## OFF

### 1NC – T

#### Interpretation: The affirmative must stick to the full range of their specified intellectual property regulation.

#### Violation: They read patent thicketing, which is a special type of patents.

#### 1] Limits, there’s a finite number of IP laws like patents, exclusivity, trade secrets, but if you can specify one use of each then the number of affs blow up because they can use any solvency advocate that says the word patent

#### 2] Ground, this arbitrarily brackets off neg ground because if I read a patents generic you can always say that it doesn’t apply. This model disincentivizes ultra-narrow affs. If this happens in round it’s proof of abuse

#### 3] TVA, just read your aff but with only patents instead of one and done

#### Competing interps – you can’t be reasonably topical – it’s a binary question

#### No RVIs – T’s a stock issue, not a reason you should win

#### Reject the team – anything else servers out of plan text which is a voter because it moots the NC

## Off

### OFF

#### CP: Member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over providing drug innovators a single period of exclusivity for their drug. Member nations will support the proposal and adopt the results of consultation.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it – they say yes.

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of aspirational statements about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency didnoteven seem aware of the patent proceedings, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO remained deferential to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, unwilling to take on more than a spectator role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the WHO **should not be limited to a mere spectator role in such policy discussions. It** needstoplay an active advocacy role in the debate over patent law and access to essential medicines. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate over patent law and access to essential medicines. Not only could it mediate legal disputes over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and global health inequities, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of nations are indeed stronger together.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of resistance of the dangerous nationalist populism, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

## Case

### AT: Inherency

#### We contest the thesis of the aff. 3 myths contribute to the evergreening lie; contrary to popular belief, patents cannot be extended, patents do not prevent competitors from bringing drugs to market, and automatic substitution simply reflects product advertising not an issue with the patent system

Lietzan 20 (Lietzan, Erika. “The Evergreening Myth.” CATO.org, CATO, 2020, [www.cato.org/regulation/fall-2020/evergreening-myth](http://www.cato.org/regulation/fall-2020/evergreening-myth). [Erika Lietzan is the William H. Pittman Professor of Law and Timothy J. Heinsz Professor of Law at the University of Missouri School of Law. This is condensed from her forthcoming article in the University of Akron Law Review.])//LK [Accessed 8/23/2021]

Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows. Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date. There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention. Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked. First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the com

#### Patents have checks and firms are adapting – governments are increasingly critical

Atkinson and Moodie 13 (Jonathan DM Atkinson & Rachel S Moodie, Harrison Goddard Foote Patent & Trademark Attorneys, May 2013, 10.4155/ppa.13.24) simha

Opportunities to challenge evergreening patents in Europe

Both the EPO and the national courts of the European member states provide several options for third parties to challenge patents and patent applications. Prior to a grant, any person may file third-party observations on the patentability of the invention claimed. Furthermore, these observations can be filed at any stage of the proceedings and on more than one occasion if necessary. This can be done either in the name of the interested party or anonymously. In either case, the third party filing the observations does not become a party to the proceedings. This means that the third party will not be given an opportunity to respond to any comments made by the patent applicant in response to their observations. The EPO also does not correspond with the third party or notify the third party when it issues any communication nor does it notify the third party of the applicant’s response. There is no time limit or official fee for filing thirdparty observations; however, the observations will only be considered if they are filed before the patent is granted. The EPO is not obliged to consider the observations though in practice relevant observations are usually considered and acted upon. However, monitoring the official file at the EPO and judiciously choosing the moment to file carefully structured observations represents a powerful and very cost-effective way to influence, and ideally prevent, the grant of a patent application. After grant of a patent, irrespective of whether or not any third-party observations had been filed during the pendency of the application, it is possible to file an opposition to the grant of a patent. In contrast to third-party observations, the EPO is required to consider an opposition (provided that it meets certain formal requirements) and the opponent formally becomes a party to the proceedings. One advantage of filing an opposition rather than submitting third-party observations is that the patent proprietor has less flexibility in the amendments that they can make to their patent claims after the patent has granted. Furthermore, since the Opponent becomes a party to proceedings they can then participate in the prosecution of the opposition and in the final hearing at the EPO in Munich, Germany, at which the case is decided. This allows an opponent to put forward their arguments and evidence against the patent in person. Opposition proceedings are slightly more expensive than filing third-party observations but are again a very powerful and cost-effective way of revoking entirely or limiting the scope of a granted patent. Both third-party observations and opposition proceedings are centralized procedures; this means that the entire European patent can be invalidated in all of the countries in which the patent or patent application is effective. Both procedures are very economical in comparison with the cost of litigation proceedings in the event that the patent is enforced against a third party in a particular country. An important benefit associated with filing third-party observations and filing an opposition is that they can be used to attack the European patent as a whole, which saves time and cost that is otherwise associated with attacking multiple national patents through the national courts of European member states. A third strategy is for a generics company to develop their own modifications to the known pharmaceutical and to file patent applications to these developments. For example, a generics company might beat the originator to the finish line in terms of developing a particular improved formulation or a more efficient synthetic route. This strategy is being increasingly used and is now quite widespread in the industry. Of course, the generics company would not be able to commercialize these developments without a licence to the originator patent. However, the value in this strategy arises from blocking the originator from obtaining additional patent life for such a development, plus the potential to charge royalties to the originator in the event that the originator wishes to use the improved development. If the development is valuable enough, the generics company may be able to negotiate a cross-licensing deal with the Originator whereby the generics company can commercialize their development without infringing the originator patent and the Originator can commercialize the development without infringing the patent directed to the new development. The lines between Generics companies and Originator companies are becoming increasingly blurred. Generics companies now often carry original research and many Originators are embarking on generic projects to substitute the revenue lost to the patent cliff; for example, Sandoz, which is the generic pharmaceutical division of Novartis [207]. Furthermore, numerous pharmaceutical firms, upon the expiry of their patent, licence a ‘pseudo-generic company’ to compete directly against other generics firms. This strategy deters entry into smaller drug markets since competition with the pseudo-generic can deter other generic companies from investing in entering the market [208].

