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Prudential Reasons for IPR Reform

A Report for  
**Innova-P2**

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CAPPE, University of Melbourne, May 2009

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\* The research leading to these results has received funding from the European Community's Seventh Framework Programme under grant agreement 217665. This report has been reviewed and accepted by the Innova-P2 project partners. Thanks also to Armin Schmidt for comments on an earlier draft.

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## Introduction

All humans are mortal. For some, this fact about human life is no more than the major premise of Aristotelian logic, something to be faced when the grandchildren go to university. For others, it is an almost daily occurrence, whether a sister dies of AIDS, a child of malaria or a neighbour of tuberculosis.

Death becomes a pressing *moral* concern when it is avoidable, particularly amongst the young. Of 1,000 new German parents in 2000, four lost their child before he or she turned five. In the same period, 95 new Malawian parents lost their child before the age of five. Twenty three of these children died of tuberculosis and 14 from HIV/AIDS<sup>1</sup>; diseases which are unlikely to have killed any children in the developed world.

Infant deaths due to lack of access to life-saving medicines are often attributed to the profit-seeking activities of the pharmaceutical industry, or the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.<sup>2</sup> For instance, Madeleine Bunting writes in “The profits that kill”;

patents are killing people... Drugs are only the most blatant example of how, through Trips, the developed countries have stacked the odds in their favour.<sup>3</sup>

Providing access to patent-protected drugs for under-five year olds might be one of the most urgent reasons to consider reform of the intellectual property rights (IPR) system, but there are other reasons, which receive less media attention. In particular, there are reasons for reform, which actually align *with* the self-interest of those who can afford the health care they need.

One of the aims of Innova-P2 is to advance knowledge and insight into reform plans for the current IPR system. In this report, we shall not comment on individual plans for IPR reform, which we have considered elsewhere.<sup>4</sup> Instead, we shall outline the main prudential reasons for IPR reform. Simplified, we take prudential reasons to be those that can be motivated by self-interest and cautious foresight. Ethical reasons, by contrast, are motivated by reference to principles such as justice, virtue or the avoidance of suffering. As a result, one would expect a benefit in line with one's own interests by acting upon a prudential reason, whilst one would often expect the benefit to go to another by acting upon an ethical reason. This simplified difference is clearly, if bluntly, expressed in the following extract from Alexei Sayle's novel, *Overtaken*;

I've joined a road campaign organisation... There's four thousand people killed on our roads every year and we just sort of put up with the situation... But you know I keep saying to myself, in a way it's selfish, you join this organisation because this thing has happened to you – but if I'd been a decent person I should have been in it already, I should have noticed all these people getting killed.... Like those people collecting in the pub to buy a scanner for the local

hospital because their nephew's got leukaemia but they didn't give a fuck about leukaemia before somebody they knew got ill, did they? If they were really moral they would have cared about the scanner before. I should have cared without my husband being killed.<sup>5</sup>

Prudential reasons for action are rarely universal. They usually apply to specific people in specific situations. For instance, swimming is generally considered prudent if one wants to safeguard one's health but *not* for those with artificial knee replacements. Or, it is usually considered prudent not to enter burning buildings, - unless one is a well-protected fire officer at risk of losing one's job over reluctance to do so. It is evident that the poor in developing countries have a prudential reason to push for lower drug prices through IPR reform. What we want to show is that even for those who can afford high drug prices, there are prudential reasons for supporting reform. Therefore in this report, we shall consider prudential reasons for IPR reform for those who can afford the health care they need.

In order to establish the need for reform of any existing institutional arrangement, one needs to understand its main purpose and then compare its success against its aspirations. If it does not match up, it is likely to be in need of reform. For instance, the main purpose of the German TÜV is to increase road safety. To this end, the institution issues road worthiness certificates for all cars registered in Germany on a bi-annual basis. A registered car, which does not pass the compulsory TÜV test can no longer be driven on German roads. Now, if it turned out that the tests failed to identify serious problems whilst giving users a false sense of security, the institution would be in need of reform. As it happens, it is not, and its success has led to an expansion of the model into other areas of health and safety management.

How about the patent system? The first part of this report will identify the main purpose of the patent system in order to assess whether it achieves its aspirations. The second part will then use this outcome to list prudential reasons for IPR reform. Our focus is almost exclusively on patents as filed by the pharmaceutical industry.

