## 1NC R1

### 1NC – CP

#### CP: “Member nations of the WTO” should declare medical inequality a national emergency based on [aff] and issue compulsory licenses for relevant medicines. Member nations should offer regulatory and legal assistance to nations filing a compulsory license.

#### It’s goldilocks - protects patents while allowing urgent access – the perm or the aff shatters IP protections while the CP strikes an accepted balance

**Bacchus 2020** (James, Adjunct Fellow, Cato Institute, former U.S. Representative (D-FL), and former Chairman, World Trade Organization’s Appellate Body. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” *Cato* <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#balancing-ip-rights-access-medicines-not-new-wto> December 16, 2020)DR 21

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”[7](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref7) But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.[8](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref8)

After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”[9](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref9) In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.[10](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref10) In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.[11](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref11)

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance **struck by the members of the WTO** between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

Does a Novel Virus Present Novel Issues?

Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”[12](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref12)

The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”[13](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref13)

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines.

In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”[14](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref14)

India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”[15](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref15) But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market.

Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. **Subordinating IP rights temporarily** to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth **in the 21st century is increasingly** ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus **preventing** the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules **recognize that “intellectual property rights are private rights”** and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### Compulsory licensing solves access and spills over to distribution of green tech - empirics and past precedent

* AT: Can’t manufacture—can import from foreign firms
* AT: Prices still high—MNC’s lower price to avoid CL

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\*\*\*Note: EST= Environmentally Sound Technologies\*\*\*

Even though there are limits to their effectiveness, compulsory licences are considered a valuable tool for governments to facilitate access to medicines through the prevention of patent abuses as well as the “encouragement of domestic capacities for manufacturing pharmaceuticals”. 289 According to the UNDP Human Development Report (2001), after the adoption of the TRIPS Agreement, compulsory licences were initially mainly used in Canada, Japan, the UK and the United States for products such as pharmaceuticals – particularly as a remedy to address anti-competitive practices and prevent higher prices – while no compulsory licence was issued then in developing countries largely due to pressure from Europe and the United States and the fear of long and expensive litigation against the pharmaceutical industry.290 As demonstrated in Section 5.4.1.2, in order to address developing countries’ concern, the 2001 Doha Declaration explicitly reaffirmed the right of countries to issue compulsory licences where necessary, in the interests of public health.

In order to enable countries with insufficient manufacturing capacity in the pharmaceutical sector to benefit from the compulsory licensing system, the WTO General Council adopted the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (the so-called paragraph 6 system).291 This decision essentially expanded the TRIPS flexibilities, involving two waivers: (1) with respect to the exporting country, a “waiver” of obligations to use the authorised compulsory licence predominantly for the supply of the domestic market under Article 31(f); and (2) with regard to the importing country, a waiver of the adequate remuneration requirement under Article 31(h) when remuneration is paid in the exporting Member. “Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorised in the exporting Member”. 292

In 2005, WTO Members agreed to make the waivers permanent by amending the TRIPS Agreement.293 With the approval of two-thirds of the WTO Members, the amendment entered into force on 23 January 2017. As the very first legal amendment to a WTO multilateral agreement, it was said to have shown that “[M]embers are determined to ensure the WTO’s trading system contributes to humanitarian and development goals”. 294 Likewise, such amendment could be extended to address other global concerns such as climate change in accordance with the WTO’s sustainable development objective and Articles 7 and 8 of the TRIPS Agreement.

In effect, the compulsory licensing system established within the WTO framework is not a panacea, but rather a legal guarantee of rights and ability to make effective use of compulsory licences. Since the adoption of the Doha Declaration, a number of developing countries (e.g., Thailand, Brazil, Ecuador, India and Indonesia) have issued compulsory licences to lower the price of patented medicines such as HIV/AIDS drugs.295 Additionally, in 2007, Rwanda became the first country without sufficient manufacturing capacities to use the WTO “paragraph 6 system” to import Apo-TriAvir from Apotex, a Canadian firm.296 Commentators note that since the Doha Declaration was adopted in 2001, the threat of compulsory licenceshas motivated multinational companies to “voluntarily make proactive efforts to realistically make their drugs accessible**”** either through dramatically lowering the price or by offering voluntary licences on favourable terms.297 Meanwhile, many countries have successfully used the threat of compulsory licences as leverage in drug price negotiations with pharmaceutical companies.298

The positive role of compulsory licences and the threat thereof in promoting access to medicines could inspire WTO Members to use the compulsory licensing instrument to pursue other public policy objectives such as mitigating climate change. Despite being public-health-specific, the Doha Declaration and the TRIPS Amendment set a welcome precedent in guaranteeing Members’ right and ability to make effective use of the compulsory licensing for the protection of other general public interests such as environmental protection. Bearing this in mind, the following sections examine the feasibility, opportunities and challenges of compulsory licences for EST transfer.

6.4.4.2 Compulsory Licences for Transfer of ESTs: Feasibilities and Opportunities

The TRIPS Agreement does not contain any explicit limitations on the grounds upon which compulsory licences may be granted.299 This is reaffirmed by Paragraph 5(b) of the Doha Declaration, emphasising that each Member has the right to grant compulsory licences upon the grounds it determines. As discussed in Section 1.1, climate change is “a common concern of mankind” and tackling climate change is clearly in the public interest. Thus, WTO Members have the power to grant compulsory licences for patented ESTs on the ground that such ESTs are needed to achieve climate change mitigation. This view has been endorsed by many commentators, considering that climate change mitigation could provide a valid ground for compulsory licence of ESTs.300

As previously demonstrated, read in accordance with the WTO’s sustainable development objective and Articles 7 and 8 of the TRIPS Agreement, Article 31 provides regulatory space for Members to use compulsory licences to facilitate the transfer of ESTs. Members’ right and discretion to use compulsory licences in the context of climate change is further supported by developed countries’ commitments to transfer ESTs under Article 4.5 of the UNFCCC which serve as a contextual element for the interpretation Article 31. Specially speaking, WTO Members not only enjoy great discretion to grant compulsory licences for EST patents on different grounds but also have certain flexibilities in applying the conditions for the granting of compulsory licences.