Future perspective

There is an important balance to be struck between protecting the legitimate innovations of pharmaceutical companies in order to foster developments for the benefit of the patient population as a whole and, at the same time, removing unfair obstacles for generic companies who aim to provide medicines at cost-effective prices. A system that balances these two objectives must provide temporary monopolies for funding breakthrough drugs whilst also eventually allowing those drugs to be relaunched as cost-effective generics. In general, the patent and regulatory systems accomplish this with a fair degree of success and it is only in limited cases, such as those case studies discussed above where issues of unfair extensions of monopolies arise. It is also clear that the authorities are not afraid of acting in cases in which they consider an abuse has arisen even if the letter of the law has been strictly complied with. The lesson for users of the system is simply that it is not sufficient merely to comply with the requirements of the law, but it is also necessary to consider their intended activities in the wider context of the market as a whole to determine whether or not they are ethical and reasonable. **Over the next 5–10 years we expect to see an increasingly critical eye** being cast over the granting of such patents, not just **by the national courts, but also by the patent granting authorities** themselves.

### AT: Solvency

#### There’s a reason the aff’s authors are blogs not lawyers – Evergreen doesn’t prolong patents -- secondary patents *only* cover the improvement, but the original patent dies regardlfess.

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

“Evergreening” – an Incoherent Concept

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — **a patent on an improved formulation,** for example**, is limited to that improvement** and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.

#### That solves pricing and monopoly- the improvement might be patented but generics of the original compound become incredibly cheap

**Holman 2016** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis. “IN DEFENSE OF SECONDARY PHARMACEUTICAL PATENTS: A RESPONSE TO THE UN’S GUIDELINES FOR PHARMACEUTICAL PATENT EXAMINATION” *Indiana Law Review* 50, 2016)DR 21

Rather than the blanket presumption against patents on new formulations endorsed by the Guidelines, which would tend to deny patent protection for both minor improvements and highly significant improvements, the needs of patients would be better served if the market and the judgment of patients and healthcare providers were allowed to determine the value of a new formulation on an existing drug. If the improvement is of such significance that it justifies a substantial cost premium, then society has benefited from the development of this improved mode of drug delivery, and payment of the premium is justified, in the same way that it is by development of a therapeutically useful new active ingredient. If the improvement is nominal, then payers should refuse to pay the premium, which they can do by simply purchasing the original formulation from generic companies at a discounted price. If there are market inefficiencies that somehow induce payers to pay the premium even though the improvement is minimal, then those market inefficiencies should be addressed, rather than attempting to address it by changing the standard for patentability in a discriminatory manner that targets specific categories of inventions.

#### It's illegal to extend a patent on the same drug—only new compounds can be patented

**Holman 2020** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis “Congress should decline ill-advised legislative proposals aimed at evergreening of pharmaceutical patent protection” *University of the Pacific Law Review*, 51(3), 493-524)DR 21

When critics of the pharmaceutical industry initially began talking about "evergreening," the discussion often seemed to imply that pharmaceutical companies were literally re-patenting the same product. However, those more familiar with patent law have responded by pointing out that, as a general matter, pharmaceutical companies are not simply re-patenting a product, and that various doctrines of patent law work in conjunction to prevent a company from obtaining new patents on a product that is **already on the market**. For example, at a May 7 Congressional Hearing entitled Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition, Professor David Olson of the Boston College Law School explained to lawmakers that:

It is axiomatic patent law doctrine that a later-filed patent (other than a continuation) cannot cover an earlier invention. Thus, no patent that covers an earlier composition or biologic is valid. To the extent that a patent owner says that a later-filed patent, with a later priority date and expiration date covers the same subject matter as an earlier-filed patent, that person is plainly wrong .... New patents can be filed on different formulations of a previous drug, on different manufacturing processes, and on new uses of previous drugs. Although some may call this "evergreening," new uses of drugs and new ways of producing them are the kinds of innovations that the patent system is designed to encourage. It would be a very significant change in patent law to change the law to not allow these kinds of patents in the pharmaceutical field.

