# 1NC

## OFF

### 1

#### Interp – the aff must only defend that the member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### Violation – they're extra topical – they fiat restrictions on to reduce IPP to the point that discoverable biological elements are not patentable, even for medicines- read the ev and hold the line- either they do

#### Vote neg for limits: extra-topicality allows them to tack on infinite planks to artificially improve aff solvency and spike out of DAs. Even if this specific instance of extra-t wasn't very abusive the counter-interp sets a precedent that the scope of aff fiat doesn't have to be bounded by the resolution, which outweighs on magnitude. There are tons of authors who call for doing various things with IPR which isn't bounded by the resolution.

#### D] Voter:

#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### Drop the debater – a) they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to, b) it deters future abuse and sets a positive norm.

#### Use competing interps – a) reasonability invites arbitrary judge intervention since we don’t know your bs meter, b) collapses to competing interps – we justify 2 brightlines under an offense defense paradigm just like 2 interps.

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance, b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms, c) chilling effect – forces you to split your 2AR so you can’t collapse and misconstrue the 2NR

### 2

#### Negate –

#### 1] member[[1]](#footnote-1) is “a part or organ of the body, especially a limb” but an organ can’t have obligations

#### 2] of[[2]](#footnote-2) is to “expressing an age” but the rez doesn’t delineate a length of time

#### 3] the[[3]](#footnote-3) is “denoting a disease or affliction” but the WTO isn’t a disease

#### 4] to[[4]](#footnote-4) is to “expressing motion in the direction of (a particular location)” but the rez doesn’t have a location

#### 5] reduce[[5]](#footnote-5) is to “(of a person) lose weight, typically by dieting” but IP doesn’t have a body to lose weight.

#### 6] for[[6]](#footnote-6) is “in place of” but medicines aren’t replacing IP.

#### 7] medicine[[7]](#footnote-7) is “(especially among some North American Indian peoples) a spell, charm, or fetish believed to have healing, protective, or other power” but you can’t have IP for a spell.

### 3

#### The role of the ballot is to determine whether the resolution is a true or false statement – anything else moots 7 minutes of the nc and exacerbates the fact that they speak first and last since I should be able to compensate by choosing – it’s the most logical since you don’t say vote for the player who shoots the most 3 points, the better player wins.

#### Reject their framing on inclusion – they exclude all offense except what follows from their specific fwk which shuts out those without the resources to prepare.

#### The ballot says vote aff or neg based on a topic and five dictionaries[[8]](#footnote-8) define to negate as to deny the truth of and affirm[[9]](#footnote-9) as to prove true which means it’s constitutive and jurisdictional.

#### Their framing justifies permissibility since it only tells you what to do in face of one problem which means everything outside that instance isn’t condemned.

### 4

#### CP text: The member nations of the world trade organization should

#### ---eliminate patent protections except for indigenous patents.

#### ---establish an international legal instrument to protect indigenous intellectual property

#### That is in line with indigenous demands.

**WIPO no date** WIPO, xx-xx-xxxx, "Traditional Knowledge and Intellectual Property – Background Brief," No Publication, <https://www.wipo.int/pressroom/en/briefs/tk_ip.html?fbclid=IwAR2iLd8fJ4lNl_fhhwQBHvCdoFEfB44H5GHIWBBb0xGPVBt1fRJT-uzUXDU> SJ//DA