As to the grounds for compulsory licensing, first, Members may issue compulsory licences for the lack of local working of certain EST patents. To the extent that local production of certain patented ESTs is needed to mitigate climate change, such local working requirements constitute a bona fide distinction rather than discrimination as to whether products are imported or locally produced in Article 27.1. As demonstrated in Section 6.4.2.2, some countries, such as Brazil, permit compulsory licences in cases where the invention is not (sufficiently) exploited locally.301

Second, Members may issue compulsory licences to address IP-related abuses and anti-competitive practices in the process of the transfer of ESTs. As pointed out by Reichman et al. (2008), compulsory licences for anticompetitive practices afford countries another set of options to facilitate the access to patented ESTs, “especially when foreign firms refuse to deal with local firms or refuse to make technologies available at prices that local firms can afford”. 302 In this case, compulsory licensing may proceed without prior negotiation efforts and the licensee may exploit the patent at issue regardless of the location of the predominant market.303

Third, WTO Members may consider climate change as a “national emergency or other circumstances of extreme urgency” within the meaning of Article 31(b), thereby permitting compulsory licensing for certain EST-related patents. The TRIPS Agreement neither defines the concept of “national emergency” or “other circumstances of extreme urgency” nor does it provide guidance for what is meant by these concepts. Again the Doha Declaration affirms that “[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency”, but added that “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”. 304 According to Correa (2002), the reference to “HIV/AIDS, tuberculosis, malaria and other epidemics” suggests that an “emergency” may not be restricted to a short-term problem, but can also be a long-lasting situation, and such recognition implies that “specific measures to deal with an emergency may be adopted and maintained as long as the underlying situation persists, without temporal constraints”. 305 The Rio+ 20 Outcome Document (A/RES/66/288) reaffirms that “climate change is one of the greatest challenges of our time” and stresses that combating climate change represents “an immediate and urgent global priority”. 306 The preamble of the 2015 Paris Agreement explicitly recognises that climate change poses an “urgent threat”. 307 Accordingly, WTO Members, in particular, those countries suffering the most from climate change, may well argue that climate change constitutes “a national emergency” or another circumstance of “extreme urgency” within the meaning of Article 31(b) of the TRIPS Agreement, therefore permitting compulsory licences for certain EST-related patents. No prior negotiations are needed for such licences, which would therefore promote rapid access to critical ESTs by the countries concerned.

Turning to the conditions for the granting of compulsory licences, although these conditions are strict, interpreting these clauses in their context in accordance with the WTO’s sustainable development objective and Articles 7 and 8 of the TRIPS Agreement would provide Members some policy space to facilitate the transfer of patented ESTs. As discussed in Section 6.4.3.1.1, the procedural requirement that a licence must be considered “on its individual merits” (Article 31(a)) does not prevent WTO Members from setting parameters for the granting of compulsory licences regarding certain categories of technologies that are needed to mitigate climate change. As discussed in Section 6.4.3.2.1, Article 31(h) embodies substantial flexibilities in determining the level of, and the basis upon which, adequate remuneration is paid and, in particular, the need for the transfer of ESTs could be an important consideration in establishing the level of compensation.

In general, compulsory licensing is seen as a means of ensuring easy access to, and wide dissemination of, ESTs throughout the world.308 The use of compulsory licences and the threat thereof to ensure the availability and affordability of essential medicines have provided a powerful precedent supporting that such licences could be used to facilitate access to essential ESTs.309 As is the case with essential medicines described above, not only compulsory licences are indispensable when an EST-patent holder refuses to transfer the essential technologies at all, but often the mere threat to impose a compulsory licence may compel the EST-patent holder to engage in voluntary licensing or lower the price of the patented ESTs.310 As mentioned in Section 6.4.2.1, using compulsory licences to facilitate access to ESTs have been recommended by Agenda 21 and incorporated into the US Clear Air Act. Therefore, countries, at least those with sufficient technological capabilities, can facilitate access to patented ESTs by using or threatening to use compulsory licences in accordance with the relevant rules set forth in the TRIPS Agreement.311

#### Diffusion occurs and solves climate. The issue is inexperience and lack of political will

* At: WTO backlash- CL for climate now, just from U.S.
* AT: Royalties- cheaper with them than making own
* AT: Can’t manufacture- CL lets them buy from foreign firms- Article 31

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Much of the discussion on technology transfer has been concerned with the issue of climate change mitigation. However, for developing countries, technology would probably be more important for adaptation. They will need technology in agriculture so that **crops can withstand the impacts of climate change**. They will need technology to deal with water stress, greater occurrence of existing diseases, and the arrival of new diseases.

The Intergovernmental Panel on Climate Change (IPCC) has listed the various hurdles to technology transfer, including high capital costs, limited access to capital, poor access to information, institutional and administrative difficulties in developing technology transfer contracts, lack of infrastructure to absorb riskier technologies, absence of economic incentives, and IPRs (Metz et al. 2000). Sale or licensing of intellectual property is an important component of transfer of technology in the international context.

Technologies protected by IPRs need to be licensed. The nature of the IPR regime is an issue in so far as it determines the terms of licensing. Therefore, there is a great likelihood of production and usage costs increasing because of payments made to obtain licences. In some case, the owner may just refuse to grant a licence altogether as such technologies are used as barriers to entry (Aoki and Small 2004). DuPont, for example, refused to grant licence for the production of chlorofluorocarbon substitutes to Korean and Indian firms that sought **to meet the phase-out requirements for ozone-depleting substances** (South Centre 2001). Such refusal can further dampen the diffusion of technology. Often, production of relevant goods that embody such technology is cheaper in developing countries even after payments of royalties. Given this context, it has been suggested that the issuance of compulsory licences can be a tool for faster diffusion of climate-friendly technologies (Barton 2007; Khor 2008).

4.3 Compulsory licensing. Compulsory licence, a statutorily created licence that allows others to pay a royalty and use an invention without the patentee’s permission, is an important feature of IPR law. It also includes the government authorizing itself to use an otherwise protected intellectual property without having to obtain the permission or authorization of a patent holder in cases of national emergency or use towards a public good. The issue of compulsory licensing becomes a case for consideration when a patent holder is not willing to share the technology with others voluntarily. Compulsory licensing introduces competition in the markets and hence makes the relevant goods and services cheaper.

The term compulsory licence does not figure as such in the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). However, it can be read into the provision of the Agreement on other use (of the patented subject matter) without authorization of the right holder. Exceptions to the rights of patent holders11 and principles on measures for preventing the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology also provide reasonable flexibility for resorting to the provision of compulsory licensing.12

In the US, 28 USC 1498 is the seminal legal provision relating to the government use of patents and copyrights. The process provided under this provision empowers the US government to use and authorize the use of a patent without any requirement to seek a licence or negotiate the use. It also entitles the patent right owner to compensation by fi ling a suit in the US Court of Federal Claims for recovery of his “reasonable and entire compensation”.

The US has a long history of compulsory licensing, which has been mostly used as an antitrust remedy in cases of patent abuses. In Besser Manufacturing, the court quoted compulsory licensing as “a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief.”5 Similarly in the Glaxo Group case, the court stated that “mandatory selling on specifi ed terms and compulsory patent licensing at reasonable charges are recognized antitrust remedies.”6 The General Electric case is an interesting case in which the court required General Electric to issue “free” licences for light bulb patents to its competitors. 7 In the Microsoft Corporation case the district court endorsed compulsory licensing as “a remedy closely connected with the theory of liability in this case …. To ensure that no practices likely to result in monopolization….provisions plainly fall within public interest.”

There also exists a host of specific environmental and health legislation in the US that provide for the targeted licensing of specific technological applications to meet public health needs and specific environmental objectives like air pollution control. 42 USC Sec 7608 provides for mandatory licensing of air pollution prevention inventions under Title 42 (Public Health and Welfare) under the Clean Air Act. Mandatory patent licences have also been granted under Section 308 of the Clean Air Act.9 The defence sector has been one of the major consumers of the compulsory licenses issues by the US government.

