

# Intellectual Property Rights and the TRIPS Agreement

## An Overview of Ethical Problems and Some Proposed Solutions

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## Abstract

The Agreement on Trade-Related Aspects of Intellectual Property Rights negotiated in 1986 under the auspices of the General Agreement on Tariffs and Trade, the institutional predecessor of the World Trade Organization, incorporated substantial and uniform protections of intellectual property rights into the international trade system. A large body of contemporary academic literature suggests that intellectual property rights on socially valuable goods such as essential medicines give rise to a number of ethical problems. This review paper seeks to give an overview of these problems. Moreover, it offers an outline and discussion

of a number of proposals as to how these problems might be alleviated. The paper is primarily descriptive in character. This means that although a personal perspective is sometimes offered, the primary ambition of the paper is not to argue for, and defend, a particular solution to the issues discussed. The aim is rather to highlight, explain and put into perspective a number of important arguments in the debate on the ethical nature of intellectual property rights so that policy-makers and other stakeholders are relatively well-equipped to make up their own mind on the issue.

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This paper—a product of the Trade and Integration Team, Development Research Group; and the Development Dialogue on Values and Ethics, Human Development Network—is part of larger work programs on trade and intellectual property rights and on ethical issues in development policy. Policy Research Working Papers are also posted on the Web at <http://econ.worldbank.org>. The author may be contacted at [JSonderholm@worldbank.org](mailto:JSonderholm@worldbank.org).

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# **Intellectual property rights and the TRIPS agreement: An overview of ethical problems and some proposed solutions**

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## **1. Introduction**

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) negotiated in the 1986 Uruguay Round under the auspices of the General Agreement on Tariffs and Trade, the institutional predecessor of the World Trade Organization (WTO), incorporated substantial and uniform protections of Intellectual Property Rights (IPRs) into the international trade system (WTO 1986). All developing-country members of the WTO agreed to respect relatively stringent worldwide norms of patent protections no later than 2005. A few least-developed countries remain exempt from protecting patents until 2013 and patents on pharmaceuticals until 2016 (Reichman 2009:247). In the past decade, the United States (US) has pursued a number of bilateral and regional Free Trade Agreements (FTAs) in different parts of the world. These ‘TRIPS plus’ agreements include the North American Free Trade Agreement (NAFTA) and the Dominican Republic-Central America–United States Free Trade Agreement (CAFTA-DR). It is a distinct feature of many of these bilateral agreements that they go beyond the multilateral standards on IPRs imposed by the TRIPS agreement (Fink and Reichenmiller 2005).<sup>1</sup>

A large body of contemporary academic literature suggests that IPRs as implemented in the TRIPS agreement and various US FTAs give rise to a number of ethical problems. This review paper seeks to give an overview of what these problems are. Moreover, it offers an outline and discussion of a number of proposals as to how these problems might be alleviated. The paper is primarily descriptive in character. This means that though a personal perspective is sometimes offered, the primary ambition of the paper is not to argue for, and defend, a particular kind of answer to the issues discussed. The ambition is rather to highlight, explain and put into perspective a number of important arguments in the debate on the ethical nature of IPRs so that

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<sup>1</sup> For more on the NAFTA and CAFTA-DR agreements, see <http://www.fas.usda.gov/itp/agreements.asp> [accessed October 1, 2009].

policy-makers and other stakeholders are relatively well-equipped to make up their own mind on the issue.

Before moving on to a more detailed outline in the next section of how IPRs, as implemented in the aforementioned trade agreements, are a cause for ethical concern, it is instructive to add one last introductory remark. The ethical problems raised by IPRs are most pertinent when it is socially valuable goods such as life-saving medicines and genetically modified seeds that are given Intellectual Property (IP) protection. The discussions in this paper will almost exclusively revolve around just one product type in order to bring out the broader theoretical problems/issues caused by the implementation of IPRs. In line with much contemporary literature on the ethical dimensions of IPRs, the product type in question is life-saving medicines.

## **2. TRIPS, IPRs and the problems of access and availability**

Pogge (2005) offers a good overview of how innovation is currently incentivized under the TRIPS agreement and how this agreement might lead to ethically problematical outcomes. It is an expensive, time consuming and financially risky endeavor to produce new and safe drugs for the market. Advanced chemical research and long clinical trials must be undertaken, and in case both of these prove successful, there awaits an often lengthy approval process. Given that pharmaceutical companies must bear all the costs of the development process, it is no surprise that such companies are reluctant to undertake research and development (R&D) of new drugs unless the financial prospects of doing so are bright. Without IPRs on pharmaceutical innovations, such prospects would be everything but bright. The reason for this is that as soon as an inventor firm introduces a new innovation on the market, other companies will copy (through

reverse engineering) the innovation, and given that these other companies have had no costs in terms of R&D, they will be able to charge a price for the product that is much lower than the one charged by the inventor firm. The market price for the product will therefore very likely be driven down to just above marginal costs of production, and the inventor firm will be unable to recoup its R&D costs. A macroeconomic setup for the buying and selling of drugs that does not offer innovators IPRs to their innovations is therefore likely to lead to a market failure of undersupply of pharmaceutical innovations.

IPRs are a socio-economic tool that create a temporary monopoly for inventor firms and enable such firms to charge prices for their innovations that are many times higher than the marginal cost of production of the innovations.<sup>2</sup> This allows the inventor firms to salvage their research costs and secure a profit on their innovations. So, in virtue of increasing the financial attractiveness of engaging in the process of producing pharmaceutical innovations, IPRs can be, and often are, instrumental in correcting the market failure of undersupply of pharmaceutical innovations.

However, the introduction of IPRs for pharmaceutical innovations often creates another market failure that consists in the fact that a number of mutually beneficial transactions between seller and buyer do not take place. The relatively high price of an IP protected drug squeezes certain potential buyers out of the market: namely those buyers who are able and willing to buy the product if it was priced somewhat above its marginal costs of production but cannot afford the product when it is priced at the profit maximizing level that obtains during the period in

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<sup>2</sup> Patents are a type of IPRs. In the US, they normally have a duration of 20 years. See <http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent> [Accessed October 4, 2009]. The actual patent life of a medicine is, however, quite often shorter because the patent has been taken out prior to Food and Drug Administration (FDA) review of the medicine.

which the product is IP protected.<sup>3</sup> The feature of IPRs that they squeeze out certain potential buyers from the market creates what might be labeled the ‘exclusion problem’ or ‘access problem’ (Ravvin 2008:116; Selgelid 2008:134). According to some, the exclusion/access problem is morally troubling when it is life-saving medicines and not merely computer software, music CDs or movie discs that some group of people is excluded from having access to (Pogge 2005:187; Love and Hubbard 2007:1524).

The exclusion/access problem is not the only thing that follows in the wake of the TRIPS agreement which imposes strong IPRs on all product types. A different problem is the ‘availability problem’ (Selgelid 2008:134; Love and Hubbard 2007:1551). This problem is fruitfully introduced in the context of R&D of drugs for diseases that mainly affect people in low-income countries. Diseases which mainly lead to suffering and death in low-income countries include malaria, leishmaniasis and Chagas’ disease (Ridley, Grabowski, and Moe 2006:316). R&D of drugs for diseases that mainly affect people in low-income countries is very limited.<sup>4</sup> The primary reason for this is that the financial resources of many of the people who are in need of these drugs are close to nonexistent: many poor people simply do not have sufficient money to pay for drugs for their ailments. For-profit pharmaceutical companies therefore have little economic incentive for investing resources into the R&D of drugs for these diseases.<sup>5</sup>

The availability problem is a consequence of the fact that the incentivizing mechanism for innovation constituted by IPRs establishes a direct link between the incentive to innovate and

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<sup>3</sup> In economic theory, ‘deadweight losses’ designate the type of losses that occur when someone is able and willing to pay more than the marginal cost of production for a product but is not willing or able pay the patent price for it (Ravvin 2008:112; Pogge 2008b:77; Hollis 2008:125).

<sup>4</sup> According to one study, less than 1% of the 1223 new medicines launched on the international market between 1975 and 1997 were destined specifically for tropical communicable diseases (Trouiller et al. 2001).

<sup>5</sup> It has therefore grown common to think of these diseases as ‘neglected diseases’.

the price of the innovative product. Under the TRIPS agreement, profits are generated exclusively from sales, so the higher a price a product can command on the market, the higher is the incentive to invest resources into the R&D process of it. The TRIPS agreement with its strong protection of IPRs is therefore not an agreement that is conducive to the investment in R&D of products that are socially valuable to predominantly poor populations or populations that are small.<sup>6</sup> Socially valuable goods (including life-saving medicines) to such populations are simply not being made available at the same rate as goods that are socially valuable to rich populations of a significant size.