### **The Main Purpose of Patent Rights**

Invention is a time-consuming business. It usually requires creativity, resources and time. Once an invention has been made it may be copied by competitors. In order to enable inventors to enjoy the fruits of their labour, most states protect *intellectual* property through patents and other mechanisms. This allows inventors to exploit their brainchild for a limited period without unwanted competition. The patent allows its owner to block the market entry of copied products and thereby gives him or her the opportunity to recoup expenses through monopoly pricing.<sup>6</sup>

At the same time, most market economies have legal systems in place to avoid the formation of commercial monopolies. So-called competition law, or antitrust law in

the United States of America (USA), is designed specifically to stop commercial enterprises from reaching a position that enables them to set monopoly prices. Yet, the same outcome is not only tolerated by states when it comes to patent holders, but is actively promoted.

The reason most market economies have institutionalised competition law is that monopolies tend to lead to excessive pricing, which harms consumers. Without pressure from competitors, unreasonable or predatory prices can be set, in particular if consumers cannot easily forego the transaction. Whilst one may do without luxury items such as skis or plasma screens, food, school books, blankets, pharmaceuticals etc. are essential for human well-being. High prices will be therefore be paid if necessary leaving poorer consumers without access to these essential goods. This leads to market inefficiencies, which economists call deadweight losses. "Deadweight loss occurs when people are excluded from using the good even though their willingness to pay are [sic] higher than the marginal cost."<sup>7</sup> Competition law is therefore a protective mechanism against market inefficiencies, which are harmful to consumers, in particular those with low purchasing power.

Why then are consumers not also protected against monopoly pricing by, for instance, pharmaceutical patent holders? Why are patents deemed to be compatible with competition law? This apparent conflict would only make sense if the profits of the pharmaceutical industry were not in fact the main purpose of patents and some higher good outweighed the disadvantages of granting monopoly pricing powers. That this is indeed the case can best be shown through a major IPR treaty or, in the case of the USA, constitutional law.

In 1970 the *Patent Cooperation Treaty* was opened for signatures. Today, it covers 141 countries.<sup>8</sup> In its preamble, the signatories laid out the main reasons for granting monopoly powers to innovators through patent rights, as follows:

1. to make a contribution to the progress of science and technology,
2. to facilitate and accelerate access by the public to the technical information contained in documents describing new inventions,
3. to foster and accelerate the economic development of developing countries ... by providing easily accessible information on the availability of technological solutions applicable to their special needs and by facilitating access to the ever expanding volume of modern technology.<sup>9</sup>

The first reason - the progress of science and technology - is mirrored in the US constitution which gives Congress the power;

to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries [in other words, to institute patent rights, copyrights and trademarks].<sup>10</sup>

The main purpose of patent rights is expressed as the progress of science, which is given priority over the protection of consumers' purses. The reason why science is deemed to progress through patent rights is two-fold. First, if innovators can expect to recoup research and development costs within the monopoly interval, they are much more likely to take on the burden of innovation. A figure which is often quoted to illustrate this burden is US\$ 800 million to bring a pharmaceutical product to market.<sup>11</sup> As a result of thus encouraging innovation, more drugs, more consumer products and more scientific knowledge will become available. Second, as the innovator needs to disclose publicly the details of the invention in return for patent rights, other innovators can benefit from the discovery in at least two ways:

- (a) by not investing funds in a research effort that has already been completed and,
- (b) by being able to copy the invention using the details disclosed to patent offices after the monopoly interval has expired.

The latter refers to point two of the *Patent Cooperation Treaty*, namely "to facilitate and accelerate access by the public to the technical information contained in documents describing new inventions".

Point three within the *Patent Cooperation Treaty* makes reference to the special needs of developing countries, in particular the need to access modern technology to support development. It may strike some as surprising that the needs of developing countries were listed in support of patent rights in the most prominent early patent treaty, which has the support of 141 countries. In the area of pharmaceutical innovation, patent rights are frequently seen as opposed to the interests of developing countries. According to the latest statistics from the World Intellectual Property Rights Organisation (WIPO),<sup>12</sup> the USA and Japan obtained more than 50% of all patents world-wide in 2006. During the same period, ten countries (Japan, USA, South Korea, Germany, China, France, Russia, UK, Netherlands and Switzerland) held 88% of all patents granted. Whilst the recent success of China in terms of patent applications shows that former developing countries can develop the know-how to make use of the patent system, other developing countries lack the resources and skills to follow suit. At the same time, an estimated 2 billion people lack access to essential medicines, including those priced out of their reach due to patent protection.<sup>13</sup>

