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A method for understanding generic procurement of HIV medicines by developing countries with patent protection

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ABSTRACT

Patent protection on medicines may frustrate access by blocking generic competition. Nevertheless, circumstances may still allow for generic procurement to occur anyway, especially for humanitarian cause. But to what extent does this occur? And which legal flexibilities may facilitate such procurement?

We attempted to design a replicable methodology that involved linking antiretroviral (ARV) patent data (1260 patents for 12 medicines) from a World Intellectual Property Organization patent study on the 2013 World Health Organization's (WHO) Model List of Essential Medicines to all available matching procurement records in the WHO's Global Price Reporting Mechanism. We then cross-referenced these with lists of legal flexibilities which facilitate generic access where patents have been granted (e.g., supplier companies' patent non-enforcement policies, voluntary and compulsory licenses) to estimate plausible relevance.

The patent data corresponded to 1924 generic procurement transactions (1.34 billion units) from 85 countries. While patents were relatively less common in these countries (the median coverage was 20%), over half (53%) of the generic procurements nevertheless aligned with patent protection in the exporting and/or importing country. The disproportionately high relevance of patents despite their lower numbers can be explained by their presence in key medicine-exporting countries and/or those with larger populations.

We noted, however, that developing countries still seemed able to buy generic versions of these essential ARVs. A combination of legal flexibilities may have played important roles, but voluntary licensing agreements (VLs) between originator companies and generic ones appeared to align with the largest volumes of generic procurement where we estimated patent protection. If true, VLs may warrant proportionate attention from observers as a heavily relied upon international mechanism for facilitating generic access so that the implications can be better understood; however, we hope others repeat similar studies to investigate whether these results hold with different methodologies and samples of patented medicines, contexts, and timeframes.

1. Introduction

An increasing number of international medicine patent landscapes are available online and in academic journals (Boulet et al., 2003; I-MAK, 2016; Medicines Patent Pool, 2016; UNITAID, 2017; World Intellectual Property Organization, 2015). These studies identify and compile lists of patents internationally for a given product or set of products. Such studies began within the context of the debate between advocates of patent rights and of medicine access during the beginning of the global campaign for HIV, malaria, and tuberculosis medicines. The concern is that patent protection may exclude generic competitors from market entry and enable suppliers to keep prices above what payers in developing countries can afford, thereby constraining medicine access and causing ethical concerns. Patent studies were therefore conducted to estimate the potential for medicine access to be complicated by patent protection by locating exactly where in developing countries medicine patents had been filed. Several studies (Attaran, 2004; Attaran and Gillespie-White, 2001; Beall and Attaran, 2016a,b;

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Cavicchi and Kowalski, 2009, 2011) found that medicine patents are far less common in low-income countries than in wealthier ones—the implication was that there is less potential for medicine access and patent protection to conflict in resource-poor settings than in wealthier countries.

While these patent studies contributed much-needed empirical precision to the debate, they did not go far beyond counting the number of patents that had been filed on key medicines and the number of countries covered by them (some additionally documented which patents were on the substance of the active ingredients, which are more likely to block generic competition). There are at least two reasons why relying on the patent data alone could distort approximations of the potential for where patent protection and medicine access might come into conflict. While patents are granted on a country-by-country basis, the populations and manufacturers are not equally distributed across them. Just two medicine patents filed, for example, in India or China could have considerable global health impact since a large proportion of the developing world resides there (1.3 billion and 1.4 billion respectively) and since both of these countries are major exporters of generic medicine supplies to other developing countries. The availability of generic medicines in the importing country, therefore, can be impacted by patent protection in the exporting country abroad, even when there is no relevant patent protection in force domestically whatsoever (Boelaert et al., 2002; Shadlen, 2007). From this perspective then, basing one's assessment of the potential for patent protection to impact developing countries' access to generic medicines only upon the prevalence of patents—without taking into account the unequal distribution of populations and of medicine exporters—could lead to considerable *under*-estimations.

