# 1AC

### 1AC – Adv – Pandemics

#### Only the plan can solve covid access – inequalities heighten the risk of mutations and uneven development – neg objections miss the boat.

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According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11

Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14

This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. Allowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution.

TRIPS: Barrier to Equitable Health Care Access

The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16

Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19

A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21

The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding.

Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines.

One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer.

Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities.

Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally.

India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing.

Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

India’s Role in Ensuring Vaccine Equity India's response to COVID-19 at the global level was primarily two-fold. First, its proactive engagements in the regional and international platforms. Second, its policies and programmes to provide therapeutics and vaccines to the world. Since the beginning of the COVID-19 pandemic, India has been advocating international cooperation and policy coordination in fighting it. For instance, in April 2020, India co-sponsored a UN resolution that called for fair and equitable access to essential medical supplies and future vaccines to COVID-19. Later, in October 2020, India also put pressure on developed countries with a joint WTO proposal for TRIPS waiver. India’s Vaccine Maitri initiative also aims vaccine equity. As of 29 May 2021, India has supplied 663.698 lakh doses of COVID-19 vaccines to 95 countries. It includes 107.15 lakh doses as a gift to more than 45 countries, 357.92 lakh doses by commercial sales, and 198.628 lakh doses to the COVAX facility.29 The COVAX initiative aims to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of their income level. India has decided to supply 10 million doses of the vaccine to Africa and one million to the UN health workers under the COVAX facility. India has also removed the IPR of Covaxin that would help platforms like C-TAP once WHO and developed countries’ regulatory bodies approve the vaccine. If agreed, the waiver would benefit India in many ways. First, more vaccines will help the country to control the pandemic and its recurring waves. Second, it will be a boost to India's pharma industry, particularly the generic medicine industry. According to the Biotechnology Innovation Organization, 834 unique active compounds are involved in the current R&D of COVID-19 therapeutics, vaccines, and diagnostics. It means that thousands of new patents are awaited, and that will hinder India's ability to produce COVID-19 related medical products. Only through a waiver, this challenge can be addressed. Similarly, scientists note that mRNA is the future of vaccine technology. However, manufacturing mRNA vaccines involves complex processes and procedures. Only a very few Indian manufacturers have access to this technology; however, that too is limited. Once Indian companies have access to mRNA technology, it will help country’s generic medicine industry and boost India’s economy. Therefore, even if the WTO agrees on a waiver for a period shorter than proposed, India should accept it. In addition, mRNA vaccines can be produced in lesser time compared to the traditional vaccines. While traditional vaccines’ production takes four to five months, mRNA needs only six to eight weeks. Access to this technology will be vital for India in expediting the fight against COVID-19 and future pandemics. Finally, a waiver may strengthen India's diplomatic soft power. At present, what hinders India's Vaccine Maitri initiative is the scarcity of vaccines at home. On the other hand, China is increasing its standing in Africa, South America and the Pacific through vaccine diplomacy. The WHO approval of the Chinese vaccines and lack of access to vaccines by most developing countries, opens up huge space for China to do its vaccine diplomacy. Here, India should convince its Quad partners, particularly Australia and Japan, who oppose the waiver that vaccine production in developing countries through TRIPS waiver will enable the grouping to deliver its pledged billion doses of COVID-19 vaccine in the Indo-Pacific region. In short, the proposed waiver, if agreed, will help India in addressing the public health crisis by producing more vaccines and distributing them at home; economically, by boosting its generic pharmaceutical industry, and diplomatically, providing vaccines to the developing and least-developed countries. Therefore, India should use all available means and methods, from trade-offs to pressurising, to make the waiver happen.

#### Yes scale-up for covid.

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Currently many idle suppliers can’t begin vaccine production until they upgrade and repurpose existing manufacturing capacity for new technology. Opponents often argue that this step is the true barrier to rapid scale-up. One high-profile detractor, BIO President and CEO Michelle McMurry-Heath, argues that “handing [needy countries] the blueprint to construct a kitchen that — in optimal conditions — can take a year to build will not help us stop the emergence of dangerous new Covid variants.”

This argument ignores two core truths: In many cases, manufacturing capacity needs only repurposing which can take mere months. And Covid-19, at the current global response and vaccination rates, will be a threat for years.

Both truths suggest that we pass the blueprint and build the kitchen.

Facilitating structures to transfer technology and capacity are already in place. The WHO launched the mRNA technology transfer hub model last month to provide manufacturers in low- and middle-income countries with the financial, training, and logistical support needed to scale up vaccine manufacturing capacity. Scores of manufacturers in these countries have already expressed interest. This initiative, however, requires recipient manufacturers to acquire the IP necessary for mRNA technologies— which is currently missing.

#### Independently strategic patenting harms innovation incentives during pandemics – encourages reproduction of generics and decrease breakthroughs.

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As the COVID-19 pandemic is sweeping through the world, thousands of people urgently need access to affordable medicines. Based on past experience of treatments for other life-threatening diseases, there is a fear that access to any vaccines and treatment that may be developed in the future will be affected by patents, leading to unaffordably high prices. However, the problem of high drug prices is not new. It had been inflating healthcare budgets and posing a serious risk to the affordability and accessibility of medicines for society well before the pandemic.Footnote3 This problem is further exacerbated by the fact that, despite the alleged surge in investments into pharmaceutical R&D, current statistics indicate that the number of new breakthrough medicines is decreasing.Footnote4 On the other hand, the number of drugs that contain modifications of existing medicines is growing, demonstrating that pharmaceutical companies have been increasingly focusing their research on incremental drug development, rather than on breakthrough innovation.Footnote5 Various reasons for high drug prices and the growing focus on incremental innovation are put forward by pharmaceutical companies, including the complexity of drug discovery and development, as well as the expensive and lengthy regulatory procedures involved.Footnote6 While these reasons play an important role in this regard, some practices by pharmaceutical companies substantially contribute to this problem.Footnote7 In particular, pharmaceutical companies have been increasingly engaging in strategic patenting to delay or even block generic competition.Footnote8 These practices attracted the attention of the European Commission, which discussed them more than a decade ago in its 2009 Pharmaceutical Sector Inquiry Report.Footnote9 The Commission identified a series of patent strategies which it described as aiming “to extend the breadth and duration of [originators’] patent protection”Footnote10 and “to delay or block the market entry of generic medicine”.Footnote11 Such findings have fuelled debates as to whether these strategies may be deemed unlawful and violate EU competition rules, while also being justifiable business practices under patent law. Until today, no agreement has been reached either on the legality of these practices, or on an efficient legal tool to assess them. As a result, despite there being solid evidence that such strategies may block generic competition, allowing originators to maintain artificially high drug prices and preventing patients from accessing cheaper generics, they remain outside the ambit of the Commission’s activities. Instead, the Commission has been focusing on more straightforward patent-related practices, such as reverse payment agreements.

This article argues that strategic patenting by pharmaceutical companies requires a long-overdue intervention by competition authorities. It aims to attract their attention to the harmful effects of strategic patenting. Specifically, it will contest the argument traditionally put forward by originator pharmaceutical companies that the intervention of competition law into patenting practices will reduce their incentives to innovate. The paper will argue to the contrary that, along with a more immediate negative effect in the form of high drug prices that is widely explored in the literature,Footnote12 strategic patenting also affects dynamic competition by stifling innovation. Importantly, it will be explained that the assessment of the effect of this practice should focus not only on innovation by originators, but should also take a wider market perspective by assessing its effect on follow-on innovation by generic companies. The latter argument is often overlooked. The paper will outline the current approach to strategic patenting that considers this practice lawful, and will provide arguments for the intervention of competition law. This, in turn, will open the possibility for competition authorities to investigate this practice in order to prevent its harmful effect on innovation and consumer welfare. Moreover, while patent law may provide certain mechanisms to deal with strategic patenting, such as raising the bar for patentability of pharmaceutical follow-on inventions,Footnote13 these tools may not be effective in all cases. Therefore, as will be explained further, competition law may be a more suitable tool to address the negative effects of strategic patenting.Footnote14

The article will be organised as follows. It will first discuss the complex structure of the pharmaceutical industry, focusing on its key players for the purpose of this article: originators and generic companies. It will further explore patenting practices employed by pharmaceutical companies and will define the notion of strategic patenting. The article will then argue that the latter strategy is against the rationale of patent and competition laws, as it stifles competition by impairing incentives to innovate of both originators and generic companies. Finally, it will discuss the current approach to strategic patenting that considers this practice lawful, and will argue that it should be subject to scrutiny under the rules of competition law, to address its negative effects.