It is indeed a more realistic assessment of the current situation to note that patent rights on pharmaceuticals are problematic rather than beneficial for most developing

countries. This was shown, for instance, by Lee Branstetter<sup>14</sup> who surveyed the empirical evidence on increased innovation through patent rights in developing countries. He found that patent rights do not strengthen local innovators but instead promote further the success of pharmaceutical companies in the North. More generally, the UK's Commission on Intellectual Property Rights noted that developing countries rarely have the wealth and infrastructure to take advantage of the opportunities provided by the IPR system.<sup>15</sup> As a result, "IP protection will have little impact" on trade, investment and growth in such countries.<sup>16</sup> But of course, IP protection does have a detrimental impact on price levels. Critics of the system therefore maintain that such protection will "harm the local population and benefit none but the developed world".<sup>17</sup>

It is in recognition of this situation that a World Trade Organisation (WTO) Ministerial Conference decided in 2001 that the right to protect public health and promote access to medicines for all takes priority over the right of innovators to be rewarded with monopoly price controls. The *Doha Declaration on the TRIPS Agreement and Public Health* affirms that patent rights "should not prevent Members from taking measures to protect public health",<sup>18</sup> thereby prioritising public health concerns over innovator reward.

Based on the above, we can therefore establish the aspirational purpose of patent rights as follows:

- to promote the progress of science
  - by rewarding innovators with the power to block the market entry of copied products for a limited period, which effectively gives them monopoly pricing opportunities to recoup research and development costs
  - and by requiring the disclosure of the invention through the innovator,
- with the proviso applicable to the pharmaceutical sector that, in case they conflict, the protection of public health and access to medicines for all takes precedence over patent holders' rights to charge monopoly prices.

Having thus established the main purpose of patent rights, one can compare its success against its aspirations in order to ask whether the system is in need of reform. Do patents promote the progress of science effectively and is the precedence of public health over innovator reward in the area of pharmaceuticals maintained as the Doha Declaration demands?

In relation to the first part of the aspirational goal of the patent system, the next section addresses the question of whether the patent system indeed promotes the

progress of science. The second section looks at the proviso of this main goal, namely the priority of acceptable public health levels over innovator reward.

### **Patents and the Progress of Science**

"I like Monday mornings" said Nobel Laureate in Medicine, Richard Roberts, at the 6<sup>th</sup> Meeting of the African Society of Human Genetics.<sup>19</sup> "Science is a wonderful thing", he continued. "If you have a passion for science, it will fulfil your life". In 1993, Roberts received the Nobel Prize for the discovery of split genes and mRNA splicing. He and his team have discovered and characterised more than 100 Type II restriction enzymes. He has sold his enzymes all over the world and has not taken out patents on any. In his view, "by patenting things you don't get good quality products as you restrict science".

It is beyond the scope of this report to discuss critically whether the progress of science is always in the interests of humankind. In the general area of medicine and health care - the context of this report - we shall assume it is. Throughout most of human history, it was accepted that women died regularly in childbirth, families lost children before adulthood, and people died of pneumonia, whooping cough and diarrhoea. That drugs and health care services are now available to avoid such suffering and premature death is the welcome result of the progress of science.<sup>20</sup> We shall therefore take it for granted that the progress of medical science serves the interests of humankind as a whole.<sup>21</sup> Consequently, if the current IPR system does not promote the progress of science as effectively as it could, we all have a prudential reason to motivate for IPR reform. It is in our best interests to support a system that does effectively promote scientific progress.

The following describes two prominent reasons for Richard Roberts' assessment that the current patent rights system restricts rather than promotes scientific progress.

