# Novice AC

#### I affirm – Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

**Because the resolution asks what we *ought* to do, my value is Morality.**

#### The criterion for determining morality is minimizing suffering. No coherent theory of justice or morality can deny that suffering is morally bad. Each of us knows from our own experiences that suffering is a moral evil, and that other people experience suffering in the same way we do. Therefore, if we regard everyone’s pain as morally equal, we are obligated to minimize the amount of suffering people experience.

#### Moreover, maximizing utility is the only way to affirm equal and unconditional human dignity.

**Cummiskey ’90 -** David Cummiskey. [Associate Philosophy Professor at Bates College].Kantian Consequentialism. Ethics, Vol. 100, No. 3. 1990. http://www.jstor.org/stable/2381810.

We must not obscure the issue by characterizing this type of case as the sacrifice of individuals for some abstract “social entity.” It is not a question of some persons having to bear the cost for some elusive “overall social good.” Instead, the question is whether some persons must bear the inescapable cost for the sake of other persons. Robert Nozick, for example, argues that “to use a person in this way does not sufficiently respect and take account of the fact that he is a separate person, that his is the only life he has.” But why is this not equally true of all those whom we do not save through our failure to act? **By emphasizing solely the one who must bear the cost if we act, we fail to** sufficiently **respect** and take account of **the many other separate persons**, **each with only one life, who will bear the cost of our inaction.** In such a situation, what would a conscientious Kantian agent, an agent motivated by the unconditional value of rational beings, choose? A morally good agent recognizes that the basis of all particular duties is the principle that “rational nature exists as an end in itself” (GMM 429). Rational nature as such is the supreme objective end of all conduct. **If one** truly **believes** that **all rational beings have** an **equal value**, then **the** rational **solution** to such a dilemma **involves maximally promoting the lives and liberties of as many** rational beings **as possible** (chapter 5). In order to avoid this conclusion, the non-consequentialist Kantian needs to justify agent-centered constraints. As we saw in chapter 1, however, even most Kantian deontologists recognize that agent-centered constraints require a non- value-based rationale. But we have seen that Kant’s normative theory is based on an unconditionally valuable end. How can a concern for the value of rational beings lead to a refusal to sacrifice rational beings even when this would prevent other more extensive losses of rational beings? **If the moral law is based on the value of rational beings and their ends, then what is the rationale for prohibiting a moral agent from maximally promoting these two tiers of value? If I sacrifice some for the sake of others, I do not use them arbitrarily, and I do not deny the unconditional value of rational beings. Persons may have “dignity**, **that** is, an unconditional and incomparable worth” that **transcends** any **market value** (GMM 436), **but persons also have a fundamental equality that dictates that some must sometimes give way for the sake of others** (chapters 5 and 7). The concept of the end-in-itself does not support the view that we may never force another to bear some cost in order to benefit others. If one focuses on the equal value of all rational beings, then equal consideration suggests that one may have to sacrifice some to save many.

### Contention 1: Covid-19

#### The only way to solve the pandemic is global vaccination, but current production is woefully short.

Public Citizen 3/29 - Public Citizen [“Public Citizen is a nonprofit consumer advocacy organization that champions the public interest in the halls of power. We defend democracy, resist corporate power and work to ensure that government works for the people – not for big corporations. Founded in 1971, we now have 500,000 members and supporters throughout the country. We don’t participate in partisan political activities or endorse any candidates for elected office. We take no government or corporate money, which enables us to remain fiercely independent and call out bad actors – no matter who they are or how much power and money they have.”], “Waiver of the WTO’s Intellectual Property Rules: Facts vs. Common Myths,” *Public Citizen Global Trade Watch Series*. March 29, 2021. Accessed Aug. 10, 2021. <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/> AT

The COVID-19 public health disaster and resulting economic crises won’t end anywhere unless people everywhere are vaccinated. Despite this obvious truth, rich countries with only 14% of the global population have secured preferential access to over 50% of projected global vaccine supplies. Ongoing outbreaks anywhere allow the virus to mutate, threatening the whole world with vaccine-resistant variants or more deadly or easily spread variants. Governments invested billions to create the vaccines. But, there is a dire shortage, with no end in sight. As we enter the second quarter, about one billion doses have been produced in 2021. We need 10 to 12 billion to reach global herd immunity. And we will need far more if, like flu vaccines, they must be repeated or require booster shots. In every region, there are existing firms that could gear up production and governments willing to invest in expanding supply. But WTO rules require countries to guarantee pharmaceutical corporations monopoly control. More than 100 countries support a temporary, emergency suspension of these WTO rules, so more vaccines, treatments and diagnostic tests can be manufactured in as many places as possible. The United States and a handful of other WTO members are blocking the waiver: They won’t even agree to negotiate about waiver language to address whatever concerns that they may have with the current text. Donald Trump started this self-defeating blockade. President Joe Biden must reverse it to speed the end of the COVID-19 pandemic.