Pharmaceutical Innovation and Generic Competition in the Pharmaceutical Industry

The pharmaceutical industry is unique in its complexity. It is characterised by heavy state regulation and, sometimes, by the competing interests of the pharmaceutical business and society. It also involves multiple actors, including originators,Footnote15 marketing authorisation bodies, generic companies,Footnote16 doctors, pharmacies and patients. Each of them plays their part in the lengthy and complicated process of transforming a chemical compound into an effective and affordable medicine, which is then prescribed, dispensed and consumed. In these complex relationships, the two key players have crucial roles. On the one hand, originators play an important role in developing new and improved medicines for the benefit of society. On the other hand, generic companies benefit society by supplying cheaper equivalents of the originators’ medicines, which leads to the reduction of drug prices and facilitates access to affordable medicines. When the interests of these two players are kept in balance, benefits are maximised for society, which receives innovative and improved medicines, as well as timely access to generic drugs. However, if the balance swings towards one of the players, then society loses out, as there will be insufficient access to either innovative or affordable medicines. Therefore, both pharmaceutical innovation and generic competition must be duly incentivised and protected.

Moreover, these two elements of the pharmaceutical industry are constantly interacting and have a profound impact on each other. In particular, pharmaceutical innovation is the backbone of the pharmaceutical industry, in which originators play an important role. The process of drug development is long and complicated, requires significant investments, and bears considerable commercial risks.Footnote17 It is also highly regulated, including, among other things, the requirement for originators to obtain a special authorisation from a designated state authority to market a drug. Such marketing authorisations are granted to the originators only if they can prove that the drug is safe and effective, which typically requires lengthy and expensive clinical trials.Footnote18

In order to protect these significant efforts and investments, pharmaceutical companies rely heavily on the exclusivity granted by intellectual property rights, and in particular, patents.Footnote19 Patents provide a 20-year monopoly right, during which a pharmaceutical company enjoys market exclusivity and can charge a monopoly price for its products. Originators argue that strong patent protection is essential in order to recoup investments, as well as to incentivise them to engage in further innovation.Footnote20 Once such patent protection expires, however, other companies may develop generics of a branded drug, and start competing with the originator for the market. This is called generic competition. Generic drugs are bioequivalent versions of a branded drug that has lost its patent protection.Footnote21 It is estimated that the generic entry typically leads to, on average, an 80 per cent market share loss and a 20–30 per cent reduction of a drug price, with further price decreases with each additional generic entrant, leading, in some instances, to a fall in price of up to 90 per cent.Footnote22 A representative example of the effect of generic competition on the originators’ drug prices is the significant decrease in price and dramatic loss of profits by Eli Lilly. The expiration of a patent protecting its blockbusterFootnote23 antidepressant Prozac in 2001 resulted in a loss of almost 70 per cent of its market and $2.4 billion in annual U.S. sales.Footnote24 This effect of generic competition is beneficial for society, as it reduces the financial pressure on healthcare budgets and increases the accessibility of drugs.

Patenting Practices by Pharmaceutical Companies

As was mentioned above, generic competition is prevented during the life of a patent protecting an active compound of a drug (a so-called “basic” or “primary” patent).Footnote25 Such a basic patent covers an active ingredient itself and, therefore, provides the strongest protection for the product. Therefore, generic competition normally starts only after the basic patent expires, or if a generic company succeeds in invalidating it. While in the past pharmaceutical companies mainly protected their products with a single patent covering an active compound,Footnote26 they now increasingly seek additional patent protection on various aspects of a drugFootnote27 in order to protect their market position.Footnote28 Such additional patents are often called secondary patents.Footnote29 A pharmaceutical company may want to obtain secondary patents, which protect such aspects of a drug as, for example, its process of manufacture, formulation and/or specific form, etc. Therefore, even after the basic patent protecting an active compound expires, a drug may still be protected by other secondary patents. This may result in the extension of the scope and length of the protection of a product, especially if secondary patents have a later expiration date than a basic patent.Footnote30 This, in particular, may occur if, for example, the process of producing an active compound disclosed in the basic patent is sufficient only for reproducing this compound in a laboratory, but it is unsuitable for producing it on a large commercial scale.Footnote31 If the originator was able to secure a secondary patent that protects such a large scale manufacturing process, it would prevent generics from using this process for producing their generic versions of a drug; otherwise they would risk infringing this secondary patent.Footnote32 However, a unique feature of pharmaceuticals is that an active ingredient can be manufactured using different methods and processes, can exist in different forms or can be used in different formulations. Therefore, when a basic patent on an active ingredient expires, other companies can develop alternative methods of production, forms or formulations of this active compound and start competing with the originator company.Footnote33 While such patenting strategies by originators are lawful in principle, some of them may be problematic. In particular, in anticipation of the loss of patent protection, originators may engage in strategic patenting which artificially prevents generic competition and results in an extension of their market monopoly.Footnote34

Defining Strategic Patenting

In its Sector Inquiry Report, the European Commission explained that the drug development process consists of three main stages: (i) the R&D stage, which ends with the launch of a drug on the market; (ii) the period between the launch and the patent expiry; and (iii) the period after the patent expiration, when generics can enter the market.Footnote35 During the second stage, i.e. after the launch of a drug, originators seek to maximise their income from the product in order to recoup their R&D investments and earn profits before the commencement of generic competition.Footnote36 It is also during this stage that pharmaceutical companies seek to prolong their market exclusivity.

In recent years, pharmaceutical companies have been increasingly relying on the strategic use of the patent system to combat the pressure of generic competition. Such practices are often called “life cycle management” by originators and proponents of the practice. For example, as Burdon and Sloper explained, “[a] key element of any life cycle management strategy … is to extend patent protection beyond the basic patent term for as long as possible, by filing secondary patents which are effective to keep generics off the market”.Footnote37 However, critics have characterised the practice as “evergreening”,Footnote38 as it essentially evergreens the patent protection and the exclusivity of a product.Footnote39 For instance, Bansal et al. explain that evergreening “refers to different ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly, particularly over highly lucrative ‘blockbuster’ drugs, by filing disguised/artful patents on an already patent-protected invention shortly before expiry of the ‘parent’ patent”.Footnote40

During its investigation into the pharmaceutical industry, the European Commission found that the number of patents granted and pending applications significantly increases with the value of a drug, i.e. “blockbuster medicines can even be protected by up to nearly 100 INNFootnote41-specific EPO patented bundles and applications …, which in one particular case led to 1,300 patents and applications across all the EU Member States”.Footnote42 The Commission also found that the ratio of primary to secondary patents is 1:7, where the latter “mostly concern formulations, processes and non-formulation products…, such as salts, polymorphic forms, particles, solvates and hydrates”.Footnote43 As a result, the Commission concluded that the practice of “maximising patent coverage in such a way is the creation of a web of patents”, which affects the generics’ ability to “develop a generic version of the medicine in form of a salt, crystalline or amorphous form”, because it “would inevitably infringe a patent (for example, a patent for the relevant salt, crystalline or amorphous form of the medicine)”.Footnote44 Each of such patents would typically have a later expiration date, which effectively extends a period of market exclusivity beyond the expiration of a basic patent.Footnote45 In addition, most of these patents that protect such follow-on modifications are so-called “sleeping” patents, i.e. patents which a company has no intention of commercialising.Footnote46 Moreover, such modifications may provide little or no therapeutic benefits to the patient compared to the original drug.Footnote47 Nevertheless, such patents allow originators to secure the most efficient, broadest and longest possible protection for their successful products.Footnote48

The denser the web of secondary patents, the more difficult it is for generics to develop their generic equivalents, even if they know that only a few patents of a large portfolio would, in fact, be valid and infringed by their products.Footnote49 Despite such knowledge, it is impossible to be certain before introducing a generic whether this will be the case and, thus, whether the generic company will be subject to injunctions preventing the sale of their generic products.Footnote50 Such practice, therefore, provides an appreciable competitive advantage for originators by creating a significant legal and commercial uncertainty for generics in relation to the possibility of their market entry.Footnote51

This paper argues that such a strategic use of the patent system by pharmaceutical companies is against the shared goal of patent and competition laws of facilitating innovation for the benefit of society. As will be explained further, in addition to a more immediate negative effect in the form of high drug prices, strategic patenting may also impair innovation by reducing originators’ incentives to innovate, and affecting generics’ ability to develop alternative generic products. Strategic patenting, therefore, may enable originators to avoid competitive pressures by preventing generic competition without a need to engage in genuine innovation.