#### *The Tragedy of the Anti-Commons*

In 1968, Garrett Hardin famously described the Tragedy of the Commons, i.e. the invariable overuse of commonly owned resources.<sup>22</sup> In its essence, the Tragedy of the Commons captures the dilemma that everybody's self-interest demands the overuse of common resources, even though this will lead to their depletion. The standard example used to illustrate the Tragedy involves a common pasture where a number of cattle farmers have grazing rights. Let us say that there are ten farmers. For each of them, it is rational to let as many cattle as possible graze on the common land even if this will lead to the pasture's ruin. The reason why it is rational to do so is that the farmer personally receives all the benefits from releasing an additional cow onto the land, whilst he only carries one tenth of the harm caused. The reverse is true for the Tragedy of the Anti-commons;



Anticommons property can best be understood as the mirror image of commons property. A resource is prone to overuse in a tragedy of the commons when too many owners each have a privilege to use a given resource and no one has a right to exclude another. By contrast, a resource is prone to underuse in a “tragedy of the anticommons” when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use.<sup>23</sup>

According to Heller and Eisenberg,<sup>24</sup> the Tragedy of the Anti-Commons has become an increasing problem in biomedical research since the 1980s, when universities and publicly funded institutions were suddenly encouraged to privatise their research through patenting. Howard Schachman has captured this development well in his view on changing university priorities, which moved from “publish or perish” to “patent and prosper”.<sup>25</sup> Of course, patents had existed long before the 1980s and had always excluded others from scarce resources. Yet, Heller and Eisenberg did not want to criticise the patent system *per se*. According to them, a serious disincentive to innovation and the progress of science occurs when the patent thicket<sup>26</sup> becomes so dense that innovators require multiple licences to create a single new product. Each relevant patent then sets up another “tollbooth on the road to product development”,<sup>27</sup> thereby adding both cost and time constraints to innovation.

The reason this has become an increasing problem over recent decades is two-fold. First, today's innovations are much more complex than earlier ones and often rely on recent prior inventions that are still under patent protection. Economists talk about “quality ladders” in this context,<sup>28</sup> where one product leads to a sequence of other products, all of which are improvements on earlier ones. Second, research tools are increasingly under patent protection due to a rise in broad-scope patents.<sup>29</sup> As a result of the above, further discoveries can be inhibited because innovators shrink from the required information gathering and coordination efforts as well as from the cost implications involved in negotiating multiple licences with owners of previous inventions.<sup>30</sup>

Empirical research has indeed confirmed that firms will abandon research when too many relevant patents are held by competitors,<sup>31</sup> or that delays in product development are to be expected at least. A survey conducted in Switzerland indicated that the existence of prior patents “holds up the development of applications such as medical tests”.<sup>32</sup> A large-scale survey undertaken in the USA found that the existence of multiple “patents indeed creates hold-ups and prevents the innovation of products, particularly in biomedicine”.<sup>33</sup> Chris Holman summarises the situation as follows;

Patents are intended to promote science and innovation by providing a reward for invention ... Paradoxically, patents accomplish this by restricting access to the patented technology.

Although the patent system is inherently a double-edged sword, we as a society have concluded that the incentive benefits of patents generally outweigh their exclusionary costs. With respect to certain technologies, however, there is a concern that the negative effects of exclusion might outweigh any pro-innovation justifications for the patent grant. In the realm of the life sciences, this concern has been raised particularly in connection with patents on “upstream” inventions [e.g. on research tools].<sup>34</sup>

This Tragedy of the Anti-Commons is one justification for Richard Roberts' claim that "by patenting things ... you restrict science". It means that the main goal of patents, i.e. the progress of science, is not promoted as effectively as it could be if the patent thicket were cut down. As the system does not achieve its main aim as smoothly as imaginable, one has here a prudential reason for IPR reform:

*Societal interest in the progress of science is hindered by characteristics of the system, namely the so-called patent thicket or the Tragedy of the Anti-Commons.*

#### *Paying Lawyers versus Innovation*

Effective patent protection relies on the costly expertise of lawyers at all stages of the process from negotiating a patent to litigating for its defence. In addition, lawyers' expertise is required when defending a firm against other companies' claims of patent infringement. At the beginning of the 21<sup>st</sup> century, a UK patent application including renewal fees cost on average £3,500 as compared to £5,500 in the USA. Litigation costs per defended patent were on average £0.2-1 million in the UK and £1-2 million in the USA.<sup>35</sup> And the occurrence of litigation is on the increase, partly because the patent thicket is so dense that there is a risk companies might infringe by accident. "For the most 'valuable' drugs and health patents, the estimated probability of litigation during the lifetime of the patent is more than 25%" in the USA.<sup>36</sup>