The current international system for protecting intellectual property was fashioned during the age of industrialization in the West and developed subsequently in line with the perceived needs of technologically advanced societies. However**, in recent years, indigenous peoples, local communities, and governments, mainly in developing countries, have demanded equivalent protection for traditional knowledge systems. In 2000, WIPO members established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), and in 2009 they agreed to develop an international legal instrument (or instruments) that would give traditional knowledge, genetic resources and traditional cultural expressions (folklore) effective protection. Such an instrument could range from a recommendation to WIPO members to a formal treaty that would bind countries choosing to ratify it.** Traditional knowledge is not so-called because of its antiquity. It is a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. As such, it is not easily protected by the current intellectual property system, which typically grants protection for a limited period to inventions and original works by named individuals or companies. Its living nature also means that “traditional” knowledge is not easy to define. **Recognizing traditional forms of creativity and innovation as protectable intellectual property would be an historic shift in international law, enabling indigenous and local communities as well as governments to have a say over the use of their traditional knowledge by others.** This would make it possible, for example, to protect traditional remedies and indigenous art and music against misappropriation, and enable communities to control and benefit collectively from their commercial exploitation. Although the negotiations underway in WIPO have been initiated and propelled mainly by developing countries, the discussions are not neatly divided along “North-South” lines. Communities and governments do not necessarily share the same views, and some developed country governments, especially those with indigenous populations, are also active. Two types of intellectual property protection are being sought: **Defensive protection aims to stop people outside the community from acquiring intellectual property rights over traditional knowledge. India, for example, has compiled a searchable database of traditional medicine that can be used as evidence of prior art by patent examiners when assessing patent applications. This followed a well-known case in which the US Patent and Trademark Office granted a patent (later revoked) for the use of turmeric to treat wounds, a property well known to traditional communities in India and documented in ancient Sanskrit texts. Defensive strategies might also be used to protect sacred cultural manifestations, such as sacred symbols or words from being registered as trademarks.** Positive protection is the granting of rights that empower communities to promote their traditional knowledge, control its uses and benefit from its commercial exploitation. Some uses of traditional knowledge can be protected through the existing intellectual property system, and a number of countries have also developed specific legislation. However, any specific protection afforded under national law may not hold for other countries, one reason why many indigenous and local communities as well as governments are pressing for an international legal instrument. WIPO’s work on traditional knowledge addresses three distinct yet related areas: traditional knowledge in the strict sense (technical know-how, practices, skills, and innovations related to, say, biodiversity, agriculture or health); traditional cultural expressions/expressions of folklore (cultural manifestations such as music, art, designs, symbols and performances); and genetic resources (genetic material of actual or potential value found in plants, animals and micro-organisms). Although for many communities traditional knowledge, genetic resources and traditional cultural expressions form part of a single integrated heritage, from an intellectual property standpoint they raise different issues and may require different sets of solutions. In all three areas, in addition to work on an international legal instrument, WIPO is responding to requests from communities and governments for practical assistance and technical advice to enable communities to make more effective use of existing intellectual property systems and participate more effectively in the IGC’s negotiations. WIPO’s work includes assistance to develop and strengthen national and regional systems for the protection of traditional knowledge (policies, laws, information systems and practical tools) and the Creative Heritage Project which provides hands-on training for managing intellectual property rights and interests when documenting cultural heritage. Traditional knowledge When community members innovate within the traditional knowledge framework, they may use the patent system to protect their innovations. However, traditional knowledge as such - knowledge that has ancient roots and is often informal and oral - is not protected by conventional intellectual property systems. This has prompted some countries to develop their own sui generis (specific, special) systems for protecting traditional knowledge. There are also many initiatives underway to document traditional knowledge. In most cases the motive is to preserve or disseminate it, or to use it, for example, in environmental management, rather than for the purpose of legal protection. There are nevertheless concerns that if documentation makes traditional knowledge more widely available to the general public, especially if it can be accessed on the Internet, this could lead to misappropriation and use in ways that were not anticipated or intended by traditional knowledge holders. At the same time, documentation can help protect traditional knowledge, for example, by providing a confidential or secret record of traditional knowledge reserved for the relevant community only. **Some formal documentation and registries of traditional knowledge support sui generis protection systems, while traditional knowledge databases - such as India’s database on traditional medicine - play a role in defensive protection within the existing IP system. These examples demonstrate the importance of ensuring that documentation of traditional knowledge is linked to an intellectual property strategy and does not take place in a policy or legal vacuum.** In the WIPO talks, many argue that use of traditional knowledge ought to be subject to free, prior and informed consent, especially for sacred and secret materials. However, others fear that granting exclusive control over traditional cultures could stifle innovation, diminish the public domain and be difficult to implement in practice. Genetic resources Genetic resources themselves are not intellectual property (they are not creations of the human mind) and thus cannot be directly protected as intellectual property. However, inventions based on or developed using genetic resources (associated with traditional knowledge or not) may be patentable or protected by plant breeders’ rights. In considering intellectual property aspects of use of genetic resources, WIPO’s work complements the international legal and policy framework defined by the Convention on Biological Diversity (CBD), and its Nagoya Protocol, and the International Treaty on Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization. Issues under discussion at WIPO include: Defensive protection of genetic resources: This strand of the work aims at preventing patents being granted over genetic resources (and associated traditional knowledge) which do not fulfil the existing requirements of novelty and inventiveness. In this context, to help patent examiners find relevant prior art, proposals have been made that genetic resources and traditional knowledge databases could help patent examiners avoid erroneous patents and WIPO has improved its own search tools and patent classification systems. The other, more controversial, strand concerns the possible disqualification of patent applications that do not comply with CBD obligations on prior informed consent, mutually agreed terms, fair and equitable benefit-sharing, and disclosure of origin. “Biopiracy” is a term sometimes used loosely to describe biodiversity-related patents that do not meet patentability criteria or that do not comply with the CBD’s obligations – but this term has no precise or agreed meaning. Disclosure requirements: A number of countries have enacted domestic legislation putting into effect the CBD obligations that access to a country’s genetic resources should depend on securing that country’s prior informed consent and agreeing to fair and equitable benefit sharing. WIPO members are considering whether, and to what extent, the intellectual property system should be used to support and implement these obligations. Many, but not all, WIPO members want to make it mandatory for patent applications to show the source or origin of genetic resources, as well as evidence of prior informed consent and a benefit sharing agreement. Parallel discussions are also taking place in the World Trade Organization’s Council on Trade Related Aspects of Intellectual Property (TRIPS). WIPO also deals with the intellectual property aspects of mutually agreed terms for fair and equitable benefit-sharing. It has developed, and regularly updates, an online database of relevant contractual practices, and has prepared draft guidelines on intellectual property clauses in access and benefit-sharing agreements. Traditional cultural expressions Traditional cultural expressions (folklore) are seen as integral to the cultural and social identities of indigenous and local communities, embodying know-how and skills, and transmitting core values and beliefs. Protecting folklore contributes to economic development, encourages cultural diversity and helps preserve cultural heritage. Traditional cultural expressions can sometimes be protected by existing systems, such as copyright and related rights, geographical indications, appellations of origin, trademarks and certification marks. For example, contemporary adaptations of folklore are copyrightable, while performances of traditional songs and music may come under the WIPO Performances and Phonograms Treaty. Trademarks can be used to identify authentic indigenous arts, as the Maori Arts Board in New Zealand, Te Waka Toi, has done. Some countries also have special legislation for the protection of folklore. Panama has established a registration system for traditional cultural expressions, while the Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture gives “traditional owners” the right to authorize or prevent use of protected folklore and receive a share of the benefits from any commercial exploitation. Developing an international legal instrument Because the existing international intellectual property system does not fully protect traditional knowledge and traditional cultural expressions, many communities and governments have called for an international legal instrument providing sui generis protection. **An international legal instrument would define what is meant by traditional knowledge and traditional cultural expressions, who the rights holders would be, how competing claims by communities would be resolved, and what rights and exceptions ought to apply. Working out the details is complex and there are divergent views on the best ways forward, including whether intellectual property-type rights are appropriate for protecting traditional forms of innovation and creativity. To take just one example, communities may wish to control all uses of their traditional cultural expressions, including works inspired by them, even if they are not direct copies. Copyright law, on the other hand, permits building on the work of others, provided there is sufficient originality. The text of the legal instrument will have to define where the line is to be drawn between legitimate borrowing and unauthorized appropriation.** On genetic resources, countries agree that intellectual property protection and the conservation of biodiversity should be mutually supportive, but differ on how this should be achieved and whether any changes to current intellectual property rules are necessary. **Representatives of indigenous and local communities are assisted by the WIPO Voluntary Fund to attend the WIPO talks, and their active participation will continue to be crucial for a successful outcome**. WIPO members have agreed to expedite their work so as to decide in late 2012 whether to convene a diplomatic conference for final adoption of one or more international instruments.

