# 1NC-round 2-Presentation

## 1

#### Interpretation: IP protections refer to copyright, trademarks, GI’s, patents, ID’s, and trade secrets

WTO No Date [World Trade Organization] [DS] [https://www.wto.org/english/tratop\_e/trips\_e/intel1\_e.htm]

(i) Copyright and rights related to copyright.back to top The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author. Also protected through copyright and related (sometimes referred to as “neighbouring”) rights are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work. (ii) Industrial property.back to top Industrial property can usefully be divided into two main areas: One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin). The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive. Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities. A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing. The protection is usually given for a finite term (typically 20 years in the case of patents). While the basic social objectives of intellectual property protection are as outlined above, it should also be noted that the exclusive rights given are generally subject to a number of limitations and exceptions, aimed at fine-tuning the balance that has to be found between the legitimate interests of right holders and of users.

#### Violation – data exclusivity is a term several countries are trying to get protected by TRIPS – but it is fundamentally different from other IP protections

MSF May 2004 [Technical Brief, “Data exclusivity in international trade agreements: What consequences for access to medicines?”] [DS] [https://www.citizen.org/wp-content/uploads/dataexclusivitymay04.pdf]

“Data exclusivity” is a term covering measures some governments, especially the US, are seeking to include in bilateral and regional trade agreements. The implications of such measures need to be understood, because they could have far-reaching ramifications for access to medicines. Data exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine. Data exclusivity is completely separate from patents. In fact, the strongest impact may be felt in a country where there is no patent for a medicine - if data exclusivity is granted this will provide a monopoly for a set period (e.g. five years). This short briefing paper outlines the consequences of data exclusivity for access to medicines and explains why countries are not obliged to agree to it. What kind of data are we talking about? “Data exclusivity” refers to test and other data that a pharmaceutical company must provide to a drug regulatory authority (DRA) in order to get first-time registration for any new medicine it wishes to market in a country. This test data is necessary to demonstrate the efficacy and safety of the drug. Registration - or marketing approval – by the DRA is needed before a medicine can be marketed in a country. When generic manufacturers later apply to register another version of an already-registered medicine, they only have to demonstrate that their product is therapeutically equivalent to the original. To fulfil the efficacy and safety requirements, the drug regulatory authority relies on the registration file of the original manufacturer. So what kind of exclusivity is it? In order to delay competition from generic manufacturers, multinational companies have been pushing hard to obtain exclusive rights over their test data. During this period of “data exclusivity”, the DRA is not authorised to rely on information in the originator dossier to approve/register generic versions of a medicine. This period of exclusivity may vary from five years in the US to eight-10 years in the EU and can be found in developed countries mostly in medicines legislation. Such legislation also exists in a limited number of developing countries. Practically, data exclusivity prevents DRAs from registering generic versions of a medicine during a limited period, unless the generic manufacturer independently carries out its own tests showing the safety and efficacy of the medicine. What are the consequences of data exclusivity for access to generic medicines? The biggest impact of data exclusivity is on medicines that are not patented in some countries, as a result of pre-TRIPS patent laws excluding pharmaceutical patents. This is the case of most antiretroviral medicines in Guatemala for instance1 , where generic manufacturers will now have to wait five years from the date of approval of the original medicine in Guatemala before obtaining registration of their own version of the medicine2 . In other words, even when a medicine is not protected by any patent, multinational pharmaceutical companies are assured a minimum period of monopoly in countries that provide data exclusivity. This is clearly going beyond the TRIPS Agreement (see further below). In other situations, where a medicine is protected by patents, data exclusivity may constitute a barrier to the use of compulsory licenses. If a generic manufacturer is granted a compulsory license to overcome the patent, it will not be able to make effective use of the license if it has to wait for the expiry of data exclusivity before it can get its generic version approved by DRA and put on the market. Therefore, countries will need to ensure that the use of compulsory licences are not restricted by data exclusivity. Data exclusivity is a means of impeding generic competition, and maintaining artificially high prices, thereby restricting access to medicines. Moreover, it could be considered unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. Clinical trials could expose patients to sub-optimal treatment. Proof of therapeutic equivalence should be sufficient. 1 This is because Guatemala only introduced patent protection for pharmaceuticals in November 2000. Consequently, all medicines which were applied for patent protection before this date cannot be patented in Guatemala (except for new improved versions that meet the patentability criteria). See MSF report Drug patents under the spotlight – Sharing practical knowledge about pharmaceutical patents, May 2003. 2 In accordance with Decree 09-2003, and the recently signed Central America Free Trade Agreement (CAFTA) with the United States. What is the relationship between data exclusivity and patents? Patent application is made well before the application for drug registration, at the stage of basic research, but since patents now last for 20 years, they usually expire after the data exclusivity period. The schematic graph below illustrates the interference of patents and data exclusivity. basic preclinical clinical application drug research research research for registration approval end of 20-year patent 2-4 years 4-5 years 2-3 years start of 20-year patent 5-year data exclusivity Is data exclusivity another kind of intellectual property right? Compared to more traditional intellectual property rights such as patents and copyrights, data exclusivity is very unusual since it does not require any inventive activity for it to be granted. Data exclusivity protection is instead only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate the safety and efficacy of their new medicine. Although the TRIPS Agreement now requires some protection for this sort of data, it does not require that exclusive rights be granted in the same way as patents or copyright.