If, on the other hand, a patent owner files new method patents and then asserts that a competitor cannot make the originally-claimed drug without infringing the new method, **the new patent** is either **invalid** or being asserted too broadly. If the patent owner uses trade secret methods to produce its drug, and later seeks to patent those trade secret methods, then the patent owner is seeking an invalid patent and can be liable for fraud on the patent office if the patent owner did not disclose that the method was used as a trade secret for more than a year before filing. 9

#### Their anticommons point make no sense, just because someone’s name is on a patent doesn’t mean they use it to their will. Companies are the ones that actually hold these patents and control what happens to the goods. This point has absolutely no link to the rest of the aff. Also prefer our recent evidence, their stuff is from 1998, a lot has changed since then

### AT: Innovation – Turn

#### One and done model kills innovation—chilling effect

**Magiera 2021** (Melissa S., J.D. Candidate, 2021, Indiana UniversityRobert H. McKinney School of Law; B.S. 2017, Indiana University Purdue University Indianapolis – Indianapolis, Indiana. Recipient of the Papke Prize for Best Note in Volume 54, endowed by and named in honor of David R. Papke, former R. Bruce Townsend Professor of Law and faculty advisor to the Indiana Law Review “Leaving the Evergreening Problem to the Patent Experts--The USPTO, the PTAB, and the Federal Circuit” Indiana Law Review, 54(1), 195-220.)DR 21

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.94 A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as “one-and-dones.” 95 Patents are meant to be issued for innovations, not for products.96 Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research “new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents.” 97 The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society. 98 Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.99 Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug. 100 If enacted, the legislation could also “erode[] incentives and threaten[] innovation,” which is what the patent system was created to protect. 101

#### Follow on innovation is key to drug development and perceptual safety

Chris **Holman 20** joined C-IP2 as a Senior Scholar in 2014, and he became the Senior Fellow for Life Sciences at C-IP2 in August 2020. He is a Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology, 2-7-2020, "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection," Geneva Network, <https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/> ]//AAli

* AZT started out as cancer drug but broke through for aids
* Lumigan cause redeye – people stopped taking it