In Europe, although compulsory licensing has not been as frequent as in the US, the IMS Health case is considered to be a landmark case in this regard. In this case, the European Court of Justice laid down certain conditions under which a compulsory licence can be granted.10 In the Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, prior negotiations in circumstances of national emergency and public noncommercial usage have been waived. In such cases, payment for a patent licence has been fixed at 4 percent of the remuneration given by the importing country.

Some South Asian countries too have legal provisions for compulsory licensing. Sections 84 and 92 of the Indian Patent Act 1970 (along with revisions) relate to the issuance of compulsory licences. The Act states that after three years from the date of sealing of a patent, an interested party may apply to the Controller for the grant of a compulsory license alleging that the reasonable requirements of the public with respect to the invention have not been satisfi ed or that the invention is not available at a reasonable price (CUTS 2006). Pakistan also has similar provisions. Under Sri Lanka’s Intellectual Property Act No 36 of 2003, compulsory licences can be issued only in extreme cases. This could be because Sri Lanka signed a bilateral agreement with the US in 1991 limiting the grounds for the use by Sri Lanka of compulsory licensing of patents.

Article 31 (c) of the TRIPS Agreement also provides that a country can use such a measure “to remedy a practice determined after judicial or administrative process to be anti-competitive”. Hence, countries can invoke their competition law where “abuse of dominance” is included as one of the anti-competitive practices and the source of dominance is an IPR. However, the provision also requires that the possibilities of obtaining a voluntary licence must be exhausted before a compulsory licence is sought. Similarly, Article 40 of the TRIPS Agreement dealing with control of anti-competitive practices in contractual licences provides that: “Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.” Hence, refusal to give a licence along with under-servicing of the market can also be interpreted as an anti-competitive practice. The right of WTO members to make use of compulsory licences in the interest of public health has been explicitly recognized in the Doha Declaration on Public health and the August 2003 Decision by WTO members. Pursuant to these, the General Council of the WTO amended the TRIPS Agreement on 6 December 2005.13

A compulsory licence can be granted in cases such as meeting government requirements, abuse of patent rights, national emergency, public non-commercial use and technical advance of considerable economic significance over the existing patent. Accordingly, Thailand issued a compulsory licence in late 2006 for five years on Efavirenz, an AIDS drug patented by Merck. Brazil followed suit in 2007.

The TRIPS Agreement recognizes countries’ freedom to determine what constitutes national emergency in their context. While the flexibility rests with countries to determine when and in which cases compulsory licences can be used, in the absence of any specifications or directives, there is bound to be some confusion or conflict. To make use of the provisions for compulsory licensing for diffusion of climate-friendly technologies, first and foremost, climate change mitigation has to be treated as a public good. It is also important to lay down detailed guidelines and specifications to help a country identify a technology that can be eligible for the issuing of a compulsory licence. Similarly, eligibility criteria for the countries may be specified.

Under the World Intellectual Property Organization’s Development Agenda, some developing countries have talked about the use of compulsory licensing to promote greater access to technologies. However, developed countries, particularly, the US and the EU, have argued that compulsory licensing and its effects thereof would also send a strong signal to potential and current investors that their investment is not safe and welcome (WIPO 2005). Interestingly, it is not developing countries who invented the concept of compulsory licensing. As discussed above, it has been used on several occasions in the US and the EU. In particular, the US has been quite an enthusiastic user of it. However, the US and the EU feel that developing countries may not be “responsible” enough in its use.

The IPR issue is included in many regional and bilateral trade agreements—mostly of the North-North and North-South variety—as well. However, by and large, such agreements adopt higher standards of IPR protection, meaning that they will make compulsory licensing more difficult. The IPR-related provisions in the North American Free Trade Agreement (NAFTA) are similar to those of the TRIPS Agreement, which allows the use of compulsory licences without specifying the grounds for issuing them.

However, NAFTA also provides for detailed provisions on the rights of patent owners in the case of compulsory licensing, and since its coming into force, there has been a significant reduction of compulsory licences both in the US and Canada (Kommerskollegium 2008). Some bilateral trade agreements signed by the US have even more restrictive provisions. For example, four such bilateral agreements (US-Vietnam, US-Jordan, US-Singapore and US-Australia) limit the use of compulsory licensing to emergency situations, anti-trust remedies, and cases of public non-commercial use (Fink and Reichenmiller 2005).

The real effectiveness of compulsory licensing to promote transfer of technology, however, will depend on the market conditions of the relevant products and technologies. It is important that there are capable and willing fi rms to receive a compulsory licence. This will require a sufficient number of firms producing the same or similar products. Markets for climate-friendly products and technologies are unlikely to meet such conditions as they are highly concentrated. The concentration is even higher in particular segments of the industry (Sawhney 2006). If a firm remains a virtual monopoly for a sufficiently long period of time, then it becomes extremely difficult for any other firm to enter that industry. If there is no firm with adequate capability to receive a compulsory licence of some technology and use it, a mere legal provision for compulsory licensing is of little use.

The US is the world’s largest producer of environmental technologies and occupies about 33 percent share of the international market. The other major suppliers are the EU (particularly Germany) and Japan. The Office of Environmental Industries of the US proudly claims that developing nations simply do not have the technologies (Nanda 2008a). It is very likely that the situation would be quite similar in the case of technologies that relate to climate change mitigation.

In a recent study based on patenting between 1978 and 2003, it was found that innovation in climate change technologies is highly concentrated in three countries, namely Japan, Germany and the US, which accounts for two thirds of total climate innovations in 13 technologies (Dechezleprêtre et al. 2008). If developing countries need to make use of compulsory licensing in order to make these technologies better accessible, they will need domestic companies with manufacturing capabilities. However, they are unlikely to have such capabilities in most of these technologies.

Developing countries will find it difficult to make compulsory licences work in climate-friendly products and technologies, as most of them do not have much production capabilities. Indeed, production capacities are limited in developing countries also because they do not have access to the technologies. These products are very different from pharmaceutical products. For example, Bangladesh, an LDC, has capabilities to produce pharmaceutical products, but a relatively advanced developing country like India does not have much capability in climate change mitigation technologies.

#### Balancing patent protection with rapid transfer of green tech is the only way to solve climate change

**Probst et al. 2021** (Benedict Probst, University of Cambridge. PhD on economics of clean energy transition from the University of Cambridge. Simon Touboul, MINES Paris Tech, PSL University, Matthieu Glachant MINES ParisTech and Antoine Dechezleprête, OECD. “Global Trends in the Innovation and Diffusion of Climate Change Mitigation Technologies,” pre-print under review in *Nature Portfolio.* <https://www.researchsquare.com/article/rs-266803/v1> Last updated Feb. 2021)DR 21

After almost two decades (1995-2013) of increasing patenting rates in low-carbon technologies, our analysis shows an overall decline in CCMT-patenting trends since 2013. Low fossil-fuel and carbon prices, as well as lower private and public funding for low-carbon technologies after the financial crisis, have likely contributed to the decline. This decline is worrisome, particularly because a range of studies shows that the availability of low-carbon technologies is critical for mitigating dangerous climate change 33. While there is an overall decline in patenting, our analysis also shows that the least affected is the ICT-sector.