#### Vote neg for limits and ground – data exclusivity does not require inventive activity, which skirts the innovation DA and access CP’s and makes advantage areas fundamentally different from other affs – it also opens the floodgate to any investment that has been made ever which explodes the topic and makes neg prep unfeasible.

#### Topicality is a voting issue that should be evaluated through competing interpretations – it tells the negative what they do and do not have to prepare for—there’s no way for the negative to know what constitutes a “reasonable interpretation” when we do prep – reasonability is arbitrary and causes a race to the bottom, proliferating abuse

#### No RVIs—it’s your burden to be topical. RVI’s deter legitimate theory like T and disclosure and are illogical because you shouldn’t win for doing a good thing – logic outweighs because it’s the basis for all arguments.

## 2

#### Interpretation: The aff must defend more than one member nation of the WTO reducing IPP

Guide to Grammar 4 [The Guide to Grammar and Writing is sponsored by the Capital Community College Foundation, <http://guidetogrammar.org/grammar/plurals.htm>] whs-ee

The plural form of most nouns is created simply by adding the letter s.

more than one snake = snakes

more than one ski = skis

more than one Barrymore = Barrymores

#### Violation: they only defend Jordan

#### It applies to The Member Nations:

#### Upward entailment test – spec fails the upward entailment test because saying that nations ought to reduce IPP in one country does not entail that those nations ought to reduce all kinds of IPP

#### Adverb test – adding “usually” to the res doesn’t substantially change its meaning because a reduction is universal and permanent

#### Vote neg:

#### Semantics outweigh:

#### T is a constitutive rule of the activity and a basic aff burden – they agreed to debate the topic when they came here

#### Jurisdiction – you can’t vote aff if they haven’t affirmed the resolution

#### It’s the only stasis point we know before the round so it controls the internal link to engagement – there’s no way to use ground if debaters aren’t prepared to defend it

#### 1] Precision – if we win definitions the aff is not topical. The resolution is the only predictable stasis point for dividing ground—any deviation justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### 2] Limits and ground – forcing them to defend plural means they have to strategically choose nations that have common features like types of IP protections or geopolitical tensions to avoid losing to PICs which is a more limited caselist and ensures link magnitude to core topic generics while still allowing for a robust set of affs

#### C/A voting issues, competing interps, and no RVI’s.

## 3

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

**Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.**

**Marjanovic and Fejiao ‘20** Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/> C.VC

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

## Case

#### Jordan IPR is essential for continuing their decade-long growth and global expansion of domestic pharma companies

WIPO 21 — (World Intellectual Property Organization, “Evolving Towards IP-Fueled Innovation“, Available Online at https://www.wipo.int/ipadvantage/en/details.jsp?id=2647, accessed 10-1-2021, HKR-AR)