Despite the important role of intellectual property rights in incentivizing innovation, the patenting of pharmaceutical innovation is frequently accused of impeding access to medicine. Criticism of the prevailing patent regime has focused in particular on patents directed towards follow-on innovation, i.e., innovation that seeks to improve upon existing pharmaceuticals and their use in treating patients. Patents on follow-on innovation are often derided as “secondary” patents, with the implication that the underlying inventions are somehow lesser in nature than the subject matter claimed in “primary” patents, i.e., the drug active ingredient per se. While implicitly acknowledging the legitimacy of primary patents, critics of so-called secondary patents contend that patents on follow-on innovation allow drug innovators to “evergreen” their products, i.e., to extend the period of patent exclusivity beyond the expiration of any original patent on the drug active ingredient, and in doing so contribute to the high cost of drugs, thereby limiting the ability of patients to access the drugs upon which they have come to rely. In 2015, the United Nations Development Programme (UNDP) issued a document entitled Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective (the “Guidelines”), which, in an effort to promote access to medicines, recommends that courts and patent offices implement newly heightened patentability requirements for follow-on pharmaceutical innovation that would be uniquely stringent and largely unprecedented. 1 In 2017, I challenged many of the assertions made in the Guidelines in an article entitled In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination (“Defense of Secondary Patents”), which provides numerous examples of so-called secondary patents that have withstood validity challenges in the courts and patent offices throughout the world and which were directed towards follow-on pharmaceutical innovation clearly meriting patent protection. 2 More recently, I teamed up with legal scholars Timo Minssen and Eric Solovy in authoring Patentability Standards for Follow-on Pharmaceutical Innovation (“Patentability Standards”), an article that reiterates the important role of follow-on pharmaceutical innovation in addressing compelling human health concerns, and which proposes what we consider to be the appropriate standards and criteria to be applied in assessing the patentability of this sometimes underappreciated aspect of medical innovation. 3 Why Protect Follow-On Innovation? The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was only years later that its potential application in the fight against AIDS was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate). “Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself. Compatibility with TRIPS The heightened requirements of patentability proposed in the Guidelines not only pose a threat to important follow-on pharmaceutical innovation, but if they were to be adopted could constitute noncompliance with certain international treaties, including in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), which the 164 Members of the World Trade Organization (WTO) have agreed to abide by. The TRIPS Agreement requires WTO Members to provide certain minimum levels of protection for patentable inventions, thus placing substantive limitations on the ability of WTO Members to raise the bar for patentability. The TRIPS Agreement in no way sanctions subject matter-specific heightened requirements of patentability; to the contrary, the antidiscrimination provision in the TRIPS Agreement affirmatively precludes such measures. Unfortunately, this point is all too often lost in discussions of international and domestic patent policy. Best Practices for Evaluating the Patentability of Follow-On Pharmaceutical Inventions Patentable Subject Matter In Patentability Standards my co-authors and I endorse what we believe to be the proper standards for assessing the patentability of follow-on pharmaceutical innovation, which are essentially the same standards currently being applied in the US, Europe and other nations in compliance with the TRIPS Agreement. As a general matter, inventions arising out of follow-on pharmaceutical innovation, and in particular the categories of “secondary” invention identified in the Guidelines, should be deemed patentable subject matter so long as the various substantive requirements of patentability, including novelty, non-obviousness, and practical utility are satisfied. Although the US Supreme Court’s 2012 Mayo decision appears to have rendered many diagnostic inventions patent ineligible in the United States, the Court explicitly noted that the decision was not intended to adversely affect the patent eligibility of new methods of using drugs, and the patent eligibility of drugs and drug improvements remains generally noncontroversial in the US. In particular, the Guidelines’ recommendations that new methods of using a drug should be presumptively treated as patent ineligible “discoveries,” and that drug metabolites are not patent eligible because they can be produced by physiological processes, should be rejected. An inventive method of using a drug to treat disease is a significant advance in medicine, not a mere “discovery,” and it is a mistake to conflate naturally-occurring metabolites with drug metabolites, which as a general matter are not naturally-occurring molecules and which can in many instances constitute important contributions to medicine in and of themselves. Utility / Industrial Application The requirement of utility/industrial application likewise should generally not be an issue for follow-on pharmaceutical innovation, since by their nature these inventions involve a new form or mode of use of a pharmaceutically active chemical entity of known therapeutic potential. It is important to emphasize that compliance with the utility requirement does not require a showing that the follow-on invention provide some beneficial utility not otherwise provided by the prior art. If a follow-on pharmaceutical invention does not provide any significant benefit over the prior state-of-the-art, regulatory authorities and a well-functioning market should ensure that the patent will not significantly impact access to medicine. Novelty Under the TRIPS Agreement, an invention can be denied patent protection if, as of the effective filing date, it is not novel (i.e., new) relative to the “prior art,” as defined by statute and case law in domestic systems. The prior art consists of publications and other public disclosure of the invention, and under some circumstances encompasses certain non-public uses and offers for sale. Significantly, in order to have effect the prior art generally must enable one skilled in that field of technology to make and use a claimed invention without engaging in undue experimentation. For example, the generic disclosure of a large group of molecules comprising some common structural core does not necessarily destroy the novelty of each and every molecule encompassed by that disclosure. The rationale behind this approach, which is well-established in jurisdictions such as the US and Europe, is that while a generic disclosure can easily be defined so as to encompass millions and even billions of individual molecules, it does not meaningfully enable the identification, synthesis, and clinical use of a specific molecule falling within the genus that is later found to provide some specific utilitarian benefit not shared by other members of the group. The Guidelines would upset the status quo by declaring patents directed to inventions of this type (referred to in the Guidelines to as “selection patents”) as generally invalid for lack of novelty. But if a paper disclosure encompassing a large group of molecules, the vast majority of which have never been made or tested, is deemed sufficient to render every molecule falling within the group unpatentable, the incentive for drug companies to invest in identifying and developing a potentially safe and effective pharmaceutical compound falling within the group will be severely dampened. Identifying a specific molecule with the safety and efficacy profile required of a successful human therapeutic is a veritable search for a needle in a haystack, and without the potential for patent protection in cases in which a valuable needle is recovered too many haystacks will remain inadequately searched.

