## Advantage

#### IP undermines competition and keeps medicine prices high.

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Intellectual property undermines competition and keeps prices high¶ As MSF has seen repeatedly for medical products critical to our operations, competition among multiple manufacturers is a proven way to reduce prices and increase access. Without competition, single suppliers can set prices high, and limited supply options leave vulnerabilities, including dependence on a sole manufacturer’s ability to maintain consistent supply. The effects of IP monopolies like patents on competition and supply for pharmaceutical products are well documented.11,12,13 Yet, as increasingly recognised, and discussed in more detail within this document, patent-based monopolies can also be a barrier in the field of vaccine production and have posed challenges to vaccine development for decades.¶ Traditional narrative of technology transfers and lack of consideration of patent barriers ¶ Prior experiences of developing vaccines for diphtheria, whole-cell pertussis, polio, measles, mumps, influenza, rubella, and yellow fever in World Bank-classified low- and middle-income countries had suggested that patents do not play a major role in modifying the behaviour of vaccine manufacturers. Historically, these vaccines have been developed using conventional egg-based and cell culture-based methods generally not protected by patents. In these cases, the process of manufacturing and key ‘know how’\* was considered a barrier to entry for new competitors.14¶ When looking at the manufacturing experiences of some older vaccines, this perception is an oversimplification. The development of the hepatitis B vaccine, for example, dating back nearly half a century, faced patent barriers resulting in monopolies and high prices.15 The two manufacturers of recombinant hepatitis B vaccines, Merck and SmithKline Beecham, needed licences to more than 90 patents from universities, public institutes and private companies to produce their vaccines. Despite the contributions of publicly funded R&D, product prices at introduction were as high as $40 per dose for this 3-dose regimen (equivalent to more than $87 per dose in real terms in 2016).¶ Patents are increasingly an issue for development of newer vaccines¶ Patent activity in the field of vaccine development and manufacturing has been increasingly recognised as problematic over the past 15 years, according to manufacturers interviewed for this report. International organisations with vaccines expertise such as WHO and Gavi, the Vaccine Alliance, have similarly noted that patent thickets are an increasing concern for vaccines.16¶ For medical products such as PCV and HPV vaccines, patent barriers can slow the development process, increase costs, increase uncertainty and deter or even block other manufacturers considering entering the market.17 A recent analysis by Chandrasekharan et al. found 106 Patent Cooperation Treaty (PCT) applications “potentially relevant to the manufacturing of pneumococcal vaccines”† and 93 patents applications “relevant to the manufacturing of HPV vaccines.”18¶ The patent applications and discussions with manufacturers indicate that broad monopolies are being pursued for these vaccines, through tactics such as using overly general language in patent claims concerning the scope of the inventions. According to national criteria, many of these patents or applications could be challenged or rejected due to their weak technical merits. With patents sought for PCV and HPV vaccine technology in major and emerging markets, like Brazil, China, Europe, India, and the US, governments and other stakeholders seeking to encourage competition and access to affordable vaccines must consider how to mitigate the constraints that pending and granted patents in developing countries place on the ability of potential competitor vaccine manufacturers to develop or sell competitor vaccines.¶ Patents undermine competition throughout PCV and HPV vaccine manufacturing and beyond¶ Patents can act as barriers throughout vaccine development, manufacturing and administration processes. PCV and HPV vaccine products are protected by a series of patents and patent applications, covering all aspects including starting materials, composition, process technologies, and methods of using vaccines, including age groups, vaccine presentations and schedules. Potential competitor vaccine manufacturers considering entering the market may face patent challenges “in any step of the development process starting from preclinical R&D, to scale up, formulation and licensure in the markets of choice, and hence may alter their decision pathways… at each step.”19¶ The typical strategy for a vaccine manufacturer seeking a patent monopoly is to use broad, non-specific claim language to define what they claim is the invention. Many of those patents and applications do not merit patent protection according to national laws, and many are used mainly to maximise the scope of monopoly.¶ Starting materials¶ Starting materials patents cover the inputs/initial ingredients for making a vaccine, including various chemical reagents, host cells, vectors, and DNA and/or RNA sequences of various types. These inputs are highly likely to be required for vaccine production. If the rights to use these materials in vaccine manufacturing are not obtained by a company, it may be very difficult to ‘design around’ the need for these materials. These materials have often been patented years ago and they may now be in the public domain, as is the case for PCV and HPV vaccines.