### **3. Two standard solutions to the access problem**

As emphasized by (Pogge 2005), there are two standard solutions to the access problem. One of the solutions commonly goes under the name of ‘differential pricing’ and is the idea that an IP protected product is sold at different prices in different geographic regions. In high-income countries, the product is sold at one price whereas it is sold at a lower price in low-income countries. By pricing the product in this way, an inventor firm is, at least in theory, able to get the best of two worlds. High profits on the product are secured in markets with a high buying power without sacrificing the medium to low profits that come from selling the product in markets with a relatively low buying power. In addition to this, the diminished price of the product in low-income countries means that the inhabitants of these countries have an easier access to the product than they would have if the product was priced at the level of high-income countries. For someone who sees the access problem as morally problematic when it comes to

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<sup>6</sup> Orphan diseases are diseases which only very few people suffer from. Drugs for such diseases are therefore an example of a type of product that is only valuable to a small population.



life-saving medicines, this latter feature of differential pricing makes differential pricing a prima facie attractive pricing scheme for life-saving medicines.

The other standard solution to the access problem goes under the name ‘compulsory licensing’. This mechanism bestows a right to governments to issue production licenses for IP protected innovations (e.g. life-saving medicines) that are needed to respond to public emergencies.<sup>7</sup> For example, on the assumption that the HIV/AIDS pandemic currently existing in Sub-Saharan Africa counts as a public emergency for a number of countries in this region, the governments of these countries can authorize the production and marketing of cheaper generic versions of IP protected HIV/AIDS drugs on the condition that the authorized generic firms pay a small license fee to the IP holders. The market entry of companies producing generic versions of HIV/AIDS drugs will very likely drive down the price on these drugs to just above their marginal cost of production, and this will in turn ease access to the drugs.

Both of the two standard solutions to the access problem are problematical. (Ravvin 2008:114) gives an overview of some of the problems that pertain to these solutions. With respect to differential pricing, the primary concern is that of the seepage of cheaply sold drugs from poor countries to rich ones through parallel trade and smuggling. This point is also emphasized by other commentators (Love and Hubbard 2007:1549; Pogge 2008a:239). Furthermore, there is an issue of social justice in the sense that rich people in low-income countries will have access to a given medicine at a relatively low cost, whereas poor people in high-income countries will have to pay a high price for the very same medicine. According to

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<sup>7</sup> The right of individual countries to issue compulsory licenses in cases of public emergencies was clarified and emphasized in the 2001 Doha Declaration on the TRIPS agreement. The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights. See: [http://www.who.int/medicines/areas/policy/doha\\_declaration/en/index.html](http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html) [Accessed September 20, 2009].

(Love and Hubbard 2007:1525), 50 million consumers in India have incomes comparable to that of Europeans, and to some it is controversial that this segment of people should have access to a given drug at a low price whereas poor, uninsured people in, say, the US should have to pay a high price for the very same drug (Knowledge@Wharton 2002).

When it comes to compulsory licensing, a number of problems are often cited. First, the WTO originally only allowed national governments to issue compulsory licenses to generic manufacturers that would produce products for domestic consumption. As was quickly recognized, this meant that compulsory licensing was no help to countries that lacked a domestic generic drug manufacturing capacity (Reichman 2009:248). With the exception of Brazil, India and China, all low-income countries basically lack such capacity. A 2003 WTO General Counsel Decision therefore allowed that countries with a domestic drug manufacturing capacity could issue a compulsory license to a domestic producer which would then be legally entitled to export the medicine in question to a low-income country that need the drug to overcome a national emergency. As chronicled in some literature on compulsory licensing, the 2003 WTO amendment to TRIPS has been a fiasco because the judicial process involved in getting an export license is complex and riddled with practical hurdles and red tape (Johnston and Wasunna 2007:18). Echoing this and based on a study of Rwanda's 2007 attempt to import HIV/AIDS medicine under the WTO General Counsel Decision 2003 and the ensuing process involving Canadian generic drug manufacturer Apotex, Matthew Rimmer concludes that it is undesirable to codify the WTO General Counsel Decision 2003 because it has failed to provide a speedy, efficient, and cost-effective delivery of essential medicines (Rimmer 2008).

Second, compulsory licensing has social costs that may negate the short term benefits compulsory licensing has in virtue of improving access to life-saving medicines (Bird 2009).

Chief among these social costs are: i) a risk of diminished direct investment in countries that resort to compulsory licensing because owners of IP protected products will seek out more business-friendly legal environments, ii) a risk that the company which obtains a compulsory license will ‘shadow price’ the original high price of the IP protected product and thereby generate dead weight loss of its own in pursuit of profits, iii) a risk that compulsory licensing will reduce the research-driven pharmaceutical sector’s incentives to innovate and iv) a risk that the governments of countries that house companies whose products have been subject to a compulsory license by a foreign government will retaliate with trade sanctions that could seriously harm the economy of the nation that has issued the compulsory license.

A line of thought that draws attention to the long-term social costs of compulsory licensing is, in my opinion, worthy of serious attention. Point iii) made by Bird is especially strong. Pogge also makes this point by arguing that if compulsory licenses are widely used, then pharmaceutical companies are likely to be deterred from investing in R&D of drugs that are likely to be subjected to compulsory licensing. For-profit pharmaceutical companies are therefore likely to eschew this type of R&D entirely. In turn, compulsory licensing will constitute a further barrier to R&D of drugs for diseases that primarily exist in a developing world setting (Pogge 2008a:240; Pogge 2009:188).

If neither differential pricing nor compulsory licensing constitutes an attractive way of alleviating the access problem created by IPRs, what other options are available to those who search for a solution to this problem? The following three sections will present and discuss three high-profile suggestions about how the current IPR system as implemented under the TRIPS agreement can be amended so as to alleviate both the access and availability problem.

#### **4. A simple prize scheme**

The idea of using monetary prizes to stimulate R&D of pharmaceutical products is popular among contemporary theorists (Power 2006; Outterson, Samora, and Keller-Cuda 2007; Stiglitz 2006; Love 2007; Love and Hubbard 2007; Cragger and Price 2009).<sup>8</sup> Prize schemes come in a number of different variations. A rather simple scheme is one in which a monetary prize is awarded to the pharmaceutical company that first develops a drug that meets the requirements with respect to medical profile as determined by an independent committee of experts. A key feature of such a scheme of R&D stimulation is that it severs the traditional link between the price of a pharmaceutical product and the incentive to innovate. By severing this link, the hope is to stimulate R&D of i) drugs for diseases that predominately affect populations in low-income countries and ii) drugs for which there is no big market (for example, advanced antibiotics or drugs for orphan diseases).

In exchange of the monetary prize, the innovator forswears the IPR to the innovation, and it is placed in the public domain where it will be open to generic manufacturing. Such manufacturing will likely bring the price of the innovation down to close to cost of production which in turn will minimize the access problem and the economic inefficiency stemming from dead weight losses. Current medical examples of this prize mechanism include the Prize4Life (which aims to advance research on amyotrophic lateral sclerosis) and the Archon X prize for low-cost gene-sequencing techniques (Love 2007).

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<sup>8</sup> It is worth noting that The Medical Innovation Prize Fund Act (H. R. 417), introduced to the US Congress in January 2005 by Senator Bernard Sanders, calls for the implementation of cash prizes to stimulate R&D of pharmaceutical products.

A prize scheme of the above kind is no doubt theoretically appealing. It is, however, vulnerable to a number of objections prominent among which is what might be labeled the ‘winner-takes-all’ objection (Pogge 2008c:128; Barder et al. 2005:4). The fact that a prize mechanism only awards a prize to the company that first reaches a specific pharmaceutical goal adds significant risk and uncertainty to companies that are entertaining the idea of engaging in a R&D of the specified product. The usual uncertainties that for-profit pharmaceutical companies have about whether or not their basic research will pan out and whether or not the various stages of clinical trials will be successful are now conjoined with the risk of not knowing whether or not they will win the race against competing companies in terms of being the company that first wins regulatory approval of a drug with the specified properties. Drug development is expensive, and it is therefore very undesirable for a company to enter into, and take second place, in a race in which the winner takes all.<sup>9</sup> In such a scenario, expenses to basic research and clinical trials are likely to be wasted.

An economically rational decision of a for-profit pharmaceutical company to enter into a winner-takes-all race therefore presupposes close to perfect comparative knowledge in the sense that a company must possess not only a good estimate of its own chances of reaching the pharmaceutical goal but also a good estimate of competing companies’ research efforts and degree of success in clinical trials involving their contender for the prize. Such comparative knowledge is difficult to come by, and companies that do not possess it are therefore likely to refrain from entering the competition for the prize. This reduces the number of for-profit pharmaceutical companies doing R&D on the target product, and it reduces the competitive

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<sup>9</sup> A commonly cited estimate of the cost of bringing a new drug to market puts the cost at US\$800 million. See The Tufts Center for the Study of Drug Development: <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6> [Accessed August 2, 2009].

conditions of the companies that do engage in such R&D. Both of these things slow down the development process of the target product and delay its point of market entry.

