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Improving Global Health: Intellectual Property Rights and Alternative Ways of Incentivizing Innovation

Sadie Regmi

Introduction

According to the Universal Declaration of Human Rights, ‘everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services’.¹ Yet millions of people die every year because they cannot afford medicines that already exist.² As the high price of medicines is largely due to monopoly rights that are granted to their innovators, and not due to the costs of production, intellectual property rights (IPRs) seem to be at conflict with the right to medical care. In addition, funding for diseases does not correspond to the disease burden in the world, causing tropical diseases prevalent in low- and middle-income countries (LMICs) to be largely ignored. This has also raised questions about whether IPRs and the incentives they provide to only pour research resources into the disease burden of the world’s richest minority are reinforcing health disparities.³

Lack of incentives for research into neglected diseases (NDs) has been attributed to the loose IPR regimes in LMICs.⁴ In 1994, IPRs were globalized through the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which all member states of the World Trade Organisation (WTO) are bound by.⁵ The logic behind this was simple; high-income countries have strict IPRs and their disease burden is not ignored, the disease burden of LMICs

- 1 United Nations General Assembly, *Universal Declaration of Human Rights* (1948) www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf, [accessed 30 November 2010].
- 2 Graham Dutfield, ‘Delivering Drugs to the Poor: Will the Trips Amendment Help?’, *American Journal of Law & Medicine* 34 (2008), 107–24.
- 3 Solomon R. Benatar, ‘Reflections and Recommendations on Research Ethics in Developing Countries’, *Social Science & Medicine* 54, no. 7 (2002), 1131–41.
- 4 Monique F. Mrazek and Elias Mossialos, ‘Stimulating Pharmaceutical Research and Development for Neglected Diseases’, *Health Policy* 64 (2003), 75–88.
- 5 WTO, ‘Agreement on Trade-Related Aspects of Intellectual Property Rights’, in *Marrakesh Agreement Establishing the World Trade Organisation*, ed. World Trade Organisation (1994).

with weak IPRs is ignored, hence implementing stricter IPRs should incentivize research into the disease burden of LMICs with formerly weak IPRs. Yet, in 2007, 12 years after TRIPS was implemented, there was little documented evidence of any improvements in the 90/10 gap, fuelling questions about the motivations behind the globalization of IPRs and the wisdom of the TRIPS agreement.⁶

Margaret Chan, Director-General of the World Health Organisation (WHO), asserts the ‘need for a system of intellectual property that rewards innovation in the interest of keeping it sustainable’.⁷ Most public policy on drug patents is based on the notion that patents could, overall, be more conducive to public welfare because they incentivize innovation. Awareness of the shortcomings of the current system is a prerequisite of effectively comparing IPRs to the alternatives. The aim of this essay is thus to assess such shortcomings.

The TRIPS agreement

Ever since IPRs and trade were linked by the United States in the 1980s, various attempts have been made to globalize IPRs through bilateral and multilateral trade agreements.⁸ Arguably, the most successful of these attempts, at least in terms of making IPRs applicable in many countries, was the 1995 TRIPS agreement.

With regard to pharmaceuticals, TRIPS requires:⁹

- Patents for pharmaceutical products and microorganisms to have a 20-year duration, starting when the inventor files for the patent
- Patent rights of imported products to be upheld
- Patented holders to get exclusive marketing rights until the patent expires.

6 Jillian Claire Cohen-Kohler, ‘The Morally Uncomfortable Global Drug Gap’, *Clinical Pharmacology & Therapeutics* 82 (2007), 610–14. Gaëlle Krikorian, ‘New Trends in IP Protection and Health Issues’, in *The Political Economy of HIV/Aids in Developing Countries*, ed. Benjamin Coriat (Cheltenham: Edward Elgar, 2008), 52–77.

7 Margaret Chan, ‘Strengthening Multilateral Cooperation on Intellectual Property and Public Health’, text of presentation at the World Intellectual Property Organisation Conference on Intellectual Property and Public Policy Issues, (2009), www.who.int/dg/speeches/2009/intellectual_property_20090714/en/index.htm [accessed 22 April 2012].

