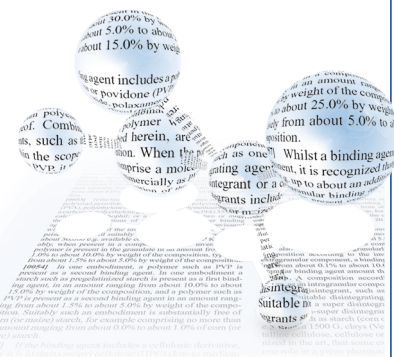


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Compulsory pharmaceutical patent licensing in Brazil: the controversy of public interest



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Compulsory license cases worldwide indicate that every exception rule brings controversy, even when foreseen in international agreements and supported by national laws, especially when the terms and conditions are not consistently defined, leaving gaps for subjective interpretations, which dangerously affect legal security and may favor arbitrary decisions. Compulsory licenses have become a controversial issue in Brazil since the Federal Government, through the Health Ministry, issued decrees stating public interest on certain antiretroviral medicines in order to justify the compulsory licensing thereof during price negotiations with the patentees [201].

Background to compulsory licensing in Brazil

The Brazilian Industrial Property Law (BIPL) states that compulsory licences may take place under four circumstances [1]:

- When a patent holder “exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power”;
- Non- or insufficient exploitation of the object of the patent within Brazil, except when it is not economically feasible;
- If a patent is indispensable for the exploitation of a second patent voluntarily licensed by the same patent holder, this second case known as crossed compulsory licence;
- In case of a national emergency or declared public interest.

A compulsory license has never been requested by an interested third party supported by the two first situations recited above. However, the Brazilian government has once exercised the right of claiming public interest for licensing patents compulsorily and took advantage of such a right during price negotiations with antiretroviral manufacturers in several instances, relying on Decree no. 3,201, of 6 October 1999 [2].

Brief history of compulsory licensing cases in Brazil

In 2001, Roche accepted a price reduction of 40% on nelfinavir after the Health Ministry had announced the public interest in such medicine [3]. In 2003, a new price reduction was achieved for nelfinavir and four other antiretrovirals, namely lopinavir (Abbott), efavirenz (Merck Sharp & Dhome), tenofovir (Gilead) and

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atazanavir (Bristol Myers) [202]. In 2005, the Health Ministry officially declared public interest on the antiretroviral association lopinavir and ritonavir (Kaletra®, Abbott), indicating that the compulsory licensing of the respective patents was imminent. A negotiation with the company, subsequent to such decision was well succeeded, although controversial, resulting in a contract with doubtful clauses, fixing the price of the drug for six years and foreseeing a 10% increase for the recently granted thermostable formulation of the drug, almost annulling the initial price reduction [203].

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The most emblematic case occurred in 2007, when, after refusing a 30% price reduction proposed by Merck, the Health Ministry declared public interest in efavirenz and subsequently granted a compulsory license of patents PI 1100250–6 and PI 9608839–7 [101,102], respectively pertaining to the drug and drug synthesis of efavirenz owned by Merck Sharp & Dhome on 4 May 2007 [2,202]. The main argument used in favor of the compulsory license was that 42% of the total number of patients under the HIV governmental program were treated with efavirenz, thus, acquiring generic versions of the antiretroviral would represent savings of approximately US\$235 million over a period of 5 years [4]. The compulsory license of the efavirenz patents was granted on the ground of public interest, for public noncommercial use, for a period of 5 years (renewable for an equal period) with a 1.5% royalty fee for the patent owner [2,204].

The controversy of public interest

On 8 January 2001, motivated by the recently issued Decree no. 3,201, which regulates the compulsory licensing of patents declared of public interest, the US government filed a request for a panel before the WTO to discuss the issue of compulsory licensing in Brazil, which provides for the granting of legal, compulsory licences in cases of national emergency and public interest and according to the USA, infringes international rules and does not guarantee the protection of patent rights [3].