Three other, well known problems with a simple prize mechanism should also be mentioned. First, by making a commitment to award a prize to the company that first develops a particular kind of drug, the donors do not guard themselves against the possibility that at time  $t$  in the future when the prize is awarded, there is no demand for the product. For example, when an effective vaccine for malaria is developed there might not be any demand for such a vaccine given that the disease has been eradicated through other means (say, extended spraying with new and improved insecticide or extended use of new and improved bed nets). In such a scenario, donor funds spent on a malaria vaccine are wasted (Barder et al. 2005).

Second, a prize mechanism offers very strong incentives to for-profit companies to meet the target profile of the required drug but only weak incentives to develop a drug that exceeds the target profile or a useful drug that does not quite meet that profile (Hollis 2007:81). Third, a prize mechanism does not offer any incentives to produce 2<sup>nd</sup> generation drugs for medical condition  $x$  once the first entry drug for  $x$  has been awarded a prize (Barder et al. 2005:23).

## **5. Advance market commitments**

What has been coined an ‘Advance Market Commitment’ (AMC) is another pull-mechanism for pharmaceutical R&D.<sup>10</sup> The AMC idea was first introduced by Michael Kremer in 2001 (Kremer 2001a, 2001b). The idea was further refined in a 2004 book co-authored with Rachel Glennester

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<sup>10</sup> A pull-mechanism for pharmaceutical R&D should be distinguished from a push-mechanism for such R&D. The former rewards research outcomes (by increasing the financial return on a fully developed product) whereas the latter subsidizes research inputs. The paradigm example of a push-mechanism for pharmaceutical R&D is government funding for research activities that take place at a public university. Such funding ‘pushes’ a certain research agenda (for example, that of finding an effective cure for malaria or HIV/AIDS) by decreasing the R&D costs of the entity that pursues the agenda.

(Kremer and Glennerster 2004). In 2005, the think tank Center for Global Development (CGD) issued a report in which the AMC idea was discussed in detail and in which a recommendation was made to the international donor community to implement the idea (Barder et al. 2005). Subsequent publications on the AMC idea include a 2006 World Bank framework document and a 2008 paper by the AMC Economic Expert Group (Levin 2008; WB 2006).

Discussion of the AMC idea is of renewed interest given recent developments in the international donor community. In June 2009, the Global Alliance for Vaccines and Immunization (GAVI), the World Bank, WHO, UNICEF and a number of donors launched the first ever AMC. This pilot AMC is designed to accelerate development of vaccines that meet developing country needs, bring forward the availability of effective pneumo vaccines, accelerate vaccine uptake and test the AMC idea for potential future applications.<sup>11</sup>

The fundamental characteristics of an AMC are as follows: a donor (or a number of such) makes a legally binding commitment to heavily subsidize the future purchase of a set amount of a medical drug that is not yet fully developed. The donor commitment presupposes three things: i) the drug meets the medical target product profile (including effectiveness and public health impact), ii) there is demand for the drug and iii) for-profit pharmaceutical companies that have signed a guarantee and supply agreement with the donor(s) must offer a lower, long-term 'tail price' after the funds of the AMC are depleted. An AMC can be used both for late-stage products (those in the final stages of regulatory approval and for which manufacturing capacity is being established) and for early-stage products (those requiring scientific progress and extensive testing of candidate medicines) (Barder et al. 2005:30).

CGD's development of the AMC idea involves both a late-stage and an early-stage AMC. The early-stage AMC is for a malaria vaccine. Important details of this AMC include that donors

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<sup>11</sup> See [http://www.vaccineamc.org/pneu\\_amc.html](http://www.vaccineamc.org/pneu_amc.html) [Accessed August 11, 2009].

promise to pay US\$ 14 of the cost of up to 200 million treatments at a guaranteed price of US\$ 15 per treatment. The buyers of the malaria vaccine are developing country governments which will contribute with US\$ 1 per treatment (for the first 200 million treatments).<sup>12</sup> In return for being given the opportunity to sell their product at US\$ 15 per treatment, which is a price that constitutes a huge mark-up on the cost of production, for-profit pharmaceutical companies promise to provide further treatments (after the initial 200 million treatments) at a sustainable base price that reflects the cost of production (about US\$ 1 per treatment). An Independent Adjudication Committee (IAC) will determine the technical specification of the vaccine together with the question of which products meet this specification. Finally, and very important, if a company develops a 2<sup>nd</sup> generation, medically superior product (as verified by the IAC), this product will also be eligible for the price guarantee. The price guarantee will apply to the first 200 million treatments bought, shared among the eligible products according to demand.

An AMC with these specifications will create a market worth close to US\$ 3 billion which for-profit pharmaceutical companies can tap into, and the hope is that a donor created market of this magnitude will make it economically attractive for pharmaceutical companies to invest in the development and production of the required pharmaceutical product (Barder et al. 2005:30).

One theoretical feature of an AMC that is highlighted by its proponents is that an AMC is an incentivizing mechanism that creates a market for developing world medicines that is analogous to the market for medicines in high-income countries (Barder et al. 2005:29). By underwriting the future purchase of developing world medicines, donors create strong financial incentives for for-profit pharmaceutical companies to compete to bring products to market

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<sup>12</sup> The pilot AMC launched by GAVI and partners sets the price per dose for an eligible vaccine at US\$7. See: [http://www.vaccineamc.org/files/AMC\\_FactSheet2009.pdf](http://www.vaccineamc.org/files/AMC_FactSheet2009.pdf) [Accessed August, 10, 2009].



quickly. Superior pharmaceutical products can also compete for a market share just as they can in the ‘normal’, affluent pharmaceutical market in the US, Japan and Europe. In virtue of creating market conditions that mimic the market conditions under which for-profit pharmaceutical companies normally operate, the hope is that an AMC scheme will be able to attract the kind of serious and sustained R&D of drugs for the developing world that the for-profit pharmaceutical sector historically has been reluctant to commit to.

In their development of the AMC idea, CGD emphasizes that what is being created is a market and not a prize (Barder et al. 2005:28). The reason for this emphasis is that the AMC idea is compatible with a design in which donors commit to subsidizing the purchase of a set quantity of treatments of a future drug from the company that *first* develops a drug that meets the medical target profile. Under this design option, an AMC functions much like the kind of simple prize mechanism described in the previous section. CGD is eager to avoid an AMC design that resembles that type of prize mechanism because of the problems associated with such a scheme.

It is instructive to briefly go through how CGD’s AMC design avoids the four problems that mar a simple prize mechanism. This enables one to appreciate the significant strengths of an AMC scheme. First, there is no winner-takes-all problem because the proposed AMC creates a market in which several for-profit companies can compete for eligible funds. Donors have not committed themselves to heavily subsidize a specific quantity of the first developed drug that meets the specifications set up by the IAC. Second, there is no problem with a potential lack of demand at time *t* in the future when a drug is developed. By making it clear that they will only subsidize the purchase of drugs for which there is a demand, donors avoid the problem of locking themselves into a legally binding commitment to spend money on a pharmaceutical product that nobody wants (Barder et al. 2005:37).

Third, in virtue of creating a market in which new and medically superior products can compete for funding with initial market entrants that merely meet the initial target specifications, an AMC avoids the problem of not providing an incentive to develop and bring to market products that exceed the target profile as initially described by the IAC. In their report, CGD stresses this point (Barder et al. 2005:47). Fourth, for reasons similar to the ones mentioned in connection with the previous point, the AMC cannot be criticized for not providing incentives to develop 2<sup>nd</sup> generation drugs for medical condition x once the first entry drug for x has been approved for funding by the donors. It is here worthwhile to remember that the AMC is demand driven. So, if a new and medically superior pharmaceutical product becomes available on the market, it is to be expected that buyers will switch to this product.<sup>13</sup> This is of course on the assumption that there are still funds left in the AMC to subsidize the acquisition of this new product.