Over the last decade, the concentration of CCMT innovation in few (mostly high-income) countries has remained largely stable. This concentration indicates that existing climate policies and market forces have not led to a more diverse set of CCMT-inventing countries. Nonetheless, both China (ranked 5th in global CCMT inventions) and Taiwan (7th) have caught up substantially over the last decade. China is also the major recipient of CCMT from high-income countries, receiving 72% of transferred technologies from high to middle-income countries from 2013-2017. Yet, overall emerging economies remain less specialised in CCMT technologies than the global average. The lack of specialisation of emerging economies in CCMT also points towards a more fundamental challenge: many emerging economies may be hesitant to fully engage in a low-carbon transition if there are few jobs in the low-carbon sector of the economy to which existing jobs in high-carbon sectors can be shifted (e.g., coal mining).

Our findings indicate two important lessons: First, there is a dangerous downward trend in low-carbon inventions. It is particularly worrisome that the Paris Agreement does not appear to have reversed the downward trend in low-carbon patenting. Second, our findings underscore the need for more transfers to developing and emerging economies where most CO2-emissions increases are set to occur. While global transfers do not merely occur between industrialised countries, most of the transfers from high-income to middle-income countries go to China. Hence, transferring more technologies to other emerging economies – such as South Africa, Brazil, and Russia – is critical to mitigating climate change.

#### Short-term action to mitigate climate change solves extinction and nuclear war

**Pester 8/30/21** (Patrick, staff writer for Live Science. His background is in wildlife conservation and he has worked with endangered species around the world. Patrick holds a master's degree in international journalism from Cardiff University in the U.K. and is currently finishing a second master's degree in biodiversity, evolution and conservation in action at Middlesex University London. Citing **Luke Kemp, a research associate at the Centre for the Study of Existential Risk at the University of Cambridg**e in the United Kingdom AND **Michael Mann, PhD, distinguished professor of atmospheric science at Penn State**. “Could climate change make humans go extinct?” [https://www.livescience.com/climate-change-humans-extinct.html August 30](https://www.livescience.com/climate-change-humans-extinct.html%20August%2030), 2021)DR 21

According to Mann, a global temperature increase of 5.4 degrees Fahrenheit (3 degrees Celsius) or more could lead to a collapse of our societal infrastructure and massive unrest and conflict, which, in turn, could lead to a future that resembles some Hollywood dystopian films.

One way climate change could trigger a societal collapse is by creating food insecurity. Warming the planet has a range of negative impacts on food production, including increasing the water deficit and thereby reducing food harvests, [Live Science previously reported](https://www.livescience.com/58891-why-2-degrees-celsius-increase-matters.html). Food production losses can increase human deaths and drive economic loss and socio-political instability, among other factors, that may trigger a breakdown of our institutions and increase the risk of a societal collapse, according to a study published Feb. 21 in the journal [Climatic Change](https://go.redirectingat.com/?id=92X1590019&xcust=livescience_us_1191050396230939400&xs=1&url=https%3A%2F%2Flink.springer.com%2Farticle%2F10.1007%2Fs10584-021-02957-w&sref=https%3A%2F%2Fwww.livescience.com%2Fclimate-change-humans-extinct.html).

Related: [Has the Earth ever been this hot before?](https://www.livescience.com/65927-has-earth-been-this-hot-before.html)

Past extinctions and collapses

Kemp studies previous civilization collapses and the risk of climate change. Extinctions and catastrophes almost always involve multiple factors, he said, but he thinks if humans were to go extinct, climate change would likely be the main culprit.

"If I'm to say, what do I think is the biggest contributor to the potential for human extinction going towards the future? Then climate change, no doubt," Kemp told Live Science.

All of the major [mass-extinction events](https://www.livescience.com/mass-extinction-events-that-shaped-Earth.html) in Earth's history have involved some kind of climatic change, according to Kemp. These events include cooling during the Ordovician-[Silurian](https://www.livescience.com/43514-silurian-period.html) extinction about 440 million years ago that wiped out 85% of species, and warming during the [Triassic](https://www.livescience.com/43295-triassic-period.html)-[Jurassic](https://www.livescience.com/28739-jurassic-period.html) extinction about 200 million years ago that killed 80% of species, Live Science previously reported. And more recently, climate change affected the fate of early human relatives.

While [Homo sapiens](https://www.livescience.com/homo-sapiens.html) are obviously not extinct, "we do have a track record of other hominid species going extinct, such as [Neanderthals](https://www.livescience.com/28036-neanderthals-facts-about-our-extinct-human-relatives.html)," Kemp said. "And in each of these cases, it appears that again, climatic change plays some kind of role."

Scientists don't know why Neanderthals went extinct about 40,000 years ago, but climatic fluctuations seem to have broken their population up into smaller, fragmented groups, and severe changes in temperature affected the plants and animals they relied on for food, according to the [Natural History Museum](https://www.nhm.ac.uk/discover/who-were-the-neanderthals.html) in London. Food loss, driven by climate change, may have also led to a tiny drop in Neanderthal fertility rates, contributing to their extinction, [Live Science previously reported](https://www.livescience.com/65594-neanderthal-fertility-led-to-extinction.html).

Climate change has also played a role in the collapse of past human civilizations. A [300-year-long drought](https://www.livescience.com/38893-drought-caused-ancient-mediterranean-collapse.html), for example, contributed to the downfall of ancient Greece about 3,200 years ago. But Neanderthals disappearing and civilizations collapsing do not equal human extinction. After all, humans have survived climate fluctuations in the past and currently live all over the world despite the rise and fall of numerous civilizations.

Homo sapiens have proven themselves to be highly adaptable and able to cope with many different climates, be they hot, cold, dry or wet. We can use resources from many different plants and animals and share those resources, along with information, to help us survive in a changing world, according to the [Smithsonian’s National Museum of Natural History](https://humanorigins.si.edu/research/climate-and-human-evolution/climate-effects-human-evolution).

Related: [How would just 2 degrees of warming change the planet?](https://www.livescience.com/58891-why-2-degrees-celsius-increase-matters.html)

Today, we live in a global, interconnected civilization, but there's reason to believe our species could survive its collapse. A study published on July 21 in the journal [Sustainability](https://www.mdpi.com/2071-1050/13/15/8161/htm) identified countries most likely to survive a global societal collapse and maintain their complex way of life. Five island countries, including New Zealand and Ireland, were chosen as they could remain habitable through agriculture, thanks to their relatively cool temperatures, low weather variability and other factors that make them more resilient to climate change.

New Zealand would be expected to hold up the best with other favorable conditions, including a low population, large amounts of good quality agricultural land and reliable, domestic energy. So, even if climate change triggers a global civilization collapse, humans will likely be able to keep going, at least in some areas.