8 Peter Drahos, ‘The Universality of Human Rights: Origins and Development’, text of presentation at World Intellectual Property Organisation (1998), www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf [accessed 22 April 2012].

9 Cohen-Kohler, ‘The Morally Uncomfortable Global Drug Gap’, 610–14.

TRIPS ensured that criteria for IPRs set out in the agreement would be the minimum for all member states of the WTO, with the lowest income countries being granted a period of up to ten years to implement the required changes.¹⁰

Before the TRIPS agreement, IPRs depended on individual governments and varied massively across the globe, with countries like India having much looser IPR regimes than countries like the United States.¹¹ Critics of TRIPS argue that as the primary purpose of granting IPRs has historically been to incentivize innovation, countries should be free to choose if they want to prioritize universal access to current knowledge and technology at the expense of innovation.¹² After noting that patents work by restricting access to knowledge, Graham Dutfield states:¹³

society needs to strike a balance between private control over the use of information and its diffusion. Where the line should be drawn is very difficult to determine, but its ideal location is likely to vary widely from one country to another.

Whether a country wants to prioritize access over innovation may broadly, if a little simplistically, be said to differ depending on whether a country is high-income or industrializing. For instance, in the case of medicines, the former group could be said to have more of an interest in incentivizing innovation, as their populations generally do not face access barriers to medicines that are already available, whereas the latter group may be keener to establish basic access to medicines that are already available. However, access problems are not always confined to LMICs; the recent licensing of the drug amifampridine, which was only a slight modification of the unlicensed 3,4-diaminopyridine, but 50–70 times more expensive, caused neurologists in the United Kingdom to voice their concern.¹⁴ Furthermore, lack of research into NDs shows that lack of access is not the only major barrier to healthcare in LMICs. Fourteen million people die of NDs every year and 90 per cent of these deaths occur in LMICs.¹⁵

While both opponents and proponents of globalizing IPRs agree that there is a lack of research into NDs, they disagree on why this is the case. Proponents argue that loose IPR regimes in LMICs is a factor deterring research into NDs and that lack of IPRs in those countries makes tropical disease research uneconomical. Their view is that the globalization of IPRs provides incentives

10 Ibid.

11 Murphy Halliburton, 'Drug Resistance, Patent Resistance: Indian Pharmaceuticals and the Impact of a New Patent Regime', *Global Public Health* 4 (2009), 515–27.

12 Drahos, 'The Universality of Human Rights: Origins and Development'.

13 Dutfield, 'Delivering Drugs to the Poor: Will the Trips Amendment Help?', 107–24.

14 Nigel Hawks and Deborah Cohen, 'What Makes an Orphan Drug?', *British Medical Journal* 341 (2010), 1076–8.

15 Mrazek and Mossialos, 'Stimulating Pharmaceutical Research and Development for Neglected Diseases', 75–88.

for research into NDs.¹⁶ Opponents believe stricter IPRs will do little to incentivize research into NDs, also termed ‘diseases of the poor’, because of differences in the ability of people from HICs and LMICs to pay for drugs. They contend that research will continue to focus on developing drugs for those who are able to pay more, and point to the billions poured into ‘lifestyle’ drugs for the rich, which can be defined as ‘drugs used for non-health problems or for conditions that lie at the boundary between a health need and a lifestyle wish’¹⁷ to justify their view.¹⁸ In their opinion, globalizing IPRs will do little to redress the 10/90 gap, whereby 90 per cent of the disease burden in the world only gets 10 per cent of research funding, while the increased prices of drugs and damage to generic drug industries (such as those found in India) will deprive many of life-saving drugs.¹⁹

The linking of trade and IPRs is particularly interesting if we see the debates as being between the interests of high-income countries versus those of low- and middle-income ones. For instance, let us consider again the fact that all member states of WTO have to sign the TRIPS agreement, which requires minimum IPR standards. Paul Collier in his book ‘The Bottom Billion’ states:²⁰

The essence of the World Trade Organisation is that the reduction in our trade restrictions is something that we concede only in return for others doing likewise. . . . [Countries at the bottom billion] have virtually no role in an organisation that is designed for bargaining. The countries at the bottom have no markets of any interest to the rest of the world, and so their high trade restrictions are also of no interest.