## **6. Objections to the AMC idea**

- *The role of an independent medical expert committee in an AMC*

It is a necessary feature of any AMC scheme that a committee of experts must describe in significant detail what medical properties a pharmaceutical product must have in order to be eligible for inclusion in the AMC scheme. As extensively discussed in the literature, there are several serious problems associated with this requirement

First, it is not clear how this committee of experts can establish the exact medical profile of a drug in advance of (or early into) the R&D phase of the target drug (Ravvin 2008:118; Hollis 2007:81). Proponents of AMCs recognize this problem. Kremer and Glennerster

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<sup>13</sup> CGD is eager to design an AMC scheme in which there are strong incentives to always buy the best available medicines. From the point of view of CGD, it is a sub-optimal outcome if the best available medicines are not the ones that are purchased (Barder et al. 2005:65).

acknowledge that an AMC “must specify the desired research outputs before hand, and coming up with the right specification and eligibility requirements may be difficult” (2004:64). CGD states that “Clearly, it is difficult to say in advance exactly what the characteristics of the successful vaccine will be” (Barder et al. 2005:44). It should be mentioned here that the most likely candidates for AMC schemes are vaccines in late-stage development. The reason for this is that the technical characteristics of vaccines can be described relatively well at this stage. As noted in the literature, vaccines are more suitable for AMC schemes than other pharmaceutical products because their side effects are less problematic than other types of products. For other types of drugs, the nature and extent of undesirable side effects are often known only after stage III clinical trials (Hollis 2008:126; Love and Hubbard 2007:1545).<sup>14</sup> These considerations seriously put into question the potential of AMC schemes to effectively incentivize R&D on early-stage products. This is rather unfortunate since it is R&D of these products that is in the greatest need of being incentivized. As nicely pointed out by Hollis, products that are in late-stage development are the products that require the least R&D incentives, since the innovating firm is already close to having a product that can enter the market (Hollis 2008:131).

Second, in order to avoid gaming possibilities and unfair advantages to specific for-profit pharmaceutical companies, the committee members that decide the exact medical profile of the targeted drug must come from outside the for-profit pharmaceutical sector. This means that the decision about drug profile is centralized and not made by the people who are closest to the developing process and have the best knowledge of which routes of R&D are most promising and cost-effective (Pogge 2008c:129).

Third, the decision about which diseases to target with the AMC scheme is open to undesirable political and commercial interference in the sense that certain parties have vested

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<sup>14</sup> For more on this point, see (Hollis and Pogge 2008:107).

interests in pursuing the eradication of particular diseases (Ravvin 2008:119). These parties can lean on and offer bribes to the committee members in order to steer their decisions in a certain direction. It is important to note that because a simple prize scheme also necessarily involves an expert committee that decides what medical properties a pharmaceutical product must have in order to be eligible of reward, these three objections also have force against such an incentivizing scheme.

What can be said in response to these three points of criticism? With regards to the latter two, the literature does not (to my knowledge) offer any solutions. However, as a way of countering the critique that it is difficult for an IAC to specify in advance the exact medical profile of the targeted vaccine, CGD and Kremer and Glennerster suggest that the IAC should be bestowed with a right to modify the technical specification of the target vaccine as it sees appropriate. This right to modify cannot, however, be used to make it more difficult for companies to develop an eligible vaccine. The initial technical specifications can only be weakened by the IAC so as to allow into an AMC scheme medically useful vaccines that do not meet the initial specifications in full (Barder et al. 2005:43; Kremer and Glennerster 2004:79). This move is, however, problematical in two respects.

First, it significantly complicates the R&D deliberations of individual companies. De facto, they do not have a fixed goal to work towards, and this saddles them with great uncertainty with respect to what detailed research avenues to pursue. Imagine that company x pursues research avenue A which is more time consuming and expensive than research avenue B. Company x does this because it anticipates that A better than B will lead to a product with the target profile originally set by the IAC. At the same time, company y pursues research avenue B. After years of research, company x does not have a product that meets the initial target profile,

but things are going well for the company, and there is good reason to believe that within a few years, the company will have a drug that has the required profile. At the same time, company y has a product that does not exactly meet the required specifications, but the product is nonetheless medically useful.

If the IAC now lowers the medical bar and allows donors to sign a guarantee and supply agreement with y, company x is in dire straits and has good reasons for feeling that it is being treated unfairly. The fixed goal that the company relied on in making its crucial R&D decisions turned out not to be fixed at all, and the company is now being economically punished for pursuing a research avenue that proved to be an effective and cost-efficient way to create a drug with the originally required profile. As the company tries to complete its R&D, the funds of the AMC are being depleted, and even if the product of company x is superior to the product of company y, x has no guarantee that when it finally is ready to market its product, there are enough funds left in the AMC for it to recoup its R&D expenses.

Second, the move opens up for the possibility that those companies that have a vested economic interest in seeing the bar lowered will try to influence the committee members with the use of bribes and other illegitimate means.

- *Winner-takes-all features of an AMC*

An important reason for proponents of AMCs to be confident that this incentivizing mechanism will be successful in augmenting the amount of R&D of drugs for neglected diseases is that AMCs create a market that reproduces existing market incentives to develop medicines for affluent markets (Barder et al. 2005:30;37;45). In other words, the market created by an AMC is

seen to mimic the market for drugs for Type I diseases.<sup>15</sup> In my opinion, this key assumption about how similar the two types of markets are in important business related aspects is controversial. In at least one important respect, the market created by an AMC is different from the type of regular market that for-profit pharmaceutical companies normally operate in. It is key to bring out this disanalogy between the two types of markets because the disanalogy has as a result that some of the problems of a prize scheme discussed in section 4 also blemish an AMC scheme. The problems in question are the winner-takes-all problem and the problem that an economically rational decision to embark on R&D requires close to perfect comparative knowledge.

In what important sense does the market created by an AMC differ from regular, affluent pharmaceutical markets? In regular, affluent pharmaceutical markets, for-profit companies have at least two instruments by which they can compete for market share: product quality and product price. Companies that do not have the medically superior product on the market can compensate for this by selling their product at a lower price than that of the superior competitor product. In this manner, companies with medically inferior products can still have sizeable market shares and make a considerable profit on their products. Regular, affluent pharmaceutical markets are, in other words, not winner-takes-all markets in the sense that the company with the medically superior product reaps all the earnings.

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<sup>15</sup> WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) has introduced a three-category classification of diseases. Type I diseases are incident in both rich and poor countries, with large numbers of vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and examples of noncommunicable diseases abound (e.g. diabetes, cardiovascular diseases, and tobacco-related illnesses). Many vaccines for Type I diseases have been developed in the past 20 years but have not been widely introduced into the poor countries because of cost. Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries. Type III diseases are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). See (WHO 2006:13).

An AMC scheme does, however, create a market with the feature that at any given time during the life of an AMC, there is likely to be only one winner. Due to the fact that for-profit pharmaceutical companies with medically inferior products cannot compete on price and get significant market shares by offering their products at a lower price than that of the ‘market-leader’, it is unlikely that an AMC will create a market in which several companies simultaneously will receive payment from the AMC.<sup>16</sup> At any given time during the life of an AMC, consumers have strong incentives to demand the medically best product available because there is no price discrimination between this product and medically inferior ones. An AMC scheme prohibits ‘me-too’ drugs (Barder et al. 2005:47). Every new drug entrant is therefore a significant medical improvement as compared to the incumbent one(s). This is likely to have as a result that as soon as a new drug enters the market, the ones that are already on the market lose a very substantial percentage of their market share. By its very design, an AMC scheme is therefore likely to continuously push out of the market the medically 2<sup>nd</sup> and 3<sup>rd</sup> best products.

These considerations show that though an AMC scheme does not create a winner-takes-all market of a kind identical to the one created by a simple prize scheme, an AMC scheme does create a market that has winner-takes-all features that do not exist in regular, affluent markets. A scheme of the latter kind therefore has some undesirable affinity with a scheme of the former kind.

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<sup>16</sup> CGD allows for the possibility that several different products will be licensed at about the same time within the first year of an AMC. It is suggested that in a scenario such as this, it would be sensible to allow the different products to share the market at the outset. To achieve this, the AMC could allow a window of one year from the entry time of the first entry drug within which second qualifying products would be eligible for the guarantee without having to demonstrate superiority. (Barder et al. 2005:47). This means that in the unlikely scenario in which two or more products are licensed within the first year of an AMC and in which there is significant demand for all products and in which no superior product is licensed in the lifetime of the AMC, it is likely that several different products simultaneously benefit from the AMC scheme.

- *AMCs and the need for close to perfect comparative knowledge*

This point of criticism requires an example to get under way. Company x signs a guarantee and supply agreement with the AMC donors for its product A that meets the minimum medical requirements set by the IAC. A is the first AMC eligible product, and during the first year of the AMC scheme, company x sells 10 million doses of A (we may imagine that one dose equals one treatment). After one year, company y launches product B that is medically superior to A. Consumers shift to B, and y quickly makes the minimum revenue on B that compels it to supply B at a low price after the funds of the AMC are depleted.<sup>17</sup> Meanwhile, company x is unable to secure any further purchase contracts in addition to its original contracts for 10 million doses of A.