Ever since its inception, the Jordanian pharmaceutical industry has steadily grown into the country’s highest value-added export industry. By 2010, sixteen pharmaceutical companies were exporting 81% of their production per year to over sixty countries, with high quality products and affordable pricing driving demand. In 2008, sales of the top ten pharmaceutical companies exceeded US$ 500 million. For much of its history, Jordan’s pharmaceutical industry has focused on producing affordable generic drugs. Jordan’s accession to the World Trade Organization (WTO) in 2000 and a free trade agreement with the United States in 2001 strengthened its intellectual property (IP) system, and the Jordanian pharmaceutical industry has been evolving as a result. Leading this evolution is Al Hikma Pharmaceuticals (Hikma), the largest pharmaceutical company in Jordan.

Founded in the capital of Amman in 1978 by Mr. Samih Darwazah, Hikma’s initial focus was to develop a branded pharmaceuticals business across the Middle East and North Africa region (MENA), which it did by manufacturing patented pharmaceutical products under license. In 1991, the company’s success led it to establish a presence in the United States through the acquisition of West-Ward Pharmaceuticals (West-Ward). In only three years Hikma became compliant with United States Federal Drug Administration (USFDA) regulations, and in 1996 it became the first Arab company to receive USFDA approval. Shortly after its early successes in the United States, Hikma established an innovative injectable pharmaceutical manufacturing venture in Portugal targeting the MENA and Portugal markets. By the late 1990s, Hikma’s organic innovation and presence in Europe, MENA and North America led to significant expansion of the company.

Licensing and Partnerships

Hikma’s early success came through the manufacturing and marketing of branded generic drugs. While this continues to be an important part of the company’s overall strategy, Jordan’s comprehensive economic reforms, its accession to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and the country’s increased level of IP protection brought many new opportunities for Hikma. The greatest of these was the increased confidence of international partners, which brought even more licensing and partnership opportunities. Prior to Jordan’s IP reforms, companies in the country would use slightly different formulas to manufacture a patented product for the generic market. While this was not considered to be IP infringement, it proved difficult to attract foreign investment in the industry. Under the new IP laws, Jordanian companies seeking to make generic versions of patented products cannot use different formulas or ingredients; they must use the exact, patented formula. To do so would require licensing and partnership agreements with the patent holder, and this change brought an opportunity that Hikma was quick to seize upon.

Obtaining products under license has always been a part of Hikma’s strategy, and the new IP laws helped the company capitalize on the increased appeal of the country’s pharmaceutical industry generated for foreign investors. The company’s strong market position and established infrastructure made it a clear partner for multinational pharmaceutical companies seeking access to fast growing MENA markets. By the time IP laws in Jordan changed, Hikma already had a proven track record of working with global licensing partners, and its USFDA approved facilities combined with its highly skilled workforce and existing production capabilities made the company even more attractive to multinational partners. In 2007, the company’s successful utilization of new domestic IP laws through increased licensing agreements and partnerships yielded profits of US$ 198 million. As of 2010, it manufactured and marketed 40 licensed branded products through partnerships with multinational corporations such as LG Life Sciences of the Republic of Korea, Sinclair of the United Kingdom and MonoSolRx of the United States.

Licensing deals and partnerships have also given Hikma unique acquisition opportunities, which in turn have brought the company access to new markets. In 2007, Hikma acquired Arab Pharmaceutical Manufacturing (APM), which was the third largest pharmaceutical company in Jordan, through which it significantly increased its presence in Saudi Arabia, as APM gets over one third of its revenue from Saudi Arabia. That same year, it entered the Egyptian market through the acquisition of Alkan Pharma, which became Hikma Egypt, and also entered Germany through acquiring two well known pharmaceutical companies in the injectable oncology market: Ribosepharm and Thymoorgan. These acquisitions, along with new licensing agreements, allowed the company to launch 28 new products, receive 167 approvals and submit 74 regulatory filings in Europe, Jordan and the United States in 2007.