Applying Collier’s argument to TRIPS, HICs are able through the WTO to impose their own priorities of an environment conducive to innovation over the access priorities of LMICs because of their economic dominance. As LMICs have more to lose if HICs impose sanctions upon them than vice versa, LMICs accept the public health losses caused by strict IPRs in favour of being part of a global trade network such as the WTO.²¹

16 Ibid. See also Patrice Trouiller, Els Torreele, Piero Olliario, Nick White, Susan Foster, Dyann Wirth and Bernard Pécoul, ‘Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?’, *Tropical Medicine and International Health* 6 (2001), 945–51.

17 David Gilbert, T. Walley and B. New, ‘Lifestyle Medicines’, *British Medical Journal* 321 (2000), 1341–4.

18 Rajashree Chandra, ‘Intellectual Property Rights and the Right to Health’, in *Knowledge as Property* (New Delhi: Oxford University Press, 2010), 192.

19 Trouiller, Torreele, Olliario, White, Foster, Wirth and Pécoul, ‘Drugs for Neglected Diseases: A Failure of the Market and a Public Health Failure?’, 945–51.

20 Paul Collier, ‘Trade Policy for Reversing Marginalisation’, in *The Bottom Billion* (Oxford: Oxford University Press, 2008), 161.

21 T. N. Srinivasan, *The Trips Agreement: A Comment Inspired by Frederick Abbott’s Presentation*, (2000), www.econ.yale.edu/~srinivas/TRIPS.pdf [accessed 30 November 2010].

Emphasizing safeguards in TRIPS: The Doha Declaration

Recognizing that TRIPS compromised access to medicines in LMICs, the international community adopted the Doha Declaration in 2001, which ‘affirmed the right of member states of the WTO to interpret and implement TRIPS in a manner supporting the protection of public health, and, in particular, access to medicines’.²² The Doha Declaration thus clarified the safeguards in the TRIPS agreement so that LMICs were able to use compulsory licensing and parallel importing provisions in the interest of public health. Through compulsory licensing, ‘the practice of authorizing a third party to make, use, or sell a patented invention without the patentee’s consent’,²³ countries can allow generic manufacture of cheap versions of patented drugs for use within the country. Countries without manufacturing capacity are able to issue compulsory licences to a pharmaceutical company in another country and subsequently import the drug for use in the domestic market, through parallel importing provisions. Middle-income LMICs such as India and Brazil, which have generic pharmaceutical companies, have thus produced cheap anti-retrovirals and exported them to countries that do not have sufficient resources to manufacture generic drugs.²⁴

Undermining TRIPS safeguards

Writing for the *Lancet* in 2009, Mongkol Na Songkhla, former minister of Public Health in Thailand, reports of political pressure pharmaceuticals and governments of more well-off nations placed on Thailand when it employed TRIPS flexibilities and issued compulsory licences for generic versions of the drug ‘efavirenz’ and the ‘lopinavir–ritonavir’ combination.²⁵ While he reports that compulsory licensing caused the number of people on efavirenz to increase from 5,000 to 20,000 and that of lopinavir–ritonavir combination to increase from 300 to 3,000, he voices concerns that in the aftermath of the use of TRIPS safeguards by Thailand and the political pressure put upon it, other LMIC nations may be discouraged from issuing compulsory licensing in the interest of public health. Other academics have noted how the US government questioned the validity of the licence and pressed Thailand to withdraw the decision to issue a compulsory licence for efavirenz and negotiate with the

22 Vanessa Bradford Kerry and Kelley Lee, ‘Trips, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?’, *Globalisation and Health* 3 (2007).