This is a very unfortunate situation for company x. It has only made US\$ 150 million in revenue which in all likelihood will not be enough to cover the R&D expenses on A. In a regular, affluent market, company x could compensate for the fact that its product faces competition from a medically superior product by selling its product at a lower cost than that of the competitor product. This avenue is, however, not open to company x under the AMC scheme. There is no way that x can undercut y in price. As long as the AMC is in operation, potential customers for company x's product have access to a medically superior product that is priced at a level close to the cost of production. Moreover, and just as devastating for company x, when the funds of the AMC are depleted, company y are under a legal obligation to provide potential customers with B at a price that hovers around the cost of production. This means that there are no prospects for company x to recoup its R&D expenses on A. It should be stressed here that the fate of company

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<sup>17</sup> It is part of CGD's proposal that designated suppliers that have not received a pre-determined minimum revenue (which is less than the total AMC) should be allowed to charge a fixed mark-up over the agreed base price until they reach the minimum revenue (Barder et al. 2005:47).



x is shared by any other company that has signed a guarantee and supply contract for a product that is medically inferior to B.

This example brings out that a rational decision of a for-profit pharmaceutical company to embark on R&D of a drug for which an AMC has been established requires close to perfect comparative knowledge of a kind similar to that required to rationally enter the type of winner-takes-all race established by a prize scheme. A company must not only possess a good estimate of its own chances of getting market approval for a drug that meets the minimum requirements of the IAC. A company must also possess a good estimate of what competing companies are doing in terms of R&D of drugs that are intended for eligibility for a subsidy under the AMC scheme. In particular, a company must have a close to perfect estimate of whether or not other companies will be able to introduce a medically superior product on the market before it has had a chance to reach the minimum level of revenue on its own drug. Such comparative knowledge is difficult to come by, and companies that do not have it are, because they should avoid ending up in a situation similar to that of company x, well advised to refrain from embarking on the type of R&D that the AMC is supposed to encourage.

A company must also have close to perfect comparative knowledge about whether or not it will be able to launch its product before (or at the same time as) a medically superior product that is launched within the first year of the AMC. To see this, consider company x which is ready to launch product A one year and one day after the launch of the initial AMC approved product (B). Imagine also that B (or some other product (C) launched before A) is medically superior to A. In this scenario, company x is unlikely to be able to make any profit on A. A is not eligible for inclusion in the AMC scheme because it is a 'me-too' drug. So, during the lifetime of the AMC, A has to compete for market shares with at least one product that is medically superior and much

cheaper. Assuming that B (or C) makes the minimum revenue set by the AMC scheme, these market conditions will never change for x because the producer of B (or C) is obligated to offering a low tail price on its product after the termination of the AMC. In order for drug companies to avoid the disastrous fate of x, they must possess the required comparative knowledge *throughout* the lengthy R&D process of their product. To possess this kind of comparative knowledge is a close to impossible task.

### **7. An advanced prize scheme: the Health Impact Fund**

In a pair of writings from 2005 and 2006, Thomas Pogge did much of the theoretical groundwork for an ambitious reform plan for how to incentivize R&D of pharmaceutical products (Pogge 2005, 2006). This work has recently culminated in the publication of a book, co-authored with Aidan Hollis, that in significant detail spells out how such a plan works (Hollis and Pogge 2008). The plan is entitled ‘the Health Impact Fund’ (HIF), and it is an important feature of the HIF that it leaves the current IPR based incentivizing scheme intact. The HIF is proposed to be an amendment to the current incentivizing scheme, and innovators have the choice of being rewarded either through the normal, IPR system or through the HIF.

The reform plan consists of three components. First, the results of any successful effort to develop (research, test, and obtain regulatory approval for) a new medicine are to be provided as a public good that *all* pharmaceutical companies may use free of charge. This component of the reform plan will dramatically diminish the exclusion/access problem. Given that new essential drugs can be freely copied by all pharmaceutical companies and introduced on the market, the price of such drugs will most likely drop to a level just above their marginal cost of production.

If this component is implemented in isolation, all economic incentive to try to develop new essential drugs will be destroyed (Pogge 2005:84). Such an undesirable state of affairs is, however, avoided by implementing the second component of the reform plan. This is the idea that inventor firms should be entitled to take out a multiyear patent on any drug they invent, and during the life of the patent, the companies should be rewarded through the HIF in proportion to the impact of their invention on the global disease burden.<sup>18</sup>

According to Pogge, this component has several desirable consequences. First, it will generate a strong incentive for any inventor firm to i) sell its innovative drug cheaply and ii) allow, and even encourage, other companies to copy the drug (Pogge 2005:189).<sup>19</sup> By taking these steps, an inventor firm ensures that its innovative drug will be accessible to an increased number of people in the low-income range, and as a consequence of this, the drug will have an increased effect on the global disease burden.

Second, the component will create a situation in which an inventor firm has incentives to see to it that patients are fully instructed in the proper use of its drug (dosage and compliance). The reason for this is that only by ensuring that its product is used properly can an inventor firm avoid the (for it) unfortunate situation in which its product is widely used but fails to make a significant impact on the global disease burden.

Third, the component will bring it about that the poor populations of low-income countries constitute a lucrative market for pharmaceutical companies. There would, for example, be strong economic incentives for pharmaceutical companies to try to develop drugs for

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<sup>18</sup> It is the feature of the HIF that innovators are rewarded with a monetary prize from a centralized fund that makes it reasonable to describe the HIF as a 'prize proposal'. It is an 'advanced' such proposal because prizes are not paid out to the first innovator that meets a particular medical target, but are paid out to innovators in proportion to the impact of their innovations on the global disease burden. This crucial distinction between two types of prize proposals is emphasized by (Love and Hubbard 2007:1520).

<sup>19</sup> It is emphasized that pharmaceutical companies that wish to be rewarded under the HIF are required to sell their products worldwide within a price window ranging between the average and marginal cost of production as determined by the fund in charge of reimbursement (Hollis and Pogge 2008:74).

neglected diseases such as malaria, tuberculosis and pneumonia. Given that these diseases affect a large number of people in the most gruesome of ways, an effective drug for any of these diseases would have a huge impact on the global disease burden. An inventor firm that could produce an effective and safe drug for any of these diseases would therefore be the recipient of a reward of considerable proportions. This feature of the HIF is likely to alleviate the availability problem that exists under the current IPR driven TRIPS scheme.

A main task associated with the second reform component consists in coming up with a set of principles that can guide the reward process. Pogge suggests that when two or more different drugs are alternative treatments for the same disease, then the reward corresponding to their aggregate impact must be allocated among their respective investors on the basis of each drug's market share and effectiveness (Pogge 2005:191). As acknowledged by Pogge, things get, however, more complicated when an essential drug is not a single product but a 'drug cocktail' that combines various drugs that have been developed and manufactured by different companies.

The third component of Pogge's reform plan consists in developing a fair, feasible, and politically realistic allocation of the costs associated with the second component. According to Pogge and Hollis, effective implementation of the reform requires that much of its costs be borne by high-income countries. A reasonable minimum funding level for the reform plan is estimated at US\$ 6 billion which roughly amounts to 0.01 percent of global income (Hollis and Pogge 2008:44). To make this increased spending realistic, taxpayers and politicians of the high-income countries need to be given compelling reasons for supporting it. Pogge is of the opinion that his plan can be supported by prudential considerations (Pogge 2005:192).

First, the new incentivizing scheme will lead to significantly lower prices for essential drugs for consumers in high-income countries. Under the current free-market scheme, consumers

in these countries pay high prices for essential drugs either directly or through contributions to commercial insurance companies. Second, by giving the poor citizens of low-income countries a free ride on the pharmaceutical research conducted for the benefit of citizens in the affluent countries, the latter citizens are building goodwill toward themselves in the developing world by demonstrating in a tangible way their concern for the horrendous public-health problems these populations are facing (Pogge 2005:193). Third, the reform plan will create top-flight medical-research jobs in high-income countries. Fourth, it will enable these countries to respond more effectively to public-health emergencies and problems in the future by earning them more rapidly increasing medical knowledge combined with a stronger and more diversified arsenal of medical interventions (Pogge 2005:193).

## **8. Objections to the HIF**

- *Practicality matters*

One objection raised against the HIF concerns practical barriers to its implementation (Sonderholm 2009b). First, the second component of the reform plan requires the involvement of an international agency whose job it is to keep track of various drugs' impact on the global disease and pay rewards to pharmaceutical companies. The involvement of such an agency in the macroeconomic setup raises transaction costs and provides ample opportunity for corrupt behavior on the part of employees of the agency and those who can influence them.<sup>20</sup> It is estimated that around 10% of the monetary resources going into the reform plan will have to be spent on administration and assessment (Hollis and Pogge 2008:31).

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<sup>20</sup> It is true that there are transaction costs involved with the current system for incentivizing research and development of essential drugs. Most importantly, this system requires both patent offices and patent courts, but, as Rosenberg notes "a patent system's greater reliance on individuals to pursue their own interests directly, instead of through an intervening government, is generally more effective than any alternative" (2004:84).