**The vaccine shortfall causes widespread death and poverty.**

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It is obvious that current production capacity cannot supply enough vaccines for the entire world. Many people in low- and middle-income countries around the globe will not get vaccinated until at least 2022 unless the world manufactures many more doses, according to the British Medical Journal. The world’s poorest countries may wait until 2024 for mass immunization, if it happens at all, reports the Economist Intelligence Unit.

The global vaccine apartheid unfolding right now could cost millions of lives and push tens of millions more into poverty. The devastation will be felt for a generation. A new International Chamber of Commerce report concluded that the world could face economic losses of more than $9 trillion under the scenario of wealthy nations being fully vaccinated by mid-2021, but poor countries largely shut out. Wealthy countries like the United States would bear nearly half of that hit. Vaccinating just half of low- and middle-income countries’ populations could reduce global losses by $5.5 trillion.

#### A waiver provides legal certainty that unlocks global production.

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Most critically, there simply is not enough supply to go around now or for every year in the future during which the whole world will need regular COVID vaccination to keep the virus under control. Thankfully, scores of countries are ready to invest in building new or repurposing existing production capacity. That is why more than 100 countries support a waiver of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). These countries seek certainty that if they adjust their domestic laws and practices to support that investment by providing access to the necessary technology, they will not get dragged into expansive WTO litigation or face retaliatory sanctions from countries claiming WTO violations. The waiver will also serve as a worldwide buffer against the political pressure and legal harassment to which Big Pharma subjects countries that seek to promote affordable access to medicines.¶ In many countries, the regulatory authorities that had to approve domestic use of various vaccines and other COVID-related medical products have significant information from the firms that they could share with skilled teams from local universities, government agencies and pharmaceutical manufacturers — if they were not obliged by WTO rules to guarantee monopoly control of it. And world-class pharmaceutical firms already are making generic versions of new cutting-edge HIV-AIDS medicines and pumping out vaccines based on the platform that, for instance, the Johnson & Johnson vaccine uses.

**Manufacturing capacity is widespread around the world.**

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In the press and on Capitol Hill, Big Pharma is pushing a Big Lie. The claim is that a lack of manufacturing capacity, not pharmaceutical corporation’s monopoly intellectual property (IP) protections, are thwarting greater production of COVID-19 vaccines. A related argument, with decidedly racist overtones, is that COVID-19 vaccines are too complicated for producers in developing countries to make successfully. The reality is that in every region of the world, there are multiple producers that could be greatly increasing global vaccine supplies if the technology and know-how were shared.¶ Just in Africa, “Biovac and Aspen in South Africa, Institute Pasteur in Senegal, and Vacsera in Egypt could rapidly retool factories to make mRNA vaccines,” notes a group of medicine-production experts in a recent Foreign Policy article. Indeed, a former Moderna director of chemistry revealed that with enough technology transfer and know- how-sharing, a modern factory should be able to get mRNA vaccine production online in, at most, three to four months. The Serum Institute in India already is slated to produce the AstraZeneca and Novavax vaccines, while Moderna declined to partner with a qualified Bangladeshi vaccine maker, claiming its engineers were too busy to focus beyond U.S. and EU production. In Latin America, existing facilities in Brazil, Argentina and Mexico under contract to monopoly holders are already pumping out vials, and in countries like Chile and Colombia, the pharmaceutical industry has expressed willingness to kickstart vaccine production.¶ Existing and planned contract manufacturing arrangements prove facilities in developing countries certainly can produce COVID-19 vaccines. But unless technology and know-how are shared more openly, the monopoly holders maintain absolute control over how much can be produced, what the price is and where it will be sold. So, 91% of the Johnson & Johnson vaccine that South African firm Aspen will manufacture must be shipped for sale outside South Africa, according to South Africa’s WTO Counselor. And the Serum Institute is barred from supplying upper- middle-income and high-income countries with the AstraZeneca vaccines it makes, meaning AstraZeneca can artificially segment the global market and ensure that it is the only supplier of the Oxford vaccine in the most profitable national markets, according to Doctors Without Borders.¶ Most critically, there simply is not enough supply to go around now or for every year in the future during which the whole world will need regular COVID vaccination to keep the virus under control. Thankfully, scores of countries are ready to invest in building new or repurposing existing production capacity. That is why more than 100 countries support a waiver of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). These countries seek certainty that if they adjust their domestic laws and practices to support that investment by providing access to the necessary technology, they will not get dragged into expansive WTO litigation or face retaliatory sanctions from countries claiming WTO violations. The waiver will also serve as a worldwide buffer against the political pressure and legal harassment to which Big Pharma subjects countries that seek to promote affordable access to medicines.¶ In many countries, the regulatory authorities that had to approve domestic use of various vaccines and other COVID-related medical products have significant information from the firms that they could share with skilled teams from local universities, government agencies and pharmaceutical manufacturers — if they were not obliged by WTO rules to guarantee monopoly control of it. And world-class pharmaceutical firms already are making generic versions of new cutting-edge HIV-AIDS medicines and pumping out vaccines based on the platform that, for instance, the Johnson & Johnson vaccine uses.

