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Toward a more balanced pharmaceutical patent system for developing countries: Some preliminary thoughts

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Abstract

This article seeks to overview some structural features of the pharmaceutical markets and pharmaceutical patent systems, which have a negative impact in terms of welfare outcomes (i.e. *optimal level of pharmaceutical patent protection*). It starts from the basic assumption that both innovation and health level are drivers of economic growth. By properly balancing incentives for innovation and access to affordable medicines, the combined (welfare) effect should be maximized. The dynamic interaction between *patent seekers* and *patent challengers* is critical this respect. The structural features of the pharmaceutical markets and pharmaceutical patent systems deter to a certain level patent challengers' reaction against global patent strategies. We propose measures that could help to restore the pharmaceutical patent system's ability to maximize welfare outcomes. It primarily focuses on pharmaceutical markets, pharmaceutical patent systems, and economies of developing countries.

Keywords

optimal level, patent protection, economies-of-scale, free-riding, asymmetries-of-information

Introduction

There are many drivers of economic growth, and innovation is typically named as one of those key factors.[1] The positive influence (incentive) of intellectual property rights and especially patents in fostering innovation[3] is also a common place.[5] However, this is not always the case, when correlation between patent systems and health-related industries, such as the pharmaceutical, is looked at from a welfare perspective.

Access to affordable pharmaceutical products plays a substantial role in the health level among all countries, which, in turn, it is another relevant driver of economic growth.[7] There is literature confirming that the health level is positively associated with productivity on the microlevel (i.e. health human capital constitutes a type of production factor),[11] and studies addressing the relationship between health and economic growth from a macroeconomic perspective.[12]

Thus, having a too strong pharmaceutical patent system – which prevents to a larger extent generic competition – may foster innovation[16] of medicines (introduction of new chemical entities), on the one hand, but might affect the health level of given economy, on the other hand, so the *combined effect* of these interplaying factors could be suboptimal in terms of economic growth. To the contrary, a weak pharmaceutical patent system may have a negative impact on medicines innovation, affecting both the health level and economic growth potential.

It is worth noting that this scenario differs if the *combined effect* is measured within an economy of a developed country compared to a developing one: Pharmaceutical innovation is basically concentrated in developed countries. So, the positive effect (contribution)[17] of pharmaceutical innovation as a driver of economic growth is substantially higher for economies of developed countries than in non-developed economies, where the weight of the health level in the *combined effect* plays a more relevant role. Additionally, pharmaceutical innovation is positively related to the burden of disease in developed countries but not to the burden of disease in developing countries,[19] which also increases the weight of the health level in the *combined effect vis-à-vis* pharmaceutical innovation.

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This leads to the question of the *optimal level of pharmaceutical patent protection* for a given economy, which may be defined as the level in which the contribution of incentives of the patent system to the pharmaceutical innovation and the contribution of access to medicines to the health level are maximized, in other words, properly balanced.[20]

An economy where this assumption is met (proper balance between innovation incentives and access to medicines, hereinafter, '*proper balance*') *ceteris paribus*[23] will be in a better position to achieve its economic growth potential than those with unbalanced systems.

That proper-balance view is expressly recognized and agreed at an international level. In 2001, the World Trade Organization ('WTO') Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS'), the so-called 'The Doha Declaration On The Trips Agreement And Public Health',[28] where the following was agreed:

> 'We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices' (Section 3)
>
> 'We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all' (Section 4)

However, in reality, the *proper balance* cannot be determined *ex-ante* for a given economy. The existing level of pharmaceutical patent protection will be the result of an *ex-post* dynamic interaction between *patent seekers* (patents applicants/holders) and *patent challengers* (those filing oppositions or challenging patents, willing to launch generic products) before patent offices and courts which should apply and review patentability requirements.[29]

In most jurisdictions, the task of applying patentability requirements primarily falls on patent offices and courts, though the private sector (i.e. *patent seeker* and *patent challengers*) also plays or should play an important role. Among various advantages, private sector players may have better information than public agencies and courts,[30] and will be encouraged to invest in prosecuting patents (*patent seekers*)/opposing pending patent applications and/or challenging granted patents (*patent challengers*), to the extent appropriate incentives are in place to reward those efforts.