Turning on ourselves

The last scenario to consider is climate-driven conflict. Kemp explained that in the future, a scarcity of resources that diminish because of **climate change could** potentially create conditions for wars that threaten humanity. "There's reasons to be concerned that as water resources dry up and scarcity becomes worse, and the general conditions of living today become much, much worse, then suddenly, the threat of potential nuclear war becomes much higher," Kemp said.

Put another way, climate change impacts might not directly cause humans to go extinct, but it could lead to events that seriously endanger hundreds of millions, if not billions, of lives. A 2019 study published in the journal [Science Advances](https://advances.sciencemag.org/content/5/10/eaay5478) found that a nuclear conflict between just India and Pakistan, with a small fraction of the world's nuclear weapons, could kill 50 million to 125 million people in those two countries alone. Nuclear war would also change the climate, such as through temperature drops as burning cities fill the atmosphere with smoke, threatening food production worldwide and potentially causing mass starvation.

What's next?

While avoiding complete extinction doesn't sound like much of a climate change silver lining, there is reason for hope. Experts say it isn't too late to avoid the worst-case scenarios with significant cuts to greenhouse gas emissions.

"It is up to us," Mann said. "If we fail to reduce carbon emissions substantially in the decade ahead, we are likely committed to a worsening of already dangerous extreme weather events, inundation of coastlines around the world due to melting ice and rising sea level, more pressure on limited resources as a growing global population competes for less food, water and space due to climate change impacts. If we act boldly now, we can avoid the worst impacts."

### 1NC – DA

#### Biotech R&D is set for high growth and investment now

NASDAQ 8/9 [NASDAQ is a stock market index that includes almost all stocks listed on the Nasdaq stock exchange. Along with the Dow Jones Industrial Average and S&P 500, it is one of the three most-followed stock market indices in the United States. This article was written by NASDAQ contributors and published on CNBC. The editorial staff of CNBC did not contribute to the creation of this study.) “Why the Nasdaq Biotechnology Index is poised for a run of sustainable growth” CNBC, NASDAQ, 8/9/2021, <https://www.cnbc.com/advertorial/2021/08/09/why-the-nasdaq-biotechnology-index-is-poised-for-a-run-of-sustainable-growth-.html>] RM

Between the recent bio innovation success stories in the battle against Covid-19 and the technology-driven advances ushering in new efficiencies for research and development (R&D), **the biotech industry has never been more relevant**.

As home to more than 265 companies, the pioneering Nasdaq Biotechnology Index (NBI) has long been committed to providing healthcare’s innovators with access to the capital they need to keep moving forward. Now, investors have access to the Index’s companies through a new ETF, the Invesco Nasdaq Biotechnology ETF (IBBQ).

Launched in 1993, in the wake of the original “biotech revolution” led by the discovery of recombinant DNA, NBI® remains the most representative index in the space. In fact, 98% of all U.S. listed biotech companies are listed on Nasdaq. When considering the massive growth taking place in the sector, it’s no surprise that NBI has outperformed both the S&P 500 (SPX) and Health Care Select Sector Index (IXVTR) in certain market environments.

According to Mark Marex, Index R&D Senior Specialist for Nasdaq who recently compiled an in-depth report on the NBI, global events and digital acceleration have contributed to the Index’s recent strong performance; and Nasdaq’s dedication to maintaining a true benchmark for technology-driven healthcare innovation has provided a framework for growth.

Building the ideal benchmark

Given the existence of pureplay biotech firms, hybrid biopharmaceutical companies, and less R&D-intensive pharmaceutical manufacturers, creating a single benchmark that truly captures the biotech sector and the symbiotic relationships among its players is no easy task.

One of the unique aspects of NBI, versus biotech-focused indexes created by other index providers, is its subsector classifications split between Biotechnology and Pharmaceuticals. As of June 30, 2021, ICB (FTSE Russell’s Industry Classification Benchmark) classified 222 NBI companies as Biotechnology and 47 as Pharmaceuticals. The resulting split by index weight is approximately 65% and 35%, respectively, which illustrates the major difference between the two groups: Pharmaceutical companies tend to be much larger than Biotechnology firms.

This split within a single index provides advantages for investors: While offering some exposure to more established pharmaceutical companies, it also includes R&D-heavy biotech firms that over time may transition into biotech-driven pharma companies. That’s exactly what happened this year when NBI’s largest company, Amgen (AMGN / $144Bn), was reclassified by ICB from Biotechnology to Pharmaceuticals. By retaining firms as they straddle the two classifications over the course of their lifecycle, NBI presents potential growth advantages when compared with index providers that focus rigidly on one classification versus the other.

Home to world-changing breakthroughs

Nasdaq’s vision for the Index has served it well, **both in terms of its longevity and its current role as a champion of the companies paving the way for a post-pandemic world through their technological advances and life-saving treatments**. The broad reach of NBI constituents across multiple fronts in the fight against Covid-19, for example — from diagnosis to vaccines and treatment —demonstrates the strength of its core approach.

NBI companies including Gilead and Regeneron made headlines for their successes during the pandemic with antiviral therapeutics and antibody-based therapeutics for high-risk patients. But it’s the stunning success of m-RNA vaccine technology from Moderna and BioNTech, two NBI companies, that most clearly showcase the home run potential among the biotech entrepreneurs in the space.

And while NBI is currently up 8.2% YTD on a price-return basis (as of June 30) **versus a broader market gain of 14.4% by SPX**, the S&P Biotechnology Select Industry Index (SPSIBI) is down 3.7%.

It’s worth noting that in 2020, NBI outperformed SPX with a price gain of 25.7% versus 16.3%, respectively. This shows the resilience of the NBI and the inherent strength of its current mix of companies.

The possibilities of accelerated R&D

As a whole, the life-changing work being done by NBI constituents requires enormous amounts of R&D. In 2020, R&D expenses for the entire group totaled $68.5Bn, nearly 31% of these companies’ revenue totals. Two-thirds of NBI’s firms reported R&D expenses that exceeded their revenues

For several NBI companies, however, these massive investments provided tangible benefits in the fight against Covid-19. Undoubtedly, years of back-end work and minimal profits ultimately helped deliver the very products that are now driving historic returns. Psychologically, their breakthroughs demonstrated the enormous potential of science and technology to serve humankind.

Looking ahead, **revolutions in Mapping and Engineering processes, boosted by rapid advancements in Machine Learning and Artificial Intelligence, are fostering a true fusion of Biology and Technology that could transform the traditionally costly and labor-intensive R&D function**. Some research estimates these advances could reduce the failure rate of drugs by up to 45% and shorten drug trials by up to 50%. The result could be even more breakthroughs, performed much more efficiently, greatly increasing the returns on biopharmaceutical R&D.

Even a conservative interpretation of the above numbers would significantly reduce R&D costs and boost the market capitalization of therapeutics companies from the current $2Tn up to $9Tn as soon as 2024, according to estimates from ARK Financial.

Meanwhile, increasingly cost-effective human genomics could revolutionize several other industries, from agriculture to biofuels.