¶ Several patent applications were filed on HPV vaccine starting materials from the mid-1990s. For instance, Merck filed a patent application on the basic HPV DNA,20 covering the most common antigen types HPV 16 and HPV 18. The application attempts to protect recombinant DNA sequences encoding the important antigenic proteins of papillomavirus and purified virus-like particles comprised of the recombinant proteins. It also tries to cover the methods of making and using the recombinant proteins. Merck additionally filed a patent application seeking monopoly protection over virus-like particles containing HPV 18.21 Where granted as claimed, these patents could block anyone who plans to develop alternative HPV vaccines during the patent term. These two Merck applications, where granted, should have started to expire around the world beginning in 2015-2016.¶ A number of newer patent applications since the 2000s on HPV vaccines are also related to starting materials. It is a common practice to file such ‘second-generation’ applications to seek additional commercial advantages. For instance, GSK filed a patent application22 claiming modified DNA sequences of HPV which provide enhanced levels of expressed antigen. This patent would expire in 2023 where granted. Another example is a GSK patent application23 related to cross-reactivity, where HPV 16 and HPV 18-containing constructs can be used in a vaccine that protects against other HPV antigens besides 16 and 18. The detailed effects of these newer patent applications on follow-on development of alternative HPV vaccines require further analysis.¶ Vaccine composition¶ Vaccine composition patents typically seek to cover the resulting combination of immunologically important parts of the vaccine, plus associated materials, such as adjuvants, buffers and preservatives. These types of patents can potentially have strong blocking effects.¶ One of the key patents that Pfizer is seeking for its PCV13 product relates to the vaccine’s composition.24 See more details on this PCV13 patent application and why it represents an unwarranted obstacle to pricelowering competition for PCV in the PCV13 patent opposition case study.¶ There are numerous other examples of vaccine composition patents and these may also warrant further analysis for the effects they may have on competition. For example, Pfizer, GSK and other companies have further filed a series of patent applications claiming different aspects of PCV compositions including those covering up to 20 and 26 valent PCV vaccines.25¶ Process technologies¶ Patents related to vaccine process technologies grant monopolies on the way a vaccine is manufactured. The specific manufacturing methods depend on the type of vaccine. Many different patents and patent applications have been identified that cover or attempt to cover various aspects of vaccine process technologies. ¶ For example, basic conjugation technology needed for PCV manufacturing is patent protected in at least six countries.26 This patent is broad and non-specific, blocking competitors from using a general process for combining several vaccine elements (a polysaccharide, e.g., derived from a Pneumococcus, activated with a specific organic compound and then joined to a carrier protein) to obtain a conjugated immunogenic product. These patents have already begun to expire as of 2016. Until expiry, a vaccine manufacturer wanting to offer a more affordable PCV is required to address this barrier in countries where the patent has been filed or granted.¶ Some other examples of patents filed by different applicants claiming different process technologies related to PCV production may also warrant further analysis to assess their potential impact on competition for PCV vaccines.27¶ Methods of using vaccines¶ ‘Methods of use’ patents seek a monopoly on the way a product is used, for example how a vaccine is administered to children. Depending on the specific claim language, this can include patents on various vial presentations, dose regimens, populations or age groups covered, other elements related to the presentation and packaging of the vaccine itself, or the use of the vaccine in people.¶ These patents are highly problematic because they may undermine the ability of Ministries of Health and clinicians to practise medicine and immunise children in the most appropriate way, free from any potential patent infringement risks. Additionally, these patents may also make potential competitors liable if their product labels and package inserts include information on dosage regimens or methods of use that are under the scope of the concerned patents. This can be the case even if more affordable competitor vaccine products themselves do not infringe on an originator’s patents on a given vaccine.¶ One example of this is a GSK patent application28, which essentially seeks a monopoly on administering PCV after a child has received tetanus and/or diphtheria vaccines.\* This ‘preimmunisation’ claim term is particularly broad; many national immunisation programmes could have a national vaccination protocol through which a child may receive tetanus or diphtheria vaccines before getting PCV.