



## ORIGINAL ARTICLE

# The impact of intellectual property regulation on global medical technology innovation

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Received 19 December 2014

Accepted 9 February 2015

Published Online First

5 March 2015

## ABSTRACT

Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. At the same time, device patents and their legislation can be barriers to innovation for developing countries. This article reviews the current landscape of international intellectual property regulation and reasons why inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices. Finally, we highlight some opportunities for frugal approaches to intellectual property protection as well as propose more imaginative legislation in developing countries.

Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. At the same time, device patents and their legislation can be barriers to innovation for developing countries. For example, the WHO has developed a 'Compendium of innovative health technologies for low-resource settings'.<sup>1</sup> Most of these technologies are inexpensive to develop, inexpensive to manufacture and relatively easy to use. Nevertheless, the WHO clearly states that inclusion in their Compendium does not necessarily mean "the use of the technologies is...in accordance with the national laws and regulations of any country, including...patent laws."

Of course, it would be a challenge to innovate in the absence of legislation on trademark laws and trade secrets. Since the profitability of devices depends on leveraging existing pathways for device development, manufacturing and distribution, intellectual property (IP) protection is a major aspect of commercialisation of technologies. Certainly investors in new

start-ups look for IP protection as a high priority. Regulation of IP, therefore, is necessary to stimulate invention and new technologies.

However, for technologies in low-resource settings, IP protection has historically been sparse. The World Intellectual Property Organisation reports that in 2012, high-income countries shared 64.5% of the world's total number of patents, while lower-middle-income countries held only 2.9%, with low-income countries owning only 0.4%.<sup>2</sup> This disparity clearly demonstrates limited IP support for frugal innovation emerging from developing countries. Ironically, inventors in low-resource settings are presented with an abundance of important clinical needs and fewer established infrastructure constraints, so that there is a vast untapped potential for innovations to originate in these settings and move to the more developed world (known as reverse innovation).<sup>3</sup>

Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.<sup>1</sup> High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market.

<sup>1</sup>These results are based on personal communication with a cross-section of presenters from the WHO's Parallel Sessions Presentations at the Second Global Forum on Medical Devices held in Geneva, Switzerland on November 2013.



To cite: Chao TE, Mody GN. *BMJ Innov* 2015;1:49–50.

An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies).

Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it.

Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.<sup>4</sup> This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.<sup>5</sup>

As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation.

Nevertheless, there do exist some opportunities for frugal approaches to IP. Simplified legislation or pro bono opportunities for counsel allow an effective system of justice for inventors to take full advantage of legislation to promote innovation.<sup>6</sup> Grants and other forms of non-dilutive funding enable inventors to develop global health technologies without being overly concerned about licensing or investment opportunities. Some potential legislative changes also could be made, such as creation of public-private partnerships that could facilitate government-funded research to be protected and

disseminated at affordable cost in such countries.<sup>7</sup> Other existing exemptions in international agreements could be implemented, including research exemptions for experimental uses of IP or government imposed non-exclusive or compulsory licensing.<sup>8</sup>

While there remains potential for more imaginative IP legislation in developing countries, original technologies continue to be developed in these settings. On the international stage, forums such as the WHO Global Forum on Medical Devices highlight emerging technologies that “impact the continuum of care ranging from screening to diagnosis, treatment and rehabilitation under the Universal Health Coverage Strategy.”<sup>9</sup> These platforms demonstrate that despite the hurdles faced by developing economies in capturing the benefits of IP laws, global health technologies can be and will continue to be developed outside of these limitations.

**Acknowledgements** The authors would like to thank Dr Paul Yock and Jeff Schox, Esq, for their assistance with content and editorial guidance for this manuscript.

**Contributors** TEC and GNM conceived of and wrote this manuscript.

**Competing interests** TEC is a cofounder and has stock ownership in Torix Medical, Inc.

**Provenance and peer review** Not commissioned; internally peer reviewed.

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