Of course, it could be argued that despite the diversion of considerable funds from research to filing of patents and litigation, the progress of science is still best served through the current system. Strong patent protection, one could maintain, does attract high litigation costs, but is still the best way to encourage innovation. This claim is difficult to prove or refute empirically. But Bessen and Meurer have recently set out to do so. In *Patent Failure – How Judges, Bureaucrats and Lawyers put Innovators at Risk*, they compare the costs of disputes and the considerable upward trend in litigation with the benefits generated for innovators through the IPR system and conclude "that patent litigation is a real problem for innovators and it does impose a cost on investment in innovation".<sup>37</sup> And they go further than this, arguing that;

legal costs are not the only costs of litigation that affect innovating firms. Business costs of litigation can be much larger and can take many forms. Business can be disrupted as managers and researchers spend their time producing documents, testifying in depositions, strategizing with lawyers and appearing in court. Litigation strains the relationship between the two parties and might jeopardize cooperative development of the patented technology or cooperation on some other front. Firms in a weak financial position might see their credit costs soar because of the bankruptcy risk possibly created by patent litigation. Preliminary injunctions can shut down production and sales while the litigation pends.<sup>38</sup>

For these reasons the system is being increasingly criticised by prominent Western economists. For instance, in 2008 the Manchester Manifesto Group was formed under the leadership of two renowned Nobel Laureates: John Sulston and Joseph Stiglitz. The Group has brought together "a critical mass of research expertise ... drawn from a broad range of academic disciplines and relevant sectors, including economics, science, innovation, law, philosophy, ethics and public policy ... to build a better future for humanity"<sup>39</sup> by investigating who owns science. The Group notes, amongst others, two reasons why the current patent system hinders innovation and the progress of science, namely that:

- Navigation and implementation of the patent system, negotiation, bargaining and litigation require costly expertise.
- The operation of the current system often prevents the holders of IP rights themselves from realising the full benefits of these rights, for example because of the costs involved in asserting them.<sup>40</sup>

We therefore have a second justification for Richard Roberts' claim that "by patenting things ... you restrict science", and a second prudential reason for IPR reform:

*Investment in innovation and scientific progress is significantly hampered by the high legal costs associated with the patent system.*

The potential beneficiaries of medical scientific progress include all of humankind (assuming access questions can be resolved). Therefore we all have a prudential reason for IPR reform. In addition, scientists whose work is being hampered by the patent thicket and high legal costs, have an additional prudential reason for IPR reform.

### **Patents and Public Health**

The 1970's *Patent Cooperation Treaty*, perhaps naively, assumed that more reliable international patent rights would "foster and accelerate the economic development of developing countries ... by facilitating access to the ever expanding volume of modern technology". Since then, patent cooperation between countries has intensified significantly, in particular through the TRIPS Agreement.

TRIPS was negotiated by WTO members in the 1986-94 Uruguay Round of the General Agreement on Tariffs and Trade (GATT) treaty. It took effect on 1 January 1995. Essentially, it demands that common types of intellectual property are recognised and effectively protected through national law, whether the intellectual property rights holder is a native or a foreigner within the country. Thus protected are patents, trade marks, designs, copyrights, plant breeder rights, geographic indications, trade secrets and circuit layout rights. Most developing countries had until 1 January 2005 to introduce the new requirements, whilst in 2002 the deadline for least developed countries was extended to 1 January 2016.

*The Patent Cooperation Treaty* assumption that patent rights would promote access to modern technologies in developing countries has been revised in the context of TRIPS. As noted earlier, a Ministerial Conference of the WTO adopted the *Doha Declaration on the TRIPS Agreement and Public Health*, which noted, in line with TRIPS:

- We recognize the gravity of the public health problems afflicting many developing and least developed countries.
- We also recognize the concerns about ... [IPR's] effects on prices.
- We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.
- We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to ... promote access to medicines for all.<sup>41</sup>

International patent rights are therefore recognised as potentially conflicting with satisfactory public health levels in developing countries.

