Licks
ATTORNEYS

Naples Roundtable

Phoenix Issue III
Exhaustion in developing countries: the case of Brazil

February 15, 2016, Naples, Florida

Contents

1. Exhaustion in international treaties
2. Exhaustion in the Brazil: Statutory with support from Courts.
3. Compulsory license and article 31bis of TRIPS Agreement
4. Impact on pharma?
5. Impact on developing countries?

Exhaustion in international treaties: Paris Convention; WTPO TRIPS, TPP

Paris - Articles 4(bis) (1) of the Paris Convention: protection of patents is bound by the jurisdictional borders of the territory of each Member State. "***Patents: Independence of Patents Obtained for the Same Invention in Different Countries.*** […]

TRIPS - Art. 6 - Exhaustion - "*For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.*"

TPP - Article 18.11: Exhaustion of Intellectual Property Rights *"Nothing in this Agreement prevents a Party from determining whether or under what conditions the exhaustion of intellectual property rights applies under its legal system."*

Statutory national patent exhaustion in Brazil: no need to reserve rights.

Licks ATTORNEYS

Trademark exhaustion: international - Art. 132 The owner of a trademark may not: […] III - prevent the free circulation of products **placed on the internal market** by himself or by another with his consent, […].

Copyright exhaustion: international - Art. 29 The express prior authorization of the author of a literary, artistic or scientific work shall be required for any kind of use […]

Patent rights / enforcement before civil courts - Art. 42 A patent confers on its proprietor the right to prevent third parties from manufacturing, using, offering for sale, selling or **importing** for such purposes without his consent: I - a product that is the subject of a patent; II - a process, or product directly obtained by a patented process; […]

Patent exhaustion: international - Art. 43 The provisions of the previous article do not apply: **[…]** IV - to a product manufactured in accordance with a process or product patent that has been placed on the **internal market** directly by the patentee or with his consent; [...]

Enforcement of patent rights against imports in Brazil: caveats from case law

Licks ATTORNEYS

The burden is on patent owner. Defendant does not need to prove affirmative defenses (Sudop v. Maclens, Dec. 2008). Similar to Judge Dyk dissent and DOJ position.

Courts sometimes have problems to understand international exhaustion, domestic exhaustion and sales in a country where patent protection is not available.

Plaintiff seeking to enforce patent rights cannot make claims that products imported by third parties are bad or dangerous. Enforcement should be limited to the IP rights. (Galena v. Pharmaspecial, June 2011).

However…
The Cuban cigars case:
Importation of cigars by a company without a license allowed by the Superior Court of Justice.
(Habanos v. Nobres Tabacos, April 2011).

Compulsory license

Licks
ATTORNEYS

Compulsory license in Brazil

Articles 68 and 70 of Patent Statute provide five possibilities for competitors to seek a compulsory license. These possibilities require an administrative procedure filed by the private part before the BRPTO. The BRPTO has never granted a compulsory license under these provisions.

Article 71 of Statute #9,279 of 1996 provides two possibilities of government use without authorization of the right holder. These provisions can only be pursued by the Government. Decree #3,201 of 1999, as amended by Decree 4.840 of 2003, was used to compulsory license Merck's patents covering Stocrin (efavirenz) represents the only case of compulsory license.

Statute #12,270 of 2010 establishes an eighth possibility of compulsory license and/or government use, this time as a trade sanction. Article 2, IV, g of mentioned statute allows the Brazilian Council of Ministers of the Board of Foreign Trade (CAMEX) to license a patent in case of noncompliance, by a member, with WTO obligations.

Compulsory license: the case of article 31bis of WTO TRIPS Agreement

Amendment of the TRIPS Agreement (WT/L/641 - 8 December 2005)

"Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;"

Inclusion of Article 31bis and an annex to the TRIPS Agreement after Article 73.

31bis: "*1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement."*

Compulsory license: the case of article 31bis of WTO TRIPS Agreement

Licks ATTORNEYS

Article 31(f) of the TRIPS Agreement states that production under compulsory licensing must be predominantly for the **domestic market**.

The main concern was that this limitation could harm the ability of members that cannot manufacture pharmaceutical products from importing from countries where pharmaceuticals are patented.

31bis amendment will allow any member country to export pharmaceutical products made under a compulsory license.

Members need to change their own laws.

According to WTO, the US accepted the amendment in December 2005; Japan in August 2007; EU in November 2007; Canada in June 2009; and Brazil in November 2008.

However, Brazil did not internally implement the amendment (pending a presidential decree or law).