On the other hand, patents often do not actually block generic competition in reality, even in the United States and Canada where linkages between the patent system and drug regulatory bodies are strong (Beall et al., 2015a,b). A recent patent study of cardiovascular medicines found that of the 24 medicines for which patents appeared in the medicine patent registers of the United States or Canada, generic equivalents were readily available in the respective country for 16 of these medicines (66.7 percent) (Beall et al., 2016). A number of circumstances may allow for generic competitors to present in the same markets where valid patents are in force, especially once the original patents on the active ingredient's molecule have expired. For example, a patent on a process for manufacturing a medicine does not preclude others from using different processes for making and selling it. Further, most countries leave it to the patent holders to enforce their exclusive market rights by taking infringers to court (Bhardwaj et al., 2013; Boulet et al., 2003). Should generic suppliers conduct their own legal assessment and identify weak or invalid patents, these companies may make a calculated decision to enter the concerned medicine markets anyway and infringe, confident that they will win if challenged in court by the patent holders (Bhardwaj et al., 2013; United States Food and Drug Administration, 2015). These situations are common in medicine markets and help the patent system self-regulate, as dubious patents will be ignored or challenged (Boulet et al., 2003; Hemphill and Sampat, 2012). From this perspective then, basing one's assessment of the potential for patent protection to impact access upon the prevalence of patents—without taking into account the many circumstances in which patents do not block generic competition—could also lead to considerable *over*-estimations.

Further, when it comes to global public health, there are additional legal flexibilities that give more reason to suspect that generic medicines may still be accessible even where patents have been granted. First, members of the World Trade Organization (WTO) with Least-developed Countries (LCDs) status have been given an extension until 2033 to align their medicine patent laws with the requirements of the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement, meaning that there may be more flexibility for LDCs to procure generics even if they have also granted patents on those medicines (World Trade Organization, 2015; 2016). Second, originator companies of brand name products have begun to voluntarily license generic manufacturers to supply their products in certain developing countries in exchange for a negotiated royalty rate (Friedman et al., 2003; International Federation of Pharmaceutical Manufacturers and Associations (2015)). Third, on occasions when the public health demand for a key medicine is extremely high and originator companies are unwilling to license other suppliers to meet that need, countries may take action to bypass patent protection in order to authorize generic procurements or generic suppliers to enter the market; this flexibility is called compulsory licensing (World Trade Organization, 2006). Fourth, originator companies may publicly declare their intention to refrain from enforcing their patents on key medicines for global health (e.g., antiretrovirals (ARVs) for treating HIV) in specific regions of the developing world, so that generic suppliers can proceed there without fear of legal recourse (International Federation of Pharmaceutical Manufacturers and Associations (2015)).

In sum, the prevalence of medicine patents in developing countries might *under*- or *over*-estimate the extent to which medicine patents might block generic competition in the real global marketplace, especially within the context of humanitarian cause. Recent debate on this subject has signaled the need for further research in this area ('t Hoen and Bermudez, 2015; Beall et al., 2015a,b). Therefore, studies that attempt to link patent data and with actual procurement data would add a valuable level of nuance. As both patent data and procurement data are becoming increasingly available, it is now possible to attempt such linkages. It is further possible in some instances to link these data to those on the use of the aforementioned legal flexibilities. The objective of this article, then, is to document an initial attempt at linking these kinds of datasets where they are available within the context of the campaign for HIV medicine access and to report on the results. This study's research questions were as follows: To what extent are developing countries that have granted patent protection on essential ARVs procuring generic equivalents of those same medicines? And which legal flexibilities may have been relevant for facilitating this access?

2. Methods & materials

Step 1: Selection of essential ARVs

For our product selection, we relied upon our previous study (Beall, 2015; Beall and Attaran, 2016a,b) of the 2013 WHO Model List of Essential Medicines (MLEM) (World Health Organization, 2013), which identified 13 ARVs that are likely to be under patent protection in some developing countries. This identification was done by using the national medicine product and patent registers of the United States (United States Food and Drug Administration, 2015) and of Canada (Health Canada, 2015a, 2015b). We limited our sample to only to patented ARVs that were sold by a single supplier in the United States or Canada, rather than those for which generic equivalents were already readily available in North America. This procedure and the results are discussed in more detail in the previous WIPO report and journal article (Beall and Attaran, 2016a,b; Beall et al., 2017).

Step 2: Linking to and validating the international patent data