Commercialization

Hikma commercializes its products under three major segments: branded, injectable and generic pharmaceuticals. The branded segment manufactures branded generic pharmaceutical products for sale across the MENA region and Europe. The company has been involved in branded pharmaceuticals since its start, and as such enjoys a very good reputation in this area. The company’s injectable segment manufactures injectable generic pharmaceutical products in powder, liquid and lyophilized forms for sale in MENA, Europe and the United States. Lastly, the generic segment produces non-branded generic pharmaceutical products. This segment is focused primarily on the United States, as it is the largest market for the company’s non-branded generic products. The company’s business in this segment is operated by West-Ward, and as of late 2010 it sold 49 generic compounds in 108 dosage forms and strengths.

The company has twelve world class manufacturing facilities which provide it with the flexibility to select the most appropriate manufacturing strategy for a particular product, taking into account factors such as cost, regulatory requirements and capacity. Manufacturing facilities are located in Jordan and Saudi Arabia, five of which have been approved by the USFDA, which provides the company with the capability to produce products for the United States market at a lower cost. Maintaining a local manufacturing presence in the MENA region is essential for the company’s growth, as some markets restrict the range of products that can be imported from outside the region.

Research and Development

Sparked by Jordan’s new IP framework, Hikma has secured the resources it needs to continue and expand its research and development (R&D) activities through licensing agreements, partnerships and acquisitions. The company’s R&D team is spread throughout Europe, Jordan and the United States, and focuses on developing technically challenging products such as injectables, complex formulations, unstable compounds and sustained release tablets and capsules. The R&D team aims to continually increase the number of approvals that it receives from regulatory authorities in its markets for newly developed products which have a strong market potential.

Hikma’s R&D division is in charge of product formulation, process design and monitoring of bio-equivalency testing for all of its business segments. Beyond developing new products, it also improves existing products and manufacturing techniques, as well as performing R&D activities related to the manufacture of chemical synthesis, fermentation and purification. To accelerate its R&D efforts, Hikma aims to invest up to six percent of its total annual revenue in R&D, and also cooperates with leading R&D organizations through its collaborative partnerships. All of these factors have allowed Hikma to transform into a company that not only produces generics, but into a company that innovates new products, making a substantial impact to the growth of the company and the Jordanian pharmaceutical industry. At the end of 2009, Hikma’s R&D department contributed to a total of 116 compounds and 190 dosage forms and strengths pending regulatory approval, giving the company a significant pipeline of innovative new products.

Patents and Trademarks

In 2007, Hikma filed its first Patent Cooperation Treaty (PCT) international patent application for a nanoparticle pharmaceutical carrier invention made in collaboration with the Queen’s University of Belfast. By 2010, the company has also filed three patent applications with the European Patent Office (EPO).

Because branded products are an important part of Hikma’s business, the company has protected several of its brand names through registering trademarks. The company has utilized the international Madrid system to register a trademark for its Cefofix antibiotic in 1992, which was granted in 1995. It has also registered its name and slogan, “Hikma Quality,” with the Trademarks and Designs Registration Office of the European Union (OHIM).

Business Results

As the IP landscape in Jordan has changed, so has Hikma’s approach to its future growth and success. Foreign investment, licensing, partnerships and acquisitions have all contributed to Hikma’s rapid growth. The company’s success was recognized internationally in 2005 when it was listed on the London Stock Exchange. In 2007, it had an increase in revenue of 41.6% from the previous year. By 2009, Hikma was the fifth largest pharmaceutical company in the MENA region, enjoying a 3.7% market share, 12.4% annual growth rate and over US$ 400 million in sales. For the six months ended June 30, 2010, revenue was up 11.3% and operating profit was up by 20.2% on the previous year. The company is one of the top twenty generic prescription providers in the United States, has a geographic footprint spanning 49 countries, and is the licensing partner of choice for multinational companies looking to expand into the MENA region.

An Effective IP System for Economic Growth

Jordan’s strengthened IP system has helped put the Jordanian pharmaceutical industry on the path of innovation. While many Jordanian companies were previously focusing on manufacturing generic drugs, Hikma is an example of a company that is now creating its own patentable drugs and innovations. Inspired by Hikma’s success, Jordanian pharmaceutical companies have expanded their distribution networks to over sixty countries worldwide. Jordan has evolved into a leading knowledge economy in the region, and the pharmaceutical industry is just one example how IP can lead the growth of an entire economy.

