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## Intellectual Property and Access to Essential Medicines: A Tenuous Link?

**CALVIN W.L. HO AND KLAUS M. LEISINGER**

According to the World Health Organization,<sup>1</sup> essential medicines are medicines that satisfy priority health care needs of a population, and they are selected with regard to disease prevalence, safety, efficacy, and comparative cost-effectiveness. In addition, they are intended to be available in functioning health systems at all times in adequate amounts, in appropriate dosage forms, with assured quality, and at affordable prices.

Affordability is commonly regarded as central to the accessibility of essential medicines. However, keeping the price of medicines low has been argued by some to be inimical to pharmaceutical innovation and investment. This has in turn led to a criticism of the pharmaceutical industry, which performs a critical socio-economic function of drug development, but allegedly at an unjustifiably high profit margin that precludes access by many of those who need the medicines. From about the middle of the last century onwards, the politics of drug development assumed a more complex character for a number of reasons that are related to the globalisation of research and development, drug production, and intellectual property rights. With more than two billion people in low- and middle-income countries (LMIC) lacking adequate access to essential medicines,<sup>2</sup> there is growing demand on the pharmaceutical industry to contribute to improving access to medicines for the poor in these countries.<sup>3</sup> The sustainable way forward is one that balances the interest in drug innovation and development with alleviating the health-related sufferings and burdens of the world's poor in the long run. These are not irreconcilable goals, but it is important not to essentialise (or unduly simplify) the relationship between price of essential medicines and their accessibility. In addition,

a clearer articulation of roles and priorities is necessary among the many and varied stakeholders encompassed.

In this paper, we attempt to broaden the way in which the relationship between the price of essential medicines and their accessibility may be considered. We also highlight the importance of multi-stakeholder discussion and collaboration, with focus on the corporate responsibilities of pharmaceutical companies. Our aim is to contribute to constructive dialogue on these responsibilities, and to give emphasis to the (still contested) view that partnerships and collaboration among multiple stakeholders are urgently needed to facilitate drug innovation and development, as well as to improve equitable access to medicines.

## **Intellectual Property Rights and the Price of Essential Medicines**

Proponents of intellectual property rights argue that a patent rights regime, for instance, could increase human welfare. The prospect of acquiring temporary monopolies in patents over pharmaceutical innovation and development could incentivise private investment. Once developed, commercialisation of the innovation would facilitate the use and spread of these new technologies and products. As the argument goes, the social costs associated with monopoly rents that patent holders derive should be adequately compensated by the benefits of new technologies and products.

While plausible in theory, a number of situational obstacles persist. Many countries, especially those with limited resources at their disposal, do not have the innovative and absorptive capabilities. A criticism of the international intellectual property regime established by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has been in restricting the ability of local actors in low-resource settings to acquire capabilities for technological acquisition and accumulation, and unjustly entrenching the privileged position of wealthy countries as its main beneficiaries. The inability of resource-poor countries to participate in global pharmaceutical innovation has been observed to have contributed to two important issues in global health.<sup>4</sup> First, there is a deficiency in global health innovation in drugs that target diseases affecting resource-poor countries. Second, a mismatch has been observed between the health needs of resource-poor countries and their health-care capabilities. To be sure, the TRIPS regime provides two policy outlets, should intellectual property rights unduly preclude access to essential medicines. These are parallel importation and compulsory licensing, which could

be applied under certain conditions. For the former, a country may engage in parallel importation if the international doctrines of patent exhaustion are adopted. Hence, parallel importation is precluded for a country that adopts a national (rather than international) doctrine of exhaustion. As for the latter, a country may import, produce and distribute a patented drug without the consent of the patent-holder if this is necessary to meet its important public health needs and if certain procedural conditions are met. A compulsory licence, if issued, must be predominantly for domestic use. Where resource-poor countries are concerned, a key limitation of this provision is their inability to produce drugs domestically. In 2005, TRIPS was amended to enable export-capable countries to produce generic versions of drugs for importation by these resource-poor countries. To date, only Canada has granted a compulsory licence for export under its patent law, which was revised to give effect to the TRIPS waiver of the domestic use requirement.

As many developing countries have achieved or are adopting universal health coverage, pressure is expected to increase on governments to keep prices affordable in the areas of high unmet needs. For countries with a strong domestic generics industry, the prospect of local profit will undoubtedly add to the pressure to refuse or dispense with patent protection for certain high cost medicines. In an analytical approach that evaluates disease impact and lack of alternatives against price per patient of a product and volume (or number of patients), diseases with high unmet need and high profits, such as HIV, cancer and Hepatitis (B or C), are identified as presenting the highest risk of patent infringement at a country level.<sup>5</sup> Other than compulsory licensing, the patent offices and the courts in many of these countries have adopted a much stricter standard of innovation to reject or revoke patents for certain innovative and expensive medicines. The refusal of a patent award to Novartis for Glivec by the Supreme Court of India is a case in point.<sup>6</sup>