By any measure, there is much to be excited about across the spectrum of biotech — especially coming out of a global pandemic. And while no person, nor index, can truly predict what the future holds, chances are strong that companies sitting within NBI will have a hand in leading the way.

“**For investors**, the Index already serves as a fascinating lens through which to view human society’s scientific and technological advancements,” says Mark Marex. “To me, it’s very exciting to ponder what the researchers, scientists, and business leaders in this space will accomplish next.”

#### IPR protections are key to sustain healthcare investments and manufacturing. Independently, it’s key to broader vaccine production.

Roberts 6/25/21 [James M. Roberts is a Research Fellow for Economic Freedom and Growth at the Heritage Foundation. Roberts' primary responsibility as one of The Heritage Foundation's lead experts in economic freedom and growth is to edit the Rule of Law and Monetary Freedom sections of [Index of Economic Freedom](https://www.heritage.org/index/). An influential annual analysis of the economic climate of countries throughout the world, the Index is co-published by Heritage and The Wall Street Journal.) “Biden’s OK of Global Theft of America’s Intellectual Property is Wrong, Dangerous.” 6/25/2021, The Heritage Foundation, Commentary—Public Health] RM

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.

**Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes**.

The best way to prevent and treat new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

Three U.S. companies—Pfizer, Moderna, and Johnson & Johnson—created and manufactured the world’s most effective mRNA COVID vaccines in record time. An increasing majority of Americans have now been inoculated, but much of the developing world remains in desperate need of vaccines. Americans naturally want to help. The question is how.

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines. This, he said, would help make the vaccines more plentiful and available in needy countries. **It’s a short-sighted approach and doomed to fail.**

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them.

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. **It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.**

Signaling that the United States will not fight to defend their intellectual property rights **actively undermines innovation and manufacturing** in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the **future development of vaccines** needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, **compulsory licensing legalizes the theft of intellectual property**. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding.  **It is and has been a bulwark of American prosperity**, but the strength of that protection has been weakening in the past few decades. **Compulsory licensing contributes to the erosion** of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

**The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production**.

That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### COVID was a precursor to deadlier pandemics—vaccine production will determine everything.

Lander 8/4/21 [Eric Lander, President Biden’s Science Advisory and Director of the White House Office of Science and Technology Policy) “Opinion: As bad as Covid-19 has been, a future pandemic could be even worse—unless we act now” 8/4/21, The Washington Post] RM

[Coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_3) vaccines can end the current pandemic if enough people choose to protect themselves and their loved ones by getting vaccinated. But in the years to come, we will still need to defend against a pandemic side effect: collective amnesia.

As public health emergencies recede, societies often quickly forget their experiences — and **fail to prepare for future challenges**. For pandemics, such a course would be disastrous.

**New infectious diseases have been emerging at an accelerating pace,** and they are spreading faster.

Our federal government is responsible for defending the United States against future threats. That’s why President Biden has asked Congress to fund his plan to build on current scientific progress to keep new infectious-disease threats from turning into pandemics like covid-19.

As the president’s science adviser, I know what’s becoming possible. For the first time in our history, we have an opportunity not just to refill our stockpiles but also to transform our capabilities. However, **if we don’t start preparing now for future pandemics, the window for action will close.**

Covid-19 has been a catastrophe: The toll in the United States alone is [more than 614,000 lives](https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/?itid=lk_inline_manual_11) and has been estimated to exceed [$16 trillion](https://jamanetwork.com/journals/jama/fullarticle/2771764), with disproportionate impact on vulnerable and marginalized communities.

But a future pandemic could be even worse — unless we take steps now.

It’s important to remember that the virus behind covid-19 is far less deadly than the 1918 influenza. The virus also belongs to a well-understood family, coronaviruses. It was possible to design vaccines within days of knowing the virus’s genetic code because 20 years of [basic scientific research](https://science.sciencemag.org/content/372/6538/109.full) had revealed which protein to target and how to stabilize it. And while the current virus spins off variants, its mutation rate is slower than that of most viruses.

**Unfortunately, most of the 26 families of viruses that infect humans are less well understood or harder to control**. We have a great deal of work still ahead.

The development of [mRNA vaccine technology](https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/?itid=lk_inline_manual_17) — thanks to more than a decade of foresighted basic research — was a game-changer. It shortened the time needed to design and test vaccines to less than a year — far faster than for any previous vaccine. And it’s been surprisingly effective against covid-19.

Still, there’s much more to do. We don’t yet know how mRNA vaccines will perform against other viruses down the road. And **when the next pandemic breaks out, we’ll want to be able to respond even faster.**

Fortunately, the scientific community has been developing a bold plan to keep future viruses from becoming pandemics.

Here are a few of the goals we should shoot for:

The capability to design, test and approve safe and effective vaccines within 100 days of detecting a pandemic threat (for covid-19, that would have meant May 2020); manufacture enough doses to supply the world within 200 days; and speed vaccination campaigns by replacing sterile injections with skin patches.

Diagnostics simple and cheap enough for daily home testing to limit spread and target medical care.

Early-warning systems to spot new biological threats anywhere in the world soon after they emerge and monitor them thereafter.

We desperately need to strengthen our public health system — from expanding the workforce to modernizing labs and data systems — including to ensure that vulnerable populations are protected.

And we need to coordinate actions with our international partners, because pandemics know no borders.

These goals are ambitious, but they’re feasible — provided the work is managed with the seriousness, focus and accountability of NASA’s Apollo Program, which sent humans to the moon.

Importantly, these capabilities won’t just prepare us for future pandemics; they’ll also improve public health and medical care for infectious diseases today.

Preparing for threats is a core national responsibility. That’s why our government invests heavily in missile defense and counterterrorism. We need to similarly protect the nation against biological threats, which range from the ongoing risk of pandemics to the possibility of deliberate use of bioweapons.

Pandemics cause massive death and disruption. From a financial standpoint, they’re also astronomically expensive. If, as might be expected from [history](https://www.cfr.org/timeline/major-epidemics-modern-era) and current trends, we suffered a pandemic of the current scale every two decades, the annualized cost would exceed $500 billion per year. Investing a much smaller amount to avert this toll is an economic and moral imperative.

The White House will put forward a detailed plan this month to ensure that the United States can fully prepare before the next outbreak. It’s hard to imagine a higher economic or human return on national investment.

#### Ecosystem sensitivity from climate change means future pandemics will cause extinction—assumes COVID

Supriya 4/19 [Lakshmi Supriya got her BSc in Industrial Chemistry from IIT Kharagpur (India) and a Ph.D. in Polymer Science and Engineering from Virginia Tech (USA). She has more than a decade of global industry experience working in the USA, Europe, and India. After her Ph.D., she worked as part of the R&D group in diverse industries starting with semiconductor packaging at Intel, Arizona, where she developed a new elastomeric thermal solution, which has now been commercialized and is used in the core i3 and i5 processors. From there she went on to work at two startups, one managing the microfluidics chip manufacturing lab at a biotechnology company and the other developing polymer formulations for oil extraction from oil sands. She also worked at Saint Gobain North America, developing various material solutions for photovoltaics and processing techniques and new applications for fluoropolymers. Most recently, she managed the Indian R&D team of Enthone (now part of MacDermid) developing electroplating technologies for precious metals.) “Humans versus viruses - Can we avoid extinction in near future?” News Medical Life Sciences, 4/19/21, https://www.news-medical.net/news/20210419/Humans-versus-viruses-Can-we-avoid-extinction-in-near-future.aspx] RM

Expert argues that human-caused changes to the environment can lead to the emergence of pathogens, not only from outside but also from our own microbiome, which can pave the way for large-scale destruction of humans and **even our extinction**.