¶ If granted, this patent may have a strong blocking effect on the use of any alternative PCV in national immunisation schedules. GSK has applied for this PCV patent in Great Britain (withdrawn in 2011), Brazil, Eurasian Patent Organisation and Morocco.29 The application was also filed, but subsequently withdrawn, in various other jurisdictions, including Australia, Canada, China, Germany and the European Patent Office, South Korea, and abandoned in India, following pre-grant opposition.30 It has already been granted in South Africa.31¶ Patents related to age groups¶ Patent claims can also cover specific age groups to which the vaccine can be administered. If granted, these patents can restrict competition by blocking other manufacturers from selling vaccines for administration to the specified (and likely necessary) age groups. For example, the European Patent Office granted a patent32 to GSK for a method of using a ‘two dose’ HPV16/18 vaccine.33 The patent application includes a patent claim stating that the vaccine is formulated for administration ‘to a subject 14 years of age or below’.34 It indicates a monopoly on immunising people who are 14 years old or younger, which covers the full age range of girls recommended by WHO to receive HPV vaccines.35 This may well be a patent that blocks competition in Europe and prevents competitor manufacturers from offering more affordable versions of HPV vaccines that protect against these two critical strains of HPV. In its PCT application36, the initial claims of the equivalent patent are even broader, covering the use of the concerned method for females aged ‘25 years or under’, ‘9 to 25 years’, ‘9 to 14 years’, ‘15 to 19 years’ and ‘20 to 25 years’, thereby seeking to cover all possible vaccination schedules for the full ranges of ages for whom HPV vaccine would be most effective.¶ Patents related to vaccination schedule and presentation¶ Dose regimens are formalised schedules by which medicines or vaccines are administered, including the dose of the vaccine, the number of doses in a period of time and the time between doses. The patenting of these regimens, including for vaccines, effectively grants a patent holder a monopoly that inhibits the development of competitor products that may need to be administered in the same or a similar dosing regimen, and undermines the ability of medical professionals to prescribe the most medically sound regimens based on health needs.¶ For example, a GSK patent application on the HPV vaccine37 contains very broad claims. The technology in this GSK patent application covers both bivalent\* and quadrivalent† HPV vaccines and claims a process of administering a ‘two-dose regimen’ consisting of a first dose and a second dose, wherein both doses can be either bivalent or quadrivalent, covering all virus types causing cervical cancer. It is sufficiently broad to affect manufacturers who intend to move towards two-dose regimen administration for their bivalent or quadrivalent HPV products, while a two-dose schedule is currently recommended by WHO for HPV.38 This patent application has been issued in Europe39 for the ‘two-dose’ bivalent HPV vaccine, and the vaccine was approved for marketing by the European Commission in December 2013. Applications have also been filed in Australia, Canada, China, India, New Zealand, South Korea and the US. It has been withdrawn in the Philippines and refused in Ukraine.40¶ In other situations, broad claims in patent applications could also seek monopoly protection over the vial presentation and carry concerning implications for the launch of alternative versions of the vaccine by followon manufacturers. Vial presentation refers to the format of the vaccine, in terms of the number of doses, the volume and the weight contained within one unit of production. For example, it could refer to a single-dose pre-filled syringe, a 10-dose vial with 2 ml per dose, a 20-dose vial and so on.¶ Multi-dose vial presentations, where more than one dose of the vaccine is contained in a vial, are an advantage for developing country immunisation programmes because they decrease cold chain capacity requirements and ease vaccination programme logistics. Multi-dose vials, in general, also have a lower price per dose compared to single-dose vial and/or syringe formats. Pfizer filed a patent application concerning a multidose vial PCV13,41 which includes broad claims related to specific presentations, including pre-filled vaccine delivery devices (such as a syringe) as well as a vial container. If granted as claimed, it might effectively block the development and launching of alternative versions of multi-dose vial PCV13 and secure the market of using such presentations (multi-dose vials) for only Pfizer’s product. The monopoly associated with this patent could mean that public health programmes looking to switch to multi-dose vial PCV13 or a pre-filled ‘device,’ such as a pre-filled syringe, would either have to stay with a single dose vial format or have to use Pfizer’s version only. This patent has been granted in Australia, South Korea, the US and by the European Patent Office.42 An equivalent application has also been filed in China43 and India44, where the applications are pending examination.¶ Summary¶ There are many different aspects of vaccines that are being patented, in many cases undeservingly so per national laws. These patents pose significant barriers for other manufacturers to enter the market and contribute to a competitive environment that could help lower prices and increase access. Taken together, these patents indicate that throughout the vaccine development process and beyond, patents pose a threat to affordable vaccines by impeding, and possibly outright blocking price-lowering follow-on competition. In some cases, potential competitors have opportunities to address and overcome these barriers providing they have the time, resources, technical know-how and an accurate assessment of the vaccine patent landscape.

