Research Policy 46 (2017) 693–707

Contents lists available at ScienceDirect

Research Policy

journal homepage: www.elsevier.com/locate/respol

Secondary pharmaceutical patenting: A global perspective

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ARTICLE INFO

Article history:
Received 7 January 2016
Received in revised form
21 December 2016
Accepted 9 January 2017
Available online 13 February 2017

Keywords:
Pharmaceuticals
Patents
TRIPS
Developing countries
Patent quality
Patent examination

ABSTRACT

Pharmaceutical firms' use of secondary patents to extend periods of exclusivity generates concerns among policymakers worldwide. In response, some developing countries have introduced measures to curb the grant of these patents. While these measures have received considerable attention, there is limited evidence on their effectiveness. We follow a large sample of international patent applications in the US, Japan, the European Patent Office, and corresponding filings in three developing countries with restrictions on secondary patents, India, Brazil, and Argentina. We compare primary vs. secondary grant rates across countries, consider the differential fates of "twin" applications filed in multiple countries, and undertake detailed analyses of patent prosecution in the three developing countries. Our analyses indicate that measures to restrict secondary patents in developing countries are having limited impact. In none of these three countries are specific policies toward secondary patents the principal determinant of grant rates. Our analyses also suggest the importance of other procedural aspects of patent systems, beyond the formal policies targeting secondary applications, that affect outcomes for these applications in developing countries.

1. Introduction

Taking out multiple patents on different aspects of a drug in order to cordon off competitors is standard practice in pharmaceuticals. In addition to primary patents, firms commonly attempt to acquire *secondary* patents on alternative forms of molecules, different formulations, dosages, and compositions, and new uses. Devising patenting strategies to extend periods of protection is an essential aspect of "life cycle management" in the pharmaceutical industry (Burdon and Sloper, 2003; Howard, 2007; European Commission, 2009; Sternitzke, 2010; Ellery and Hansen, 2012; Kapczynski et al., 2012). This paper discusses policy challenges raised by secondary patenting, provides comparative data on secondary patent grant rates, and evaluates the effectiveness of restrictions on secondary patents in developing countries.

While firms increasingly attempt to obtain secondary patents, policymakers have grown concerned about their effects, since they can extend periods of exclusivity beyond the dates in which protection would otherwise lapse if the only protection came from the primary patent on the molecule. Some have argued that patents on alternative molecular forms, formulations, or uses are of lower "quality" than primary patents too, in that they are less likely to be novel or manifest inventive step (Correa, 2007; Kesselheim, 2007; Eisenberg, 2008). And as with more general debates over patent quality (Jaffe and Lerner, 2004; de Rassenfosse et al., 2016; GAO, 2016), there are concerns that patent offices worldwide may erroneously grant secondary applications that don't warrant patentability, but once granted restrict competition.

Secondary patents are a particular source of concern in developing countries, where pharmaceutical patenting is new. The World Trade Organization's (WTO) 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) required developing countries to change their patent laws to be more like those in developed countries. Prior to TRIPS few developing countries allowed pharmaceutical products to be patented. Doing so is now obligatory for nearly all WTO members.[1]

While TRIPS universalizes pharmaceutical patenting, some developing countries have exploited flexibilities built into the agreement to try to limit the grant of secondary patents. Three prominent examples of countries doing so are India, Brazil, and Argentina. Fearing the effects that secondary patents might have on pharmaceutical markets and access to medicines, and worried by

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[1] Thirty-four WTO members classified as "Least Developed Countries" are exempted from this obligation until 2033. Before TRIPS many developing countries allowed for process patents in pharmaceuticals, but not product patents.

http://dx.doi.org/10.1016/j.respol.2017.01.005
0048-7333/

the difficulties of circumventing or removing patents once granted, each of these countries introduced provisions to restrict secondary patenting.

These countries' approaches toward secondary patents have been championed by academics, civil society groups and non-governmental organizations, and cited as models to be emulated (Reichman, 2009; Kapczynski, 2013; South Centre, 2011; UNAIDS, 2011). They have also been criticized by the pharmaceutical industry as unfair limitations on their abilities to obtain patents (PhRMA, 2016).[2] Though there are policy concerns, and some research indicating that many secondary patents are issued in developing countries (Abud et al., 2015; Correa et al., 2011), there is little evidence on the share of secondary applications granted and the effectiveness of countries' specific restrictions.