23 Colleen Chien, ‘Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?’, *Berkeley Technology Law Journal* (2003).

24 Kerry and Lee, ‘Trips, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?’

25 Mongkol Na Songkhla, ‘Health before Profits? Learning from Thailand’s Experience’, *Lancet* 373 (2009), 441–2.

company that held the patent.²⁶ They believe LMICs are reluctant to exploit TRIPS safeguards and see the American and pharmaceutical industry reaction to the Thai case as being representative of the pressure on LMICs not to make use of TRIPS safeguards, asserting ‘maintaining one’s standing as a trading partner committed to IPRs has so far taken precedence over access to medicines’.²⁷

These TRIPS safeguards are further undermined through TRIPS-plus agreements in bilateral Free Trade Agreements (FTAs) that often require stricter IPR standards. The standards put forward by the United States work either by introducing new measures that are absent from TRIPS, or by requiring countries to forego TRIPS safeguards. A summary of these measures is provided in Table 8.1.

Carsten Fink and Patrick Reichenmiller, in a Trade Note by the World Bank Group, note that the preferential access to US markets that may be given in return for stricter IPRs are time-bound and liable to be taken away in future FTAs, whereas IPR regimes, once implemented, are unlikely to change. They also note that policies, including IPR policies, are evaluated from time to time, but that trade agreements with specific IPR criteria compromise the ability of countries to change course, concluding, ‘the benefits and costs associated with protecting pharmaceutical patents vary from country to country . . . insufficient flexibility in over-riding patents can have a detrimental impact on the protection of public health’.²⁸

Considering the effort the international community seems to have taken to strengthen TRIPS safeguards in the Doha Declaration, it seems odd that LMICs should sacrifice these provisions so readily in bilateral FTAs. In Krikorian’s opinion, due to attempts to reinforce IPR standards in the world for the past 30 years, the United States has advance knowledge of what it wants to obtain from trade negotiations, in contrast to LMICs, which frequently do not have IPRs on the agenda or ‘have the vaguest, if any, notion of what is at stake’. In addition to these factors, Krikorian cites the United States’ economic dominance and disparities in access to expert knowledge as reasons for why LMICs sign up to the United States’ stringent IPR standards.²⁹

Krikorian’s representation of LMICs as not knowing the implications of IPRs is not wholly convincing, especially in light of her claim in the same chapter that the 2001 Doha discussions led ministries of health and commerce to acquire ‘an unparalleled sense of the public health implications of IP protection’. Nevertheless, her analysis of how the choice for LMICs is often between losing the United States as a trading partner and sacrificing access to

26 Kerry and Lee, ‘Trips, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?’

27 Ibid.

28 Carsten Fink and Patrick Reichenmiller, *Tightening Trips: The Intellectual Property Provisions of Recent Us Free Trade Agreements* (2005), <http://siteresources.worldbank.org/INTRANETTRADE/Resources/Pubs/TradeNote20.pdf> [accessed 30 November 2010].

29 Krikorian, ‘New Trends in IP Protection and Health Issues’, 52–77.

medicines has been echoed by various other academics.³⁰ While I have only used examples of American FTAs, it must be noted that the European Union is currently in the process of negotiating TRIPS-plus measures with India, with greatly adverse implications for the world's generic drug market.³¹

Alternatives to IPRs for incentivizing innovation

There appears to be a conflict between the IPRs and the availability of medical care, at least in LMICs, because the former can restrict access to medicines. However, if it is true that IPRs incentivize research and development of healthcare products to a great degree, it is possible that IPRs are, on balance, conducive to greater health. By incentivizing innovation, IPRs bring newer and better drugs into the market, which must be an improvement on lack of new medicines.³² The latter argument rests on two presumptions: that IPRs incentivize innovation and that they are justified in so far as the effects they have on innovation outweigh the public health compromises made in reduced access. However, a key message of the report of the WHO Commission on Intellectual Property Rights, Innovation and Health is 'because the market demand for diagnostics, vaccines and medicines needed to address health problems affecting LMICs is small and uncertain, the incentive effect of intellectual property rights may be limited or non-existent'.³³ According to the evidence, IPRs are not only restricting access to medicines, but also not providing incentives for research into the diseases that afflict the majority of the world. In light of the failings of the current system to provide adequate healthcare products for many people in LMICs, several initiatives have been proposed.

Public-private partnerships

The various public-private partnerships (PPPs) devoted to research of NDs exemplify the progress being made to tackle the global burden of disease.³⁴

30 Carlos Maria Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines', *Bulletin of the World Health Organisation* 84 (2006), 399–404. Kerry and Lee, 'Trips, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?'