#### Millions, including many children, die from pneumonia and HPV, but low-income countries and families can’t afford the vaccines to prevent them.

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Through our operations, MSF teams vaccinate thousands of vulnerable children each year against pneumonia, the number one killer of children under five years worldwide. MSF is also starting to provide vaccinations against human papillomavirus (HPV), a sexually transmitted infection that can lead to cervical cancer, one of the leading cancer killers of women in developing countries. The World Health Organization (WHO) recommends vaccination with the pneumococcal conjugate vaccine (PCV) for all children worldwide and HPV vaccination for girls worldwide. However, these vaccines are often unaffordable for developing countries. Millions of children around the world are left unprotected from pneumonia or HPV when Ministries of Health cannot afford to incorporate these vaccines into their national immunisation programmes.¶ Pneumonia¶ Globally, pneumonia kills nearly one million children every year.2 Children in crisis-affected contexts are particularly susceptible to pneumonia, and MSF medical teams often see its deadly effects in our health facilities. PCV can prevent many cases of pneumonia and is currently manufactured for children by just two companies: Pfizer and GlaxoSmithKline (GSK). Unfortunately, PCV is priced out of reach of many parents, governments and treatment providers, due in part to high prices caused by a lack of sufficient competition. Approximately one third of the world’s countries have not been able to introduce PCV because of its high price.3 Millions of vulnerable children living in countries such as Jordan, Thailand and the Philippines are left without affordable access to this life-saving vaccine. According to 2015 WHO/UNICEF estimates, 60% of the world’s infants (81.6 million) were not receiving PCV in 2015, either because they lived in one of 55 countries that had not yet introduced the vaccine, or they were not being reached by the routine immunisation services in their country.¶ MSF provides PCV through our work in countries such as Central African Republic, Ethiopia, Greece, South Sudan, Syria and Uganda, among others. From 2009 to 2014, MSF negotiated with Pfizer and GSK to obtain a sustainable, affordable price for PCV, exceptionally accepting a limited-term donation, with agreement from both Pfizer and GSK that they would work on longer-term solutions to improve affordability. In the absence of such a solution, MSF and other humanitarian organisations continued to struggle to purchase PCV at an affordable price. For example, in 2016 MSF paid 60 Euros (US$68.10) for one dose of the Pfizer product to vaccinate refugee children in Greece – 20 times more than the lowest PCV price offered by Pfizer and GSK. ¶ In 2015, faced with the impossibility of obtaining an affordable price, MSF launched a public campaign – A Fair Shot – calling on both companies to lower the price of PCV for humanitarian use and in all developing countries. Because of this pressure, in late 2016, both Pfizer and GSK finally agreed to extend their lowest global price to humanitarian organisations vaccinating in emergencies, but not to developing countries more broadly.4 Many governments, providers, and parents still struggle to afford PCV.¶ Human papillomavirus¶ The World Health Organization (WHO) estimates that more than one million women are living with cervical cancer worldwide, most often as a “consequence of a long-term infection with human papillomavirus (HPV).” WHO also notes that most cases occur in developing countries;5 in 2012, more than a quarter of a million women died from cervical cancer in developing countries.6¶ Two companies, GSK and Merck, manufacture vaccines that protect against two (GSK), four and nine (Merck) different types of HPV. Types 16 and 18 are associated with 71% of cases of cervical cancers and are present in all three vaccines.7 Despite the importance of this vaccine, by mid-2016, only 65 countries had introduced HPV vaccines.8 Prices for the vaccines range from $4.50 per dose at the lowest global price up to $193 per dose in the US private sector.9 In contrast, based on peer-reviewed manufacturing estimates, HPV vaccines could be manufactured for as little as $0.50 to $0.60 per dose.10¶ MSF provides cervical cancer screenings and HPV vaccines in some projects, for example in the Philippines, and is preparing to do so in Zimbabwe.

**Poverty and disease are mutually reinforcing, causing staggering suffering and injustice.**

**Hollis & Pogge ’08 -** Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008) AT

In 2004, some 970 million people, around 15 percent of the world’s population, were living below the extreme poverty line of $1 a day (more strictly defi ned, $392.88 annually) in 1993 Purchasing Power Parity (PPP) terms (Chen and Ravallion 2007, 16579).3 Furthermore, those living below this very low poverty line fell on average around 28 percent below it. Th eir average annual purchasing power therefore corresponded to approximately $420 in the US in 2008 dollars.4¶ Th ese are the poorest of the poor. Th e World Bank also uses a somewhat less miserly poverty line, namely $2 dollar a day, or an annual amount of $785.76 PPP 1993. Th e Bank’s data show that around 40 percent of the world’s population, or over 2.5 billion people, lived in income poverty so defi ned in 2004,5 with this population falling on average 41 percent below this higher line.6 Individuals In this much larger group could buy, on average, about as much in 2004 as could be bought in the US in 2008 for $690.¶ The Effects of Global Income Poverty on Health¶ The effects of such extreme income poverty are foreseeable and extensively documented. It is estimated that around 13 percent of all human beings (830 million) are chronically undernourished, 17 percent (1.1 billion) lack access to safe water, and 41 percent (2.6 billion) lack access to basic sanitation (UNDP 2006, 174, 33). About 31 percent (2 billion) lack access to crucial drugs and 25 percent (1.6 billion) lack electricity (Fogarty n.d., IEA 2002). Some 780 million adults are illiterate (UNESCO 2006), and 14 percent of children aged between fi ve and 17 (218 million) are child laborers, more than half in hazardous work (ILO 2006, 6).¶ Worldwide, diseases related to poverty, including communicable, maternal, perinatal, and nutritionrelated diseases, comprise over 50 percent of the burden of disease in low-income countries, nearly ten times their relative burden in developed countries (WHO 2006b, 3). If the developed world had its proportional share of poverty-related deaths (onethird of all deaths), severe poverty would kill some 16,000 Americans and 26,000 citizens of the European Union each week.¶ The cycle of mutually reinforcing poverty and disease besetting low income countries, and particularly the poorer communities in these countries, could be broken by signifi cantly reducing severe poverty. But it is also possible to make substantial progress against the global burden of disease more directly by improving health care in developing countries.¶ Poverty does not merely render poor people more vulnerable to disease, but also makes it less likely that they can obtain medical treatment for the diseases they contract. This is because in poor countries medical care is rarely available for free, and poor people are typically unable to buy either the care needed by themselves or their families or the insurance policies that would guarantee them such care. The price of health care in poor countries therefore also plays a crucial role in explaining the catastrophic health situation among the global poor.