#### This low innovation turns their superbugs point because innovation is key to solving

**Gallagher 16** [Chris Gallagher is now focused primarily on federal policies in Washington, DC. Chris has been involved in nearly every substantial New Hampshire economic regulatory initiative over the last 25 years. He has served as general counsel for the New Hampshire Bankers Association and has represented New Hampshire utilities, hospitals, insurers, aggregate manufacturers and numerous other entities. This experience provides him with a uniquely respected voice on Capitol Hill, enabling him to communicate effectively with members whose federal decision-making must reflect and respect the complexities of their home-state constituents. A frequent speaker and commentator in local and national media on policy issues, regarding financial services, privacy, business and government, Chris has testified on financial services issues before U.S. House and Senate Committees and has been a panelist in Capitol Hill briefings on intellectual property issues. [7-14-2016, "The superbugs are here, but where are we?," IPWatchdog, <https://www.ipwatchdog.com/2016/07/14/superbugs/id=70874/> ]AAli

* citing NIH study

In short, human failure to survive the spread of superbugs may be politically self-inflicted! In simplest terms, two overarching realities at work. First, the superbugs are here. Their expanding hordes are not just festering in some far-off foreign country. They flourish here at home. The super-bug¹s equivalent of Darwin’s species-supportive coral reef is as near as your neighborhood health care center and wherever else our formerly-effective antibiotics were made most available and mindlessly mis-used. We are incubating and accelerating their spread. So whether or not this process causes the world¹s next pandemic, it may well become our country’s next health crisis. Second, the anti-patent advocates and worldwide health care hand-wringers both are effectively pursuing IP degradation and other biopharma price controls that will kill our life science innovation ecosystem’s capacity to effectively respond to the superbugs. The system cannot work without private investment. We now are nowhere near ready to disrupt, much less degrade superbugs’ elusive shapeshifting. Worse, we are witnessing more destruction of the means to obtain effective countermeasures. Instead of encouraging the deployment of financial incentives needed to support the herculean efforts of Dr Fauci, we are doing just the opposite. Read the short NIH report, or at least the excerpts below. They describe the situation NOW. The development of new antibiotics by the pharmaceutical industry, a strategy that had been effective at combating resistant bacteria in the past, had essentially stalled due to economic and regulatory obstacles. Of the 18 largest pharmaceutical companies, 15 abandoned the antibiotic field. Mergers between pharmaceutical companies have also substantially reduced the number and diversity of research teams. Antibiotic research conducted in academia has been scaled back as a result of funding cuts due to the economic crisis. (Emphasis my own) Antibiotic development is no longer considered to be an economically wise investment for the pharmaceutical industry.14 Because antibiotics are used for relatively short periods and are often curative, antibiotics are not as profitable as drugs that treat chronic conditions, such as diabetes, psychiatric disorders, asthma, or gastroesophageal reflux. A cost­ benefit analysis by the Office of Health Economics in London calculated that the net present value (NPV) of a new antibiotic is only about $50 million, compared to approximately $1 billion for a drug used to treat a neuromuscular disease. Because medicines for chronic conditions are more profitable, pharmaceutical companies prefer to invest in them. Another factor that causes antibiotic development to lack economic appeal is the relatively low cost of antibiotics. Newer antibiotics are generally priced at a maximum of $1,000 to $3,000 per course compared with cancer chemotherapy that costs tens of thousands of dollars. The availability, ease of use, and generally low cost of antibiotics has also led to a perception of low value among payers and the public. NIH concludes as follows: Rapidly emerging resistant bacteria threaten the extraordinary health benefits that have been achieved with antibiotics.14 This crisis is global, reflecting the worldwide overuse of these drugs and the lack of development of new antibiotic agents by pharmaceutical companies to address the challenge.14 Antibiotic-resistant infections place a substantial health and economic burden on the U.S. health care system and population.1 Coordinated efforts to implement new policies, renew research efforts, and pursue steps to manage the crisis are greatly needed. Imagine what will happen if the anti patent, price controlling have their way with Congress and a new Administration. In short, the superbugs are scary. Our life science ecosystem that so effectively responded to once unmet biomedical needs is not able or ready to disarm them. As NIH notes above, the usual risk-reward incentives are badly out of balance. Predictable ROI is insufficient to attract investment, which means it is time for government, academia, biopharma, and special healthcare interest groups to close ranks and fall in behind NAIAD’s Dr Fauci. Finger-pointing slogans by self-appointed saviors of the world’s down-trodden will not end this evolutionary crisis. Caving in to big tech’s anti-patent crusade or politically imposed price controls will surely make matters worse. Relying on biopharma to fight these fights alone will not resolve the problem. The superbugs aren’t coming — they are here! We need nothing less than a collaborative life science coalition to simultaneously fight this multi fronted evolutionary battle in the courts, our research labs , our medical centers and especially on Capitol Hill. Drug developers compete in a world-wide market. Perceived return on investment (ROI) is the linchpin for life science commercialization. So in the private sector, where traditional ROI incentives no longer work patents either must be strengthened or ROI targets must be adjusted down. The only certainty in todays uncertain IP world is the politically weakening our innovation ecosystem with patent degradation and price controls is plainly counterproductive. In the global marketplace, it doesn’t matter whether foreseeable future market demand is shrunk, or predictable ROI is masked by the intrusive uncertainties of Bayh-Dole price-based March-in, Colombian compulsory licensing, Indonesian “process-product” word games, India and China’s mercantilism or Canada’s Promise Doctrine. If early stage investment in the war against the superbugs fails to enable adequate predictable ROI, commercialization and development simply will not happen.