In relation to the issue of corruption, it is worth stressing the unfortunate empirical fact that corrupt behavior is a rather widespread phenomenon amongst (government) officials in many of those developing countries in which data collection needs to be undertaken (Lambsdorff 2008). Pogge has argued that data about the global burden of disease and the health impact of various medicines collected under the reform plan would be useful beyond the strict purposes of this plan (Hollis and Pogge 2008:31). The data would, for example, enable better prescribing as the relative therapeutic benefits of different products were better understood. The vulnerability of the assessment procedure for corruption would, however, reduce the usefulness of the gathered data in comparison with data produced by standard academic and governmental research programs.

Second, it will be difficult for the agency in question to secure accurate information about the impact that various drugs have on the global disease burden. The problem is not only one of coming up with a plausible metric that can be used to determine a drug's impact on the global disease burden.<sup>21</sup> Assuming that this can be done, there is a further and more practical problem of applying the metric and doing the actual field work of visiting huge, poor and often geographically isolated populations and getting an accurate overview of what the disease burden is in the area and how various drugs are contributing to its reduction. Visits of this kind must be made all over the world and on a continuous basis. Even with the best of wills on the part of those who partake in this gigantic exercise, the chances of misrepresenting causal efficacy, failing to report data, making wrong estimates and miscalculating data-input are huge, and any error with respect to the reporting, filing and computation of empirical data results in an unjust

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<sup>21</sup> There is general agreement among the proponents of the HIF that the most promising metric candidate is the Quality-Adjusted-Life Year (QALY) system which currently is being used by national health systems in Australia, Canada, the UK and USA to measure the health impact of pharmaceuticals (Ravvin 2008:120; Hollis 2008:127-128; Selgelid 2008).

distribution of rewards. In relation to this, it is worthwhile to draw attention to a recent estimate of the reliability of data pertaining to the global disease burden and projections about what the global disease burden will be at some future point.

The best data comes from countries with the strongest vital registration systems - i.e., for the reporting and recording of each death and its cause, among other things. Unsurprisingly, however, such systems are usually weakest and often absent in developing world countries. There is less confidence in current disease burden estimates in poor countries, and the authors of the GBD [Global Burden of Disease] studies urge 'great caution' in the use of their projections of future disease burden in places like Sub-Saharan Africa in particular (Murray and Lopez, 1996:331). For the purpose of a full-pull program, then, that data is weakest in the very places where it is wanted most. (Selgelid 2008:138).

- *Prudential appeal*

Sonderholm (2009b) has raised worries about the prudential appeal of the HIF. This point of criticism requires an example to get under way. A is a drug that immediately reduces the symptoms of diarrhea in infants and keeps the symptoms at bay for up to four weeks. It is successful in 40% of cases and comes in the form of two pills that cost US\$ 2 to produce. B is a drug that immediately reduces the symptoms of diarrhea in infants and keeps the symptoms at bay for up to four weeks. It is successful in 90% of cases and comes in the form of a powder that needs to be dissolved in 25 centiliter of clean water that should be drunk by the infant. Moreover, B should be stored at refrigerator temperature. The production cost of B is  $\frac{1}{4}$  of that of A.

In this scenario it is likely that the producer of A will receive a higher reward than the producer of B. This is so because A is likely to have a greater impact on the global disease burden than B. This stems from the fact that the effectiveness of A does not require something which is quite often lacking in developing countries and which B requires in order to be effective (clean drinking water and cooled storage capacity). So, certain infrastructure features of the regions in which infants with diarrhea commonly live contribute in a very tangible way to the relatively small reward that producer of B will receive under Pogge's reform plan.

Pharmaceutical companies that are driven by the profit motive will soon realize that the economic prospects of developing high-tech essential drugs aimed at the medical needs of the populations in developing countries are meager.<sup>22</sup> As a result, they will predictably reorient at least some of their research and development efforts towards low-tech drugs. There will also predictably be an emergence of new pharmaceutical companies that have as their only focus the development of low-tech essential drugs that address the medical needs of the populations of developing countries.

These are developments that will be welcomed by Pogge. There is, however, a question with respect to what prudential reasons there are for citizens in high-income countries to support a reform plan that results in these developments (Sonderholm 2009b). It is true that the emergence of this new niche of drug development will likely create new jobs, but the funding for these jobs will come from the fund that pays for the second component of the reform plan, and as Pogge himself has stressed, it is high-income countries that must shoulder 'much of the costs' associated with the setting up of this fund (Pogge 2005:192). So, the vast majority of resources that are needed to pay for these new research jobs in the developed countries are being provided

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<sup>22</sup> What is meant here by a 'high-tech drug' is a drug that requires clean drinking water, electricity and/or educated health personnel in order to be effective. Conversely, a low-tech drug is a drug that requires neither of these things in order to be effective



by the developed countries themselves. No new capital (or only very little) flows, in other words, into the economies of these countries, and in case some of these new niche pharmaceutical companies are situated in a developing country, economic resources are flowing from developed countries into developing ones.

What about Pogge's suggestion that the existence of these niche pharmaceutical companies within high-income countries will result in these countries gaining useful medical knowledge that would be to the benefit of their citizens? One reply is here that if the objective is to create new medical knowledge for the benefit of the citizens of high-income countries, resources are not best spent by funding research that is hindered in the sense that it must yield an output that is effective under the type of social and physical infrastructure that commonly obtain in low-income countries. Research undertaken for the benefit of citizens of high-income countries would be much more likely to succeed if it was allowed to develop drugs that require for their effectiveness *all* the technological, educational and financial resources that exist within the healthcare systems of such countries (Sonderholm 2009b).<sup>23</sup>

▪ *Causal attribution*

Michael Selgelid has identified a problem of causal attribution for the reimbursement process essential to the HIF (2008:140). This is the problem of determining the extent to which any reduction in the global disease burden, or the burden of any singular disease, is the result of one intervention as opposed to another. Selgelid nicely illustrates the problem with an example:

For simplification, we can illustrate this problem at the level of the individual. Imagine that someone who would have died from malaria ends up living because she receives a

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<sup>23</sup> (Sonderholm 2009b) contains further discussion of the prudential reasons offered by Pogge in favor of the HIF. For a reply to the critiques raised in (Sonderholm 2009b), see (Peterson, Hollis, and Pogge 2009).

partially effective vaccine and gains access to a mosquito net. Even with perfect data availability, it may then be dubious to say that it was either the vaccine or the mosquito net that saves her life - and it may be dubious to say that there are some numbers  $x$  and  $y$  such that her survival is  $x$  % caused by the vaccine and  $y$  % (where  $y = 100 - x$ ) caused by the net. To illustrate this point, an analogy can be made with genetics. If a person with a gene that increases the chance of dying of cancer actually gets and dies of cancer, it would be wrong to think that there are some numbers  $x$  and  $y$  such that her death is  $x$  % caused by the gene and  $y$  % caused by the environment. It is the interaction between one's genes and one's environment that leads to her cancer/death, and there is little to be said about the quantitative extent to which her death is due to one cause as opposed to the other (Selgelid 2008:140).

The causal attribution problem is a significant threat to the viability of health impact measurement by either QALYs or DALYs (Disability-Adjusted-Life Years). In turn, it is a threat to the viability of the HIF as such. This is so because the crucial reimbursement process of the HIF is exactly premised on the idea that pharmaceutical companies are rewarded in proportion to the effect that their products have on the size of the global disease burden. The significance of the problem is further underscored by the fact that many successful medical interventions are ones that involve a number of different active ingredients (e.g. antiretroviral treatment for HIV/AIDS).

A simple prize scheme, AMCs and the HIF are not the only examples of incentivizing schemes that are currently being discussed by academics, policy-makers and members from the think tank and NGO sectors as changes/amendments to the TRIPS regime. Other such mechanisms include wild-card patent extensions (Spellberg et al. 2007; Outtersson, Samora, and

Keller-Cuda 2007; Sonderholm 2009c), patent buyouts (Kremer 1998) and priority review vouchers (Ridley, Grabowski, and Moe 2006; Kesselheim 2008).<sup>24</sup> No single mechanism is likely to be without problems, so the question of which of these mechanisms (if any) to endorse is going to be a comparative matter in which the strengths and weaknesses of the individual proposals are weighted against each other.<sup>25</sup>

It is a common feature of all these incentivizing mechanisms than they do not advocate the abolishment of IPRs. Each of the mechanisms (merely) constitutes a change or amendment to the IPR regime as established by the TRIPS agreement. The underlying sentiment is perhaps that though IPRs do lead to some unfortunate outcomes in terms of access and availability problems, IPRs are at least to some extent defensible as an incentivizing mechanism for innovation of some types of products (though perhaps not life-saving medicines).<sup>26</sup> The next section will provide an overview of the historically two classical defenses of IPRs.

## **9. Two defenses of the ethical legitimacy of IPRs**

Traditionally, two distinct lines of thought have been fielded for the suggestion that IPRs (including those on socially valuable goods) are ethically justifiable. One line of thought appeals to a natural right of an inventor to control the use of her innovation(s). This is the libertarian

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<sup>24</sup> (Barder et al.) offer an illustrative and exhaustive table of the various incentivizing mechanisms currently receiving attention in the literature (2005:23).