The USA demanded abolition of the rule that allows compulsory licensing of products in cases of ‘national emergency’ or ‘public interest’. The concern of

the complainants focused on the requirement of patent holders to transmit the necessary information for reproducing the protected object as well as installation supervision and other technically and commercially applicable aspects. Furthermore, according to the complaint, the Brazilian legislation should be amended in order to restrict and clearly define the concept of national emergency, so that the pharmaceutical industry is aware of the exact circumstances under which the government may require the compulsory license of drug manufacturing secrets [3].

In contrast, Brazil claimed that the USA would be taking a very protectionist attitude in order to protect the profits of its pharmaceutical industry, a posture that would undermine the efforts of the Brazilian government – particularly in its campaign against AIDS, which is based on the production of cheaper generic drugs. The Brazilian government argued that the law served the interests of the country, preventing medicine shortages or the practice of abusive pricing by the industry, highlighting that the legislation under complaint actually met WTO rules, since the general principle of compulsory licensing is part of the international agreements [3].

The above argumentation has been extensively discussed in recent years and until today, a clear, detailed and transparent definition of what motivates the public interest for compulsorily licensing patent rights in the country is yet to be achieved.

Decree no. 6108/07, whereby the Brazilian Government granted the compulsory license of efavirenz patents, does not clarify such issue and does not even make reference to Ordinance no. 886/07 from the Health Ministry, which officiated the public interest on efavirenz [2,4]. The Ordinance, in its turn, does not recite any reasonable arguments, such as the high price of the product impacting the federal budget or the need to meet a larger number of patients, extensively used by the Brazilian government during negotiations. Such omission of arguments, in the official documents supporting the compulsory license of efavirenz, brought on an apparent arbitrariness and negative consequences in pharmaceutical industry investments in the country.

Discussion & future perspective

The compulsory licensing provisions of BIPL comply with article 31 of the TRIPS agreement, especially in view of Article 8, which states that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health” [5]. However, Article 31 of TRIPS also foresees that “the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other

independent review by a distinct higher authority in that Member”; and “any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member” [5].

Unfortunately, Article 71 of BIPL, which states that compulsory licensing applies “in case of a national emergency or declared public interest”, does not encompass the above provisions, giving rise to doubtful decisions on the merits of compulsory licensing [1].

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In line with the provisions of the TRIPS agreement, among all legally supported reasons for a compulsory license, the most reasonable one which could possibly be sustained by the Brazilian authorities on behalf of the compulsory licensing of patents would be an eventual abuse of economic power by the patentees. In this case, the BIPL provides that any decision relating to the remuneration provided in respect to patents compulsorily licensed by such motive should be subjected to judicial or other independent review by a distinct higher authority and, most importantly, it has to be clearly evidenced in the terms of the law, avoiding arbitrary decisions based on subjective reasons without legal support.

Finally, it is clear that the equality of treatment was not applied to Merck Sharp & Dohme in the efavirenz case, which had its IP arbitrarily seized and was simply not given the right of contesting the compulsory license

decision in any instance. Such measure definitely brings uncertainty to research-based companies and damages Brazilian IP rights. Moreover, as explained above, the Brazilian government had other multilateral and legally supported alternatives for seeking compulsory license of patents, which would permit further discussion and perhaps a more reasonable jurisprudence for similar future cases.

The declared public interest based on a simple reduction of budget is a subjective and arbitrary argument that should not configure a reason for compulsorily licensing IP rights, especially in a country with one of the highest tax burdens in the world.

The damages for the economy and security patent enforcement in Brazil caused by the compulsory licensing of efavirenz and the declared public interest on other antiretroviral drugs in the past have motivated a change of philosophy in the Brazilian government. Since then, the Brazilian government has not exercised or discussed any compulsory licenses and has moved towards a more flexible and multilateral policy when it comes to defending the public interest.

Finally, the ongoing maturation of the patent system and IP rights enforcement indicate that the adoption of such arbitrary measures will not take place in the future.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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