### AT: Pandemics

#### Their impact starts at 4%

Cotton-Barratt 17 [Owen Cotton-Barratt, PhD in Pure Mathematics, Oxford, Lecturer in Mathematics at Oxford, Research Associate at the Future of Humanity Institute, 2/3/2017, Existential Risk: Diplomacy and Governance, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf]

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Islands cause burnout even in the worst-case scenario

Andie Sophia **Fontaine**, Writer for Grapvine, 10-3-20**19**, "From Iceland — Iceland May "Save Humanity From Extinction" In Event Of A Global Pandemic, Researchers Say," Reykjavik Grapevine, <https://grapevine.is/news/2019/10/03/iceland-may-save-humanity-from-extinction-in-event-of-a-global-pandemic-researchers-say/> ]//AAli

Iceland is amongst the few “island refuges” that could save the human race from complete extinction in event of a global pandemic, researchers from the University of Otago, Wellington and Adapt Research have concluded. The researchers were asked to rank 20 island nations that could act as starting points for rebuilding humanity from the ashes of a mass extinction event. One of the co-authors of the research paper, which was published in the journal Risk Analysis, believes that the risk of human extinction has never been higher, and that the threat is rising as technology advances. “Discoveries in biotechnology could see a genetically-engineered pandemic threaten the survival of our species,” co-author Professor Nick Wilson of the University of Otago said. “Though carriers of disease can easily circumvent land borders, a closed self-sufficient island could harbour an isolated, technologically-adept population that could repopulate the earth following a disaster.” The lead author of the study, Dr. Matt Boyd, goes a step farther in asserting that humans might, accidentally or on purpose, create the catalyst of their own undoing. “The worst case scenario could see multiple genetically engineered pandemic organisms being released at once,” he said. “We need to be ready for these situations. Our study shows that certain island nations have the characteristics needed to preserve technological culture through a catastrophic event,” adding, “It may be that a clear and pressing need arises where the only option for humanity is an island refuge.” The criteria by which the researchers assessed which island nations would be a good place for humanity to rebuild itself included elements such as the island nation’s location, population, resources and society. By these parameters, Australia came out on top on account of its “vast oversupply of energy and food”, followed by New Zealand and Iceland.

#### The more people that die, the lower the probability they come into contact with each other – we’re winning impact defense on multiple places

#### On superbugs in particular

#### Either they cant solve or no impact

Fikes 17 – U-T San Diego's biotechnology reporter; covered the industry since 1990, internally cites study by authors from Harvard Medical School [Bradley J., 5/11/2017, “Long before the dinosaurs, antibiotic-resistant superbugs thrived”, The San Diego Union-Tribune, <http://www.sandiegouniontribune.com/business/biotech/sd-me-antibiotic-resistance-20170511-story.html>] AMarb

There’s a good reason why antibiotic-resistant bacteria are so tough, and it has less to do with humans than previously thought, according to a new study. A class of bacteria containing particularly troublesome superbugs that today plague hospitals dates back at least 425 to 450 million years, according to a team of Massachusetts researchers. Called enterococci, these hardy bacteria have endured several mass extinctions, including the Permian catastrophe of about 252 million years ago that destroyed nearly all species, including the trilobites. They survived the extinction of non-avian dinosaurs at the end of the Cretaceous without missing a beat. Using genetic techniques to track the diversification of enterococci, the researchers found that this group dates back to the time when animals first left the water for land. Moreover, their divergence also matched the emergence of new animal species, especially after the Permian extinction. The implication for those fighting superbugs is that antibiotic resistance is part of a survival toolkit that has been baked into their DNA for hundreds of millions of years. Overcoming everything Mother Nature could throw at them, these ancient bacteria are well-equipped to handle antibiotics and other means of controlling them that humans can devise. “Enterococci are distinguished from their ancestors and appear to have been selected for, by virtue of having developed a hardened cell wall and the ability to cope with environmental stress —traits that now render them resistant to denaturing solvents, disinfectants, and intrinsically, to many antibiotics,” the study concluded. “These are exactly the traits that enable them to persist in the modern hospital environment. Thus, the emergence of enterococci as leading hospital pathogens appears to have been foreordained by events of at least 425 mya.”

