

## **Intellectual Property Rights versus the Right to Access Essential Medicines**

*Why do patents still pose a threat to drug access after the Doha Declaration?*

### **Introduction**

The right to access essential medicines is currently being violated for people in one-third of the world.<sup>1</sup> Could the international community rectify this situation then it would constitute a significant step towards preventing the 10 million deaths that occur annually from lack of access to health technologies.<sup>2</sup> The Doha Declaration was intended as a shield for developing countries against the drug access repercussions of universalised intellectual property standards. However, where almost a decade later pharmaceutical patents are still threatening access it is time we examined why this 'solution' is failing, and what can be done to rectify the situation.

### **The Threat Drug Patenting Poses to the Right to Access Essential Medicines**

#### *TRIPS*

In-country taxes and tariffs, drug procurement efficiency, distribution costs and dispensing fees all influence the accessibility of drugs through decreasing their affordability.<sup>2,3,4</sup> However, it is only the effect of patents on pricing which the international community has determined through international law, which arguably makes this problem a global responsibility. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed under the auspices of the World Trade Organisation (WTO) in 1994 and has demanded almost global recognition of pharmaceutical product patents for a minimum of 20 years.<sup>4,5</sup> This imposition has arguably had the greatest impact on developing countries because it requires them to respect patent rights where they did not before, at the expense of their domestic production and use of generic drugs. Pre-TRIPs many countries excluded the pharmaceutical sector from patenting entirely to circumvent the consequence of granting companies a price monopoly which in many instances would lead to drug costs inflated out of the reach of the poor.<sup>6,7</sup> However, because TRIPS has demanded strict patenting standards, recent

pharmaceutical innovations have become less affordable and accessible where cheaper generic versions of patented drugs have been made illegal and can no longer offer price competition.<sup>8,9,10</sup> The consequence has been a violation of the right to access essential medicines at the expense of intellectual property rights (IPRs) which has been particularly exemplified by the crisis of access to excessively priced anti-retrovirals for millions of HIV/AIDS sufferers during the 90s.<sup>11,12,13</sup>

### *The Doha Declaration*

The international community's response to this problem of drug patenting was to draft a new framework for interpreting TRIPs, namely the Doha Declaration, which re-emphasised the importance of prioritising public health over IPRs and outlined several 'flexibilities' or 'safeguards' regarding patenting that could be utilised to this effect. 'Compulsory licensing' permitted the generic manufacture of patented drugs in order to address public health crises, and the approval of the practice of 'parallel importation' was re-iterated, validating the import of cheaper drugs from other countries where the patent rights are considered to be 'exhausted'.<sup>14,15</sup> Finally, the '30<sup>th</sup> August Decision' concluded in 2005 was intended to solve the problem of developing countries without manufacturing capacity, where the issuance of compulsory licenses in developed countries solely for export of drugs to poorer countries was legitimised.<sup>16,17,18</sup> However, though the flexibilities have promoted access to medicines in particular situations with some degree of success<sup>19,20,21,22,23</sup>, the safeguards are overwhelmingly underutilised and the patent problem persists with a vengeance.<sup>24,25</sup>

### *Post-Doha*

It can be argued that the failure of the Doha Declaration to meet its objective is that it never offered a feasible solution to the problem, given the legal complexity of the flexibilities which are burdensome to implement.<sup>1,26,27,28,29</sup> However, the response of pharmaceutical companies and interested developed countries to preserve stringent intellectual property standards at all costs has ensured that the safeguards have never reached their full potential. Court cases have been threatened and executed, to effectively quash any initiatives to apply patent rights flexibly.<sup>30,31</sup> Free trade agreements have been

relentlessly pursued by the US and the EU to prohibit the use of TRIPS safeguards through law with so called 'TRIPS-plus' provisions.<sup>32,33,34</sup> The maintainers of stringent IPRs have shown no mercy to the public health problem patents pose, and as such the majority of countries have been coerced, bullied, or punished in order to ensure the Doha Declaration remains a dusty collection of rhetorical principles rather than a workable solution to the access crisis.<sup>24,35,36,37,38,39,40,41,42</sup>

### **Global Inequalities and Influence; Why is the Doha Declaration failing?**

A closer examination of the forces driving the failure of the Doha declaration is required in order to find a solution to the patent problem. Considering the economic and political environment that the principles of the Doha Declaration were being applied to, I have identified three underlying factors limiting the pursuit of justice with regard to access to essential medicines. Firstly, the global trade market is disadvantaging developing countries to the extent that in many instances efforts to address the patent problem are overshadowed by remedial action taken to address trade inequalities. Secondly, the egregious economic and political power imbalances between states has put the respect for access to medicines at the mercy of developed country governments, which have largely chosen to pursue commercial objectives rather than promote moral justice. Finally, a failure to regulate the pharmaceutical industry effectively has facilitated its tyrannical reign to reap profits rather than health benefits from access to medicines.