Whenever there is a change in any system, it will cause other changes to reach a balance or equilibrium, generally at a point different from the original balance. Although this principle was originally posited by the French chemist Henry Le Chatelier for chemical reactions, this theory can be applied to almost anything else.

In an essay published on the online server Preprints\*, Eleftherios P. Diamandis of the University of Toronto and the Mount Sinai Hospital, Toronto, argues that changes caused by humans, to the climate, and everything around us will lead to changes that may have a dramatic impact on human life. Because our ecosystems are so complex, we don’t know how our actions will affect us in the long run, so humans generally disregard them.

Changing our environment

Everything around us is changing, from living organisms to the climate, water, and soil. Some estimates say about half the organisms that existed 50 years ago have already become extinct, and about 80% of the species may become extinct in the future.

As the debate on global warming continues, according to data, the last six years have been the warmest on record. Global warming is melting ice, and sea levels have been increasing. The changing climate is causing more and more wildfires, which are leading to other related damage. At the same time, increased flooding is causing large-scale devastation.

One question that arises is how much environmental damage have humans already done? A recent study compared the natural biomass on Earth to the mass produced by humans and found humans produce a mass equal to their weight every week. This human-made mass is mainly for buildings, roads, and plastic products.

In the early 1900s, human-made mass was about 3% of the global biomass. Today both are about equal. Projections say by 2040, the human-made mass will be triple that of Earth’s biomass. But, slowing down human activity that causes such production may be difficult, given it is considered part of our growth as a civilization.

Emerging pathogens

Although we are made up of human cells, we have almost ten times that of bacteria just in our guts and more on our skin. These microbes not only affect locally but also affect the entire body. There is a balance between the good and bad bacteria, and any change in the environment may cause this balance to shift, especially on the skin, the consequences of which are unknown.

Although most bacteria on and inside of us are harmless, gut bacteria can also have viruses. If viruses don’t kill the bacteria immediately, they can incorporate into the bacterial genome and stay latent for a long time until reactivation by environmental factors, when they can become pathogenic. They can also escape from the gut and enter other organs or the bloodstream. Bacteria can then use these viruses to kill other bacteria or help them evolve to more virulent strains.

An example of the evolution of pathogens is the cause of the current pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several mutations are now known that make the virus more infectious and resistant to immune responses, and strengthening its to enter cells via surface receptors.

The brain

There is evidence that the SARS-CoV-2 can also affect the brain. The virus may enter the brain via the olfactory tract or through the angiotensin-converting enzyme 2 (ACE2) pathway. Viruses can also affect our senses, such as a loss of smell and taste, and there could be other so far unkown neurological effects. The loss of smell seen in COVID-19 could be a new viral syndrome specific to this disease.

Many books and movies have described pandemics caused by pathogens that wipe out large populations and cause severe diseases. In the essay, the author provides a hypothetical scenario where a gut bacteria suddenly starts producing viral proteins. Some virions spread through the body and get transmitted through the human population. After a few months, the virus started causing blindness, and within a year, large populations lost their vision.

Pandemics can cause other diseases that can threaten humanity’s entire existence. **The COVID-19 pandemic brought this possibility to the forefront**. If we continue disturbing the equilibrium between us and the environment, we don’t know what the consequences may be and **the next pandemic could lead us to extinction.**

### 1NC – Framing

#### The standard is maximizing expected well-being

#### 1) Actor-specificity: side constraints freeze action because government policies always require trade-offs since they have finite resources—the only justifiable way to resolve those conflicts is by benefiting everyone. Actor-specificity first -- different agents have different ethical obligations.

#### 2) No act-omission distinction – choosing to omit is an act itself – governments actively decide not to act so there is no omission. Also, If we foresee a consequence, then it is intrinsic to our action since we intend it to happen

#### 3) Util is a lexical pre-requisite to any other framework: Threats to life preclude the ability for moral actors to effectively utilize and act upon other moral theories since they are in a constant state of crisis – that inhibits the ideal moral conditions which other theories presuppose, which turns and outweighs their framework.

#### 4) Phenomenal introspection --- it’s the most epistemically reliable --- historical moral disagreement over internal conceptions of morality such as race prove the fallibility of non-observational based ethics --- introspection means we value happiness because we can determine that we each value it --- just as I can observe a lemon’s yellowness, we can make those judgements about happiness.

#### 5) Only consequentialism explains degrees of wrongness—if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first.

#### 6) Reject calc indicts:

#### A] Empirically denied—both individuals and policymakers carry out effective cost-benefit analysis which means even if decisions aren’t always perfect it’s still better than not acting at all

#### 7) High magnitude, low probability first

Bostrom 13 [(Nick, Philosopher and professor (Oxford), Ph.D. (LSOE), director of The Future of Humanity Institute and the Programme on the Impacts of Future Technology), “Existential Risk Prevention as Global Priority,” Global Policy, Vol 4, Issue 1, http://www.existential-risk.org/concept.html] TDI