The main effects of the tension between monopoly prices on patented drugs and public health levels are borne by the poor in developing countries. They already face greater hazards in terms of pollution, crime, and sexual violence than the rich, who can better protect themselves against such hazards. In addition, dire need or debt may force them to incur additional health risks by working in, for instance, mining, unsafe manufacturing/agricultural industries or sex work. Without access to medical knowledge and/or resources to seek medical help, they also bear a hugely disproportional burden of disease and premature deaths. In fact, one third of all deaths yearly (18 million) are from poverty-related causes.<sup>42</sup> According to Jeffrey Sachs:

The greatest tragedy of our time is that one sixth of humanity is not even on the development ladder. A large number of the extreme poor are caught in a poverty trap, unable on their own to escape from extreme material deprivation. They are trapped by disease, physical isolation, climate stress, environmental degradation, and by extreme poverty itself. Even though life-saving solutions exist to increase their chances for survival – whether in the form of new farming techniques, or essential medicines, or bed nets that can limit the transmission of malaria – these families ... simply lack the financial means to make these crucial investments.<sup>43</sup>

Within this context, women make up nearly 70 per cent of the world's 1.3 billion people living in poverty and bear an unfair proportion of the global disease burden: girls are twice as likely to die from malnutrition and preventable childhood diseases as boys, while almost twice as many women suffer from malnutrition as men.<sup>44</sup> In 1985, 35% of the HIV+ population in Africa were women, but by 2004 this had increased to almost 50%, 67% of whom were aged 15-24.<sup>45</sup>

How far are patents responsible for the hugely disproportional burden of disease and premature deaths borne by the poor?

The IP system is one factor among several that affect poor people's access to healthcare. Other important constraints ... are the lack of resources, and the absence of a suitable health infrastructure... to administer medicines safely and efficaciously".<sup>46</sup>

Yet, there is conclusive evidence that high prices of under-patent drugs hamper access to life-saving medicines. It has been calculated that access to anti-retroviral therapy could be increased by 30% through the elimination of patent protection.<sup>47</sup> A study in Uganda has shown that 50,000 rather than 1,000 HIV/AIDS patients could afford anti-retrovirals if the price fell from \$6,000 to \$600 per year (combined with modest investment in health infrastructure). A study on the same topic showed that "poor people can use ARVs if the price is right".<sup>48</sup> In Uganda, the number of patients treated increased threefold when generic competitors entered the market and the original drug prices were reduced.<sup>49</sup>

As can be seen, the patent system indeed has a detrimental effect on public health levels in developing countries, which can be clearly stratified both by class and gender. Yet, we established earlier that the progress of science promoted through the patent system comes with a proviso applicable to the pharmaceutical sector. The protection of public health and access to medicines for all takes precedence over patent holders' rights to charge monopoly prices. It is clear that this goal is not being achieved within the current system. Hence, one may want to motivate for system reform. This could be done for prudential or for ethical reasons.

At the outset of this report we noted that ethical reasons for reform are motivated by reference to principles such as justice, virtue or the avoidance of suffering. Prudential reasons, by contrast, refer to self-interest and cautious foresight. According to Jeffrey Sachs, we (the affluent in developed countries) "can choose to end ... extreme poverty by the year 2025".<sup>50</sup> We can decide to do so for ethical reasons, as one of us [PS] has outlined in *The Life You Can Save*.<sup>51</sup> Or we can do so for prudential reasons. The following summarises the main prudential reasons for patent reform in the context of its detrimental effect on public health in developing countries.

### *Public Health and the Duties of Governments*

The human right to health, often called "the right to the enjoyment of the highest attainable standard of physical and mental health",<sup>52</sup> is recognised by various international instruments. Most prominently, it is included in the *Universal Declaration of Human Rights* as Article 25.1 which reads:

Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.<sup>53</sup>

The right is also included in the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), which demands that "steps ... be taken by the States parties ... to achieve the full realization of this right".<sup>54</sup> It is also included in the *International Convention on the Elimination of All Forms of Racial Discrimination*,<sup>55</sup> the *Convention on the Elimination of All Forms of Discrimination against Women*,<sup>56</sup> and the *Convention on the Rights of the Child*.<sup>57</sup>

The above Covenants and Conventions are all legally binding. They impose a duty on States to strive for the realisation of the right to health,<sup>58</sup> amongst others. It is therefore not a matter of charity whether citizens of member States have access to health care services or not. It is a matter of contractual obligation. Just as heads of States cannot decide that they would rather put taxes into large, army-protected mansions for members of parliament than a functional judicial system, they cannot reasonably decide to ignore public health levels and their citizens' rights to health.