Strategic Patenting Contradicts the Rationale of the Patent System and Competition Law

In the competitive markets, the success of a company is based on its business performance.Footnote52 In order to compete on performance by “offering better quality and a wider choice of new and improved goods and services”Footnote53 firms must innovate. Realising the importance of protecting innovation, which is considered to be the main driver of economic growth,Footnote54 states have put in place various mechanisms to ensure a suitable environment for its advancement. These include granting the property rights to the results of innovation in the form of patents, as well as implementing competition law rules to stimulate dynamic competition.Footnote55

Specifically, one of the main justifications for the patent system is the encouragement of innovationFootnote56 that serves as an engine for economic growth and development.Footnote57 The patent system pursues this aim by offering the patent owners a period of exclusive rights as a reward for their innovative efforts and an incentive to engage in further innovation.Footnote58 Therefore, intellectual property rules, and patents in particular, are seen as an essential element of undistorted competition on the internal market.Footnote59 These exclusive rights are considered to be a necessary incentive to invest in R&D and innovation, particularly in such sectors as pharmaceuticals, where the R&D costs are high, but the costs of copying the R&D results are marginal.Footnote60 At the same time, the “innovation theory”, embodied in the EU competition law rules and policy, is designed to stimulate innovation by fostering competition on the markets.Footnote61 The competition law rules keep markets innovative by maintaining effective competition through preventing the foreclosure of markets and maintaining access to them.Footnote62 The rationale is that firms react to pressures of competition by continuously seeking to innovate.Footnote63 Therefore, patent and competition laws complement each other, as on the one hand, existing competition creates pressures on firms, forcing them to innovate, the so-called “stick”, while on the other hand, patent law provides a “carrot” in the form of the exclusive right, thus inducing innovators to innovate.Footnote64 These two bodies of laws are seen as “complementary efforts to promote an efficient marketplace and long-run, dynamic competition through innovation”.Footnote65 As the European Commission noted “both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof”.Footnote66 These two bodies of laws, therefore, have the same fundamental goal of enhancing innovation for the benefit of consumer welfare.

Importantly, patent and competition laws are designed to stimulate not only innovation of “pioneer” innovators, but they are also aimed at facilitating follow-on innovation.Footnote67 Patent law contains provisions that require inventors to disclose information about their inventions, as well as providing exceptions such as experimental use and compulsory licensing, which allow third parties to access the inventions still under patent protection.Footnote68 Therefore, along with pioneer innovators, the rationale of incentives to innovate in patent law also applies to follow-on innovators, balancing the interests of these two types of inventors.Footnote69 Similarly, competition law aims at stimulating all types of innovation, including follow-on innovation.

On the other hand, EU competition law proscribes practices that reduce incentives to innovate both for “pioneer” and follow-on innovators. This is enshrined in Art. 102(b) TFEU, which prohibits abuses that consist of, inter alia, limiting technological development. For example, in AstraZeneca the General Court considered that the company’s practice of misusing the patent system had the potential of reducing its incentives to innovate and was anticompetitive.Footnote70 In MagillFootnote71 and Microsoft,Footnote72 the courts found that the IP rights owners abused their dominant positions by blocking innovation of their potential competitors. More recently, several decisions by the European Commission also emphasised the importance of protecting innovation. In January 2018, the Commission fined QualcommFootnote73 €997 million for abusing its market dominance in LTEFootnote74 baseband chipsets.Footnote75 The Commission considered that the exclusivity payments that Qualcomm paid to Apple denied rivals the possibility to compete on the merits, and deprived European consumers of genuine choice and innovation.Footnote76 Furthermore, in July 2018, the Commission found in Google Android that Google abused its dominant position, and fined the company €4.34 billion for anticompetitive restrictions it had imposed on mobile device manufacturers and network operators to strengthen its dominant position in general internet search.Footnote77 The Commission considered that Google’s restrictive practices denied other companies the chance to compete on the merits and innovate.Footnote78 Finally, in 2017 the Commission issued its decision, in which it took the view that Amazon abused its dominant positions on the markets for the retail distribution of e-books by inserting the so-called “parity clauses” in the agreements with its e-book suppliers.Footnote79 It concluded that these clauses had the potential of reducing the incentives to innovate both by e-book suppliers and retailers.Footnote80

These decisions demonstrate that the European Commission recognises the fundamental importance of protecting innovation. They confirm that strategies that are capable of stifling innovation and reducing the incentives to innovate may constitute an abuse of dominance under Art. 102 TFEU. It is argued in this article that, along with the practices condemned by the Commission in the decisions discussed above, strategic patenting can also harm innovation by impairing incentives to innovate of both originators and generic companies, and therefore should raise competition law concerns.

Strategic Patenting Impairs Originators’ Incentives to Innovate

While originator companies typically argue that the competition law intervention into their patenting practices will reduce their incentives to innovate,Footnote81 this article asserts that strategic patenting itself reduces originators’ incentives. Thus, in a properly functioning system, when a patent protecting a product is close to expiration the originator would be encouraged to innovate further in order to introduce a new product on the market and maintain its competitive position. However, by engaging in strategic patenting, the originator’s incentive to innovate diminishes as it enjoys its monopoly position by merely procuring numerous secondary patents that shield its current product from generic competition. Therefore, when companies engage in such strategic patenting, they are merely protecting themselves from the competitive pressures that competition law aims to establish.

Maintaining that this practice is lawful, originators argue that strong patent protection is essential for recouping their investments, as well as for incentivising them to engage in further innovation.Footnote82 Such a position may find some support in the arguments put forward by Joseph Schumpeter and his followers, who claimed that since monopoly increases the reward of the innovator, monopolists are more prone to innovation.Footnote83 However, as Lowe noted:Footnote84

the empirical evidence of the past few decades has worked against Schumpeter and in favor of Kenneth Arrow, who contends that in favoring monopolies Schumpeter underestimated the incentives for innovation that competition can offer. Monopolists tend to want to keep their monopolies by resorting to any measures that can keep new entrants out. Firms under competitive pressure from actual or potential competition, on the other hand, are less complacent and know that inventing a new product is their best strategy for maintaining and increasing their market share.

In the same vein, the Commission emphasises the importance of competition for the incentives to innovate, stating that: “[r]ivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains.”Footnote85

Evidence from the pharmaceutical industry confirms that strategic patenting reduces incentives to engage in genuine and meritorious innovation. In many cases, strategically accumulated secondary patents are of marginal quality and are typically the result of routine research activities.Footnote86 For example, in Perindopril the European Commission revealed that most of the secondary patents, procured as part of the originator company’s anti-generic strategy, were seen by the company as “blocking” or “paper”, some of which it considered involved “zero inventive step”Footnote87 and a purely editorial task.Footnote88 Moreover, these follow-on pharmaceutical inventions are specifically timed around the expiration of the basic patent and can be developed on demand.Footnote89 In AstraZeneca the Commission noted that the company designed to “[f]ile a patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster product omeprazole to slow down generic entry at a specifically defined time, close to the expiration of the basic patent.Footnote90 The main aim of these patents is to increase uncertainty for generic companies as to the possibility of their market entry.Footnote91 Therefore, while many of these secondary patents may be trivial and potentially invalid, the originator pursues them to protect its current successful product from generic competition.Footnote92

Even if a company continues to engage in innovation in parallel to pursuing strategic patenting, it still protects itself from the pressures of competition, which would have forced the company to innovate faster and would thus provide consumers with better products and/or access to cheaper generic versions earlier. As Ullrich argues:Footnote93

A slowdown in the transition of the new medicines from the protected status of a proprietary medicine to the status of generic products manufactured and distributed in open competition does not simply mean a loss of static efficiency, namely a loss of consumer well-being due to a slowdown in the reduction of process. Rather, such a slowdown also involves the risk of a loss of dynamic efficiency in that it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate more quickly.