A patent system will tend to reach an *optimal level of pharmaceutical patent protection* if symmetric incentives exist, which encourages both *patent seekers* and *patent challengers* to act (proper balance).[30] Only under such a landscape (with symmetric incentives), the dynamic interaction referred above will lead to an *optimal level of pharmaceutical patent protection* contributing to economic growth.

This article aims to overview some key structural features of pharmaceutical markets, especially in developing countries; it analyzes how these features may have an impact on the outcome of the patent system (*level of pharmaceutical patent protection*). It finalizes with some suggestions based on the findings, for guiding the patent system toward the *optimal level of pharmaceutical patent protection*.

Overview of some structural features

Pharmaceutical markets are characterized primarily by two types of companies. The first type consists of R&D-based companies ('RBC').[31] These companies carry out research into new pharmaceuticals ('innovative products'), develop them from the laboratory to marketing authorization and sell them on the market.[31] Their products are largely covered by patents. The second type of company is generally referred to as a 'generic company' ('GC'). They produce and sell pharmaceutical products which, generally speaking, are not covered by patents.[31] These generic products contain the same active pharmaceutical ingredients as the innovative product and can therefore be used for the same treatments. However, the products are generally sold at a much lower price than the original product, contributing to access and health level of an economy.

In developing countries, GCs are/still are local-based companies[32] compared to RBC, which act globally.

RBC use *Patent Strategies* to protect their pharmaceutical products from generic competition. According to the European Commission, RBC '[. . .] may file for a multitude of patent applications (on process, reformulation, etc.) protecting the product in addition to the base patent with the aim of creating several layers of defense. Such a multitude of patents is often referred to as a "patent cluster"'.[33] The European Commission also states, that '[t]he consequence of maximizing patent coverage in such a way is the creation of a web of patents. In such a situation, any attempt to develop a generic version of the medicine in a salt, a crystalline, or amorphous form would inevitably infringe a patent

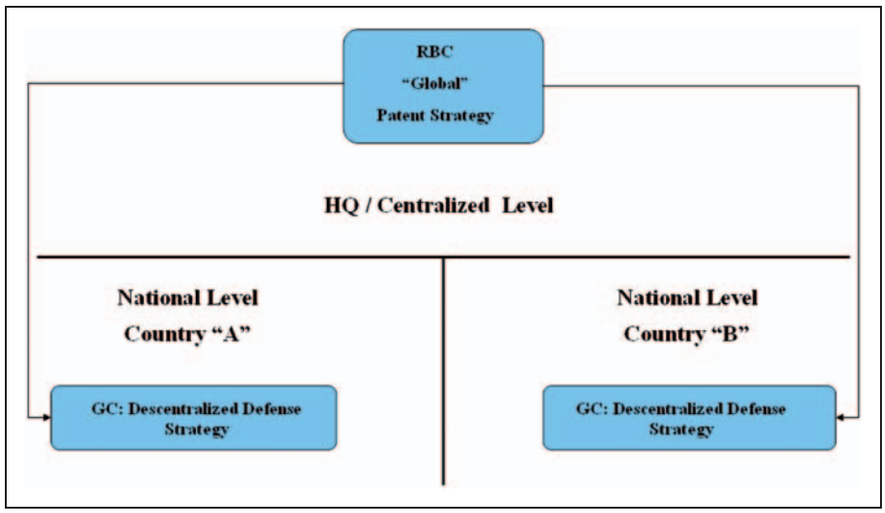

Figure 1. Economies-of-scale problem.

(for example, a patent for the relevant salt, crystalline, or amorphous form of the medicine)'.[34]

Thus, GCs are faced with said *Patent Strategies* and they will or will not react (opposing applications/challenging patents), depending on the existing incentives/disincentives for doing so. The following are, among others, disincentives typically faced by GCs, which make them reluctant to react, affecting the proper balance.