However, one may question whether governments indeed have a *prudential* or *self-interested* reason for patent reform if they cannot discharge their duties towards their citizens. TRIPS may have inbuilt enforcement mechanisms, but human rights conventions typically have not. By analogy, one could say that Member States have made certain promises about the right to health. Yet, without sanctions for those who fail to honour these promises, one can only speak of *ethical* reasons for patent reform, not prudential reasons. It is ethical to keep promises. Self-interest only comes in when the failure to do so is penalised.

Interestingly though, such penalisation does occur through litigation efforts by non-governmental organisations (NGOs). With increasing frequency, human rights activists are mounting legal campaigns in both developing and developed countries to force governments to keep their promises on the right to health.<sup>59</sup> One of the best-known examples is *Cruz Bermudez et al. v the Ministerio de Sanidad*, which was decided by the Venezuelan Supreme Court in 1999. Cases are also being brought to national courts - typically at the Supreme Court or Constitutional Court level - or to regional organisations. A prominent example for the latter was *SERAC v Nigeria*,

which was decided by the African Commission for Human and People's Rights in 2001.

The action in *Cruz Bermudez et al. v the Ministerio de Sanidad* was brought by 170 people living in Venezuela with HIV/AIDS. They argued that their right to health was violated by the government's failure to provide anti-retroviral drugs. The Supreme Court accepted part of the claim and ordered the Ministry;

to provide anti-retrovirals, medications necessary for treating opportunistic infections and diagnostic testing, free of charge for all Venezuelan citizens and residents. The Ministry was also ordered to develop the policies and programs necessary for affected patients' treatment and assistance, and make the reallocation of the budget necessary to carry out the Court's decision.<sup>60</sup>

The action in *SERAC v Nigeria* was brought by an NGO, the Social and Economic Rights Action Centre (SERAC). They claimed that the Ogoni People's right to health was violated by the Nigerian government who allowed the contamination of their immediate environment by the state-owned Nigerian National Petroleum Company. In 2001, the African Commission for Human and People's Rights found Nigeria guilty of violating the right to health of the Ogoni People and asked the government to stop all current violations, compensate victims and conduct an independent investigation into human rights abuses.<sup>61</sup>

Known as judicial activism,<sup>62</sup> this approach to enforce the right to health through the courts is becoming increasingly popular. As a result, governments who have signed the ICESCR and similar conventions but who are unable to supply access to life-saving drugs to their citizens due to high monopoly prices, have a prudential interest in patent reform. It is in their self-interest to avoid court orders and the related costs.<sup>63</sup>

### *The Reputation of Pharmaceutical Companies*

In business, a good reputation matters. The pharmaceutical industry, in general, suffers from a bad one. A study undertaken in the United States showed that of media references to the industry 57% were unfavourable, 18% neutral and only 25% positive.<sup>64</sup> Given that the majority of USA citizens enjoy the benefits of drugs and services tailored to their health needs, this is a stunning result.

One can only imagine what a similar survey would indicate if undertaken in, for instance, South Africa, where the industry undertook a "disastrous public relations move"<sup>65</sup> in trying to stop the government from fighting a public health HIV/AIDS crisis by cheaply reproducing under-patent drugs. In 1998, 39 pharmaceutical companies filed a lawsuit against the South African government for producing

generic drugs to treat the country's AIDS sufferers. After years of disputes, the companies finally dropped the lawsuit mostly due to the ensuing public outcry.<sup>66</sup>

Another study has shown that the pharmaceutical industry is increasingly seen as taking unfair advantage of consumers through excessive drug pricing.<sup>67</sup> This aligns with dramatic media references, such as the one quoted above - "Profits that kill".<sup>68</sup>

There are at least two reasons why a bad reputation in the context of high monopoly prices is bad for pharmaceutical business.<sup>69</sup> The first refers to ethical consumers, the second to employee satisfaction. If pharmaceutical companies want to continue selling to all sections of the market, including ethical consumers, and if they want to attract the best employees, they need to improve their reputation.