#### We have a duty to assist others when the tradeoff is morally insignificant. This simple precept is more compelling than arcane moral reasoning or tortured negative fantasizing about remote catastrophes. If you came across a drowning child, would you wade in to save them or contemplate the possibility that you might cause nuclear war?

Singer ’72 - Peter Singer [Prof. Bioethics at Princeton] “Famine, Affluence, and Morality” Philosophy and Public Affairs, vol. 1, no. 1 Spring 1972 AT

My next point is this: if it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we ought, morally, to do it. By "without sacrificing anything of comparable moral importance" I mean without causing anything else comparably bad to happen, or doing something that is wrong in itself, or failing to promote some moral good, comparable in significance to the bad thing that we can prevent. This principle seems almost as uncontroversial as the last one. It requires us only to prevent what is bad, and to promote what is good, and it requires this of us only when we can do it without sacrificing anything that is, from the moral point of view, comparably important. I could even, as far as the application of my argument to the Bengal emergency is concerned, qualify the point so as to make it: if it is in our power to prevent something very bad from happening, without thereby sacrificing anything morally significant, we ought, morally, to do it. An application of this principle would be as follows: if I am walking past a shallow pond and see a child drowning in it, I ought to wade in and pull the child out. This will mean getting my clothes muddy, but this is insignificant, while the death of the child would presumably be a very bad thing. The uncontroversial appearance of the principle just stated is deceptive. If it were acted upon, even in its qualified form, our lives, our society, and our world would be fundamentally changed. For the principle takes, firstly, no account of proximity or distance. It makes no moral difference whether the person I can help is a neighbor's child ten yards from me or a Bengali whose name I shall never know, ten thousand miles away. Secondly, the principle makes no distinction between cases in which I am the only person who could possibly do anything and cases in which I am just one among millions in the same position.

## Solvency

#### The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines using the mechanisms described by MSF ’17:

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Countries can take a variety of steps to promote competition in vaccine manufacturing and help mitigate the complex patent thickets that could block, delay or increase uncertainties around access to multiple sources of vaccines. Governments should adopt public health-oriented IP policies, making full use of TRIPS flexibilities in both substantive and procedural aspects of national patent laws. Countries should:

• Encourage and accelerate follow-on development and competition of vaccines and vaccine technologies through the introduction and use of broad Bolar exemptions. This will support an early start for research and clinical studies by follow-on manufacturers, and support independent follow-on research and development.

• Apply strict patentability criteria for vaccine and vaccine technologies in patent examination and judicial proceedings. Countries should closely scrutinise patent applications concerning common methods of treatment, dosage forms and claims concerning specific age groups. Countries should reject trivial changes to known vaccine technologies, or composition patent applications that merely present the assembly of more ingredients using a known technology.

• Implement robust pre- and post-grant opposition procedures in national patent law systems that allow greater public scrutiny and opportunities to challenge unmerited patent applications from an early stage. Procedures that allow third-party observation but lack a mandatory hearing requirement could be improved to provide better transparency and accountability to the public.

• Improve use of compulsory licencing. Governments should strengthen the mechanisms of issuing compulsory licences to facilitate the most expedited access to multiple sources of vaccines and to safeguard public health.

• Strengthen technical capacity to ensure patent examiners apply strict patentability criteria and screen out unmerited applications in a timely manner. This will provide clarity on the patent landscape concerning important vaccines and technologies.