The economies-of-scale problem

Global Patent Strategies are typically designed by RBC at headquarter/centralized level[35] and then spread out to a national/subsidiary level for their implementation. *Global Patent Strategies* are highly complex tools created by patent experts (typically PhDs) leveraging economies of scale (one complex *Global Patent Strategy* for many countries).[36]

Once 'exported', *Global Patent Strategies* are implemented at a national level, i.e., inter alia, (1) patent applications are filed according to the centrally defined pattern; (2) litigations strategies related to said patents applications/patents are carried out.[37]

Against said *Global Patent Strategies*, in case GC decide to react, *Decentralized Defense Strategies* are put in place. These GC's defense strategies do not benefit from economies of scale, since they typically look as follows: many weak *Decentralized Defense Strategies* for one country. In general terms, GCs do not have the resources nor highly skilled experts for designing sophisticated defenses by which they could offset *Global Patent Strategies*. Therefore, *Decentralized Defense Strategies* tend to be ineffective tools *vis-à-vis Global Patent Strategies* (Figure 1).

The free-riding problem

Even if a GC reacts against a *Global Patent Strategy* which blocks entry, investing resources in filing oppositions or challenging patents, and succeeds (e.g. invalidating the relevant patents), it will face the following problem: the challenging GC will not be the only one entering into the market (launching a generic product), but other GC will do the same without having invest resources in 'opening' it (free-riding problem).

The free-riding problem deters the reaction of GC against *Global Patent Strategy* affecting proper balance (Figure 2).[39]

The asymmetries-of-information problem

Which patents cover a certain pharmaceutical product ('relevant patents')? This is a question not always easy to answer for GC. First, reliable databases run by national patent offices are needed (this is rather an exception in developing countries). Second, even if reliable databases exist, it is not straightforward[40] to search for the relevant patents which could cover the pharmaceutical product a GC desires to launch to the market. Third, once the relevant patents are identified, there is a sizeable cost associated with legal determinations, reviews, and opinions ('assessment costs').

RBC have an information advantage *vis-à-vis* GC regarding the relevant patents which may deter (barrier to entry) generic competition (asymmetric information). To the extent complete information on the relevant patent is available, at a reasonable cost, GC will be in a position to assess, inter alia, whether (1) their generic product would infringe a patent; (2) a modification to

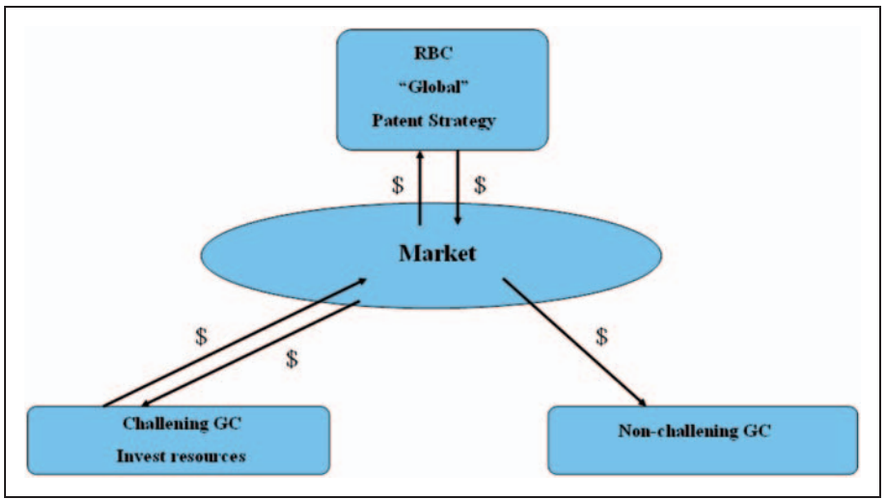

Figure 2. Free-riding problem.