#### Jordan’s economy is structurally tubed—refugee crisis, mismanagement, energy imports, water

Matthews 9/14 — (Mark Matthews, “Stable but stagnant: Transforming Jordan’s economy“, 9-14-2021, https://globalriskinsights.com/2021/09/stable-but-stagnant-transforming-jordans-economy/, accessed 10-1-2021, HKR-AR)

While U.S. and Jordanian counterterrorism efforts and military cooperation have helped prevent the spread of regional terrorism and illicit actors, Jordanians still face a pressing economic situation. Jordan’s GDP per capita has steadily declined since 2009 and the absence of structural economic reforms have constrained the country’s potential. Jordan’s bloated public sector is rife with corruption and excludes Jordan’s Palestinian majority. Jordan will face mounting struggles as sky-high unemployment mixes with a rapidly growing population.

Jordan has some of the highest levels of public debt in the Middle East at over 100% of GDP, as a result of its inefficient public sector and dependence on costly foreign energy imports. The resource-poor kingdom is the second most water scarce country in the world, and local agricultural production is alarmingly low with total annual production sufficient for only one week of domestic consumption.

While Jordan had been making significant headway building its tourism sector, the halt to global travel caused by the pandemic will undoubtedly set back progress. Jordan is the Middle Eastern country most dependent upon tourism, which accounts for nearly 20% of GDP. While a rapid return of foreign visitors to Petra and Wadi Rum would surely be beneficial, Jordan will likely be affected by regional instability in the future and should seek to capitalise on its politically stable environment beyond the tourism sector.

One sector where the country has supposedly flourished is textiles. Jordan’s success there stems from the U.S. Congress’s 1996 establishment of Qualifying Industrial Zones (QIZs), which permit the duty-free entry of exports to the US provided they contain a certain level of Israeli input. While the zones account for one of Jordan’s largest and fastest growing exports, the sector has attracted controversy for the reported abuse of workforces, which is comprised by nearly 70% of female foreign workers from South Asia.

Politics first

The influx of 1.3 million Syrian refugees has strained Jordan’s economy. While the refugee crisis remains a convenient scapegoat, it likely exacerbated pre-existing problems rather than caused them. When asked what is the most important problem facing the country, only 1% of Jordanians named Syrian refugees.

#### No Israel-Iran war—US influence, ill-equipped military, political talk

Safaei 9/17 — (Sajjad Safaei, Sajjad Safaei is a postdoc fellow at Germany’s Max Planck Institute for Social Anthropology., 9-17-21, “Israel Isn’t Strong Enough to Attack Iran“, Foreign Policy, Available Online at https://foreignpolicy.com/2021/09/17/israel-isnt-strong-enough-to-attack-iran/, accessed 10-1-2021, HKR-AR)

To speak of an imminent and undisguised IDF strike deep inside Iranian territory is to overlook a long-established norm that has for decades governed U.S.-Israel relations: Israel cannot simply ignore the wishes and concerns of its chief patron, especially when core U.S. foreign policy priorities are at stake.

This norm was expressed in clear terms by no less a figure than Israel’s former premier and Defense Minister Ehud Barak in his autobiography My Country, My Life. Here, Barak spelled out the paradigm that has shaped—and will likely continue to shape—the contours of Israeli action against Iran. “There were only two ways,” he explained, that Israel could stop the Iranians from getting a nuclear weapon (read: “nuclear program,” for Barak willfully ignores U.S. intelligence assessments that Iran had halted pursuits for nuclear weapons in 2003). One way was “for the Americans to act.” The only other option was “for [the United States] not to hinder Israel from doing so.”

But according to Barak, “hinder” is precisely what consecutive U.S. administrations have done—and are still likely to do.

Even during the military interventionism of the George W. Bush presidency, Israel did not have a blank check to do as it pleased. As Barak notes in his memoirs, when Bush learned in 2008 of Israeli efforts to purchase heavy munitions from the United States, he confronted Barak and then-premier Ehud Olmert. “I want to tell both of you now, as president,” Bush warned, “We are totally against any action by you to mount an attack on the [Iranian] nuclear plants.”