#### Preserving native sovereignty is key to cultural diversity and preserves global survival

Barsh 93 Russel Lawrence Barsh 1993 “Native American Sovereignty” University of Michigan Journal of Law Reform, Winter, 1993, 25 U. MICH. J. L. REF. 671 (Professor of Native American Studies at the University of Lethbridge)//Elmer

There no longer seems to be much difference in the Westernization of the Third World and of the indigenous world. Indigenous societies are usually more isolated geographically, so the process of convergence is understandably slower. But they are catching up. While world leaders lament the loss of biological diversity, which holds the key to the renewal and survival of ecosystems, our planet rapidly is losing its **cultural diversity**, which holds the key to the renewal and survival of human societies. Scientists and scholars search for an alternative in their theories while real alternative cultures disappear. It will be a real struggle to reassert an **indigenous perspective** on social justice, democracy, and environmental security. The hardest part of the struggle will be converting words to action, going beyond the familiar, empty rhetoric of sovereignty and cultural superiority. The struggle will be hardest here in the United States, where the gaps between rhetoric and reality have grown greater than anywhere on earth. This is the best place to begin, however, because this is the illusory "demonstration" that is studied by the rest of the world, including the indigenous peoples of other regions. Are American Indians ready to accept this global responsibility? The current generation of tribal leadership appears unwilling to try. It is firmly committed by its actions to the materialist path, and it is neutralized by its dependence on a continuing financial relationship with the national government and developers. The next generation of American Indians may be another matter. Disillusioned and critical, they may yet find a voice of their own that is both modern and truly indigenous, and they may have the courage to practice the ideals that their parents merely sloganize. Let us hope so. There is no alternative for Indian survival or for global survival.

### 5

#### Presumption and permissibility negates – a) statements are more often false than true since I can prove something false in infinite ways b) real world policies require positive justification before being adopted c) the aff has to prove an obligation which means lack of that obligation negates d) resolved in the resolution indicates they proactively did something, to negate that means that they aren’t resolved.

#### And, either it’s the case we can predict the outcome of a situation, or we cannot. We cannot, insofar as no situation is ever replicated exactly, and even if it can, there’s no guarantee the outcome will be the same. If we can predict situations, that means everyone can, which means we will always predict each other, making a paradox of action insofar as we always attempt to predict the outcomes of each other’s actions, and will cancel out the obligations.

#### And, in order to discover something, it must not be known, but in order to know to discover something, it must already be known – this makes the quest for knowledge incomprehensible and thus impossible

#### Skep is true and negates –

#### Every reason is equally as violent in its creation.

**Derrida,** Jacques Derrida, “Force of Law: The Mystical Foundation of Authority” //Massa But **justice,** however unpresentable it may be, doesn't wait.· It **is that which must not wait.** To be direct, simple and brief, let us say this: **a just decision is always required immediately, "right away." It cannot furnish itself with** infinite information and the **unlimited knowledge of conditions,** rules or hypothetical imperatives **that could justify it.** And **even if it did** have all that at its disposal, even if it did give itself the time, all the time and all the necessary facts about the matter, **the moment of decision,** as such, **always remains a finite moment of urgency** and precipitation, since it must not be the consequence or the effectof this theoretical or historical knowledge, of this reflection or this deliberation, **since it always marks the interruption of the** juridico- or ethico- or politico-**cognitive deliberation that precedes it,** that must precede it. The instant of decision is a madness, says Kierkegaard. This is particularly true of the instant of the just decision that must rend time and defy dialectics. It is a madness. **Even if time** and prudence,the patience of knowledge and the mastery of conditions **were** hypothetically **unlimited, the decision would be structurally finite,** however late it came, decision of urgency and precipitation, **acting in** the night of **non-knowledge and non-rule**