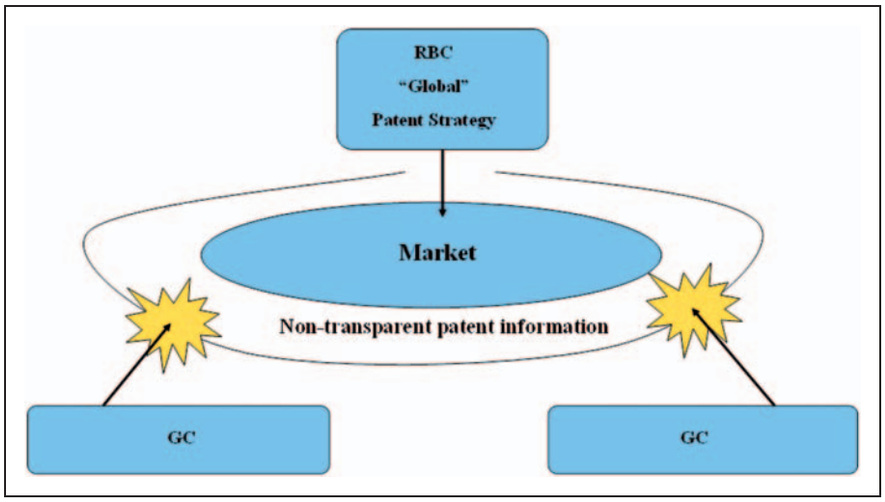

Figure 3. Asymmetries-of-information problem.

the existing generic product could avoid patent infringement (i.e. 'designing around');[41] and (3) the relevant patents could be invalidated.

From a strategic perspective, non-transparent (asymmetric) information on the relevant patents encourages filing application of patents that do not meet patentability requirements since the likelihood of opposition/invalidations tend to be low (Figure 3).

Some preliminary suggestions

The problems referred above (economies of scale; free-riding; asymmetries of information) tend to discourage GC (*patent challengers*) to react against *Global Patent Strategies*, affecting the proper balance and the dynamic interaction, which should lead to the *optimal level of pharmaceutical patent protection* enhancing economic growth.

The following are some preliminary suggestions for avoiding the negative effects arising from said structural features of pharmaceutical markets.

Consolidation of efforts

Economies-of-scale advantages of the RBC should be offset by different ways of consolidation of efforts (investing more resources) of the GC to design more sophisticated and effective defense strategies against *Global Patent Strategies*.

In order to do so, GC could allocate the efforts (resources) of all of them, in a centralized entity responsible for monitoring filings of patent applications and

patents granted. The downside of the centralized-entity model, is the typically wide range of diverging motivations, commercial interests, and business strategies of GC which could affect effectiveness of such a centralized entity.

In this sense, some degree of consolidation of generic companies is desirable. Bigger generic companies are in a better position to deal with *Global Patent Strategies*, without facing the diverging-interest problem of the centralized-entity model. Big generic companies would be able to design effective *Global Defense Strategies* acting as a *countervailing power* against *Global Patent Strategies*.

It is important to point out, that defense strategies should not be limited to oppositions and invalidation of patents: antitrust and unfair competition actions play a major role in preventing abuses of the pharmaceutical patent system; since they have a broader/complementing scope (e.g. sham practices blocking generic competition).[42]

Exclusivity-reward system

GC will be willing to invest in opposing/challenging patents to the extent they can appropriate, in an exclusive way, rents derived from the efforts (i.e., internal human/attorneys' fees, etc.) resources toward keeping the market open for generic competition. This means that only GC involved in a successful opposition/patent invalidation would be allowed to enter into the market as the exclusive generic product competing with the innovative product. This is critical for the economic analysis of litigation, where the costs of suit, the likelihood of success, and the amount that would be obtained in the event of success, are key factors for litigation assessments.[43] Thus, a plaintiff (GC) will file suit only when the expected net benefit (the expected gross benefit minus the expected costs of litigation) exceeds zero ($EB_I > 0$).[45]

Exclusivity-Reward systems can contribute, by increasing the EB_I from litigation, to avoid free-riding problem, bringing opposing/challenging activity closer to the optimum level, from a welfare perspective.

In this sense, the *180-day exclusivity period*[47], which is one of the pillars of the U.S. Hatch-Waxman System,[48] is an interesting model to look at. It is important to notice that for choosing the *exclusivity period* for each country, which functions adequately as an incentive for opposing/challenging patents, the size of the relevant pharmaceutical market and the average litigation costs involved, should be taken into account.