Following the rationale of the General Court’s statement in AstraZeneca, the practice of the originator that extends its market monopoly by relying on the patent system “potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator”.Footnote94 Such practices, according to the Court, act “contrary to the public interest”.Footnote95 Therefore, the practice of strategic patenting that protects originators’ monopolies from competitive pressures and significantly reduces their incentives to engage in genuine innovation is contrary to the rationale of the patent system, has a significant negative effect on competition and should raise competition law concerns.

Strategic Patenting Impairs Follow-on Innovation of Generic Companies

Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators:

The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97

Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100

As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns.

#### Corona escalates security threats that cause extinction – cooperation thesis is wrong.

Recna 21 [Research Center for Nuclear Weapon Abolition; Nagasaki, Japan; “Pandemic Futures and Nuclear Weapon Risks: The Nagasaki 75th Anniversary pandemic-nuclear nexus scenarios final report,” Journal for Peace and Nuclear Disarmament; 5/28/21; <https://www.tandfonline.com/doi/full/10.1080/25751654.2021.1890867>] Justin

The Challenge: Multiple Existential Threats

The relationship between pandemics and war is as long as human history. Past pandemics have set the scene for wars by weakening societies, undermining resilience, and exacerbating civil and inter-state conflict. Other disease outbreaks have erupted during wars, in part due to the appalling public health and battlefield conditions resulting from war, in turn sowing the seeds for new conflicts. In the post-Cold War era, pandemics have spread with unprecedented speed due to increased mobility created by globalization, especially between urbanized areas. Although there are positive signs that scientific advances and rapid innovation can help us manage pandemics, it is likely that deadly infectious viruses will be a challenge for years to come.

The COVID-19 is the most demonic pandemic threat in modern history. It has erupted at a juncture of other existential global threats, most importantly, accelerating climate change and resurgent nuclear threat-making. The most important issue, therefore, is how the coronavirus (and future pandemics) will increase or decrease the risks associated with these twin threats, climate change effects, and the next use of nuclear weapons in war.5

Today, the nine nuclear weapons arsenals not only can annihilate hundreds of cities, but also cause nuclear winter and mass starvation of a billion or more people, if not the entire human species. Concurrently, climate change is enveloping the planet with more frequent and intense storms, accelerating sea level rise, and advancing rapid ecological change, expressed in unprecedented forest fires across the world. Already stretched to a breaking point in many countries, the current pandemic may overcome resilience to the point of near or actual collapse of social, economic, and political order.

In this extraordinary moment, it is timely to reflect on the existence and possible uses of weapons of mass destruction under pandemic conditions – most importantly, nuclear weapons, but also chemical and biological weapons. Moments of extreme crisis and vulnerability can prompt aggressive and counterintuitive actions that in turn may destabilize already precariously balanced threat systems, underpinned by conventional and nuclear weapons, as well as the threat of weaponized chemical and biological technologies. Consequently, the risk of the use of weapons of mass destruction (WMD), especially nuclear weapons, increases at such times, possibly sharply.

The COVID-19 pandemic is clearly driving massive, rapid, and unpredictable changes that will redefine every aspect of the human condition, including WMD – just as the world wars of the first half of the 20th century led to a revolution in international affairs and entirely new ways of organizing societies, economies, and international relations, in part based on nuclear weapons and their threatened use. In a world reshaped by pandemics, nuclear weapons – as well as correlated non-nuclear WMD, nuclear alliances, “deterrence” doctrines, operational and declaratory policies, nuclear extended deterrence, organizational practices, and the **existential risks** posed by retaining these capabilities – are all up for redefinition.

A pandemic has potential to destabilize a nuclear-prone conflict by incapacitating the supreme nuclear commander or commanders who have to issue nuclear strike orders, creating uncertainty as to who is in charge, how to handle nuclear mistakes (such as errors, accidents, technological failures, and entanglement with conventional operations gone awry), and opening a brief opportunity for a first strike at a time when the COVID-infected state may not be able to retaliate efficiently – or at all – due to leadership confusion. In some nuclear-laden conflicts, a state might use a pandemic as a cover for political or military provocations in the belief that the adversary is distracted and partly disabled by the pandemic, increasing the risk of war in a nuclear-prone conflict. At the same time, a pandemic may lead nuclear armed states to increase the isolation and sanctions against a nuclear adversary, making it even harder to stop the spread of the disease, in turn creating a pandemic reservoir and transmission risk back to the nuclear armed state or its allies.

In principle, the common threat of the pandemic might induce nuclear-armed states to reduce the tension in a nuclear-prone conflict and thereby the risk of nuclear war. It may cause nuclear adversaries or their umbrella states to seek to resolve conflicts in a cooperative and collaborative manner by creating habits of communication, engagement, and mutual learning that come into play in the nuclear-military sphere. For example, militaries may cooperate to control pandemic transmission, including by working together against criminal-terrorist non-state actors that are trafficking people or by joining forces to ensure that a new pathogen is not developed as a bioweapon.

To date, however, the COVID-19 pandemic has increased the isolation of some nuclear-armed states and provided a textbook case of the failure of states to cooperate to overcome the pandemic. Borders have slammed shut, trade shut down, and budgets blown out, creating enormous pressure to focus on immediate domestic priorities. Foreign policies have become markedly more nationalistic. Dependence on nuclear weapons may increase as states seek to buttress a global re-spatialization6 of all dimensions of human interaction at all levels to manage pandemics. The effect of nuclear threats on leaders may make it less likely – or even impossible – to achieve the kind of concert at a global level needed to respond to and administer an effective vaccine, making it harder and even impossible to revert to pre-pandemic international relations. The result is that some states may proliferate their own nuclear weapons, further reinforcing the spiral of conflicts contained by nuclear threat, with cascading effects on the risk of nuclear war.

#### Uneven development causes extinction and turns every impact.

Hanna Samir **Kassab 17**. Visiting Assistant Professor of Political Science at Northern Michigan University, Prioritization Theory and Defensive Foreign Policy. Springer International Publishing, 2017. CrossRef, doi:10.1007/978-3-319-48018-3. // Re-Cut Justin

Great powers, with all their resources, power and influence, have inherent weaknesses. These weaknesses are all part of today’s international system as defined by complex interdependence, but they also emanate from weak states. Because weak states are so exposed to shock, vulnerabilities have time to ripen and become part of the international structure, thereby having what I call systemic reach. While Structural Realism posits that the system is constructed by states’ distribution of capabilities, I add that other facets of international politics—vulnerabilities—also create the system and the way states interact with each other. The systemic reach of these threats forces states to act to bolster their chances of survival. I missed this point in Weak States in International Relations Theory. This study then aims to finish what my dissertation started: to theorize how systemic vulnerabilities shape the international system and hence state behavior. The core of this work posits that positive, long-term, sustainable economic development for all states as [is] the only way to correct vulnerabilities. Creating a pragmatic, stable and sound economic policy for all states who are voluntarily open to the system (barring rogue states and peoples who prefer traditional living), is at the backbone of neutralizing vulnerability. An economically developed nation is more prepared to deal with systemic shock than others because it has the resources to do so. Developed countries are more prepared than others to deal with outbreaks of disease, financial crises, sudden environmental disaster, terrorism and drug trafficking and so on than weaker states because they have the resources to do so. Weaker, more underdeveloped states depend on great powers to bail them out during times of trouble; they know great powers must do so as a part of their hegemonic responsibility. Using theory and case studies, this work theorizes the structure of international politics in our day. Taking a holistic look at the mechanisms that guide state behavior, I demonstrate the simple fact that as a global community, we are all in this together. While states tend to pursue interests selfishly, the fact remains that one state’s trouble can spread throughout the globe. States only exist to give people the chance to practice self-determination and to survive against other states. These are all normative statements and do not reflect reality. This book is an attempt to describe reality divorced from traditional understandings of the state, taking into account changes in our world. The realists that stubbornly defend their theories (Kassab and Wu 2014) must take these matters seriously.