Compulsory license: the case of article 31bis of WTO TRIPS Agreement

Licks ATTORNEYS

31bis - Parag. 2. ”*Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement,* ***adequate remuneration*** *pursuant to Article 31(h) shall be paid in that Member taking into account* ***the economic value to the importing Member of the use that has been authorized in the exporting Member.*** *Where a compulsory licence is granted for the* ***same products in the eligible importing Member****, the obligation of that Member under Article 31(h)* **shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member**.”

Rationale of paragraph 2: avoiding double remuneration to the patentee**.**

WORKFLOW FOR COMPULSORY LICENSE UNDER ARTICLE 31BIS

Licks ATTORNEYS

Eligible importing Member

Least-developed country and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer.

Notification to the Council for TRIPS by the importing Member: (i) specifying the names and expected quantities of the product needed; (ii) confirming it has established that it has insufficient or no manufacturing capacities (other than a least developed country Member); and (iii) confirming that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence.

Information to TRIPS containg the measures to ensure that the products imported are used for the public health purposes only, preventing re-exportation. In the event that an eligible importing Member that is a developing country or a least-developed country experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

Exporting Member

A Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

Notification to the Council for TRIPS by the exporting Member of the grant of the licence: (i) providing information about the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence; (ii) indicating the address of the website referred to in subparagraph (b)(iii) above.

Possiblity of pharmaceutical products manufactured under compulsory licences to be exported to countries lacking production capacity.

The compulsory licence issued by the exporting Member under the system shall contain the following conditions: (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS; (ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and (iii) before shipment begins, the licensee shall post on a website the following information: — the quantities being supplied to each destination as referred to in indent (i) above; and — the distinguishing features of the product(s) referred to in indent (ii) above.

Impact on pharma? No

In Brazil the impact is on telecom and electronics…

Licks ATTORNEYS

FDA regulation prevent importing genuine drugs in most countries

Licks ATTORNEYS

BUYING MEDICINE FROM OUTSIDE THE U.S. IS RISKY BUSINESS

Think it's safe buying medicine from outside the United States? Think again.

Don't Risk Your Health

A BILL

To reduce prescription drug costs by allowing the importation and reimportation of certain drugs.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Personal Drug Importation Fairness Act of 2015".

Buying Medicine from Outside the U.S. is Risky Business

It's a gamble you can't afford to take

Don't play games with your health

To learn more, go to www.fda.gov/importeddrugs or call 1-888-INFO-FDA

U.S. Department of Health and Human Services
Food and Drug Administration

FDA

LOOKS CAN BE DECEIVING

The medicine you buy from outside the United States may be unsafe or ineffective.

Don't risk your health.

Impacting pharma?

Licks ATTORNEYS

Estimated **20%** of medicines sold in developing countries are counterfeit.

80% of the counterfeit drugs that are consumed in the United States come from overseas.

Last year: FDA alerted that counterfeit versions of **Cialis** 20 mg tablets were found in the mail on its way to a U.S. consumer. FDA is concerned about other possible mail shipments to consumers.

Impacting pharma? No but impact for telecom and electronics

WTO DS 472 – European Union v. Brazil - Panel pursuant to Article 6 of the WTO *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU), Article XXIII of the *General Agreement on Tariffs and Trade, 1994* (GATT 1994), with respect to certain measures concerning taxation and charges imposed by Brazil.

The EU accuses Brazil of passing legislation granting advantages in relation to taxes, duties, contributions and charges, which are contingent upon domestic production and technological development of information and communication technology (ICT), automation and related goods.

Impacting pharma? No but impact for telecom and electronics

The advantages primarily consist in tax exemptions or reductions applied in connection with taxes levied on the sale of the relevant goods or on the revenue generated through those sales.

These advantages apply in respect of a limited number of companies established in Brazil.

If Brazil looses the WTO panel, foreign companies will be able to bring products from abroad to compete with local products.

An international exhaustion system will impact telecom and electronic companies.

Impact on developing countries and Brazilian generics companies

Licks
ATTORNEYS

Impact on Brazil: low for local generic companies

Licks ATTORNEYS

Brazil's exhaustion system is good for the interests of local generic companies.

Food and Drug regulation requiring long and expensive registration aproval process are also good for local generic companies.

An **international** exhaustion system for pharma would attract the competition of international pharma companies importing cheaper drugs. These companies would, in such a scenario, operate without the risk of being accused of infringing a patent, and thus be inclined to lower prices to a competitive level.

Licks
ATTORNEYS

Thanks!

Otto Licks
otto.licks@lickslegal.com
T +55-21-3550-3702
M +55-21-99792-5232