#### Affirming negates.

**Paraphrasing Mcnamara ‘06**, Paul, 2-7-2006, "Deontic Logic (Stanford Encyclopedia of Philosophy)," No Publication, <https://plato.stanford.edu/entries/logic-deontic/index.html#4.3> //Massa

#### Premise 1—If the aff is true, it ought to be the case that members of the WTO should reduce IP protections.

#### Premise 2—It ought to be the case that the WTO reduce IP protections if and only if the members have IP protections. This is because standard logic would necessitate transferring the obligation predicate onto its necessary condition.

#### Thus, premise 3—if the aff is true, it ought to be the case that the members of the WTO has IP protections. This logically follows from “if P is Q and P is Q only if N, then N.”

#### External world skep is true.

**Neta**, Ram. “External World Skepticism.” The Problem of The External World, **2014**, philosophy.unc.edu/files/2014/06/The-Problem-of-the-External-World.pdf. //Massa

You take yourself to know that you have hands. But notice that, **if you do have hands, then you are not merely a brain floating in a vat of nutrient fluid and being electrochemically stimulated to have the sensory experiences** that you have now: such a brain does not have hands, but you do. So if you know that you do have hands, then you must also be in a position to know that you are not such a brain. **But how could you know that you are not such a brain? If you were such a brain, everything would seem exactly as it does now**; **you would** (by hypothesis) **have all the same sensory experiences that you’re having right now.** Since your **empirical knowledge of the world** around you **must somehow be based upon your sensory experiences, how could these experiences**—the very same experiences that you would have if you were a brain in a vat—**furnish you with knowledge that you’re not such a brain? And if you don’t know that you’re not such a brain, then you cannot know that you have hands.**

#### And, any account of morality is regressive since it predicates one universal rule on the existence of another moral rule. Since every human chain of reasoning must be finite according to our finite nature, such a reasoning process must terminate in a rule for which no reason can be given.

### 6

#### Reject new 1AR ROTBs –

#### 1. Infinite abuse – Reading a new ROB in the 1AR makes it so all you have to do is dump on the 1N ROB and marginally extend your warrants in the 2ar and the neg can’t do anything about it since there is no 3NR to answer the 2ar weighing or extrapolations, you already have conceded offense, all you need is the ROB.

#### 2. Reciprocity – (a) restarting the ROB debate in the 1ar puts you at a 7-6 advantage on the framing debate since I have to propose one in the 1N since 2N arguments are new – putting it in the aff makes it 13-13 (b) you have one more speech to contest my ROB and weigh, I can only possibly answer your ROB in the 2n but you can do comparative weighing in the 2ar (c) I can only read a ROB in the 1N so you should read it in your first speech as well – that’s definitionally an equal burden. Eval debate after 1nc k2 reciprocity. 3. Neg definition choice – The aff should have defined ought in the 1ac as their value, by not doing so they have forfeited their right to read a new definition – kills 1NC strategy since I premised my engagement on a lack of your definition.

#### And, reject 1AR Theory: a] double bind – Either you auto accept all responses to 2NR standards and they auto win since I can't respond, or you intervene to give 2AR credence. They’ll say it’s inevitable but it’s a sliding scale. Inevitable resolvability or intervention collapses to reasonability – which allows for substance ed and friv theory with no counter interp offense b] infinite abuse in the context of aff abuse doesn’t make sense since you can read 1ac theory and uplayer with other 1ar offs like Ks and it’s not infinite we only have 7 mins c] 7-6, 2-1 skew proves its always skewed to the aff d] they can blow up dropped arguments in the next speech and I don’t have the chance to frame them out but they can which means only dropped arguments for them are game over – turns infinite abuse. Drop the argument and RVIs on 1ar theory – a] they can initiate offensive drop the debater theory in the aff and in the 1ar while no judge would vote on 2n theory on severance B] 1AR being able to spend 20 seconds on a shell and still win forces the 2N to allocate at least 2:30 on the shell which means RVIs check back time skew – outweighs on quantifiability. Reject new 1AR paradigm issues – they have 1 more speech than me on theory so they can go for them in multiple - the 1NC paradigm issues respond to 1ac paradigm issues in mind so new ones moot theoretical offense.

## Case

#### TRIPS IP rights are key for innovation

James Bacchus 20, adjunct scholar at CATO, “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” December 16th, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-virus-present-novel-issues>

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 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

#### Weakening patents is worse – eliminates funds for R&D and halts pharma innovations that prevents an effective development of a right to health.