• Increase transparency of patent office filings to enable third parties to better understand the IP landscape, especially through procedures to promote disclosure of non-proprietary biological qualifier names74 of vaccines. Prospective manufacturers will be able to make decisions more efficiently if they understand the IP landscape clearly. Government procurement decision making will also be improved by addressing the current information asymmetry.

• Make full use of LDCs’ exemption from mandatory patent protection to accelerate access to quality assured follow-on new vaccines and encourage competition to improve affordability of vaccines.

• Demand that international organisations like WHO, Gavi, the Pan American Health Organization (PAHO) and the United Nations Children’s Fund (UNICEF) improve technical support for countries to: identify legal barriers, use flexibilities under IP laws and improve transparency of patent information to facilitate follow-on development and foster robust competition for new vaccines.75

#### The neoliberal drive to privatization created the tragedy of the anti-commons, stifling innovation through excessive protection of ever more segmented intellectual property.

Heller & Eisenberg ’98 - Michael Heller [Prof. of Property Law, Columbia Law School] & Rebecca S. Eisenberg [Prof. of Patent Law, Michigan Law], “Can Patents Deter Innovation? The Anticommons in Biomedical Research,” SCIENCE, VOL. 280, P. 698, 1998 (1998). <<https://scholarship.law.columbia.edu/faculty_scholarship/1158>> AT

Since Hardin’s article appeared, biomedical research has been moving from a commons model toward a privatization model (4). Under the commons model, the federal government sponsored premarket or “upstream” research and encouraged broad dissemination of results in the public domain. Unpatented biomedical discoveries were freely incorporated in “downstream” products for diagnosing and treating disease. In 1980, in an effort to promote commercial development of new technologies, Congress began encouraging universities and other institutions to patent discoveries arising from federally supported research and development and to transfer their technology to the private sector (5). Supporters applaud the resulting increase in patent filings and private investment (6), whereas critics fear deterioration in the culture of upstream research (7). Building on Heller’s theory of anticommons property (3), this article identifies an unintended and paradoxical consequence of biomedical privatization: A proliferation of intellectual property rights upstream may be stifling life-saving innovations further downstream in the course of research and product development.¶ The Tragedy of the Anticommons¶ Anticommons property can best be understood as the mirror image of commons property (3, 8). A resource is prone to overuse in a tragedy of the commons when too many owners each have a privilege to use a given resource and no one has a right to exclude another (9). By contrast, a resource is prone to underuse in a “tragedy of the anticommons” when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use. In theory, in a world of costless transactions, people could always avoid commons or anticommons tragedies by trading their rights (10). In practice, however, avoiding tragedy requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants (11), with success more likely within close-knit communities than among hostile strangers (12– 14). Once an anticommons emerges, collecting rights into usable private property is often brutal and slow (15).¶ Privatization in postsocialist economies starkly illustrates how anticommons property can emerge and persist (3). One promise of the transition to a free market was that new entrepreneurs would fill stores that socialist rule had left bare. Yet after several years of reform, many privatized storefronts remained empty, while flimsy metal kiosks, stocked full of goods, mushroomed on the streets. Why did the new merchants not come in from the cold? One reason was that transition governments often failed to endow any individual with a bundle of rights that represents full ownership. Instead, fragmented rights were distributed to various socialist-era stakeholders, including private or quasi-private enterprises, workers’ collectives, privatization agencies, and local, regional, and federal governments. No one could set up shop without first collecting rights from each of the other owners.¶ Privatization of upstream biomedical research in the United States may create anticommons property that is less visible than empty storefronts but even more economically and socially costly. In this setting, privatization takes the form of intellectual property claims to the sorts of research results that, in an earlier era, would have been made freely available in the public domain. Responding to a shift in U.S. government policy (4) in the past two decades, research institutions such as the National Institutes of Health (NIH) and major universities have created technology transfer offices to patent and license their discoveries. At the same time, commercial biotechnology firms have emerged in research and development (R&D) niches somewhere between the proverbial “fundamental” research of academic laboratories and the targeted product development of pharmaceutical firms (7). Today, upstream research in the biomedical sciences is increasingly likely to be “private” in one or more senses of the term—supported by private funds, carried out in a private institution, or privately appropriated through patents, trade secrecy, or agreements that restrict the use of materials and data.¶ In biomedical research, as in postsocialist transition, privatization holds both promises and risks. Patents and other forms of intellectual property protection for upstream discoveries may fortify incentives to undertake risky research projects and could result in a more equitable distribution of profits across all stages of R&D. But privatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research (16). Upstream patent rights, initially offered to help attract further private investment, are increasingly regarded as entitlements by those who do research with public funds. A researcher who may have felt entitled to coauthorship or a citation in an earlier era may now feel entitled to be a coinventor on a patent or to receive a royalty under a material transfer agreement. The result has been a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research. Researchers and their institutions may resent restrictions on access to the patented discoveries of others, yet nobody wants to be the last one left dedicating findings to the public domain.¶ The problem we identify is distinct from the routine underuse inherent in any wellfunctioning patent system. By conferring monopolies in discoveries, patents necessarily increase prices and restrict use—a cost society pays to motivate invention and disclosure. The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.