### 1AC – Plan

#### Plan text: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines during pandemics.

#### Enforcement through limited IP waivers solve – patent term extensions are normal means and solves innovation and scale-up.

Young and Potts-Szeliga 21 [Roberta; Counsel in Seyfarth’s Litigation department and Intellectual Property and Patent Litigation practice groups in Los Angeles; Jamaica Potts-Szeliga; Partner in Seyfarth’s Litigation department and Intellectual Property and Patent Litigation practice groups in Washington, DC. She also provides advice on FDA regulatory issues and is part of the firm’s Health Care, Life Sciences, and Pharmaceuticals team; “A Third Option: Limited IP Waiver Could Solve Our Pandemic Vaccine Problems,” IP Watch Dog; 7/21/21; <https://www.ipwatchdog.com/2021/07/21/third-option-limited-ip-waiver-solve-pandemic-vaccine-problems/id=135732/>] Justin

Limited Waiver Approach

This article suggests a third option, between voluntary vaccine donation and the full IP waiver proposal, that may offer a way forward. The third proposed solution is incentivized limited IP waivers that could encourage (or require) private companies to engage in licensing agreements with nations to share some, but not all, of the knowledge and designs covering the COVID-19 vaccines to the developing world. The limited IP waivers could cover the minimum necessary portions of the technology to produce basic COVID-19 vaccines. The waivers could be limited in time to the duration of the pandemic, or another term agreed to by the WTO. The term could also be defined as ending when widespread vaccination and immunity goals are achieved. The incentive for pharmaceutical companies to support such limited IP waivers could be provided in the form of patent term extensions for the technology covered by the limited IP waivers.

Extensions of patent term are already known and widely used. In the U.S., patent term adjustments are automatically added on to the patent lifespan to account for any delays by the USPTO in the patent prosecution process. In some cases, these mechanisms may extend the patent term for years. Patent term extensions also are available for regulatory delays (35 U.S.C. § 156). In particular, patents covering, inter alia, drug products approved by the United States Food & Drug Administration may be eligible for up to five years of additional patent term to give back time required to complete the regulatory review process. Both patent term adjustments and patent term extensions arise from activities beyond the control of the pharmaceutical companies. A pandemic patent term extension fashioned after such known extensions could be made used to compensate for the current pressing global health needs.

This third proposal may be achievable at the WTO. Hurdles remain and it could be months or years before the WTO reaches an agreement on any waiver of IP protections, and years before countries build factories, gather materials, and gain the expertise to produce the vaccines. A steep hurdle is that mRNA is a new technology, with no machines or experts for hire. Nonetheless, the third solution offers hope to find a middle ground that may begin to be implemented before the end of the current pandemic and be in place for the future.

The patent term extension could be provided for countries with patent offices and could be adapted based on laws and conditions in each country. Pandemic-related patent term extensions could be given for a period of time that the compulsory license is in force. With current pandemic projections of six months to two years for sufficient distribution, providing a patent term extension is reasonable and in line with the time period of many patent term extensions. Given that most pharmaceutical patents are prosecuted in multiple countries, this provides an incentive to participate in a limited waiver program.

Let’s Not Repeat Past Mistakes

It’s been a century since the last pandemic devastated the globe and the only certainty is that this will not be the last pandemic. Solutions created today lay a foundation for mitigation of the next pandemic. It’s been said that those who refuse to learn from history are doomed to repeat it, a thought too painful to contemplate with a pandemic. The industrial nations of the world have technology that others are literally dying to obtain—a high price to pay. Incentivized limited IP waivers may offer a compromise to bridge the gap between maintaining IP rights (and thus relying on charity alone) and arbitrary compulsory licensing that could deter the technological investment to create life-saving solutions in the future.

#### The plan is critical to boosting WTO legitimacy.

Navnit 21 [Brajendra; Ambassador and Permanent Representative of India to WTO; “Science has delivered, will the WTO deliver?” Helsinki Times; 1/18/21; <https://www.helsinkitimes.fi/columns/columns/viewpoint/18561-science-has-delivered-will-the-wto-deliver.html>] Justin

TRIPS waiver proposal from India, South Africa and other members

A proposal by India, South Africa and eight other countries calls on the World Trade Organisation (WTO) to exempt member countries from enforcing some patents, and other Intellectual Property (IP) rights under the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPS, for a limited period of time.

It is to ensure that IPRs do not restrict the rapid scaling- up of manufacturing of COVID-19 vaccines and treatments. While a few members have raised concerns about the proposal, a large proportion of the WTO membership supports the proposal. It has also received the backing of various international organizations, multilateral agencies and global civil society.

Unprecedented times call for unorthodox measures. We saw this in the efficacy of strict lockdowns for a limited period, as a policy intervention, in curtailing the spread of the pandemic.International Monetary Fund (IMF) in its October 2020 edition of World Economic Outlook states “…However, the risk of worse growth outcomes than projected remains sizable. If the virus resurges, progress on treatments and vaccines is slower than anticipated, or countries’ access to them remains unequal, economic activity could be lower than expected, with renewed social distancing and tighter lockdowns”. The situation appears to be grimmer than predicted, we have already lost 7% of economic output from the baseline scenario projected in 2019. It translates to a loss of more than USD 6 trillion of global GDP. Even a 1% improvement in global GDP from the baseline scenario will add more than USD 800 billion in global output, offsetting the loss certainly of a much lower order to a sector of economy on account of the Waiver.

"While making the vaccines available was a test of science, making them accessible and affordable is going to be a test of humanity"

Merely a signal to ensure timely and affordable access to vaccines and treatments will work as a big confidence booster for demand revival in the economy. With the emergence of successful vaccines, there appears to be some hope on the horizon. But how will these be made accessible and affordable to global population? The fundamental question is whether there will be enough of Covid-19 vaccines to go around. As things stand, even the most optimistic scenarios today cannot assure access to Covid-19 vaccines and therapeutics for the majority of the population, in rich as well as poor countries, by the end of 2021. All the members of the WTO have agreed on one account that there is an urgent need to scale-up the manufacturing capacity for vaccines and therapeutics to meet the massive global needs. The TRIPS Waiver Proposal seeks to fulfil this need by ensuring that IP barriers do not come in the way of such scaling up of manufacturing capacity.

Why existing flexibilities under the TRIPS Agreement are not enough

The existing flexibilities under the TRIPS Agreement are not adequate as these were not designed keeping pandemics in mind. Compulsory licenses are issued on a country by country, case by case and product by product basis, where every jurisdiction with an IP regime would have to issue separate compulsory licenses, practically making collaboration among countries extremely onerous. While we encourage the use of TRIPS flexibilities, the same are time-consuming and cumbersome to implement. Hence, only their use cannot ensure the timely access of affordable vaccines and treatments. Similarly, we have not seen a very encouraging progress on WHO’s Covid19-Technology Access Pool or the C-TAP initiative, which encourages voluntary contribution of IP, technology and data to support the global sharing and scale-up of the manufacturing of COVID- 19 medical products. Voluntary Licenses, even where they exist, are shrouded in secrecy. Their terms and conditions are not transparent. Their scope is limited to specific amounts or for a limited subset of countries, thereby encouraging nationalism rather than true international collaboration.

Why is there a need to go beyond existing global cooperation initiatives?

Global cooperation initiatives such as the COVAX Mechanism and the ACT-Accelerator are inadequate to meet the massive global needs of 7.8 billion people. The ACT-A initiative aims to procure 2 billion doses of vaccines by the end of next year and distribute them fairly around the world. With a two-dose regime, however, this will only cover 1 billion people. That means that even if ACT-A is fully financed and successful, which is not the case presently, there would not be enough vaccines for the majority of the global population.