Sarah Joseph 11, Professor of Human Rights Law, and the Director of the Castan Centre for Human Rights Law at Monash University, Sarah, “Blame it on the WTO?” http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199565894.001.0001/acprof-9780199565894-chapter-8#acprof-9780199565894-note-1350

IP protection restricts trade and competition, so IP clauses are somewhat anomalous in trade agreements, which are normally designed to decrease trade barriers. What is the justification for IP protection?44 Due to their relevance to this chapter, I will concentrate on arguments in favour of patents.45 Patents reward people for their inventions, thus encouraging creativity and innovation. Patents operate on the assumption that people are not inherently altruistic, and expect rewards for their endeavours, especially when those endeavours are risky as they may, and often do, result in costly failure.46 Furthermore, the money raised from patent protection is said to be necessary to fund the considerable costs of research and development (R&D).47 Therefore, without patents, innovation in the pharmaceutical field (or any industrial field) might grind to a standstill. While it is true that the high prices generated by patent protection may render access to drugs selective, (p.221) it is nevertheless better that a drug is available to some rather than non-existent and available to no one. The global extension of patent law mandated by TRIPS helps to ensure that patents are not undermined by the sale of competing pirated copies. Furthermore, global IP regimes should theoretically encourage greater technology transfer between countries, greater foreign direct investment, and greater local innovation within compliant states.48 All of these outcomes should accelerate the economic development of poor countries, with positive knock-on effects for human rights. Thus, perhaps it is arguable that pharmaceutical patents are justifiable under international human rights law, as they promote R&D which is essential for the future enhancement of rights to life and health. Furthermore, to the extent that they are held by natural persons, they are one way of protecting that person’s rights under Article 15(1)(c) of the ICESCR.

#### Pharma innovation is doing great now – answers all your warrants.

Lisa Jarvis, 1-17-2020, "The new drugs of 2019," Chemical &amp; Engineering News, <https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3> //Jay

Although pharmaceutical companies last year were unable to top the record-shattering [59 new drugs approved in the US in 2018](https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2018/97/i3), they were still on a roll. In 2019, the Food and Drug Administration green-lighted 48 medicines, a crop that includes myriad modalities and many new treatments for long-neglected diseases. Taken together, the past 3 years of approvals represent drug companies’ most productive period in more than 2 decades. Still, some analysts caution that the steady flow of new medicines could mask troubling indications about the health of the industry. The year brought several notable trends. The first was an uptick in the number of novel mechanisms on display in the new drugs. Roughly 42% of the medicines were first in class, meaning they had new mechanisms of action; this is a jump over the prior 4 years, when that portion ranged between 32 and 36%. Another trend was the influx of newer modalities. While small molecules continue to account for the lion’s share of new molecular entities (NMEs), making up 67% of overall approvals in 2019, the list also includes several antibody-drug conjugates, an antisense oligonucleotide therapy, and a therapy based on RNA interference (RNAi). Yet another encouraging trend was the influx of innovative therapies for underserved diseases. Standout approvals include two new drugs for sickle cell anemia (Global Blood Therapeutics’ Oxbryta and Novartis’s Adakveo), an antibiotic for treatment-resistant tuberculosis (Global Alliance for TB Drug Development’s pretomanid), and a therapy for women experiencing postpartum depression (Sage Therapeutics’ Zulresso). “The quality of the drugs over the last decade or so has steadily improved since the depths of the innovation crisis 10–12 years ago,” says Bernard Munos, a senior fellow at FasterCures, a drug research think tank. “We’re seeing stuff that frankly would have looked like science fiction back then.” Those futuristic new therapies include [Novartis’s Zolgensma](https://cen.acs.org/articles/97/i22/FDA-approves-second-gene-therapy.html), a gene therapy for spinal muscular atrophy; Alnylam Pharmaceuticals’ Givlaari, the company’s second marketed RNAi-based therapy; and several critical vaccines for infectious diseases, including Ebola, smallpox, and dengue fever. Not all those edgy therapies appear in C&EN’s list. We track approvals granted through the FDA’s main drug approval arm, the Center for Drug Evaluation and Research; drugs like vaccines and gene therapies are generally reviewed through the agency’s Center for Biologics Evaluation and Research. The new-approvals list also doesn’t include several therapies that made their way to patients for the first time, even though the FDA doesn’t consider them new drugs. For example, the agency gave its green light to Johnson & Johnson’s Spravato, making it the first new treatment option for people with major depressive disorder in more than 50 years. The drug is the S enantiomer of ketamine, an N-methyl-D-aspartate receptor antagonist that had been long approved as an anesthetic, gained notoriety as a club drug, and was used for years off label to treat severe depression ([see page 18](https://cen.acs.org/biological-chemistry/neuroscience/Ketamine-revolutionizing-antidepressant-research-still/98/i3)). Also notable in 2019 was a slight dip in the number of cancer drugs, which in recent years typically made up more than a quarter of all new medicines. Last year’s 11 cancer treatments accounted for roughly 23% of approvals.