Disclosure obligation

RBC are the most reliable source of the relevant patents. Only if they disclose the relevant patents, GC will have complete information for their strategic assessments (i.e., whether to launch, design around, challenge, etc.). RBC will not publicly disclose the relevant patents information; unless they are legally compelled to do so. Complete publicly available information on the relevant patens, tend to reduce C_I, (assessment costs) thus increasing EB_I.

Again, the U.S. Hatch-Waxman System[50] with the *Orange Book*, provides a good example in this regard.

We propose an alternative model: the '*No Disclosure / No Enforcement Rule*'. It means, only patents publicly disclosed in an official register (database) and linked to a pharmaceutical product may be enforced. In other words, relevant patents disclosure would be a legal requirement for enforcement.

The *No Disclosure/No Enforcement Rule* should contribute to erode information asymmetries between RBC and GC; thus, structurally guiding the *patent seeker* and *patent challengers* dynamic interaction toward the *optimal level of pharmaceutical patent protection*.

Concluding remarks

Innovation and health level are drivers of economic growth. *Ceteris paribus*, the combined effect of incentives for innovation an access to affordable medicines will be maximized, if a given economy reaches an *optimal level of pharmaceutical patent protection* by properly balancing both factors.

The *ex-post* dynamic interaction between *patent seekers* and *patent challengers* tend to be suboptimal, from a welfare perspective, because of some structural features (disincentives for GC) typically present in pharmaceutical markets (economies of scale; free-riding; asymmetries of information), especially in those of developing countries.

The disincentives, which deter GC's reaction against Global Patent Strategies, could, to a certain extent, be offset by consolidating the opposition/challenging efforts, establishing exclusivity-reward systems and putting in force a 'no disclosure / no enforcement rule'.

These measures could help to restore the pharmaceutical patent system's ability to maximize its welfare outcomes.

Declaration of interest

Chilean lawyers, academic at both the School of Law and the School of Medicine of the Universidad de Chile and Legal & Regulatory Affairs Manager at Laboratorio Chile S.A. The opinions expressed herein are those of the author, and not necessarily those of Laboratorio Chile S.A. nor the group it belongs to.

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45. In formal terms, P_I represents the probability of winning an individual suit, L_I the value of the recovery if the plaintiff wins, and C_I the costs that the plaintiff must bear, then a plaintiff will bring an individual suit when $P_I \times L_I - C_I > 0$.The simple term C_I is a more complex reality. Because a successful plaintiff might be able to shift some costs or fees to the defendant (and conversely might bear some of the costs or fees of a successful defendant), the precise formula for filing suit is $P_I \times L_I - [C_{I(\pi-\mathrm{NS})} + (1-P)C_{I(\pi-S)} + (1-P)C_{I(\Delta-S)}] > 0$, where $C_{I(\pi-\mathrm{NS})}$ is the amount of the plaintiff's costs and fees that are non-shifting (i.e., costs that the plaintiff must bear regardless of the suit's outcome), $(1-P)C_{I(\pi-S)}$ is the expected value of the plaintiff's costs and fees that the successful plaintiff can shift but the losing plaintiff must bear, and $(1-P)C_{I(\Delta-S)}$ is the expected value of the defendant's costs and fees that the losing plaintiff must bear. Here, we use C_I to represent this fuller analysis. For simplicity, we refer to the expected benefit, $P_I \times L_I - C_I$, as EB_I. Thus, a plaintiff will file an individual suit when $EB_I > 0$.
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Biography

José Luis Cárdenas T. holds a JD from the School of Law and a degree in pharmacokinetic and pharmacogenetics from the School of Medicines, both of Universidad de Chile. He also holds a LLM and a PhD from School of Law of the University of Freiburg (Germany). He is an academic at both the School of Law and the School of Medicine of the Universidad de Chile and Legal Affairs Manager at Laboratorio Chile S.A.

His research areas include pharmaceutical antitrust, patents, procurement, and regulations; free trade agreements; health systems; and economic constitutional law.