Past experience

During the initial few months of the current pandemic, we have seen that shelves were emptied by those who had access to masks, PPEs, sanitizers, gloves and other essential Covid-19 items even without their immediate need. The same should not happen to vaccines. Eventually, the world was able to ramp up manufacturing of Covid-19 essentials as there were no IP barriers hindering that. At present, we need the same pooling of IP rights and know-how for scaling up the manufacturing of vaccines and treatments, which unfortunately has not been forthcoming, necessitating the need for the Waiver.

It is the pandemic – an extraordinary, once in a lifetime event – that has mobilized the collaboration of multiple stakeholders. It is knowledge and skills held by scientists, researchers, public health experts and universities that have enabled the cross-country collaborations and enormous public funding that has facilitated the development of vaccines in record time – and not alone IP!

Way forward

The TRIPS waiver proposal is a targeted and proportionate response to the exceptional public health emergency that the world faces today. Such a Waiver is well-within the provisions of Article IX of the Marrakesh Agreement which established the WTO. It can help in ensuring that human lives are not lost for want of a timely and affordable access to vaccines. The adoption of the Waiver will also re-establish WTO’s credibility and show that multilateral trading system continues to be relevant and can deliver in times of a crisis. Now is the time for WTO members to act and adopt the Waiver to save lives and help in getting the economy back on the revival path quickly.

While making the vaccines available was a test of science, making them accessible and affordable is going to be a test of humanity. History should remember us for the “AAA rating” i.e. for Availability, Accessibility and Affordability of Covid19 vaccines and treatments and not for a single “A rating” for Availability only. Our future generations deserve nothing less.

#### WTO cred solves wars that go nuclear.

Hamann 09 [Georgia; 2009; J.D. Candidate, Vanderbilt University Law School; “Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System,” VANDERBILT JOURNAL OF TRANSNATIONAL LAW, http://www.jogoremoto.pt/docs/extra/duqJ53.pdf] Justin

Both Antigua and the U.S. claimed the resolution of the arbitration as a victory.99 In reality, the decision reached a midpoint between the respective countries’ positions, establishing a victory for the evolution of the international trading system itself. Voluntary compliance with WTO rules and procedures is of the utmost importance to the international trading system.100 Given the increasingly globalized market, the coming years will see an increase in the importance of the WTO as a cohesive force and arbiter of disputes that likely will become more frequent and injurious.101 The work of the WTO cannot be overstated in a nuclear-armed world, as the body continues to promote respect and even amity among nations with opposing philosophical goals or modes of governance.102 Demagogues in the Unites States may decry the rise of China as a geopolitical threat,103 and extremists in Russia may play dangerous games of brinksmanship with other great powers, but trade keeps politicians’ fingers off “the button.”104 The WTO offers an astounding rate of compliance for an organization with no standing army and no real power to enforce its decisions, suggesting that governments recognize the value of maintaining the international construct of the WTO.105 In order to promote voluntary compliance, the WTO must maintain a high level of credibility.106 Nations must perceive the WTO as the most reasonable option for dispute resolution or fear that the WTO wields enough influence to enforce sanctions.107 The arbitrators charged with performing the substantive work of the WTO by negotiating, compromising, and issuing judgments are keenly aware of the responsibility they have to uphold the organization’s credibility.108

### 1AC – Framing

#### The standard is maximizing expected wellbeing.

#### 1] Actor spec—governments must use util because they don’t have intentions and are constantly dealing with tradeoffs—outweighs since different agents have different obligations—takes out calc indicts since they are empirically denied.

#### 2] Death is bad and outweighs – a] agents can’t act if they fear for their bodily security which constrains every ethical theory, b] it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life

#### 3] Pleasure and pain are the starting point for moral reasoning—they’re our most baseline desires and the only things that explain the intrinsic value of objects or actions

Moen 16, Ole Martin (PhD, Research Fellow in Philosophy at University of Oslo). "An Argument for Hedonism." Journal of Value Inquiry 50.2 (2016): 267.

Let us start by observing, empirically, that **a widely shared judgment about intrinsic value** and disvalue **is that pleasure is intrinsically valuable and pain is intrinsically disvaluable**. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels**, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” **are** here **understood inclusively**, as encompassing anything hedonically positive and anything hedonically negative. 2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store**, I might ask: “What for**?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. **The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good**. 3 As Aristotle observes: “**We never ask** [a man] **what** his **end is in being pleased, because we assume that pleasure is choice worthy in itself**.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that **if something is painful, we have a sufficient explanation of why it is bad**. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value**. Although **pleasure and pain thus seem to be good candidates for intrinsic value and disvalue**, several objections have been raised against this suggestion: (1) that pleasure and pain have instrumental but not intrinsic value/disvalue; (2) that pleasure and pain gain their value/disvalue derivatively, in virtue of satisfying/frustrating our desires; (3) that there is a subset of pleasures that are not intrinsically valuable (so-called “evil pleasures”) and a subset of pains that are not intrinsically disvaluable (so-called “noble pains”), and (4) that pain asymbolia, masochism, and practices such as wiggling a loose tooth render it implausible that pain is intrinsically disvaluable. I shall argue that these objections fail. Though it is, of course, an open question whether other objections to P1 might be more successful, I shall assume that if (1)–(4) fail, we are justified in believing that P1 is true itself a paragon of freedom—there will always be some agents able to interfere substantially with one’s choices. The effective level of protection one enjoys, and hence one’s actual degree of freedom, will vary according to multiple factors: how powerful one is, how powerful individuals in one’s vicinity are, how frequent police patrols are, and so on. Now, we saw above that what makes a slave unfree on Pettit’s view is the fact that his master has the power to interfere arbitrarily with his choices; in other words, what makes the slave unfree is the power relation that obtains between his master and him. The difﬁculty is that, in light of the facts I just mentioned, there is no reason to think that this power relation will be unique. A similar relation could obtain between the master and someone other than the slave: absent perfect state control, the master may very well have enough power to interfere in the lives of countless individuals. Yet it would be wrong to infer that these individuals lack freedom in the way the slave does; if they lack anything, it seems to be security. A problematic power relation can also obtain between the slave and someone other than the master, since there may be citizens who are more powerful than the master and who can therefore interfere with the slave’s choices at their discretion. Once again, it would be wrong to infer that these individuals make the slave unfree in the same way that the master does. Something appears to be missing from Pettit’s view. If I live in a particularly nasty part of town, then it may turn out that, when all the relevant factors are taken into account, I am just as vulnerable to outside interference as are the slaves in the royal palace, yet it does not follow that our conditions are equivalent from the point of view of freedom. As a matter of fact, we may be equally vulnerable to outside interference, but as a matter of right, our standings could not be more different. I have legal recourse against anyone who interferes with my freedom; the recourse may not be very effective—presumably it is not, if my overall vulnerability to outside interference is comparable to that of a slave— but I still have full legal standing.68 By contrast, the slave lacks legal recourse against the interventions of one speciﬁc individual: his master. It is that fact, on a Kantian view—a fact about the legal relation in which a slave stands to his master—that sets slaves apart from freemen. The point may appear trivial, but it does get something right: whereas one cannot identify a power relation that obtains uniquely between a slave and his master, the legal relation between them is undeniably unique. A master’s right to interfere with respect to his slave does not extend to freemen, regardless of how vulnerable they might be as a matter of fact, and citizens other than the master do not have the right to order the slave around, regardless of how powerful they might be. This suggests that Kant is correct in thinking that the ideal of freedom is essentially linked to a person’s having full legal standing. More speciﬁcally, he is correct in holding that the importance of rights is not exhausted by their contribution to the level of protection that an individual enjoys, as it must be on an instrumental view like Pettit’s. Although it does matter that rights be enforced with reasonable effectiveness, the sheer fact that one has adequate legal rights is essential to one’s standing as a free citizen. In this respect, Kant stays faithful to the idea that freedom is primarily a matter of standing—a standing that the freeman has and that the slave lacks. Pettit himself frequently insists on the idea, but he fails to do it justice when he claims that freedom is simply a matter of being adequately (and reliably) shielded against the strength of others. As Kant recognizes, the standing of a free citizen is a more complex matter than that. One could perhaps worry that the idea of legal standing is something of a red herring here—that it must ultimately be reducible to a complex network of power relations and, hence, that the position I attribute to Kant differs only nominally from Pettit’s. That seems to me doubtful. Viewing legal standing as essential to freedom makes sense only if our conception of the former includes conceptions of what constitutes a fully adequate scheme of legal rights, appropriate legal recourse, justiﬁed punishment, and so on. Only if one believes that these notions all boil down to power relations will Kant’s position appear similar to Pettit’s. On any other view—and certainly that includes most views recently defended by philosophers—the notion of legal standing will outstrip the power relations that ground Pettit’s theory.