### Contention II: Innovation

**Limiting IP protections *increases* the incentive to create new drugs.**

**Light & Warburton ’11 -** Donald W. Light [Visiting professor at Stanford University and a professor of comparative health-care at the University of Medicine and Dentistry of New Jersey. He is an economic and organizational sociologist who studies health care systems and pharmaceu- tical policy.] and Rebecca Warburton [associate professor and a health economist, specializing in the cost- benefit analysis of health-related public projects. Her current research primarily concerns assessing the validity of industry-sponsored estimates of the cost of drug development, and assessing the costs and effects of patient safety improvements. She has a PhD in economics from the University of London (1995), and an M.Sc. in economics from the London School of Economics (1980); School of Public Administration, University of Victoria, British Columbia], “Demythologizing the high costs of pharmaceutical research *BioSocieties* (2011) 6, 34–50. doi:10.1057/biosoc.2010.40; published online 7 February 2011. //JH

Industry executives, well supplied with facts and figures by the industry’s global press network, awe audiences with staggering figures for the cost of a single trial, like tribal chieftains and their scribes who recount the mythic costs of a great victory in a remote pass where no outside witnesses saw the battle. Companies tightly control access to verifiable facts about their risks and costs, allowing access only to supported economists at consulting firms and universities, who develop methods for showing how large costs and risks are; and then the public, politicians and journalists often take them at face value, accepting them as fact. The global press network never tells audiences about the detailed reconstruction of R&D costs for RotaTeq and Rotarix that found costs and risks were remarkably low up to the large final trials, and that concluded the companies recovered their investments within the first 18 months (Light et al, 2009). The companies could now sell these vaccines for rotavirus for one-tenth their Western price and still earn profits. ¶Pharmaceutical companies have a strong vested interest in maximizing figures for R&D and supporting centres or researchers who help them do so. Since the Kefauver hearings in 1959–1962, the industry’s principal justification for its high prices on patented drugs has been the high cost of R&D, and it has sought further government protections from normal price competition. These include increasing patent terms and extending data exclusivity, without good evidence that these measures increase innovation (National Institute for Health Care Management, 2000; European Commission for Competition, 2008 (28 November); Adamini et al, 2009). Industry leaders and lobbyists routinely warn that lower prices will reduce funds for R&D and result in suffering and death that future medicines could reduce. Marcia Angell, the former editor of the New England Journal of Medicine, describes this as ‘ya kind of blackmail’ (Angell, 2004, pp. 38–39). She quotes the president of the US industry’s trade association as saying, ‘Believe me, if we impose price controls on the pharmaceutical industry, and if you reduce the R&D that this industry is able to provide, it’s going to harm my kids and it’s going to harm those millions of other Americans who have life-threatening conditions’. Merrill Goozner, former chief economic correspondent for the Chicago Tribune, points out that **no other research-oriented industry makes this** kind of **argument (Goozner, 2004). In fact, they do the opposite: when profits decline, they redouble their research efforts to find new products that will generate more profits**. **Not to do so guarantees** their **decline.** The industry’s view of European ‘price controls’ (actually, large-volume discounts) is that they do not allow recovery of huge R&D costs so that Europeans are ‘free riders’ on Americans and force US prices higher to pay for unrecovered costs the ‘free riders’ refuse to pay. This claim has been shown not to be supported by industry and government reports and to be illogical as well (Light and Lexchin, 2005).

**IP stifles innovation by allowing firms to prevent new competition from entering the market, driving down the incentive for R & D.**

**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

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.

### Contention 3: Medicine Prices

#### 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.

**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 I[];[\p[]p[]\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\n 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.

#### For these reasons, I urge an affirmative ballot.