“I repeat,” Bush further clarified, “in order to avoid any misunderstanding. We expect you not to do it. And we’re not going to do it, either, as long as I am president. I wanted it to be clear.” It deserves mention that according to Barak, Bush issued this warning despite knowing that Israel did not even possess the military capacity to assault Iran at the time.

According to Barak, this staunch opposition to a strike on Iran had a “dramatic” effect on him and Olmert since the Bush administration had supported Israel’s 2007 bombing of Syria’s nascent nuclear program just a year before. In both cases, Washington’s approval, or lack thereof, was demonstrably consequential.

Barak’s memoirs show that the same dynamic continued to govern U.S.-Israel relations during Obama’s presidency. He recalls how then-U.S. Secretary of Defense Leon Panetta “made no secret of the fact he didn’t want us to launch a military strike” at a time when the Obama administration was focused on putting international political and economic pressure on Iran. Panetta “urged me to ‘think twice, three times,’ before going down that road,” Barak wrote, and saw it as a given that Tel Aviv would keep Washington abreast of its decisions. “If you do decide to attack the Iranian facilities, when will we know?” he allegedly asked Barak.

According to Barak’s account, Israel was dissuaded from going forward with a supposed strike on Iran’s nuclear installations in summer 2012 “because of the damage it would do to our ties with the United States.” Washington’s demands continued to limit Tel Aviv after the finalization of the nuclear deal in 2015. Even then, Barak recalls, the Israelis could not simply act against Iran without a green light from the Obama administration: “We needed to reach agreement with the Americans about what kind of military strike we, or they, might have to take if the Iranians again moved to get nuclear weapons.”

As evinced by Barak’s autobiography, U.S. presidents are not taciturn about making their views and wishes known to Israeli officials, especially when primary U.S. foreign policy objectives are involved. Nor can Tel Aviv afford to ignore Washington’s express demands and concerns on such matters. And today, any flagrant Israeli violation of Iranian sovereignty will instantly clash with two mutually reinforcing goals that have come to define the Biden administration’s foreign policy: curbing Iran’s nuclear program through non-military means (efforts currently focused on reviving the 2015 Iranian nuclear deal) and winding down U.S. military presence in the Middle East.

These political realities make it unlikely Israel will pursue an overt strike on Iran. Just as important, however, are the military constraints that Israel faces.

To be sure, even without its ready-to-launch nuclear warheads, Israel is more than capable of delivering swift and devastating blows to Iran’s armed forces, both in the skies and seas. Its fleet of American fighter jets and bombers alone can irreparably trounce Iran’s air defenses as well as its dilapidated air force. Even Iran’s increasingly powerful, accurate, and far-reaching missile and drone systems don’t radically alter the balance of power in the skies. In short, in terms of military hardware, the IDF’s superiority over Iran’s armed forces is indisputable, not to mention otherworldly.

But this prodigious superiority will be rendered far less consequential in the event of an all-out war that lures the IDF ground forces into the battlefield. Why? Ever since the IDF’s embarrassing defeat during the 2006 war with Hezbollah, Israel’s top military brass have become acutely aware that the country’s land forces are ill-prepared for a full-scale war with a fighting force even moderately capable of packing a punch.

As shown by Israel’s own scathing inquiry into the 2006 war, as well as reports by the Washington Institute for Near East Policy and the U.S. Army, the 33-day war with Hezbollah demonstrated that the IDF ground forces had been woefully ill-prepared to fight a real war with a formidable foe.

Since then, there have been some signs of remedial measures undertaken by the IDF to address its shortcomings. Still, there is little reason to believe its ground forces have undergone a drastic improvement since the 2006 war. Unsurprisingly, when Gadi Eizenkot began his tenure as Chief of General Staff of the IDF a few months after Protective Edge (the 2014 Gaza War), he reportedly “found the ground forces in rather bad shape” and “an army that had gotten fat in … all the wrong places in the decade after the Second Lebanon War.” The picture looked more or less the same in late 2018 when the outgoing ombudsman of the Israeli Defense Ministry Maj. Gen. (res.) Yitzhak Brick warned lawmakers in a “contentious” meeting that the country’s ground forces were unprepared for a future war.