**The Aff challenges dehumanizing cultural frames that allow us to ignore human suffering. Recognition of common vulnerability is key to a politics that rejects violence, oppression, and indifference.**

**Butler ’04 -** Judith Butler [Prof. of Rhetoric and Comparative Literature, University of California at Berkeley], Precarious Life: The Powers of Mourning and Violence. New York: Verso (2006; First Published 2004). pp. 30-35 AT

Is there something to be gained from grieving, from tarrying with grief, from remaining exposed to its unbearability and not endeavoring to seek a resolution for grief through violence? Is there something to be gained in the political domain by maintaining grief as part of the framework within which we think our international ties? If we stay with the sense of loss, are we left feeling only passive and powerless, as some might fear? Or are we, rather, returned to a sense of human vulnerability, to our collective responsibility for the physical lives of one another? **Could** the experience of a **dislocation of First World safety** not **condition** the **insight into the radically inequitable ways that** corporeal **vulnerability is distributed globally?** To foreclose that vulnerability,to banish it, **to make ourselves secure at the expense of every other** human consideration **is to eradicate** one of the **most important resources from which we must** take our bearings and **find our way.¶** To grieve, and to make grief itself into a resource for politics, is not to be resigned to inaction, but it may be understood as the slow process by which we develop a point of identification with suffering itself. The disorientation of grief- “Who have I become?” or, indeed, “What is left of me?” “What is it in the Other that I have lost?” – posits the “I” in the mode of unknowingness.¶ But this can be a point of departure for a new understanding if the narcissistic preoccupation of melancholia can be moved into a consideration of the vulnerability of others. Then we might critically evaluate and oppose the conditions under which certain human lives are more vulnerable than others,and thus certain human lives are more grievable than others. From where **might a principle emerge by which we vow to protect others from the kinds of violence we have suffered,** if not **from an apprehension of a common human vulnerability?** I do not mean to deny that vulnerability is differentiated, that it is allocated differentially across the globe. I do not even mean to presume upon a common notion of the human, although to speak in its “name” is already (or perhaps only) to fathom its possibility.¶ I am referring to violence, vulnerability, and mourning, but there is a more general conception of the human with which I am trying to work here, one in which we are, from the start, given over to the other, one in which we are, from the start, even prior to individuation itself and, by virtue of bodily requirements, given over to some set of primary others: this conception means that we are vulnerable to those we are too young to know and to judge and, hence, vulnerable to violence; but also vulnerable to another range of touch, a range that includes the eradication of our being at the one end, and the physical support for our lives at the other.¶ Although I am insisting on referring to a common human vulnerability, one that emerges with life itself, I also insist that we cannot recover the source of this vulnerability: it precedes the formation of the “I.” This is a condition, a condition of being laid bare from the start and with which we cannot argue. I mean, that we can argue with it, but we are perhaps foolish, if not dangerous, when we do. I do not mean to suggest that the necessary support for a newborn is always there. Clearly, it is not, and for some this primary scene is a scene of abandonment or violence or starvation, that theirs are bodies given over to nothing, or to brutality, or to no sustenance.¶ We cannot understand vulnerability as a deprivation, however, unless we understand the need that is thwarted. Such infants still must be apprehended as given over, as given over to no one or to some insufficient support, or to an abandonment. It would be difficult, it not impossible, to understand how humans suffer from oppression without seeing how this primary condition is exploited and exploitable, thwarted and denied. The condition of primary **vulnerability**, of being given over to the touch of the other, even if there is no other there, and no support for our lives, **signifies a primary helplessness and need**, one **to which any society must attend.** Lives are supported and maintained differently, andthere are radically different ways in which human physical vulnerability is distributed across the globe. **Certain lives will be highly protected, and the abrogation of their** claims to **sanctity will** be sufficient to **mobilize the forces of war. Other lives** will not find such fast and furious support and **will not even qualify as “grievable.”¶** A hierarchy of grief could no doubt be enumerated. We have seen it already, in the genre of the obituary, where lives are quickly tidied up and summarized, humanized, usually married, or on the way to be, heterosexual, happy, monogamous. But this is just a sign of another differential relation to life, since we seldom, if ever, hear the names of the thousands of Palestinians who have died by the Israeli military with United States support, or any number of Afghan people, children and adults**. Do they have names, faces, personal histories, family, favorite hobbies, slogans by which they life?