<sup>25</sup> For reasons spelled out in (Sonderholm 2009a), my own view is that a priority review voucher scheme is an attractive option that does very well in comparison to its alternatives.

<sup>26</sup> “We support intellectual property rights as embedded in SQ [the Status Quo incentivizing mechanism involving IPRs] + HIF because we believe that they would serve important human ends better than any feasible alternative (including abolition of all intellectual property rights)” (Hollis and Pogge 2008: 66). “Of course money is needed, and governments must continue to provide money through research grants along with support for government research laboratories and research universities. The patent system would continue to play a part for applications for which no one offers a prize. The prize fund should complement these other methods of funding” (Stiglitz 2006). (Love and Hubbard 2007) are admittedly more hostile towards the traditional patent system: “Prize mechanisms can be implemented in ways that are consistent with a robust patent system, but are best implemented in systems where the patent system is used to establish ownership of inventions and therefore claims on the prize rewards, rather than through exclusive rights to market products” (2007:1554).

defense of IPRs which has its historical roots in the writings of John Locke (Locke 1690). Robert Nozick has in more modern times been an advocate for this line of thought (Nozick 1974). The libertarian view endows individuals with a natural right of appropriation. This is the idea that any innovator/worker who mixes her labor with a previously unowned object or natural resource comes to own this object or resource in full and can legitimately deny that other people use/appropriate this object or resource (though she is free to sell or give away this object or natural resource to any party of her choice).

The natural right of appropriation central to libertarianism has an important proviso (famously formulated by Locke) which is an ‘enough and as good’ clause on original appropriation. The proviso states that one can only appropriate unowned property if one leaves enough and as good for others. Where resources are scarce, one cannot legitimately stake a claim to something by annexing one’s labor to it. Neither can one come to own the scarce resource by enhancing its value. If the resource is necessary for the continued well-being of others, then the fact that x was the one who developed or improved the resource does not give x exclusive rights over it. x’s entitlement to reward for her labor is overridden by the entitlement of others to that which is necessary for their survival.

On the libertarian view, there is no morally relevant difference between, say, a farmer who mixes her labor with the land and thereby come to own the results of this interaction (the timber, the harvest, the fruits, etc.) and a medical researcher who mixes her labor with certain chemicals and thereby come to own the results of the interaction (physical objects *and* an intellectual idea/formula for an useful drug). Provided that the farmer and the medical researcher pay heed to the Lockean proviso, they both come to enjoy a strong property right on the objects that result from their mixing their labor with unowned natural resources. This natural property

right is, moreover, to be written into the legal framework and enforced by the proper authorities (police and courts of law). Libertarians can therefore see trade agreements such as TRIPS as a legitimate legal enforcement of a pre-existing natural/moral right.

The libertarian defense of IPRs have recently come under attack (Hollis and Pogge 2008:63; Pogge 2009:190). The objection is that libertarianism, with its strong emphasis on rights to individual freedom and private property, is inconsistent with IPRs. What such rights do is namely to enable individuals (innovators) to unilaterally place limits on the personal freedom of others and on what they may do with property they have legitimately acquired. IPRs on a particular medicine is for example a de facto legal limitation on what other people may do with their legitimately acquired possessions (chemicals), and this is not something that libertarianism can consistently sanction.

At its best, what the libertarian argument can yield is only that medical innovators have strong property rights on the concrete, physical tokens of their innovation (pills, powders, liquids etc.). The argument cannot yield the conclusion that innovators also have property rights on the idea/formula for the medicine. Here is how Pogge and Hollis themselves formulate the thought:

The fact that others have invented a new dance or dish or gadget or medicine gives them no right to restrict what you may legitimately do with your body and property. So long as you have violated no rights in learning about the invention and have not contracted otherwise, you are within your rights when you try to copy their dance (with a willing partner) or try to reproduce their dish, gadget or medicine from materials you legitimately own (Hollis and Pogge 2008:65).

Whether or not this objection against the libertarian defense for IPRs succeeds is a complicated question. In my view, defenders of IPRs need not, however, preoccupy themselves onerously

with finding an answer to it. The reason for this is that such defenders are not best advised to try to back up their view with the libertarian argument. To my mind, a better defense for IPRs is likely to be found by exploring a consequentialist line of thought that appeals to the social utility of IPRs. The general idea is here that IPRs are ethically justifiable because they incentivize innovative R&D which in turn increases overall human welfare.

Alex Rosenberg has presented an argument that is based on this line of thought (Rosenberg 2004).<sup>27</sup> The argument is broad in scope in the sense that it defends the ethical permissibility of IPRs on all innovations.<sup>28</sup> Two important premises of Rosenberg's argument are that good ideas are the only factor of production that does not suffer from diminishing marginal productivity (2004:79) and that welfarism should be employed as the normative basis for institutional design (2004:78). Welfarism is a form of consequentialism that states that the morally best course of action, policy or institution is the one that maximizes future human welfare. One might think that welfarism has to be opposed to the ethical legitimacy of IPRs due to the access problem caused by such rights. However, as Rosenberg correctly observes, welfarism only mandates an abrogation of IPRs if the time frame within which human welfare is calculated is narrowed arbitrarily (Rosenberg 2004:85). It is correct that in the immediate and near term, human welfare is best served by abrogating IPRs, but once the horizon is lengthened, it is not at all obvious that human welfare is best served by such a legislative step.

The source of the complication is threefold. i) Once the IPR on a given product is abrogated in order to meet the needs of those who cannot pay monopoly prices for the product, disincentive effects on investment in innovation set in. ii) Such effects will be long lasting or

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<sup>27</sup> (Maitland 2002) is another (excellent) article that on a consequentialist grounds argues against the abrogation of IPRs on socially valuable goods such as life-saving medicines.

<sup>28</sup> A distinction is here assumed between innovations and scientific discoveries. Rosenberg's argument entails that there are some very basic scientific discoveries that should not be allowed to be IP protected.

even permanent. iii) Scientific innovations are essentially completely unpredictable and more consequential in their welfare enhancing effects than any other human activity. These features of scientific innovation have as a result that the medium term and long term cost of abrogating IPRs is impossible to quantify or measure in detail. There is, however, reason to believe that the cost is huge and that it will exceed the immediate and short term benefits of abrogating IPRs.

Rosenberg offers a semi-technical argument for this claim. Assume that the population of the world will reach a fixed upper limit within the next half century and then remain there. Assume also that the total quantity of arable land, refinable mineral and non-mineral reserves and so on will remain fixed thereafter. Now, attach a number to the total level of welfare that exists at this generation: 100 units of welfare (distributed unequally among, say, ten billion people). Assume that the unequal proportions remain constant while the total welfare increases in each subsequent (20-year) generation by 10% as a result of the continued emergence and implementation of patented innovations. At generation two, the index number for welfare is 110, at generation six, it is 161.05, and at generation twelve, it is 285.3.

Suppose, however, that there is an outbreak of a serious disease in generation one and that some IP protected drug is necessary in order to bring the epidemic under control. Society cancels the IPR on the drug in question, and as a result of this, there is a 20% increase in welfare in generation two and a decline from 10% to 9% in per generation welfare increases thereafter (this decline is due to the chilling effect on innovation that the abrogation of the IPR in generation one brought about). Now, at generation two, the welfare index is at 120. At generation six, it is 169.39, but at generation twelve, the index is at 284.08. So, if one calculates

human welfare over a twelve generation time span or any longer time span, it turns out that welfarism cannot sanction the abrogation of the IPR in question.<sup>29 30</sup>

(Sonderholm 2009d) contains a discussion of Rosenberg's argument. Two objections to the argument are raised and rejected. The first objection is that since we cannot predict what will happen in the future, it makes no sense to suggest that one course of action is preferable to another because the medium and long term consequences of the former are better in a particular dimension than those of the latter in the same dimension. The second objection is that the argument expressive of a cynical and/or heartless standpoint that is not troubled by the large scale and immense suffering that is occurring in developing countries due to a lack of access to expensive IP protected drugs.

The first objection is not convincing given that the process of weighing immediate benefits with respect to human welfare against medium to long term benefits along the same dimension is one we engage in all the time. Consider, for example, our attempts to safely store nuclear waste, to cut emission of greenhouse gases and to recycle trash. If we find that these attempts are not senseless, we do so exactly on the assumption that it is reasonable to compare the immediate benefits in terms of human welfare that arise from not attempting these things with the medium to long term benefits in terms of human welfare that arise from attempting them. Moreover, most of us are willing to forego the immediate benefits that stem from not

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<sup>29</sup> Other examples might of course have different values assigned to the various variables. However, given that the abrogation of an IPR has a chilling effect on investment in innovations and that the total quantity of arable land and refinable minerals, together with the unequal distribution of welfare among an unvarying number of persons, remain constant, there *will* be a point in the future where the costs of abrogating an IPR exceed the immediate benefits of such a move.

