Licks
ATTORNEYS

Selected Compulsory License Statutes

v. 1.0 - August 19, 2021

SUMMARY

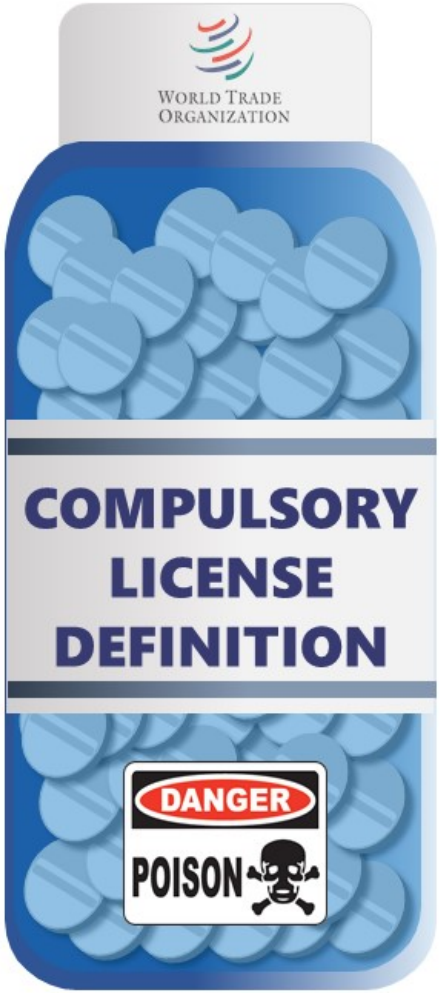
Licks
ATTORNEYS

Presentation on Compulsory License

Licks ATTORNEYS

Compulsory license in pharma post-Isentress and the entry into force of Doha's paragraph 6 system

September 2018



*"**Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner.** It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property — the TRIPS [...]"**

The term compulsory license does not appear in the TRIPS, but it is encumbered in art. 31 ***"other use without authorization of the right holder"***.

The WTO's secretariat reinforces that while associated with pharmaceuticals, compulsory license: *"could also apply to patents in any field. The agreement allows compulsory licensing as part of the agreement's overall **attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs.**"**

The Brazilian Government and legislation uses the term "***compulsory license***" for all "***government use without authorization of the right holder***".

*(Fact Sheet on TRIPS and pharmaceutical patents, 2006)

Likelihood of compulsory licenses in Brazil due to recent developments and market intelligence

Brazil's worst economic crisis: no money, no drugs, no healthcare, no votes

The Brazilian Government's budget stands at a **USD 35 billion primary deficit in 2017 (fourth year in a row).**

The Brazilian Public Healthcare System (SUS) provides free drug distribution throughout the country. Approx. **90% of the Brazilian population (180M)** makes use of SUS to some extent (World Bank 2013).

In 2015, the government spent **USD 55.9 billion** on health (IBGE). In 2016, the government passed a spending freeze that will limit public spending on healthcare to inflation for 20 years.

The 2018 federal budget set forth an outlay of **USD 56 billion** to the Ministry of Health.

While biological products represent only 5% of all drugs distributed by the government, they represent **43% of the total spent** annually by the Ministry of Health on drugs (2014).

The government procures drugs by the INN and does not make any differentiation between new drugs and generics. Biologicals follow the same rules.

Likelihood of compulsory licenses in Brazil due to recent developments and market intelligence

Recent statements supporting compulsory license

"Brazil must lead a global campaign to compulsory license patents for Hep-C drugs ".

José Serra, Minister of Foreign Affairs
former Minister of Health

"We can deliver the products prepared here in Brazil to SUS. In case the patent application is granted we'll have to discuss measures like compulsory license in order to Market it."

Jorge Bermudez, vice-president of Fiocruz

Statute #9,782 allows the MoH to procure drugs not approved in Brazil through international organizations in situations of lack or insufficiency of an BRFDA-approved product.