#### It’s just some rando who passingly calls it existential – the rest of the article is an ad for the author’s app. Existential risks are a high burden and require someone with real credentials

#### 1] Even if they’re right that superbugs are worse than normal pandemics, they can’t overcome biology – fatality trades off with transmission, islands cause burnout, pandemic response exists, and humans are still resilient even if superbugs are worse

#### 2] Risk of transmission is overstated—conventional checks solve

Smith 17—former R&D director at MicroPhage and SomaLogic (Drew, “Can A Superbug Cause A Global Pandemic?,” <https://www.forbes.com/sites/quora/2017/02/10/can-a-superbug-cause-a-global-pandemic/#3cb04e2c59aa>, dml)

Death rates from bacterial infections dropped over 90% from historic levels before the introduction of penicillin. Sanitation and vaccines are far more effective methods to control bacterial infections than antibiotics ever were or ever will be. Boring old soap and water, filtration, bleach, and alcohol kill superbugs just fine. None of these things are in short supply.

The acquisition of multiple drug resistances generally (but not always) causes bacteria to become a bit less fit and unable to infect otherwise healthy adults. The victim of this particular superbug was in her seventies and had been in and out of hospitals for over a year. This is a fairly typical profile for victims of multi-drug resistant bacteria.

The worst-case scenario, if we continue to abuse and overuse antibiotics in feedlots and hospitals, is that these bugs will pick up compensatory mutations and become more virulent. Many fairly routine procedures - chemotherapy, thoracic and orthopedic surgery - will become much more risky.

But the risk will still be largely confined to hospitalized patients. MDR bacteria are extremely unlikely to cause a global pandemic on the scale of the 1919 influenza or AIDS epidemics, so long as we continue to provide clean food and water to the public.

#### 3] SQ solves – experiments and action now mean the plan isn’t “key” – none of their uniqueness evidence is specific to antibioitics

Biochemical Society 17 (Biochemical Society, “How to solve a problem like antibiotic resistance”, March 3, 2017, ScienceDaily, https://www.sciencedaily.com/releases/2017/03/170303100429.htm)