31 'Europe! Hands off Our Medicine', in *Medecins Sans Frontieres* (2010), www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_HandsOffCampaign_FTA_ENG_2010.pdf [accessed 22 April 2012].

32 Linda R. Cohen and Roger G. Noll, 'Intellectual Property, Antitrust and the New Economy', *University of Pittsburgh Law Review* 62 (2000), 453–73.

33 Tomris Türmen and Charles Clift, 'Public Health, Innovation and Intellectual Property Rights: Unfinished Business', *Bulletin of the World Health Organisation* 84 (2006), 338.

34 Mrazek and Mossialos, 'Stimulating Pharmaceutical Research and Development for Neglected Diseases', 75–88.

Table 8.1 TRIPS-plus measures

Measure	Explanation	Implications
Patent-term extension	Extension of patents to compensate for delays in examining patent applications and granting marketing approval. It appears that delays in other countries also have to be taken into account, as has happened in the case of Bahrain.	Extension of patents will directly affect the time period after which generics can enter the market.
Test data exclusivity	TRIPS requires WTO member states to protect undisclosed test data against commercial use, but there is no mention of granting exclusive rights over the data. The bilateral FTAs put forward by the United States, in contrast, require states to grant exclusive rights for a minimum period of five years after approval of the data, regardless of whether or not the data are classed as being ‘undisclosed’.	Data exclusivity will delay generic competition, as generic manufacturers will not be able to use the data for five years to obtain marketing approval. This greatly undermines the provision of compulsory licensing, as generic manufacturers would have to compile their own data, which could be expensive and time-consuming.
Linkage	Linkage requires the registration of drugs to be linked to patent protection, which means that health authorities are not able to grant marketing approval to a generic drug if a patented version is available. Like data exclusivity, linkage is a characteristic of American FTAs, and is not present in TRIPS.	As drugs cannot be brought to the market without the approval of the patent holder, the compulsory licensing provision in TRIPS is yet again undermined.

Grounds for issuing compulsory licences	While TRIPS allows WTO member states to determine the grounds upon which to issue compulsory licences, the US–Vietnam, US–Australia, US–Jordan and US–Singapore FTAs limit the use of compulsory licences to cases of national emergency or non-commercial use.	Specifying the grounds for use of compulsory licensing undermines the ability of states to make decisions on important public health matters.
Limitations on parallel importing	The US–Australia, US–Morocco and US–Singapore FTAs give the patent holder the right to prevent parallel imports, undermining this TRIPS safeguard.	The neighbours of Australia, Morocco and Singapore, who lack manufacturing capacity will not be able to issue compulsory licences and subsequently import generics from these nations, even the event of a national emergency.
Institutional flexibility undermined	Provisions under TRIPS recognize limitations in LMICs in enforcing laws and thus do not create specific obligations to enforce IPRs over enforcing other laws. US agreements with several countries make it clear that resource limitations cannot be used as an excuse for not adhering to intellectual property regimes.	Having to enforce IPRs could direct resources away from important programmes in countries with limited resources.
Fines	In the event of IPR infringement, TRIPS requires fines to be paid in compensation for monetary losses of patent holders. By contrast, all the US FTAs require fines to be paid, whether or not the patent holders are financially affected by the infringement.	Fines that have to be paid even when there has been no financial gain are likely to be detrimental to actors in LMICs.

Source: Correa (2006), Kerry and Lee (2007), Fink and Reichenmiller, (2005).

While many PPPs funnel resources into much-needed research for NDs, some also show an awareness of problems with access and thus incorporate provisions that make access to medical treatment (once the research has delivered a product) a priority. The International Aids Vaccine Initiative is one such PPP, where the possession of IPRs by the private partner is subject to the production of vaccines for LMICs at affordable prices.³⁵ Another PPP, Medicines for Malaria Venture, retains the IPRs in LMICs, while the private partner possesses the rights in HICs.³⁶ The Global Fund to Fight AIDS, Tuberculosis and Malaria aims to coordinate the effort of donors and provide incentives for research into NDs.³⁷