#### IP Protections are key to the pharma sector – strong innovation solves future pandemics.

**Wilbur 20** [Tom Wilbur, Tom Wilbur is Director of Public Affairs at PhRMA focusing on message development and opinion research. Prior to joining PhRMA in 2019, Tom worked on Capitol Hill and on political campaigns for nearly a decade, most recently responsible for communications, campaigns and strategy for U.S. Rep. Fred Upton and the House Energy and Commerce Committee. 5-4-2020, accessed on 8-3-2021, Catalyst.phrma.org, "What they are saying: Intellectual property protections are critical as we work to defeat COVID-19", <https://catalyst.phrma.org/what-they-are-saying-intellectual-property-protections-are-critical-as-we-work-to-defeat-covid-19>] Adam

The U.S. biopharmaceutical industry depends on reliable intellectual property (IP) protections to promote the development of new breakthrough treatments and cures for patients. Strong IP protections are especially important while biopharmaceutical companies work around the clock to develop solutions to help prevent infection and treat those with COVID-19, a disease cause by the novel strain of coronavirus. In fact, many of the existing medicines and investigational medicines being tested for COVID-19 exist today because of IP and other incentives that drove their research and development.

Here is a closer look at recent comments spotlighting how strong IP protections help fuel discovery efforts for COVID-19 treatments and vaccines:

“The world has placed its profound confidence in the free enterprise of the leading scientists and innovators to reach as many solutions as possible in the shortest amount of time. It is obviously a heavy weight for researchers to bear, but not a burden…Removing the ability of these first responders to own their work while they are in the process, or after completion, undermines their efforts. Keeping these rights intact not only allows more knowledge-sharing in the fight against COVID-19 but also ensures long-term research to ready the fight against the next pandemic, as well.” – Philip Thomas, policy analyst at the Property Rights Alliance, in [Morning Consult](https://morningconsult.com/opinions/fighting-covid-19-doesnt-require-selling-out-our-innovation-ecosystem/)

“Good patent policy incentivizes inventors to find solutions, not merely for today’s, but for tomorrow’s problems… America’s biomedical innovators have assumed the risk of costly dead ends along the long, bumpy road to developing a successful drug, device or test that addresses COVID-19. They’ve shouldered this burden in good faith in a no-holds-barred race on all fronts — diagnostics, ventilators, personal protective equipment, therapeutics and vaccines. For many, the IP exclusivity over the terms of their patents will help offset R&D costs eaten now.” – James Edwards, IP consultant and Gene Quinn, President and CEO of IP Watchdog Inc., in [IP Watchdog](https://www.ipwatchdog.com/2020/04/08/facilitating-innovation-to-fight-coronavirus-act-legislation-mixed-bag/id=120483/)

“The Bayh-Dole Act represents one of the bedrock policies that has helped make the U.S. biomedical innovation system the envy of the world and a key place the world is now turning to in the search for an accessible coronavirus vaccine or treatment. Those who would misguidedly interpret Bayh-Dole march-in-rights as a price-control provision that could be leveraged in the coronavirus case or other circumstances advocate for an approach that threatens to seriously deter biomedical innovation and undermine a key pillar of America’s biomedical innovation system.” – Stephen Ezell, vice president for global innovation policy at the Information Technology and Innovation Foundation, in [Morning Consult](https://morningconsult.com/opinions/how-bayh-dole-act-facilitates-development-coronavirus-therapies/)

“The appropriate intellectual property framework is enabling the rapid R&D response. Many potential treatments are based on decades of prior R&D and investment or originally were pioneered to treat other conditions. These breakthroughs were enabled by a robust innovation eco-system underpinned by effective IP.” – Oscar Guinea, senior economist at the European Centre for International Political Economy and Koen Berden, executive director of international trade at the European Federation of Pharmaceutical Industries and Associations in [EFPIA News](https://www.efpia.eu/news-events/the-efpia-view/blog-articles/trade-policy-and-covid-19-openness-and-cooperation-in-times-of-a-pandemic/)

“From the birth of the modern pharmaceutical industry in the early 20th century, the U.S. patent system incentivized R&D in new drugs and medical treatments. Our scientists have led the world in creating breakthrough medical treatments. The vaccines and drug treatments they created improved the quality of life and extended lifespans for billions of people around the world. Instead of imposing more price controls and regulatory burdens, lawmakers should be bolstering legal protection for innovations in life-saving [COVID-19] treatments and cures. They should reform the patent laws to ensure investments continue in creating new cures.” – Adam Mossoff, patent law expert at Antonin Scalia Law School at George Mason University and senior fellow at the Hudson Institute, in [The Washington Times](https://www.washingtontimes.com/news/2020/mar/12/patent-term-extensions-will-help-speed-up-developm/)

“The right of exclusivity that IP, particularly patents, provides innovators is critical to developing and commercializing cutting-edge inventions in biopharma… American IP, including the right to exclude competitors during the limited duration of a patent term, is essential to our solving the current global medical crisis, continually introducing new cures and better therapies and sustaining the high-skill jobs in the life sciences sector.” – James Edwards, IP consultant in [IP Watchdog](https://www.ipwatchdog.com/2020/03/10/wont-stop-coronavirus-without-ip/)

Strong IP protections support America’s robust innovation ecosystem by striking a balance between promoting innovation and meeting the needs of patients who rely on lifesaving therapies, like those in development to treat COVID-19. America’s biopharmaceutical companies are committed to ensuring that treatments and vaccines developed for COVID-19 are available to all who need them. For more information on the importance of IP rights, visit our [IP page](https://www.phrma.org/advocacy/intellectual-property) and stay tuned for our next IP Explained post.