There has been much recent talk about how to target the rising tide of antibiotic resistance across the world, one of the biggest threats to global health today. While there is no doubting the size of the problem facing scientists, healthcare professionals and the pharmaceutical industry, there are innovative ways we can target antibiotic resistance in the short term, which are discussed in three articles published in Essays in Biochemistry. With only a few antibiotics in development and a long drug development process (often 10-15 years), there is concern that what is being done to combat antibiotic resistance may be 'too little, too late'. "If bacteria continue developing resistance to multiple antibiotics at the present rate, at the same time as the antibiotic pipeline continues to dry up, there could be catastrophic costs to healthcare and society globally," said senior co-author on one of the articles, Dr Tony Velkov, an Australian National Health and Medical Research Council (NHMRC) Career Development Fellow from Monash University, Victoria, Australia. While any antimicrobial resistance is concerning, the increasing incidence of antibiotic-resistant Gram-negative bacteria has become a particular problem as strains resistant to multiple antibiotics are becoming common and no new drugs to treat these infections (eg, carbapenem-resistant Enterobacteriaceae) will be available in the near future. These Gram-negative bacteria are considered the most critical priority in the list of the 12 families of bacteria that pose the greatest threat to human health that was just released by the World Health Organization. The reasons for the high levels of antimicrobial resistance observed in these critical Gram-negative organisms are explained in another paper in the same issue written by the Guest Editor of the journal, Dr Rietie Venter, University of South Australia, Adelaide, and colleagues. According to the authors, one of the main contributing factors to the increased resistance observed in Gram-negative bacteria is the permeability barrier caused by their additional outer membrane. An innovative strategy that is gaining momentum is the synergistic use of antibiotics with FDA-approved non-antibiotics. Using this novel approach, an FDA-approved non-antibiotic drug is combined with a specific antibiotic that enables it to breach the outer membrane barrier and so restore the activity of an antibiotic. The Monash University authors discuss how combining antibiotics with other non-antibiotic drugs or compounds can boost their effectiveness against Gram-negative 'superbugs'. For example, loperamide, an anti-diarrheal medication sold in most pharmacies, enhances the effectiveness of eight different antibiotics (all in the tetracycline class). In particular, when added to the tetracycline antibiotic minocycline, along with the Parkinson's disease drug benserazide, it significantly increased antibiotic activity against multi-drug resistant Pseudomonas aeruginosa, a causative agent in hospital-acquired infections such as ventilator-associated pneumonia. Polymyxins are a type of antibiotics that target Gram-negative bacterial infections and have traditionally been used as a last resort to treat serious infections such as those caused by Gram-negative 'superbugs' Klebsiella pneumoniae, P. aeruginosa and Acinetobacter baumannii. Resistance to polymyxins is not common, but in late 2015 the first transferable resistance gene to colistin (polymyxin E) was discovered (plasmid-borne mcr-1 gene). This caused significant concerns, as once resistance to polymyxins is established, often no other treatments are available. A number of researchers, including the team based at Monash University, have been testing different combinations of drugs or compounds with polymyxins to try and improve their effectiveness against these bacterial 'superbugs'. "Without new antibiotics in the near future, we must explore innovative approaches to preserve the clinical utility of important last-line antibiotics such as the polymyxins." commented senior co-author on the paper, Professor Jian Li, Head of the Laboratory of Antimicrobial Systems Pharmacology from Monash University, Victoria, Australia. Some interesting findings have ensued, with a number of different combinations having a beneficial effect. Some notable examples that increased antibiotic activity when combined with polymyxin B include: ivacaftor and lumacaftor, two new drugs used to treat cystic fibrosis; and closantel, a drug used to treat parasitic worm infections. Another interesting combination that has shown promise against methicillin-resistant Staphylococcus aureus (MRSA), according to Schneider and co-authors, is combining the antibiotics ampicillin or oxacillin with berberine. Berberine is extracted from the roots, stems and bark of plants such as barberry. In another paper in the same issue of Essays in Biochemistry, Dr Mark Blaskovich, Program Coordinator, Community for Open Antimicrobial Drug Discovery and colleagues from the University of Queensland, Brisbane, Australia, describe the key ways they believe antimicrobial resistance can be targeted. "In the short term, the greatest potential for reducing further development of antimicrobial resistance lies in developing a rapid test that can quickly tell whether or not you have a bacterial infection (as opposed to a viral cold or flu), and whether you really need an antibiotic," commented Blaskovich. "Even better if the test could say what type of bacteria, and what types of antibiotics it is resistant to. You could then treat an infection immediately with the appropriate antibiotic, rather than the trial and error method now used. These tests could be ready within the next 5 years, and would have a huge impact on reducing unnecessary antibiotic use, preserving our existing antibiotics and reducing the spread of antibiotic resistance." Regarding antibiotics in particular, Blaskovich and colleagues describe a number of possible strategies to pursue. The first of which is to improve existing antibiotics. For example, the authors recently created a modified version of the antibiotic vancomycin to increase its potency and reduce its toxic side effects. Another option is to rediscover 'old' antibiotics. In the 1950s and 60s many potential antibiotic drugs were described in the scientific literature, but due to so many choices being available at the time, only some were developed for human use. An example of this is octapeptins, which are newly rediscovered antibiotics that are now being developed to combat Gram-negative 'superbugs'. Repurposing drugs originally developed and approved for other uses has also had some success. In 2005, the Drugs for Neglected Diseases initiative identified fexinadole as a potential treatment for sleeping sickness and it is now undergoing a Phase III trial. This drug had been developed as an antimicrobial in the 1970s, but only reached pre-clinical development. In addition to the above, researchers are looking for new, untested sources of antimicrobial activity to try and develop new drugs. A recent success in this area was, teixobactin, a new antibiotic developed by NovoBiotic Pharmaceuticals, discovered by using an 'iChip' to culture and isolate soil bacteria in situ. A final option, mentioned by Blaskovich and colleagues, is crowdsourcing new antibiotics. Using this approach, the Community for Open Antimicrobial Drug Discovery, is searching for new chemical diversity by searching compounds sourced from academic chemists from around the world. "It's hard to predict which one of these methods will be the most successful in the future, but we really need to be trying all of them to have any chance of overcoming antibiotic resistance," said Blaskovich. "Non-antibiotic strategies are just as important, such as developing vaccines or probiotic therapies to prevent infections, as they can help to reduce the overuse of antibiotics. They will never completely replace antibiotics, but can help to preserve our existing antibiotics so they still work when needed." Overall, these articles and others in the new antimicrobial resistance themed issue of Essays in Biochemistry give us hope that there are viable solutions being developed to this seemingly unsurmountable global problem. It is important that all possible avenues are considered, as some less obvious approaches may end up being sources of future success. Dr Derry Mercer, Principal Scientist at NovaBiotics Ltd, a company that specialises in developing new antimicrobials, commented: "Research and development into new antimicrobials remains a vitally important pursuit for combatting the problem of antibiotic resistance, but alternative approaches to this problem are also urgently needed." He added: "Such methods include those described in the papers in the latest issue of Essays in Biochemistry, as well as vaccine development and bacteriophage therapy, to name a few. Approaches that target microbial virulence, for example targeting biofilms and/or quorum sensing, rather than more traditional directly antimicrobial drugs should also be urgently examined."