosimilarity ignores the historical reason why we have always lacked generic insulin: incremental innovation has repeatedly precluded the formation of a generic-insulin industry in North America when earlier patents expired. The history of insulin hasn't followed the standard chronology of pharmaceutical innovation, in which patent monopolies predictably give way to generic competition.

Viewed in historical perspective, insulin is not a single entity but a family of related products that has evolved through incremental improvements. Subsequent iterations of insulin represented actual innovations, each one being safer, more effective, or more convenient than its predecessor. And yet after generations of incremental innovation, insulin may be no more affordable than it was when the original patent holders sold their stake for $1 to ensure access to this essential medicine.

Pharmaceutical-industry analysts have described a repatenting tactic called evergreening, in which a series of related patents — often on metabolites or optical isomers — extend the life of a product after initial patent expiration.23 Evergreening can shift market share within a family of products: for example, after Pfizer lost patent exclusivity on the antiepileptic agent gabapentin (Neurontin) in 2004, it retained a healthy share of the market through patents on a metabolic cognate, pregabalin (Lyrica). Critics of evergreening often claim that the incremental innovations leading from a given drug to a “me-too” drug are trivial: pregabalin, for example, is not clearly safer or more efficacious than gabapentin.

But the cascading generations of insulin products can hardly be dismissed as simply “me-too” medicines. Protamine insulin offered a distinct advantage over regular insulin, NPH insulin offered a distinct advantage over protamine insulin, and so on. On the whole, insulin today is demonstrably safer and more convenient to use than products available in 1923. But whether each incremental innovation is worth the price we pay, in a world where insulin remains unaffordable to many patients with diabetes, is less certain. When lente insulin was introduced in the 1950s, some observers questioned whether its minimal theoretical advantages over NPH warranted the complexity introduced by adding another insulin formulation to the market.24 The theoretical advantages offered by the monocomponent extract insulins may sometimes have been outweighed by the inconvenience and risk caused by transitioning patients to an insulin of different potency.25 Although recombinant insulin was heavily advertised as a clinically superior agent in the 1980s (Figure 1), almost no evidence was provided to demonstrate its superiority to the best available animal-extract insulins.26 Although long-acting analogues cause less hypoglycemia than NPH does,27 it has yet to be shown that analogues lead to better long-term outcomes than standard recombinant human insulin does.28

No doubt for many patients, these incremental innovations were worth the added price. What's surprising is that the trailing edge of old insulin products did not generate a market for generic competition but rather became a set of obsolete products that were promptly removed from the U.S. market. Pork and beef insulins are not merely underutilized, they are unavailable for human use in the United States. Even when practitioners prescribe NPH and R insulin in place of insulin glargine and insulin aspart, these cheaper prescriptions are filled with newer recombinant products sold under brand names. And yet on the whole, it's hard to say that contemporary patients who cannot afford their insulin (let alone the patent-protected glucometers and test strips required to adjust the dose) are well served by having as their only option an agent that is marginally more effective than those that could have been generically available 50 or 30 or 10 years ago, had generics manufacturers introduced cheaper versions when patents expired.

Generic-drug companies have evidently not considered it worthwhile to invest in the additional good manufacturing practices needed to produce a version of insulin that may already be obsolete, when off-patent small-molecule drugs represented lower-hanging fruit. Only recently, with insulin-analogue patents expiring and no next-generation products on the horizon, have prominent generics manufacturers shown serious interest in the insulin market.

It is hard to overstate the economic and public health impact of generic drugs in improving access to safe, effective, inexpensive medications in the United States. In the early 1960s, fewer than 1 in 10 medicines dispensed in pharmacies were generic, and most prescription drugs were effectively monopolies. Today, more than 80% of prescriptions are filled with generics, which saves the health care system billions of dollars each year.29,30 These savings are critical both for payers that are squeezed by rising health care costs and for patients, because lower medication costs are associated with better adherence31 and better outcomes.32

But the case of insulin demonstrates that the generics market is like other markets — not an automatic phase in the life cycle of a drug. As the increasing waves of generic-drug shortages in the past decade also remind us, the drugs that ultimately see extensive generic competition differ from those that attract few, if any, manufacturers. The history of insulin highlights the limits of generic competition as a public health framework. Nearly a century after its discovery, there is still no inexpensive supply of insulin for people living with diabetes in North America, and Americans are paying a steep price for the continued rejuvenation of this oldest of modern medicines.

#### This isn’t just a one off – it’s been happening for the last century

Peccoud 18 Jean Peccoud [Prof. Jean Peccoud joined the department in January 2016 as the Abell chair in synthetic biology.], 9-13-2018, "After a century, insulin is still expensive – could DIYers change that?," Conversation, <https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822> DD AG

Soon after Federick Banting discovered that insulin could be used to treat diabetes in 1921, he sold the patent to the University of Toronto for about a dollar. Banting received the Nobel prize because his discovery meant a life-saving drug could become widely available. Nearly a century later, an American with diabetes can pay as much as US$400 per month for insulin, driving some uninsured patients to desperate and dangerous measures. Clearly, something went wrong.

Our lab studies biosecurity, so when we heard that a group of do-it-yourself biologists was working to solve the insulin affordability problem by figuring out how to manufacture insulin patent-free, we got to know them. After digging into the insulin affordability issue, we argue that what’s keeping insulin expensive is not patents – it’s regulations. By operating in a regulatory blind spot, DIYers could upset the status quo for drug production.

Discovering and developing drugs is expensive. Patents help drug companies recoup the costs from their investments by granting them a monopoly for a limited time. Once the patent expires, competing companies can begin producing generics: off-brand versions of a patented drug. This healthy competition drives prices down.

So why, with the original patent long-expired, is there still no affordable generic insulin?

The insulin for purchase today is not the same insulin used to treat diabetic patients nearly 100 years ago. That insulin came primarily from animals. Today, insulin is brewed up by microbes that have been genetically engineered with the gene for human insulin.

And insulin is seldom injected with an old-fashioned syringe and needle anymore. Now there are insulin pens, pumps, test strips and other devices that improve the quality of life for diabetic patients. Pharmaceutical companies have also modified the chemical formula to produce faster-acting or longer-lasting insulins.

With each of these inventions came a new patent.

But the benefits of these “improved” insulins are debatable, and there’s nothing preventing competing companies from selling older, long off-patent versions of insulin. So what’s the holdup?

Regulations keep insulin expensive

Insulin is a biologic drug, which means it’s produced by a living organism, not a chemical reaction. This process, called biomanufacturing, is more inconsistent than chemical synthesis of non-biologic drugs like aspirin.

Making reliable biologic drugs is a little like winemaking. Even though the winemaker carefully follows a well-established process, minute differences will affect the final product. It’s always wine, but some vintages are better than others and tasting the wine is the only way to evaluate the final product.

So if a new company wants to make insulin, that insulin has to be tested on patients in expensive clinical trials. Bringing a biologic drug to market can cost as much as $250 million. No company can afford that lump if it can’t file for a patent to recoup the investments.

That’s why there’s only one “generic” insulin available so far. It’s made by a company that was already a major player in the insulin market, and it’s only 15 percent cheaper than the patented version. By comparison, most non-biologic generic drugs cost 80 percent less than the original.

Obviously, regulations are important for keeping insulin safe, but at what cost? Ten percent of people living with diabetes in the U.S. are uninsured, and there are nearly 10,000 crowdfunding campaigns related to insulin on the site GoFundMe alone. Stories about diabetic patients ending up hospitalized or worse because they tried to ration their insulin are all-too common.

Tha’s key - according