#### Circumvention and they don’t solve – even if they say “durable fiat”, they have not defined the scope of the plan in the 1AC so you don’t know what the plan would materially look like

Mercurio 6/24 [Simon F.S. Li Professor of Law, The Chinese University of Hong Kong, Shatin, Hong Kong. June 24, 2021. “The IP Waiver for COVID-19: Bad Policy, Bad Precedent” <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/> Accessed 8/25 //gord0]

The role of intellectual property rights (IPRs) and access to medicines is contentious. On the one hand, IPRs encourage investment, innovation and the advancement of health science. On the other hand, the limited-term monopoly rights can result in artificially high prices and become a barrier to access to medicines. While the wisdom of the IPRs system has at times been tested, it has proven its value in the current COVID-19 pandemic as IPRs played a large role in the rapid (and unprecedented) development and availability of multiple vaccines. Despite the success, India and South Africa proposed that the World Trade Organization (WTO) waive IPRs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to increase access to vaccines and other COVID-19-related technologies.[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn1) The proposal, tabled at a meeting of the TRIPS Council in October 2020, calls on Members to waive IPRs relating to and having an impact on the “prevention, containment or treatment of COVID-19”.[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn2) The proposal attracted support from the majority of developing country Members,[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn3) but was opposed by a handful of Members including the United States (US).[4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn4) Given that consensus could not be reached within the deadline of 90 days as set out in Art. IX:3 of the Agreement Establishing the WTO, Members agreed to keep the waiver proposal on the agenda of the TRIPS Council in 2021.[5](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn5) On 5 May 2021, the US reversed its position and announced that it would support a waiver for COVID-19 vaccines.[6](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn6) To be clear, this does not mean that the US supported the waiver as proposed by India and South Africa. Instead, the US has simply agreed to negotiate the perimeters of a waiver. Others, including the European Union (EU), Canada, Australia, Norway, Switzerland, the United Kingdom (UK) and even leading developing countries such as Brazil, Chile and Mexico remain opposed or lukewarm on the waiver.[7](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn7) The US dropping opposition does not mean the concerns of other Members will simply disappear – one would hope that these nations opposed the waiver for valid reasons and did not simply blindly follow the US. Indeed, many of the above-listed Members remain unconvinced that even such a draconian step as a waiver of IPRs would accomplish the goal of increased vaccine production.[8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn8) For its part, the EU continues to favour an approach which makes better use of existing flexibilities available in the TRIPS Agreement.[9](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn9) Thus, those expecting quick agreement on the waiver will be disappointed. Negotiations at the WTO are always difficult and lengthy, and US Trade Representative Katherine Tai acknowledged that the “negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”.[10](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn10) Issues of negotiation will include the scope of the waiver. Whereas the original proposal and its amended form extend the waiver beyond patents and vaccines to include nearly all forms of IP (i.e. copyright,[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn11) industrial designs and trade secrets) as well as to all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19”[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn12) (with no requirement on how or the extent to which they are related to or useful in combatting COVID-19), the US and others seem to support a waiver limited to patents and vaccines.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn13) The length of the waiver will also be a contentious negotiating issue, with proponents seeking a virtual indefinite waiver lasting until the Membership agrees by consensus that it is no longer required – meaning even a single Member’s objection to ending the waiver would mean the waiver continues to remain in force[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn14) – as will the request that any action claimed to be taken under the waiver is outside the scope of the WTO’s dispute settlement mechanism.[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn15) These provisions will almost certainly be opposed by other Members, who would perhaps agree to a time-limited waiver which could be extended rather than an unchallengeable indefinite waiver which will be difficult to reverse. The proposal also fails to mention anything in relation to transparency and notification requirements and lacks safeguards against abuse or diversion. These points will likely also prove contentious in the negotiations. With so many initial divergences and as yet undiscussed issues, the negotiations at best could be completed by the time of the next WTO Ministerial Conference, scheduled to begin on 20 November 2021. There is precedent in this regard, as previous TRIPS negotiations involving IP and pharmaceuticals were not fully resolved until the days before the Ministerial Conferences (in 2003 and 2005).[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn16) There is also a chance that the negotiations will continue past the calendar year 2021. The chance for a swift negotiation diminished with the release of a revised proposal by India and South Africa on 22 May 2021. As mentioned above, the proposal contains no limit as to product coverage, scope, notification requirements or safeguards and proposes that the waiver will remain in effect for what could be an indefinite period. This was not a proposal designed to engender quick negotiations and a solution. Instead, the proposal perhaps reveals India’s and South Africa’s true intent to use the COVID-19 pandemic as an excuse to roll-back IPRs rather than a good-faith effort to rapidly increase access to lifesaving vaccines and treatments around the world. It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn17) The US announcement remains meaningful, however, for two reasons. First, it signals a departure from the longstanding and bipartisan support for the pharmaceutical industry, which for decades has been instrumental in setting the IP and trade agenda.[18](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn18) Second, it sends a strong signal that the US does not oppose others from waiving patent protection for vaccines. This shift may also be part of a broader and alternative strategy to increase vaccine production and distribution, whereby the US is not viewing or supporting waiver negotiations as a legal tool but more so as a threat to encourage vaccine innovators to increase production. In essence, the desired reaction would be that the IP holders increase efforts to license, transfer technology and expand manufacturing – exactly what the world needs at this time. Alan Beattie, writing in the Financial Times, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[19](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[20](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the leading vaccines using mRNA are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production. Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. The know-how and trade secrets are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up. When asked if a waiver would improve vaccine availability and equity, Watal responded: “No. It won’t. That’s clear.”[21](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn21) I share Watal’s view and do not support a TRIPS waiver for IPRs or even a limited waiver for patents. With evidence mounting that “what the proposal … will definitely not achieve is speeding up the Covid-19 vaccination rate in India or other parts of the Global South”[22](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn22) I refuse to sacrifice academic integrity by supporting a proposal simply because it is gaining traction in some circles.[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn23) IPRs played a key role in delivering vaccines within a year of the discovery of a new pathogen; it seems inexplicable that the world would abandon the system without any evidence that IPRs are limiting during the current crisis.[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn24) Moreover, innovators have been generous in licensing technology transfer and production and one would be hard-pressed to find credible reports of qualified generic producers being refused a license. This is not surprising, since multiple competing vaccines are on the market it simply does not make economic sense for innovators to refuse a license – the generic manufacturer would simply obtain a license (and market share) and pay royalties to a competitor. Instead, I support efforts to enable prompt and effective use of existing flexibilities in the TRIPS Agreement and concerted and coordinated efforts involving governments and the private sector to ensure all qualified generic producers willing and capable of manufacturing vaccines are doing so and to create supply by working to bring more facilities up to standard. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one. Killing the goose that laid the golden egg may seem appealing to some in the short term but will only ensure that no eggs are delivered in the next pandemic.