Health Impact Fund

Recognizing that the patent system was put in place to incentivize innovation, and also noting its shortcomings, namely that ‘this system does not encourage development of drugs for diseases that mainly affect poor people’, Thomas Pogge and colleagues have proposed the Health Impact Fund (HIF) as an alternative system to incentivize innovation.³⁸ HIF requires drug developers to register their product, which would entitle them to a share of a ‘reward pool’ of US\$6 billion for ten years. Their share of the reward would depend on the relative impact of their drug compared to other registered drugs in tackling the global burden of disease. The impact would be re-evaluated on a regular basis. Registration to HIF would require drug developers to produce and distribute medicines at the lowest feasible cost of production and distribution for ten years, and then to freely give out licences to generic manufacturers. HIF aims to provide incentives for research into drugs for NDs as well as for more common diseases such as HIV and coronary heart disease, but not into ‘lifestyle’ drugs. The proposers of HIF hope that the money for the reward pool, although large, would result in savings even for rich-world citizens because the cost of patents would no longer be included in the price of drugs.³⁹

Although prize funds are not a new concept, they have never been implemented on the scale that proponents of HIF would do. However, this is hardly a point against HIF, since a larger prize fund must attract more innovation, not less. As the system has broadly worked on a smaller scale, for

35 Ibid. See also *International Aids Vaccine Initiative*, www.iavi.org/Pages/home.aspx [accessed 22 April 2012].

36 *Medicines for Malaria Venture*, www.mmv.org [accessed 22 April 2012].

37 Mrazek and Mossialos, ‘Stimulating Pharmaceutical Research and Development for Neglected Diseases’. See also *The Global Fund*, www.theglobalfund.org/en/ [accessed 22 April 2012].

38 Amitava Banerjee, Thomas Pogge and Aidan Hollis, ‘The Health Impact Fund: Incentives for Improving Access to Medicines’, *Lancet* 375 (2010), 166–9.

instance through the Gates Foundation, the concept is at least known to be broadly sound.⁴⁰

As drug manufacturers would have to voluntarily register their product into the HIF, and in doing so forego the absolute monopoly they would otherwise have due to their patented product, their share of the prize fund reward would have to be sufficiently lucrative for them to follow this route. The incentivizing effect of HIF depends on the reward pool that governments agree to support and in the number of products that can simultaneously be registered with the fund. The larger the reward pool and the fewer the number of registrants, the more incentivizing the effect of HIF would be.

The current system of incentives rewards drug manufacturers on the basis of sales of their products only. The manufacturers have every incentive to advertise their product and to lobby doctors to use it. This might not be effective in healthcare systems in many HICs where decisions about the cost-effectiveness and efficacy of drugs are made by independent bodies. However, in LMICs, health-care expenses are usually met out of pocket, and consumers are thus open to exploitation; counterfeits have a big market in many LMICs.⁴¹ If markets are not deemed to be worth advertising in, they are ignored altogether, as firms have no incentive to get their drugs out to those who cannot afford them. The HIF, by altering the reward given to companies and basing it on health impact, has the potential to tackle the ‘last mile problem’, where consumers in need of medication do not acquire them due to lack of incentives for manufacturers to get medications out to those who are unable to afford them.

As the emphasis of the HIF is on health impact, it should, in theory, be an equitable scheme. However, as high income countries (HICs) will be contributing more to the fund than low- and middle-income countries (LMICs), it is possible that political interests get in the way of implementing such a scheme. It is also probable that those nations that contribute more to the fund will have more voting power and, in the absence of rigorous independent boards to assess the global burden of disease and health impact of a particular drug, it is possible that the fund will not be as equitable as its proponents hope. However, by placing the emphasis on health impact, the HIF could achieve equity both in innovation of new drugs and medical technologies and their subsequent distribution.

39 Ibid.

40 Bill and Melinda Gates Foundation, ‘Foundation and U.S. Government Give \$2.5 Million Prize for Transforming Banking Sector in Haiti’, www.gatesfoundation.org/press-releases/Pages/mobile-money-in-haiti-110110.aspx [accessed 22 April 2012].