#### *Trade Inequalities*

Principally, the current global trade markets have denied developing countries the opportunity to protect the right to access essential medicines appropriately, where they have felt it necessary to sacrifice public health in order to promote economic development in other ways. Developed countries have sustained significant leverage over the less developed by maintaining a highly unequal trade system which has induced lower income nations to resort to desperate measures to remedy their exclusion.<sup>43</sup> In this way, free trade agreements (FTAs) are perceived as the entry to lucrative western markets and patents have become the payment for the hope of a better future.<sup>35,35,44</sup> Battling to

convince countries not to trade away their right to health seems futile when countries are struggling to release the bonds of the underlying poverty and stifled economic development resulting from gross distortions in the trading system.<sup>40</sup> President Museveni of Uganda bluntly expresses this has conundrum declaring ‘if there were not agricultural subsidies [Africans] would earn enough money to buy all the drugs we want’.<sup>45</sup> Unfortunately, the FTAs appear to be doing little to address either problem, where there is little evidence that the economic costs of the risk to public health will be compensated for by the volatile trade advantages earned in return for threatening the right to access essential medicines.<sup>37,46</sup>

### *Western Economic Dominance*

The implications of over-arching economic and political power imbalances between states reflected in trade inequalities, and the commercial incentive for developed countries to maintain IPRs have effectively paralysed developing country efforts to promote access to medicines. Fundamentally, developed countries such as the US stood to gain billions of dollars from eliminating the cost of other countries ‘free-riding’ on their innovation,<sup>47</sup> thus it seems likely that upholding TRIPS standards is incentivised more by financial rather than altruistic motivations and must be interpreted as such. Unfortunately they have been well equipped to achieve this.

Firstly, developing countries have limited capacity to protect human rights universally where they have to bend their will to those developed countries they are dependent on to fulfil their needs. This power-play in itself can discourage states from taking politically sensitive steps such as utilising TRIPS flexibilities, where they fear the consequences of offending their funders.<sup>24,25</sup> Indeed, in what could be described as a cruel irony the Bush Administration allegedly allocated \$15 billion AIDS funding to the countries most willing to abide by bilateral trade agreements preventing the generic manufacture of antiretrovirals.<sup>48</sup> Secondly, developed countries can also ensure compliance to their standards by more direct strategies, such as the punishment of countries for their lawful use of international trade flexibilities with threats and the application of unilateral trade sanctions.<sup>23,24,37</sup> The US has even developed an efficient system for executing this persecution, namely their ‘Special 301

proceedings' where countries they determine to be lacking respect for stringent IP standards are blacklisted, triggering automatic investigations which can ultimately result in 'retaliatory' trade sanctions. This is apparently a legitimate reaction to the undertaking of 'unreasonable' or 'unjustifiable' practices - such as utilising TRIPS safeguards!<sup>33,49,50</sup> Unsurprisingly, under this pressure countries often admit defeat in their endeavours to promote access to essential medicines, such as the case when the government of Thailand retracted a compulsory license after threats from the US government that they would raise its tariffs on Thai jewellery imports, if they were to proceed with their claim.<sup>23,51</sup> Thus, where developed countries systematically abuse their power to maintain stringent IP standards, it is not surprising that TRIPS flexibilities are underutilised and developing countries struggle to promote access to essential medicines.

### *Pharmaceutical Industry Tyranny*

In recent decades, major multi-national pharmaceutical companies ('Big Pharma') have successfully exerted a high degree of political influence to secure outcomes which ensure its IPRs take precedence over the right to access essential medicines in developing countries.<sup>49</sup> They have achieved this dominance principally through a worryingly cyclical effect of being powerful to secure favourable government regulation, thus achieving more growth and authority, further enabling it to influence government decisions.<sup>37,52,53,40</sup> From a human rights perspective, Big Pharma's relationship with states could be justified where it is the purveyor of drugs essential to public health, for which it claims to require a high profit margin in order to invest in Research and Development (R&D).<sup>36,40,54</sup> However, the commercial success of pharmaceutical companies has become a risk to public health, where excessive profits are no longer efficiently promoting drug development, but instead are being used to secure their position of power which enables further profit-making.<sup>7,55,56</sup> R&D spending has been exaggerated, few therapeutically innovative products are being developed, and pharmaceutical revenue is instead being invested in marketing barely beneficial new pharmaceuticals and lobbying developed country governments.<sup>48,57,58,59</sup> This status of Big Pharma is ultimately incredibly harmful to ensuring the right to access essential medicines, firstly with respect to those 'neglected' diseases

which continue to lack necessary treatments,<sup>60,61,62,63</sup> but also because of the power its profits bring. In 2003 the US drug industry was able to spend \$163 million on enforcing patent rights globally (mostly directed at governments) and the movement to promote access to essential medicines through the Doha Declaration at this time undoubtedly suffered.<sup>7</sup> Moreover, capitalist Western politics has happily facilitated governments doing the bidding of the pharmaceutical industry where they can profit from it which perhaps explains the US's tenacious pursuit of stringent IP standards with no regard to the resultant health repercussions.<sup>17,51,49,50</sup> Indeed, it is essential to tackle the unjust actions of developed countries as the puppets of Big Pharma. However if we could discipline the puppet-master then perhaps respect for the right to access essential medicines might instead be played out.

### **Addressing the patent problem: UAEM's solution**

As a member of the student organisation Universities Allied for Essential Medicines (UAEM), I believe we must tackle the root cause of the threat IPRs pose to the right to access essential medicines, namely by addressing the broken system of patent inspired drug innovation. Governments and civil society need to re-orientate the pharmaceutical industry's objectives away from the pursuit of financial gratification and towards the marketing and development of drugs that facilitate the elimination of health inequalities. UAEM aspires to break the vicious cycle of the failed regulation of Big Pharma by demanding that university conducted drug research is only licensed to pharmaceutical companies under the condition that the resulting products will not be patented in low-and-middle income countries.<sup>64</sup> If we are successful the effect on access will be far-reaching; indeed a 2000 study found that 15 of the 21 drugs with the greatest therapeutic impact were developed using government funded research which is mostly conducted at universities.<sup>65</sup> Moreover, where universities generally are afforded charitable status and avow their commitment to disseminating knowledge for public good then doing anything less would be a moral injustice. It is time that society broke free from Big Pharma's stranglehold, to ensure that the right to access essential medicines is given the respect it deserves.

*Word Count: 1995*

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