This paper evaluates the effects of meases to limit secondary patents in India, Brazil, and Argentina on patent office outcomes in these countries. We do so in three ways. First, we compare differences between primary and secondary patent grant rates in these countries to differences in three patent offices (the U.S., EPO, and Japan) that do not have measures toward secondary patents. If the developing country policies are functioning effectively, we should observe differences across countries in the differential grant rates between primary and secondary patents. Second, we compare grant rates for secondary patents in developing countries for "twins," the same applications filed in different jurisdictions. Exploiting the twins nature of international patent applications is increasingly common for developed countries (Jensen et al., 2006; Hopkins et al., 2007; Lemley and Sampat, 2012; Webster et al., 2014; de Rassenfosse et al., 2016; Christie et al., 2016), but few analyses have done so for developing countries (Sampat and Amin, 2013; Sampat and Shadlen, 2015a). Third, since grant rates may be a blunt indicator of policy effectiveness, we provide data on the details of patent prosecution for secondary patent applications filed in the developing countries. This allows us to examine the role that the specific policies are having, in relation to other influences on secondary patenting grant rates. These final analyses build on and extend recent work in the U.S. that uses prosecution history data to get "inside the black box" of patent examination, to provide insights on the functioning of patent systems, beyond what can be learned from grant rates alone (Drahos, 2010; Lemley and Sampat, 2012; Carley et al., 2015; Frakes and Wasserman forthcoming).

We find that developing countries' measures to restrict secondary patents are having less impact than one might expect from the considerable attention (positive and negative) they attract. Neither India nor Brazil exhibit lower grant rates for secondary patents than for primary patents, which is a differential that we would expect to observe if these countries' measures were having their intended impact. These results are robust across the overall sample, and the sets of twin applications. Though we do observe this differential in Argentina, detailed analyses of prosecution suggest that in none of these three countries are specific policies toward secondary patents the principal determinant of grant rates. In investigating this, we find suggestive evidence that long patent office backlogs in the developing countries give applicants time to learn about the importance and quality of their applications, leading them to abandon applications deemed not worth pursuing.

In the following section we provide a general overview of the challenges posed by secondary patents globally, discuss why secondary patenting is a particularly salient policy issue in developing countries where pharmaceutical patents are new, and describe the policies that India, Brazil, and Argentina have enacted to limit the grant of such patents. In Section 3 we discuss the data sources we use to provide comparative evidence on secondary patent grant rates and to assess the roles played by the developing countries' restrictions. In Section 4 we present our empirical results, examining cross-national grant rates, grant rates for "twin" applications, and detailed analyses of secondary patent prosecution. Section 5 discusses these results. Section 6 synthesizes the main findings of the paper, addresses the limitations of the study, and points to avenues for future research.

2. Secondary patents and public policy

Secondary patents can restrict competition, deny consumers the benefit of generic entry, and thus allow for supra-competitive prices. While this is true of all patents, the grant of secondary patents draws particular criticism from those who believe they represent less research investment than novel molecules, and thus do not warrant patent protection (Correa, 2007, 2014). Related to this, because applications for secondary patents are typically filed after applications for primary patents, and patents last twenty years from the date of application, secondary patents, if granted, can potentially extend periods of market exclusivity. Pharmaceutical firms use secondary patents to retain exclusive rights to valuable, revenue-generating drugs for as long as possible, a strategy that has been attributed to the high costs of research and development, the low success rate in creating products that work in the lab and clinic and can gain regulatory approval, and the fact that significant portions of available patent periods will ordinarily have lapsed before successful products ever get on the market (European Commission, 2009). While in industry the use of secondary patents to extend periods of market exclusivity is referred to as "life cycle management" (e.g. Burdon and Sloper, 2003; Ellery and Hansen, 2012), critics use the more pejorative term "evergreening" (Rathod, 2010; Correa, 2014).

Even in the absence of specific policies targeting secondary patents, legal scholars believe that conventional patent standards, that an invention must be novel and demonstrate inventive step (in the USA, be "non-obvious") ought to make secondary patent applications more difficult to obtain (Eisenberg, 2008). But there is also concern that resource-constrained patent offices commonly grant low "quality" patents (Jaffe and Lerner, 2004), i.e. patents that do not satisfy conventional patent standards and that, with more rigorous scrutiny, would have been rejected. Some have argued that the U.S. patent system is particularly permissive, on account of the incentives facing examiners to grant patents and its unique continuation practice that can reward applicants who are persistent (Lemley and Moore, 2004; Amin and Kesselheim, 2012), though the US is not alone in being criticized in this regard (Moir, 2013). The perception that the lax application of traditional patent standards can contribute to excessive granting of low-quality secondary patents in developing countries is widespread too (Drahos, 2008, 2010; Correa, 2007, 2014; Reichman, 2009; Löfgren and Williams, 2013).

One way to address the problems that may be created by the granting of secondary patents is to invalidate them via litigation, as is common in the U.S. and many developed countries (Hemphill and Sampat, 2011). In developing countries, however, smaller markets and greater resource and information asymmetries between patent holders and potential challengers make this a less attractive solution (Sampat and Shadlen, 2015a). Rather than relying on litigation to invalidate low-quality secondary patents after they have been issued, countries implementing new patent laws under TRIPS have been encouraged to introduce measures to address secondary patents at the point of examination. Such measures try to limit the grant of secondary patents in the first place, reflecting a belief that, in the language of Drahos (2008), prevention is better

[2] One of the controversial aspects of the proposed Trans-Pacific Partnership had been to place limitations on countries' abilities to deny some secondary patents.