The maxipok rule 1.1. Existential risk and uncertainty An existential risk is one that threatens the premature extinction of Earth-originating intelligent life or the permanent and drastic destruction of its potential for desirable future development (Bostrom 2002). Although it is often difficult to assess the probability of existential risks, there are many reasons to suppose that the total such risk confronting humanity over the next few centuries is significant. Estimates of 10-20% total existential risk in this century are fairly typical among those who have examined the issue, though inevitably such estimates rely heavily on subjective judgment.1 The most reasonable estimate might be substantially higher or lower. But perhaps the strongest reason for judging the total existential risk within the next few centuries to be significant is the extreme magnitude of the values at stake. Even a small probability of existential catastrophe could be highly practically significant (Bostrom 2003; Matheny 2007; Posner 2004; Weitzman 2009). Humanity has survived what we might call natural existential risks for hundreds of thousands of years; thus it is prima facie unlikely that any of them will do us in within the next hundred.2 This conclusion is buttressed when we analyze specific risks from nature, such as asteroid impacts, supervolcanic eruptions, earthquakes, gamma-ray bursts, and so forth: Empirical impact distributions and scientific models suggest that the likelihood of extinction because of these kinds of risk is extremely small on a time scale of a century or so.3 In contrast, our species is introducing entirely new kinds of existential risk — threats we have no track record of surviving. Our longevity as a species therefore offers no strong prior grounds for confident optimism. Consideration of specific existential-risk scenarios bears out the suspicion that the great bulk of existential risk in the foreseeable future consists of anthropogenic existential risks — that is, those arising from human activity. In particular, most of the biggest existential risks seem to be linked to potential future technological breakthroughs that may radically expand our ability to manipulate the external world or our own biology. As our powers expand, so will the scale of their potential consequences — intended and unintended, positive and negative. For example, there appear to be significant existential risks in some of the advanced forms of biotechnology, molecular nanotechnology, and machine intelligence that might be developed in the decades ahead. The bulk of existential risk over the next century may thus reside in rather speculative scenarios to which we cannot assign precise probabilities through any rigorous statistical or scientific method. But the fact that the probability of some risk is difficult to quantify does not imply that the risk is negligible. Probability can be understood in different senses. Most relevant here is the epistemic sense in which probability is construed as (something like) the credence that an ideally reasonable observer should assign to the risk's materializing based on currently available evidence.4 If something cannot presently be known to be objectively safe, it is risky at least in the subjective sense relevant to decision making. An empty cave is unsafe in just this sense if you cannot tell whether or not it is home to a hungry lion. It would be rational for you to avoid the cave if you reasonably judge that the expected harm of entry outweighs the expected benefit. The uncertainty and error-proneness of our first-order assessments of risk is itself something we must factor into our all-things-considered probability assignments. This factor often dominates in low-probability, high-consequence risks — especially those involving poorly understood natural phenomena, complex social dynamics, or new technology, or that are difficult to assess for other reasons. Suppose that some scientific analysis A indicates that some catastrophe X has an extremely small probability P(X) of occurring. Then the probability that A has some hidden crucial flaw may easily be much greater than P(X).5 Furthermore, the conditional probability of X given that A is crucially flawed, P(X|¬A), may be fairly high. We may then find that most of the risk of X resides in the uncertainty of our scientific assessment that P(X) was small (figure 1) (Ord, Hillerbrand and Sandberg 2010).

#### 8) Extinction first---ethical obligation to future generations and forecloses infinite potential value.

GPP 17 – [(Global Priorities Project, Future of Humanity Institute at the University of Oxford, Ministry for Foreign Affairs of Finland) "Existential Risk: Diplomacy and Governance," 2017, Global Priorities Project, <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>] TDI

In his book Reasons and Persons, Oxford philosopher Derek Parfit advanced an influential argument about the importance of avoiding extinction:

I believe that if we destroy mankind, as we now can, this outcome will be much worse than most people think. Compare three outcomes:

(1) Peace.

(2) A nuclear war that kills 99% of the world’s existing population.

(3) A nuclear war that kills 100%.

(2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). I believe that the difference between (2) and (3) is very much greater. ... The Earth will remain habitable for at least another billion years. Civilization began only a few thousand years ago. If we do not destroy mankind, these few thousand years may be only a tiny fraction of the whole of civilized human history. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second.65

In this argument, it seems that Parfit is assuming that the survivors of a nuclear war that kills 99% of the population would eventually be able to recover civilisation without long-term effect. As we have seen, this may not be a safe assumption – but for the purposes of this thought experiment, the point stands. What makes existential catastrophes especially bad is that they would “destroy the future,” as another Oxford philosopher, Nick Bostrom, puts it.66 This future could potentially be extremely long and full of flourishing, and would therefore have extremely large value. In standard risk analysis, when working out how to respond to risk, we work out the expected value of risk reduction, by weighing the probability that an action will prevent an adverse event against the severity of the event. Because the value of preventing existential catastrophe is so vast, even a tiny probability of prevention has huge expected value.67

Of course, there is persisting reasonable disagreement about ethics and there are a number of ways one might resist this conclusion.68 Therefore, it would be unjustified to be overconfident in Parfit and Bostrom’s argument.

In some areas, government policy does give significant weight to future generations. For example, in assessing the risks of nuclear waste storage, governments have considered timeframes of thousands, hundreds of thousands, and even a million years.69 Justifications for this policy usually appeal to principles of intergenerational equity according to which future generations ought to get as much protection as current generations.70 Similarly, widely accepted norms of sustainable development require development that meets the needs of the current generation without compromising the ability of future generations to meet their own needs.71

However, when it comes to existential risk, it would seem that we fail to live up to principles of intergenerational equity. Existential catastrophe would not only give future generations less than the current generations; it would give them nothing. Indeed, reducing existential risk plausibly has a quite low cost for us in comparison with the huge expected value it has for future generations. In spite of this, relatively little is done to reduce existential risk. Unless we give up on norms of intergenerational equity, they give us a strong case for significantly increasing our efforts to reduce existential risks.

### Case

#### Expertise, processes, bio samples, cell lines, distribution, and cost are all alt causes to TRIPs – only IPR can reliably scale high quality low cost medicine

Shultz and Stevens 1/14 Mark Schultz is the Goodyear Endowed Chair in Intellectual Property Law at the University of Akron School of Law, United States. Philip Stevens is Executive Director of Geneva Network., Geneva Network, "Why intellectual property rights matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19", January 14th, 2021, https://geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/ - BD

The real challenges

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to The Lancet: “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

John-Arne Røttingen, chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.

“Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months. Unfortunately, it is not as simple as putting a recipe on the internet”

The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, he says.

Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a range of issues need to be considered such as regulatory bottlenecks; supply chain, transport and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population.

The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official estimate of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarved by the other economic costs of the pandemic.

IP is part of the solution

Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done.

This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China’s BioKangtai (200m doses), Brazil’s FioCruz, Russia’s R-Pharm and South Korea’s SK Bioscience. Collectively, such deals will see the manufacture of 2 billion doses by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers. Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middle-income countries.

IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment.

Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The Lancet Global Health concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear inter-company competition and economies of scale.

But again, these licenses model were criticised by public health NGOs and other stakeholders, who called for the confiscation of IP rights via compulsory licensing. Time has shown such calls to be mistaken.

Conclusion

As of January 2021, there are three vaccines approved by stringent regulatory authorities with several more likely to follow in the coming months. Prices of COVID-19 vaccines vary between more expensive but complex to manufacture, and cheaper ones based on existing technologies. Companies are offering their vaccines at cost, with pooled procurement mechanisms such as COVAX ready to leverage their enormous purchasing power to drive economies of scale and bring prices down further for developing countries, many of which will have the cost of vaccination subsidised by Overseas Development Assistance.

Meanwhile, the existence of multiple vaccines means there is no COVID-19 vaccine “monopoly”, and minimal risk of premium pricing. In fact, there is a competitive marketplace in which manufacturers are incentivised to refine and improve their vaccines – vital given

the new strains of the virus which constantly emerge.

Providing COVID-19 vaccines rapidly at scale is a pressing challenge for all countries but there is no evidence that overriding intellectual property rights will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil.

Manufacturing of COVID-19 vaccines is continuing at speed, and mechanisms are gearing up to ensure a rapid global role out. Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside.

Instead of sowing division and creating major distractions at venues such as the WTO, opponents of IP should stop the rhetoric. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.

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