** What defense against the apprehension of loss is at work in the blithe way in which we accept deaths caused by military means with a shrug or with self-righteousness or with clear vindictiveness? To what extent have Arab peoples, predominantly practitioners of Islam, fallen outside the “human” as it has been naturalized in its “Western” mold by the contemporary workings of humanism? What are the cultural contours of the human at work here? How do our **cultural frames for thinking the human set limits on the kinds of losses we can avow** as loss**?** After all, if someone is lost, and that person is not someone, then what and where is the loss, and how does mourning take place?¶ This last is surely a question that lesbian, gay, and hi-studies have asked in relation to violence against sexual minorities; that transgendered people have asked as they are singled out for harassment and sometimes murder; that intersexed people have asked, whose formative years are so often marked by unwanted violence against their bodies in the name of a normative notion of the human, a normative notion of what the body of a human must be. This question is no doubt, as well, the basis of a profound affinity between movements centering on gender and sexuality and efforts to counter the normative human morphologies and capacities that condemn or efface those who are physically challenged. **It must** also **be part of** the affinity with **anti-racist struggles, given the racial differential that undergirds** the **culturally viable notions of the human**, ones that we see **acted out in** dramatic and **terrifying ways in the global arena** at the present time**.**¶ I am referring not only to humans not regarded as humans, and thus to a restrictive conception of the human that is based upon their exclusion. **It is** not a matter of a simple entry of the excluded into an established ontology, but **an insurrection at the level of ontology**, a critical opening up of the questions, What is real? **Whose lives are real?** How might reality be remade? Those who are unreal have, in a sense, already suffered the violence of derealization. What, then, is the relation between violence and those lives considered as "unreal"? Does violence effect that unreality? Does violence take place on the condition of that unreality?¶ If violence is done against those who are unreal, then, from the perspective of violence, it fails to injure or negate those lives since those lives are already negated. But they have a strange way of remaining animated and so must be negated again (and again). They cannot be mourned because they are always already lost or, rather, never "were," and they must be killed, since they seem to live on, stubbornly, in this state of deadness. Violence renews itself in the face of the apparent inexhaustibility of its object. The derealization of the "Other" means that it is neither alive nor dead, but interminably spectral. The infinite paranoia that imagines the war against terrorism as a war without end will be one that justifies itself endlessly in relation to the spectral infinity of its enemy, regardless of whether or not there are established grounds to suspect the continuing operation of terror cells with violent aims.¶ How do we understand this derealization? It is one thing to argue that first, **on the level of discourse, certain lives are not considered lives at all**, they cannot be humanized, that they fit no dominant frame for the human, and that **their dehumanization** occurs first, at this level, and that this level then **gives rise to** a physical **violence that** in some sense **delivers the message of dehumanization** that is **already at work in the culture.** It is another thing to say that discourse itself effects violence through omission. If 2oo,ooo Iraqi children were killed during the Gulf War and its aftermath/ do we have an image, a frame for any of those lives, singly or collectively? Is there a story we might find about those deaths in the media? **Are there names attached to those children?**¶ There are no obituaries for the war casualties that the United States inflicts, and there cannot be. If there were to be an obituary, there would have had to have been a life, a life worth noting, **a life worth valuing and preserving, a life that qualifies for recognition.** Although we might argue that it would be impractical to write obituaries for all those people, or for all people, I think we have to ask, again and again, how the obituary functions as the instrument by which grievability is publicly distributed. It is the means by which a life becomes, or fails to become, a publicly grievable life, an icon for national self-recognition, the means by which a life becomes noteworthy. As a result, we have to consider the obituary as an act of nation-building. The matter is not a simple one, for, if a life is not grievable, it is not quite a life; it does not qualify as a life and is not worth a note. It is already the unburied, if not the unburiable.¶ It is not simply, then, that there is a "discourse" of dehumanization that produces these effects, but rather that there is a limit to discourse that establishes the limits of human intelligibility. It is not just that a death is poorly marked, but that it is unmarkable. Such a death vanishes, not into explicit discourse, but in the ellipses by which public discourse proceeds. The queer lives that vanished on September I I were not publicly welcomed into the idea of national identity built in the obituary pages, and their closest relations were only belatedly and selectively (the marital norm holding sway once again) made eligible for benefits. But this should come as no surprise, when we think about how few deaths from AIDS were publicly grievable losses, and how, for instance, the extensive deaths now taking place in Africa are also, in the media, for the most part unmarkable and ungrievable.