## **Access involves more than a Question of Price**

Patents should not be the focus of the debate on access to medicines. Although they provide desirable incentives and are a precondition for successful research and development of pharmaceutical products, they are not necessarily the sole (or even key) reason for lack of access to essential medicines. In 65 low and middle-income countries, patenting is rare for products on WHO's Model List of Essential Medicines. Only 17 of the 319 products were patentable, and only in 1.4 per cent of instances (300 out of 20,735 essential medicine-country combinations) were essential medicines patented, mostly in larger

markets.<sup>7</sup> Factors other than patents have been identified as barriers to accessing essential medicines. For instance, poverty and lack of sufficient international financial aid have been found to constitute a significant barrier to anti-retroviral treatment. In another study on the availability and affordability of essential medicines for non-communicable diseases, it was found that no medicines on the WHO Model List of Essential Drugs had study patent or exclusivity protection.<sup>8</sup> General accessibility of these medicines was found to be more complex than the presence of intellectual property rights with active pharmaceutical ingredients, dosage or administration patent or exclusivity protection. These and other studies suggest that other factors apart from price could pose a more substantial barrier to equitable access to essential medicines. Similarly, absence of patent protection does not guarantee the availability or acceptability of generic medicines in low- and middle-income countries.<sup>9</sup>

While important, price is not necessarily an adequate indicator of access to essential medicines. Nor is it a sufficient indicator of investments in pharmaceutical innovation and development. Barriers to access include regulatory approval for the use of drugs (including non-price related patent barriers),<sup>10</sup> high out-of-pocket payments (especially for catastrophic illnesses), poor medicine supply and distribution systems and insufficient health facilities. Improving access to pharmaceutical products for poor patients requires an appropriate mix of public and private research, policy and regulatory initiatives. For instance, identifying a list of essential medicines for the health care needs of the population is intended to help countries prioritise the purchasing and distribution of medicines. This could in turn reduce costs to the health system on the whole. There are also innovative strategies for the responsible use of patents under conditions of market failure.<sup>11</sup> Where the international patent regime is considered to incentivise certain investment decisions inappropriately, other funding mechanisms have also been proposed for neglected diseases that affect low-resource countries and to promote the optimum use of pharmaceutical technologies and products.<sup>12</sup>

## **Responsibilities of the Pharmaceutical Industry**

Broadening the evaluation of accessibility of essential medicines beyond the price factor should not detract us from the recognition that pharmaceutical companies continue to play a key role in improving access to medicines, particularly as the developers and manufacturers of these pharmaceutical products. What is then the ethical responsibility of the pharmaceutical industry?

A pharmaceutical company in a global economy is responsible for researching, developing and producing innovative medicines that improve quality

of life and in a manner that is economically efficient. No other societal actor has assumed this responsibility. There is a growing recognition within the pharmaceutical industry — perhaps on the basis of enlightened self-interest — that it has an obligation to improve access to medicines. A manifestation of this is that more companies have participated in the bi-annual Access to Medicines Index, which independently ranks the efforts of pharmaceutical companies to improve access to medicine in developing countries.<sup>13</sup>

Normatively, the corporate responsibility of a pharmaceutical company may be conceptualised at three levels: the “must”, the “ought to”, and the “can” dimensions.<sup>14</sup> Pharmaceutical companies “must” develop new medicines in ways that are economically efficient, and comply with applicable laws and regulations. Voluntary corporate activities to improve access to medicines can be classified as either corporate responsibility (“ought to”) or philanthropy (“can”). Exactly which activities fall into each category is part of an important debate. Research-based pharmaceutical companies have committed to improving access to medicines. While all of these corporate activities could be viewed as philanthropic (“can”) endeavours, many should also be considered as a part of a firms’ corporate responsibility (“ought to”) and business model. However, there is no consensus among pharmaceutical companies on which activities they “ought to” pursue or prioritise. Nor is there evidence about which activities are the most effective. Some pharmaceutical companies have successfully implemented differential pricing, for instance, but arbitrage has to be effectively regulated.<sup>15</sup> In addition to the “must”, “ought to”, and “can” activities, there are activities that industry “must not” engage in. For instance, the industry must not use misleading, dishonest, or illegal promotional practices in inappropriate marketing.

Ultimately, the pooling of resources, skills, experience, and goodwill across multiple stakeholders is necessary for sustainable solutions. In other words, dialogue and collaborations are needed. A practicable way forward could be in the establishment of “solution-stakeholder-teams”. Such a team would include national governments, the international community, NGOs, pharmaceutical companies, and academics from multiple disciplines including medicine, public health, business, ethics, and law. While opinions vary over how far pharmaceutical companies should improve access to (essential) medicines, it is broadly recognised that differential and tiered pricing, donations (through patient access schemes), voluntary licenses and local partnerships, creative financing and *pro bono* research services are important elements.<sup>16</sup> The impacts of joint interventions should themselves be evaluated to ensure that the collaborative objective of improving accessibility to essential medicines is met.<sup>17</sup>

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