Mindful of the gaping chink in the IDF’s armor, Israel’s highest military and political echelons are unlikely to order an overt military operation inside Iranian territory, knowing full well that such an assault will most likely lock Israel and Iran in an irreversible spiral of escalation that promises to pit ill-prepared IDF ground troops against Iranian forces and their regional allies such as Hezbollah.

But if Washington’s red light and Tel Aviv’s own military calculus render a flagrant violation of Iranian sovereignty by the IDF unlikely, then what is to account for the public, at times even garish, saber-rattling emanating from Israeli statesmen? Such threats are partly tailored for domestic consumption. In a highly militarized social context that has in recent decades steadily drifted toward the far-right, talk of bombing Iran may be an effort to not appear weak before one’s political rivals.

It may also be read, however, as a bargaining posture to strengthen Israel’s position vis-à-vis the Biden administration on issues far closer to home than the Iranian nuclear program. By continuously breathing life into the specter of striking Iran—a source of great unease in Western capitals due its catastrophic ramifications—Israeli leaders can offer to forgo their non-existent plans to enter an all-out war with Iran in return for other gains: Biden dropping his opposition to illegal settlement expansion in the occupied territories (a secondary issue for the United States) as well as more military and financial aid.

#### This first scenerio is already got solved—Israel and Jordan agreed to an expanded water sharing agreement in July 2021

#### No water wars

* Most water crises don’t cause conflict
* Often results in collaboration through water sharing agreement development
* Main causation for water wars is weak institutional capacity and political and economic dynamics

Gleick 18 [Peter Gleick, MacArthur “Genius” Fellowship and was elected to the U.S. National Academy of Sciences, world-renowned expert, innovator, and communicator on water and climate issues, cofounded the Pacific Institute, which he led as president until mid-2016, pHd from UC Berkeley, and Charles Iceland, s Director, Global and National Water Initiatives with WRI’s Food, Forests, and Water Programs, “Water, Security, & Conflict”, https://pacinst.org/wp-content/uploads/2018/08/Water-Security-and-Conflict\_Aug-2018-2.pdf]

3.2. The Role of Governance in Water Security

Most water crises do not end in conflict, migration, or acute food insecurity. Instead, people muddle through until the crises recede. Some crises even generate cooperation among local or regional parties. Understanding why water crises lead to adverse outcomes in some places and better outcomes in others will help inform strategies for reducing the risks of conflict. Why, for example, did Syria sink into civil war following a record-breaking five-year drought, while .Iordan and Lebanon avoided strife following that same drought (Adams et al. 2018)? This requires integrating analyses of meteorological and resource-related events with the diverse social, political, and economic dynamics at play.

We can postulate—based on research conducted by Wolf and his colleagues (2003) on transboundary basins— that when rapid change, either on the institutional side or in the physical system, outpaces the institutional capacity to absorb that change, the stage is set for possible water insecurity. Therefore, when we go looking for water insecurity, we need to be on the lookout for large-scale water-related change and low capacity to handle such change (this Is what the Water, Peace, and Security [WPS] consortium is attempting to do via the development of a near realtime global early warning system for potential water-related threats to human security—more on this further on in this brief).

## 2NR

#### This round is over – sementics come before pragamtics 3 reasons –

#### Semantics outweigh:

#### T is a constitutive rule of the activity and a basic aff burden – they agreed to debate the topic when they came here

#### Jurisdiction – you can’t vote aff if they haven’t affirmed the resolution

#### It’s the only stasis point we know before the round so it controls the internal link to engagement – there’s no way to use ground if debaters aren’t prepared to defend it

Our defination is specific to ouns – the bear

#### Interpretation: The aff must defend more than one member nation of the WTO reducing IPP

#### They only answer jurisdiction – that is game over because statis point and being a rule is an independent reason to vote them down.

#### Evaluate the T debate between competiting interps