1. https://www.google.com/search?q=member+definition&rlz=1C1CHBF\_enUS877US877&oq=member+definition&aqs=chrome.0.69i59j69i60l3.1863j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-1)
2. https://www.google.com/search?q=of+definition&rlz=1C1CHBF\_enUS877US877&oq=of+definition&aqs=chrome.0.69i59j69i61l3.1473j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-2)
3. https://www.google.com/search?q=the+definition&rlz=1C1CHBF\_enUS877US877&oq=the+definition&aqs=chrome..69i57j69i64j69i61j69i60l2.1976j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-3)
4. https://www.google.com/search?q=to+definition&rlz=1C1CHBF\_enUS877US877&oq=to+definition&aqs=chrome..69i57j69i60l3.1415j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-4)
5. https://www.google.com/search?q=reduce+definition&rlz=1C1CHBF\_enUS877US877&sxsrf=AOaemvI3lZsbmnXg5WHeL4m6rYGn8Vf6Aw%3A1630610232638&ei=OCMxYbCaJpO0tQb6wpGoCA&oq=reduce+definition&gs\_lcp=Cgdnd3Mtd2l6EAMyCQgjECcQRhD5ATIECAAQQzIECAAQQzIFCAAQgAQyBQgAEIAEMgUIABCABDIFCAAQgAQyBQgAEIAEMgUIABCABDIFCAAQgAQ6BwgAEEcQsAM6BwgAELADEEM6BwgjEOoCECc6BAgjECc6BQgAEJECOhEILhCABBCxAxCDARDHARDRAzoKCAAQsQMQgwEQQzoHCAAQsQMQQzoICAAQgAQQsQM6CAgAELEDEIMBOgoIABCABBCHAhAUSgQIQRgAUMLMBFjS3QRgnt8EaAJwAngDgAG2A4gB-heSAQozLjExLjEuMi4xmAEAoAEBsAEKyAEKwAEB&sclient=gws-wiz&ved=0ahUKEwiwlru9gOHyAhUTWs0KHXphBIUQ4dUDCA8&uact=5 [↑](#footnote-ref-5)
6. https://www.merriam-webster.com/dictionary/for#:~:text=English%20Language%20Learners%20Definition%20of,meant%20to%20be%20used%20with [↑](#footnote-ref-6)
7. https://www.google.com/search?q=medicine+definition&rlz=1C1CHBF\_enUS877US877&oq=medicine+definition&aqs=chrome.0.69i59.2986j0j7&sourceid=chrome&ie=UTF-8 [↑](#footnote-ref-7)
8. <http://dictionary.reference.com/browse/negate>, <http://www.merriam-webster.com/dictionary/negate>, <http://www.thefreedictionary.com/negate>, <http://www.vocabulary.com/dictionary/negate>, <http://www.oxforddictionaries.com/definition/english/negate> [↑](#footnote-ref-8)
9. *Dictionary.com – maintain as true, Merriam Webster – to say that something is true, Vocabulary.com – to affirm something is to confirm that it is true, Oxford dictionaries – accept the validity of, Thefreedictionary – assert to be true* [↑](#footnote-ref-9)