#### 4] Extinction outweighs

MacAskill 14 [William, Oxford Philosopher and youngest tenured philosopher in the world, Normative Uncertainty, 2014]

The human race might go extinct from a number of causes: asteroids, supervolcanoes, runaway climate change, pandemics, nuclear war, and the development and use of dangerous new technologies such as synthetic biology, all pose risks (even if very small) to the continued survival of the human race.184 And different moral views give opposing answers to question of whether this would be a good or a bad thing. It might seem obvious that human extinction would be a very bad thing, both because of the loss of potential future lives, and because of the loss of the scientific and artistic progress that we would make in the future. But the issue is at least unclear. The continuation of the human race would be a mixed bag: inevitably, it would involve both upsides and downsides. And if one regards it as much more important to avoid bad things happening than to promote good things happening then one could plausibly regard human extinction as a good thing.For example, one might regard the prevention of bads as being in general more important that the promotion of goods, as defended historically by G. E. Moore,185 and more recently by Thomas Hurka.186 One could weight the prevention of suffering as being much more important that the promotion of happiness. Or one could weight the prevention of objective bads, such as war and genocide, as being much more important than the promotion of objective goods, such as scientific and artistic progress. If the human race continues its future will inevitably involve suffering as well as happiness, and objective bads as well as objective goods. So, if one weights the bads sufficiently heavily against the goods, or if one is sufficiently pessimistic about humanity’s ability to achieve good outcomes, then one will regard human extinction as a good thing.187 However, even if we believe in a moral view according to which human extinction would be a good thing, we still have strong reason to prevent near-term human extinction. To see this, we must note three points. First, we should note that the extinction of the human race is an extremely high stakes moral issue. Humanity could be around for a very long time: if humans survive as long as the median mammal species, we will last another two million years. On this estimate, the number of humans in existence in the The future, given that we don’t go extinct any time soon, would be 2×10^14. So if it is good to bring new people into existence, then it’s very good to prevent human extinction. Second, human extinction is by its nature an irreversible scenario. If we continue to exist, then we always have the option of letting ourselves go extinct in the future (or, perhaps more realistically, of considerably reducing population size). But if we go extinct, then we can’t magically bring ourselves back into existence at a later date. Third, we should expect ourselves to progress, morally, over the next few centuries, as we have progressed in the past. So we should expect that in a few centuries’ time we will have better evidence about how to evaluate human extinction than we currently have. Given these three factors, it would be better to prevent the near-term extinction of the human race, even if we thought that the extinction of the human race would actually be a very good thing. To make this concrete, I’ll give the following simple but illustrative model. Suppose that we have 0.8 credence that it is a bad thing to produce new people, and 0.2 certain that it’s a good thing to produce new people; and the degree to which it is good to produce new people, if it is good, is the same as the degree to which it is bad to produce new people, if it is bad. That is, I’m supposing, for simplicity, that we know that one new life has one unit of value; we just don’t know whether that unit is positive or negative. And let’s use our estimate of 2×10^14 people who would exist in the future, if we avoid near-term human extinction. Given our stipulated credences, the expected benefit of letting the human race go extinct now would be (.8-.2)×(2×10^14) = 1.2×(10^14). Suppose that, if we let the human race continue and did research for 300 years, we would know for certain whether or not additional people are of positive or negative value. If so, then with the credences above we should think it 80% likely that we will find out that it is a bad thing to produce new people, and 20% likely that we will find out that it’s a good thing to produce new people. So there’s an 80% chance of a loss of 3×(10^10) (because of the delay of letting the human race go extinct), the expected value of which is 2.4×(10^10). But there’s also a 20% chance of a gain of 2×(10^14), the expected value of which is 4×(10^13). That is, in expected value terms, the cost of waiting for a few hundred years is vanishingly small compared with the benefit of keeping one’s options open while one gains new information.

#### 5] Weighability – only consequentialism can explain the ethical difference in breaking a promise to take someone to the hospital and breaking a promise to take someone to lunch – that outweighs –

#### A] Resolvability – there’s no way to weigh between competing offense under their fw which means their fw can’t guide action

#### B] Intuitions – they’re a necessary side constraint on all ethics – if a very well justified, logical theory concluded "rape good” you wouldn’t say “huh I guess rape is good” you would abandon it

#### 6] No intent foresight distinction for states.

Enoch 07 Enoch, D [The Faculty of Law, The Hebrew Unviersity, Mount Scopus Campus, Jersusalem]. (2007). INTENDING, FORESEEING, AND THE STATE. Legal Theory, 13(02). doi:10.1017/s1352325207070048 https://www.cambridge.org/core/journals/legal-theory/article/intending-foreseeing-and-the-state/76B18896B94D5490ED0512D8E8DC54B2

The general difficulty of the intending-foreseeing distinction here stemmed, you will recall, from the feeling that attempting to pick and choose among the foreseen consequences of one’s actions those one is more and those one is less responsible for looks more like the preparation of a defense than like a genuine attempt to determine what is to be done. Hiding behind the intending-foreseeing distinction seems like an attempt to evade responsibility, and so thinking about the distinction in terms of responsibility serves 39. Anderson & Pildes, supra note 38. I will use this text as my example of an expressive theory here. 40. See id. at 1554, 1564. 41. For a general critique, see Mathew D. Adler, Expressive Theories of Law: A Skeptical Overview, 148 U. PA. L. REV. 1363 (1999–2000). 42. As Adler repeatedly notes, the understanding of expression Anderson & Pildes work with is amazingly broad, so that “To express an attitude through action is to act on the reasons the attitude gives us”; Anderson & Pildes, supra note 38, at 1510. If this is so, it seems that expression drops out of the picture and everything done with it can be done directly in terms of reasons. 43. This may be true of what Anderson and Pildes have in mind when they say that “expressive norms regulate actions by regulating the acceptable justifications for doing them”; id. at 1511. http://journals.cambridge.org Downloaded: 03 Aug 2014 IP address: 134.153.184.170 Intending, Foreseeing, and the State 91 to reduce even further the plausibility of attributing to it intrinsic moral significance. This consideration—however weighty in general—seems to me very weighty when applied to state action and to the decisions of state officials. For perhaps it may be argued that individuals are not required to undertake a global perspective, one that equally takes into account all foreseen consequences of their actions. Perhaps, in other words, individuals are entitled to (roughly) settle for having a good will, and beyond that let chips fall where they may. But this is precisely what stateswomen and statesmen—and certainly states—are not entitled to settle for.44 In making policy decisions, it is precisely the global (or at least statewide, or nationwide, or something of this sort) perspective that must be undertaken. Perhaps, for instance, an individual doctor is entitled to give her patient a scarce drug without thinking about tomorrow’s patients (I say “perhaps” because I am genuinely not sure about this), but surely when a state committee tries to formulate rules for the allocation of scarce medical drugs and treatments, it cannot hide behind the intending-foreseeing distinction, arguing that if it allows45 the doctor to give the drug to today’s patient, the death of tomorrow’s patient is merely foreseen and not intended. When making a policy-decision, this is clearly unacceptable. Or think about it this way (I follow Daryl Levinson here):46 perhaps restrictions on the responsibility of individuals are justified because individuals are autonomous, because much of the value in their lives comes from personal pursuits and relationships that are possible only if their responsibility for what goes on in the (more impersonal) world is restricted. But none of this is true of states and governments. They have no special relationships and pursuits, no personal interests, no autonomous lives to lead in anything like the sense in which these ideas are plausible when applied to individuals persons. So there is no reason to restrict the responsibility of states in anything like the way the responsibility of individuals is arguably restricted.47 States and state officials have much more comprehensive responsibilities than individuals do. Hiding behind the intending-foreseeing distinction thus more clearly constitutes an evasion of responsibility in the case of the former. So the evading-responsibility worry has much more force against the intending-foreseeing distinction when applied to state action than elsewhere.