41 Shubham Chaudhuri, Pinelopi K Goldberg and Panle Gia, ‘Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India’, *The American Economic Review* 96 (2006), 1477–514. J. Stiglitz, ‘Scrooge and Intellectual Property Rights’, *British Medical Journal* 333 (2006), 1279–80.

Medical Research and Development Treaty (MRDT)

The MRDT aims to break the link between the cost of production and the cost of research and development, and thus proposes an alternative to the patent system for funding medical research. Countries – high income and low and middle income – would agree to contribute a certain percentage to a research fund, with the contributions increasing according to levels of gross domestic product (GDP) or per capita income.⁴²

Priorities of medical research would be identified through a Committee on Priority Medical Research and Development (CPMRD), which would meet once a year. Emphasis would be placed on improving access to knowledge, increasing technology transfer and research into priority medical research and development.⁴³

As research will be funded directly, MRDT will no doubt incentivize basic medical research. Whether MRDT will provide sufficient incentives for researchers to translate their research into effective products is much less certain. Nicoletta Dentico and Nathan Ford, in their essay ‘The Courage to Change the Rules: A Proposal for an Essential Health R&D Treaty’, cite the model used for the Human Genome Project, which was public-sector funded, as an example of the sufficiently incentivizing effect of basic research funding.⁴⁴ However, in the absence of clear aims, such as those of the Human Genome Project, and in the face of competition for funding from different researchers with varying research agendas, it is unclear whether the ‘public-goods model’ that worked for the Human Genome Project would necessarily work as well when implemented on a broader scale.

It is possible, however, that if the MRDT was subject to good governance, research funds would flow between countries, research efforts would not be duplicated and the research base of LMICs would be strengthened, thus contributing to their growth, and aiding research into diseases that primarily afflict populations of these countries, namely the communicable tropical diseases. Taking into consideration the various and sometimes opposing political commitments of the parties that will make up the governing body of the MRDT, this may be an unrealistic prospect.

The concerns about the distribution of benefits of research raised by the current IPR system are no doubt a major contributing factor to the open-access model purported by the MRDT. However, just as there may be a lack of incentives for researchers to translate basic research into usable goods, there may also be a lack of incentive in ensuring physicians and consumers of

42 Medical Research and Development Treaty (MRDT): Discussion Draft 4 (2005), www.cptech.org/workingdrafts/rndtreaty4.pdf [accessed 22 April 2012].

43 Ibid.

44 Nicoletta Dentico and Nathan Ford, ‘The Courage to Change the Rules: A Proposal for an Essential Health R&D Treaty’, *PLoS Medicine* 2 (2005), 96–9.

products are knowledgeable about new products.⁴⁵ Even if the goodwill of the actors in question was deemed to be sufficient motivation, it is not clear how such diffusion schemes would be funded. This is in contrast to the HIF where, as inventors are rewarded on the basis of health impact, they are incentivized to ensure that the distribution networks that would maximize the impact of their products are working properly.⁴⁶

A particular strength of the MRDT is its international nature; by signing up, countries would be jointly invested in important health research. Furthermore, coordination has the potential to minimise duplication of research efforts. A solution that draws on the strengths of both the HIC and the MRDT could take the shape of a global R&D treaty, the funds from which would then be used as the ‘reward pool’ of a HIF-style scheme.

Conclusion

The merits and drawbacks of intellectual property rights (IPRs) have been debated for as long as IPRs have been in place. In recent decades, the impact of IPRs on the health outcomes, particularly of those in LMICs, has been noted. In light of the significant drawbacks of the current system, and the potential merits of alternatives that have been proposed, a rethink of the model of incentivizing innovation is in order.

45 Joseph DiMasi and Henry Grabowski, ‘Patents and R&D Incentives: Comments on the Hubbard and Love Trade Framework for Financing Pharmaceutical R&D’, Submission for WHO Commission on Intellectual Property Rights, Innovation and Public Health (2004), www.who.int/intellectualproperty/news/en/Submission3.pdf [accessed 22 April 2012].

46 Selgelid, ‘A Full-Pull Program for the Provision of Pharmaceuticals: Practical Issues’, *Public Health Ethics* 1 (2008), 134–45.