Ethical consumerism is on the rise in the West with 6% of the UK adult population (2.8 million people) being committed consumers of ethical products and services.<sup>70</sup> The UK's leading alternative consumer organisation (Ethical Consumer) advises which non-prescription drugs should be avoided by consumers who want to take into account pharmaceutical companies' records on social and environmental issues. Some of the criteria used are animal testing, excessive profits, research on essential drugs for developing countries, and record on corporate lobbying.<sup>71</sup> This means that ethical consumerism can impact on pharmaceutical profits even though demand curves for pharmaceutical products are generally considered highly inelastic. Companies that ignore those who "shop with a conscience"<sup>72</sup> might face a drop in profits as market shares for ethical companies keep rising. Consequently, pharmaceutical companies have a prudential reason to consider patent reform, which would leave shareholder interests intact whilst enabling better public health levels in developing countries.

As consumers are increasingly conscious of unethical or perceived unethical business practice, so are employees. According to Philip Holden,<sup>73</sup> employees will only give their best if they can identify with something worthwhile at work and if they are proud of the purpose and the belief-system within their company. According to Blanchard and Peale,<sup>74</sup> pride in the strategic vision of one's organisation will bring out the best performance in employees and lead to high quality work and profitability. When people have negative feelings about their organisation, they often try to "even things out" by calling in sick, making private long-distance phone calls etc.<sup>75</sup> On the other hand, if they are proud of their organisation, they will try to maintain its integrity.<sup>76</sup> The key to successful businesses is therefore leaders whose integrity, vision and ethical forethought is strong enough to inspire staff.<sup>77</sup> Ethical business is a means for corporate success, i.e. increased profits. An industry that is being battered by public relation disasters such as the stand-off with the South African government or by blockbuster films such as *The Constant Gardener* will lose the trust and good will of their employees. As a result, the industry has a second





U.S. policymaking to address global health threats is complicated by a rising dependence of U.S. security on health conditions in other countries... Overall, the U.S. response to infectious diseases ... has overemphasized defensive medical countermeasures ... while underinvesting in prevention, strengthening of public health systems, and the surveillance and response capacities of developing countries.<sup>81</sup>

Both reports clearly indicate that developed countries such as the USA have a prudential reason to strengthen public health systems in developing countries to reduce the global infectious disease threat to their own citizens. It is out of self-interest at least that developed countries should intervene in whatever way is effective to reduce the heavy disease burden in developing countries. One such way would be to make life-saving drugs tailored to local health needs available at affordable prices in developing countries, an undertaking which is likely to require a reform of the patent system. We have here, therefore, a prudential reason for patent reform, which applies to citizens of affluent nations and their governments.

### **Conclusion**

Intellectual property rights, including patents, are "a tortured solution to the problem of providing a public good".<sup>82</sup> The public good to be provided is the progress of science and the continued supply of useful innovations for the benefit of all. The penalty to be paid for this public good is the temporary granting of monopoly pricing powers to innovators, an act which would normally violate competition law.

Increasingly, it is being recognised that the patent system in its current form hampers the progress of science and sets up substantial barriers for the poor to partake in its benefits. The Tragedy of the Anti-Commons and the high legal costs involved in patenting activity inhibit rather than promote further innovation as inventors shrink from the cost and time implications of, for instance, negotiating multiple licences. At the same time, a Ministerial Conference in Doha reaffirmed in 2001 that the patent system must not stop developing countries from promoting access to medicines for all. Yet, 2 billion people still lack such access to life-saving drugs, including those under patent protection.

A system that does not live up to its aspirations is ripe for reform if alternatives exist. The patent system belongs in this category, as at least three feasible reform plans are available (increased public investment in research, advance market commitments and most promisingly, the Health Impact Fund<sup>83</sup>). Humankind has an interest in medical progress and if the current system delays or hampers such progress, as this report has shown, then we all have a prudential reason to motivate for reform. At the same time, three specific stakeholder groups have further prudential reasons for patent reform. First, most world governments have signed binding conventions obligating them to ensure "the right to the enjoyment of the highest attainable standard of physical and mental health". Many developing country

governments struggle to fulfil this obligation due to the monopoly pricing powers of pharmaceutical innovators. Second, pharmaceutical companies suffer increasing contempt from the public over monopoly prices, in particular in developing countries. The ensuing bad reputation is bad for business. Third, with increased air travel, citizens in affluent countries are no longer protected from serious communicable diseases of the poor. Providing better access to drugs and health care in originating areas will improve health outlooks for the affluent even further.

Desmond Tutu once said, "If everyone who wants to see an end to poverty, hunger and suffering speaks out, the noise will be deafening". Actually, the noise would even be deafening if only those who have prudential reasons for patent reform spoke up!

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