#### 7] Substitutability—only consequentialism explains necessary enablers – if I promise someone to mow the grass, my promise gives me moral reason to mow the grass but no reason to turn on the lawn mower.

#### 8] Reject calc indicts

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

#### B] Theory—they’re functionally NIBs that everyone knows are silly but skew the aff and move the debate away from the topic and actual philosophical debate, killing valuable education

### Underview

#### 1] Aff gets 1AR theory since the neg can be infinitely abusive and I can’t check back. It’s drop the debater since the 1ar is too short to win both theory and substance. No RVI or 2NR paradigm issues since they’d dump on it for 6 minutes and my 3-minute 2AR is spread too thin. Competing interps since reasonability is arbitrary and bites judge intervention.

#### 2] Apocalyptic images challenge dominant power structures to create futures of social justice

Jessica Hurley 17, Assistant Professor in the Humanities at the University of Chicago, “Impossible Futures: Fictions of Risk in the Longue Durée”, Duke University Press, https://read.dukeupress.edu/american-literature/article/89/4/761/132823/Impossible-Futures-Fictions-of-Risk-in-the-Longue

If contemporary ecocriticism has a shared premise about environmental risk it is that genre is the key to both perceiving and, possibly, correcting ecological crisis. Frederick Buell’s 2003 From Apocalypse to Way of Life: Environmental Crisis in the American Century has established one of the most central oppositions of this paradigm. As his title suggests, Buell tells the story of a discourse that began in the apocalyptic mode in the 1960s and 70s, when discussions of “the immanent end of nature” most commonly took the form of “prophecy, revelation, climax, and extermination” before turning away from apocalypse when the prophesied ends failed to arrive (112, 78). Buell offers his suggestion for the appropriate literary mode for life lived within a crisis that is both unceasing and inescapable: new voices, “if wise enough….will abandon apocalypse for a sadder realism that looks closely at social and environmental changes in process and recognizes crisis as a place where people dwell” (202-3). In a world of threat, Buell demands a realism that might help us see risks more clearly and aid our survival.¶ Buell’s argument has become a broadly held view in contemporary risk theory and ecocriticism, overlapping fields in the social sciences and humanities that address the foundational question of second modernity: “how do you live when you are at such risk?” (Woodward 2009, 205).1 Such an assertion, however, assumes both that realism is a neutral descriptive practice and that apocalypse is not something that is happening now in places that we might not see, or cannot hear. This essay argues for the continuing importance of apocalyptic narrative forms in representations of environmental risk to disrupt conservative realisms that maintain the status quo. Taking the ecological disaster of nuclear waste as my case study, I examine two fictional treatments of nuclear waste dumps that create different temporal structures within which the colonial history of the United States plays out. The first, a set of Department of Energy documents that use statistical modeling and fictional description to predict a set of realistic futures for the site of the Waste Isolation Pilot Plant in New Mexico (1991), creates a present that is fully knowable and a future that is fully predictable. Such an approach, I suggest, perpetuates the state logics of implausibility that have long undergirded settler colonialism in the United States. In contrast, Leslie Marmon Silko’s contemporaneous novel Almanac of the Dead (1991) uses its apocalyptic form to deconstruct the claims to verisimilitude that undergird state realism, transforming nuclear waste into a prophecy of the end of the United States rather than a means for imagining its continuation. In Almanac of the Dead, the presence of nuclear waste introjects a deep-time perspective into contemporary America, transforming the present into a speculative space where environmental catastrophe produces not only unevenly distributed damage but also revolutionary forms of social justice that insist on a truth that probability modeling cannot contain: that the future will be unimaginably different from the present,

#### 3] Evolution proves our theory true

**Johnson and Thayer 16** – Dominic D. P. Johnson, D.Phil., Ph.D.\* and Bradley A. Thayer, Ph.D., “The evolution of offensive realism Survival under anarchy from the Pleistocene to the present,” https://www.cambridge.org/core/services/aop-cambridge-core/content/view/56B778004187F70B8E59609BE7FEE7A4/S073093841600006Xa.pdf/div-class-title-the-evolution-of-offensive-realism-div.pdf

Few principles unite the discipline of international relations, but one exception is anarchy—the absence of government in international politics. Anarchy is, ironically, the ‘‘ordering’’ principle of the global state system and the starting point for most major theories of international politics, such as neoliberalism and neorealism.42,43,44,45 Other theoretical approaches, such as constructivism, also acknowledge the impact of anarchy, even if only to consider why anarchy occurs and how it can be circumvented.46,47 Indeed, the anarchy concept is so profound that it defines and divides the discipline of political science into international politics (politics under conditions of anarchy) and domestic politics (politics under conditions of hierarchy, or government). Given the prominence of the concept in present-day international relations theory, it is striking that anarchy only took hold as a central feature of scholarship in recent decades, since the publication of Kenneth Waltz’s Theory of International Politics in 1979. In fact, however, **anarchy has been a constant feature of the entire multimillion year history of the human lineage (and indeed the 3.5 billion–year history of the evolution of all life on Earth before that). It is not just that we lack a global Leviathan today; humans never had such a luxury. The fact that human evolution occurred under conditions of anarchy, that we evolved as hunter-gatherers in an ecological setting of predation, resource competition, and intergroup conflict, and that humans have been subject to natural selection** for millions of years **has profound consequences for understanding human behavior**, not least how humans perceive and act toward others. Scholars often argue over whether historically humans experienced a Hobbesian ‘‘state of nature,’’ but—whatever the outcome of that debate—it is certainly a much closer approximation to the prehistoric environment in which human brains and behavior evolved. **This legacy heavily influences our decision-making and behavior today, even—perhaps especially—in the anarchy of international politics**. We argue that **evolution under conditions of anarchy has predisposed human nature toward the behaviors predicted by offensive realism: Humans**, particularly men, **are strongly self-interested, often fear other groups, and seek more resources, more power, and more influence** (as we explain in full later). **These strategies** are not unique to humans and, in fact, **characterize a much broader trend in behavior among mammals as a whole—especially primates**—as well as many other major vertebrate groups, including birds, fish, and reptiles. **This recurrence of behavioral patterns** across different taxonomic groups **suggests that the behaviors characterized by offensive realism have broad and deep evolutionary roots**. This perspective does not deny the importance of institutions, norms, and governance in international politics. On the contrary, it provides or adds to the reasons why we demand and need them, and indeed why they are so hard to establish and maintain. Until recently, **international relations theorists rarely used insights from the life sciences to inform their understanding of human behavior**. However, **rapid advances in the life sciences offer increasing theoretical and empirical challenges to scholars in** the social sciences in general and **international relations** in particular, who are therefore under increasing pressure to address and integrate this knowledge rather than to suppress or ignore it. Whatever one’s personal views on evolution, **the time has come to explore the implications of evolutionary theory for mainstream theories of international relations**. **The most obvious challenge that evolutionary theory presents to international relations concerns our understanding of human nature**. Theories purporting to explain human behavior make explicit or implicit assumptions about preferences and motivations, and mainstream theories in international politics are no exception. Many **criticisms of international relations theories focus on these unsubstantiated or contested assumptions about underlying human nature.** The parsimony of general theories depends on how well they explain phenomena across space and time; in other words, the more closely they coincide with empirical observations across cultures and throughout history. The most enduring theories of international relations, therefore, will be ones that are able to incorporate (or at least do not run against the grain of) evolutionary theory. Although Thomas Hobbes claimed to have deduced Leviathan scientifically from ‘‘motion’’ and the physical senses, he was writing two hundred years before Darwin and so had no understanding of evolution.53 International relations scholars have tended to claim to deduce their own theories from Hobbes, or subsequent philosophers who followed him, and we suggest it is time to revisit the idea of foundational scientific principles. Starting with biology, or with human evolutionary history, has never been typical in international relations scholarship, but this approach is now less exotic than it once seemed as innovators in a range of social sciences, including economics, psychology, sociology, and political science, pursue this line of inquiry.54,55,56,57 International relations stands to gain from similar interdisciplinary insights.