<sup>30</sup> Pogge is not impressed with a consequentialist defense of IPRs. He writes "The loss of freedom patents inflict on the global poor – and they number in the billions - is a huge loss in terms of disease and premature death. There is no associated gain that could compensate those suffering these losses; and the gains that patents bring to the affluent cannot possibly justify these losses either" (Pogge 2009:182). The view expressed here is undeniably correct if the time frame in which human welfare is measured is the short term, but as described above, the reasonable consequentialist argument measures fluctuations in human welfare in the medium to long term.



attempting to do any of these things in order to reduce or eliminate medium to long term costs (Sonderholm 2009d:312).

The second objection is misguided (and ironic) given that the very core of the welfarist position is the idea that the morally right course of action, institution or policy is the one that maximizes future human welfare (that is, minimizes future human ill-fare). The consistent welfarist is moved by the scale of human suffering in low-income countries due to the combination of disease and the access and availability problems (together with a host of other social, economic and cultural factors). But she is also moved by future human suffering caused by existing and new diseases, and it is because she is not prepared to prioritize the alleviation of current human suffering over the alleviation of greater, future human suffering that she is opposed to the abrogation of IPRs for drugs.

The second objection, moreover, assumes that the only way of making drugs available to those low-income populations that need them is by abrogating IPRs for such drugs. This assumption is, however, false. It is a fallacy of false alternatives to suggest that either IPRs for such are abrogated or such drugs cannot be made available to those who need them. There are alternative ways of making such drugs available to those who need them and thereby ease the access problem and the suffering that accompanies it. Trade barriers that make it impossible for developing countries to sell their products in the developed world could be eradicated. Such a move will most likely lead to a dramatic increase in the earnings of developing countries, and given that these countries are prepared to spend some, if not all, of these earnings on the welfare of their citizens, there would be a significant amount of resources available for the purchase of relevant drugs (Sonderholm 2009d:312).<sup>31</sup>

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<sup>31</sup> (Attaran 2004:163) adds some perspective to this line of thought. Data from the OECD (2002) suggests that US\$ 310 billion is spent on agricultural subsidies by Asian, European, and North American governments. According to

The above considerations conclude the overview of the main ethical issues surrounding IPRs and some of the attempts to alleviate the problems that stem from such rights. It is perhaps useful now to glance ahead and try to identify topics for further research. As it has hopefully become evident during the course of the discussion, IPRs raise empirical issues as well as conceptual ones. This is no doubt the impetus behind the multi-disciplinary nature of much of the research on IPRs found in the contemporary academic literature. Contributions are made by economists, medical professionals, legal scholars, political scientists, philosophers and members from the business community.<sup>32</sup> Given that IPRs attract attention from such a diverse body of academic disciplines, it is no surprise that topics for future research can be both conceptual and empirical in kind. In the next section, focus will be on topics of the latter kind. More precisely the aim is to point to three areas of empirical research that have the potential to cast light upon, and perhaps even solve, some of the ethical controversies surrounding IPRs.

## **10. Suggestions for future research**

As described in (Reichman 2009:256), there has been a surge in the number of compulsory licenses on pharmaceuticals - or public threats thereof - since 2006. In order to be able to better evaluate Bird's worries (outlined in section 3) about retaliatory action from pharmaceutical companies (and/or national governments from traditional innovator countries) whose products have been subject to compulsory licensing, it would be useful to have more knowledge about the extent to which the issuing of compulsory licenses has been followed up by such action. As

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Attaran, such subsidies "deny the agrarian populations of poor countries the opportunity to export products and accumulate wealth". President Museveni of Uganda has also pointed to the market distorting effects of agricultural subsidies and their relation to the question of how to finance the acquisition of drugs in low-income countries. His view is that "if there were no agricultural subsidies [in America and Europe] we would earn enough money to buy all the drugs we want" (WSJ 2003).

<sup>32</sup> The diverse academic background of the contributors to the *Journal of Law, Medicine & Ethics*' recent special issue on Pharmaceutical Innovation: Law & the Public's Health is a good example of this (JLME, Vol. 37:2, Summer 2009).

attested by Bird, retaliatory action by both pharmaceutical companies and governments is not a mere theoretical option. For example, when Thailand attempted to use its compulsory licensing powers, one pharmaceutical company withdrew pending applications for anti-AIDS drugs in response. Moreover, the US government placed Thailand on its special 301 'priority watch list' because of alleged violations of intellectual property law (Bird 2009:211).

It would also be useful to know if there is any interesting correlation between the level of direct foreign investment in a given country and this country's record with respect to issuing compulsory licenses or threatening to do so. Are countries that in recent years have issued compulsory licenses less likely to receive direct foreign investments (e.g., establishment of production and/or R&D facilities) in comparison to countries that have not made use of their WTO guaranteed right to issue such licenses? The same question can also be raised in a chronological dimension. Have some countries experienced a decline in the level of direct foreign investment after they have issued (or threatened to do so) compulsory licenses? Having a firmer grasp on these empirical issues would do much to either consolidate or deflate a common line of attack on compulsory licenses.

The second potential topic for further research has to do with the economic impact of parallel trade. As mentioned in section 3, the negative impact of parallel trade on profit potentials for pharmaceutical companies are often cited as a reason for not implementing differential pricing as a means to mitigate the access problem. Some empirical work on the economic impact of parallel trade has already been undertaken (Kanavos and Costa i Font 2005), but it would be useful to have more knowledge of this phenomenon. How big a problem is parallel trade for the pharmaceutical industry in terms of loss of profit? If examples could be given of pharmaceutical companies that have experienced reduced profits due to parallel trade and if it could be shown

that these lost profits are significant in volume, then much would be achieved in terms of underwriting traditional worries about differential pricing.

Empirical analysis of the above kind would, moreover, be interesting in relation to recent economic analysis that shows that in poor countries characterized by great disparities of income (e.g., South Africa and India), companies that seek to maximize their profits on a product will rationally charge a high price for it so that only the most affluent segment of citizens can afford it (Flynn, Hollis, and Palmedo 2009). The real reason as to why the for-profit pharmaceutical sector is adverse to charging lower prices for their products in low-income countries (with a substantial affluent class) as compared to high-income countries is perhaps not so much grounded in worries about parallel trade as in the knowledge that profits can be maximized in low-income country settings by charging a high price for the product. Showing that the impact of parallel trade only has a limited negative effect on the size of profits made on affluent markets will lend support to this hypothesis.

Lastly, but perhaps most importantly, it would be useful to have additional empirical work done on the question of what the correlation is between strong IPRs (and the enforcement of such rights) and the volume of innovation. Sector studies in the pharmaceutical and agricultural/seed production sectors would be particularly useful together with studies that examine possible correlations in developing countries and developed ones to see if the overall correlation pattern is the same in both regions. Some empirical work has already been done on the overall correlation issue, but further work would be welcome.<sup>33</sup> As mentioned in section 9, it

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<sup>33</sup> A few examples of this kind of work should be mentioned here. Léger concludes that strengthened Intellectual Property Protection (IPP) is an incentive for innovation. IPP has, however, a very limited effect in developing countries compared to industrial ones (Léger 2006). Lanjouw argues that longer product patents encourage innovation in the developed world, (due to the ability to employ monopolistic pricing schemes) and that strengthening IPRs do encourage R&D and innovation (Lanjouw 2005). Finally, Park argues that the enforcement of IPRs indirectly increases productivity by increasing investment in R&D, (due to greater returns). In the more

is a crucial premise of the consequentialist argument in favor of IPRs that weak IPRs and/or weak enforcement of such rights leads to a decline in the volume of innovation. This premise is an empirical one, and the consequentialist defense of IPRs gains significantly in strength if this premise can be further reinforced and supported by empirical findings. Conversely, if the premise cannot be underpinned in such a manner, the consequentialist argument loses credibility, and the defender of IPRs must look elsewhere for argumentative support for her view. As previously discussed, a libertarian defense of IPRs is here a possibility, but this argument has its own controversial premises.

## **11. Conclusion**

This paper has been concerned with IPRs and the TRIPS agreement. It has given an overview of the ethical problems that are commonly associated with this agreement, and it has offered a discussion of a number of common proposals as to how these problems might be alleviated. The access and availability problems were first introduced before a discussion of differential pricing and compulsory licensing was undertaken. A simple prize scheme, AMCs and the HIF were then outlined as examples of amendments to the TRIPS regime aimed at reducing the scope of the access and availability problems. The two classical defenses of IPRs were presented in section 9, and the penultimate section contained three suggestions for further empirical research that has the potential to cast light on some of the ethical issues discussed in the paper.

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developed countries however, the substantive IPRs themselves show effectiveness even when controlled for enforcement (Park 2005).

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