In November 2015, the MoH procured through Mercosur and PAHO's Strategic Fund non BRFDA-approved Darunavir-based products from Hetero Drugs. Janssen's Prezista was available in Brazil.

Congress and the BRFDA are preparing to issue new legislation that might make the procurement of non-BRFDA approved drugs easier.

Likelihood of compulsory licenses in Brazil due to recent developments and market intelligence

BRICS starts a trade agreement on compulsory licensing of 10 drugs

The idea of making all BRICS countries come together on a **trade agreement over pharmaceutical drugs produced under compulsory license** was first offered during a meeting of BRICS Ministers of Foreign Affairs held on the margins of the 71st Session of the General Assembly of the United Nations held in New York on September 20th, 2016.

José Serra, former Minister of Health and of Foreign Relations, suggested to start with **10 drugs**.

Paragraph 15 of the press release states:

> "The Ministers emphasized the need for concerted action in addressing global health challenges. In particular they recalled the importance of a common and inclusive approach to development of medicines, research and diagnostic tools to end epidemics and to facilitate the access to safe, effective, quality and affordable essential medicines."

The 8th BRICS Summit in Goa on October 15th and 16th 2016, revisited the issue. The Brazilian government proposed more explicit language to the final declaration that will mention the availability of expensive medicines to BRIC countries.
Also, the 2017 Tianjin Communiqué of BRICS Health Ministers Meeting included a commitment to "enhance cooperation (...) to increase the accessibility of affordable, quality, effective and safe drugs, diagnostics and other medical products, to improve health care service and satisfy public health demands". Also, the Health Ministers "agreed to protect their policy space against TRIPS plus provisions and other measures that impede or restrict such access".

Paragraph 15 of Brazil/India joint statement

Outcomes of the 8th BRICS summit and Brazilian president's visit to India

On October 17th, 2016. President Michel Temer, paid a visit to the Republic of India at the invitation of Prime Minister Mr. Narendra Modi.

The development of five chemical medicines and five biological products was one of the main topics of discussion. The issue was addressed by paragraph 15 of the joint statement:

> 15. **Brazil and India face common challenges in fighting both non-communicable and communicable diseases, including HIV, Hepatitis C and Tuberculosis**. In this regard, both countries underscored, as a matter of priority, their commitment to advance bilateral cooperation for the joint development of drugs, diagnostic tools and medical devices at affordable prices, so as to ensure universal access to safe, effective and high quality health care, especially to their most vulnerable populations. To that effect, **India and Brazil decided to join forces with a view to the development of five chemical medicines and five biological products** to treat diseases, including hepatitis C, tuberculosis, cancer and HIV. Both countries also decided to **intensify the successful cooperation between their regulatory agencies in order to streamline procedures related to registration and trade of pharmaceutical products** and medical devices produced by both countries.

United Nations Secretary General's High-Level Panel (HLP) on Access to Medicines

November 8th-9th WTO TRIPS Council meeting

The High Level Panel on access to Medicines was established on November 19th 2015 to "review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."

The HLP final report of September 14th 2016 with five recommendations on TRIPS flexibilities and TRIPS-plus provisions

(a) WTO Members should make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability that curtail the evergreening to ensure that patents are only awarded when genuine innovation has occurred.

(b) **Governments should adopt and implement legislation that facilitates the issuance of compulsory licenses**. Such legislation must be designed to effectuate quick, fair, predictable and implementable compulsory licenses for legitimate public health needs, and particularly with regards to essential medicines. **The use of compulsory licensing must be based on the provisions found in the Doha Declaration and the grounds for the issuance of compulsory licenses left to the discretion of governments.**

(c) WTO **Members should revise the paragraph 6 decision in order to Find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license**. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform.

United Nations Secretary General's High-Level Panel (HLP) on Access to Medicines

November 8th-9th WTO TRIPS Council meeting

(d) **Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities**. Instances of undue political and commercial pressure should be formally reported to the WTO Secretariat during the Trade Policy Review of Members. WTO Members must register complaints against undue political and economic pressure, and take punitive measures against offending Members.

(e) **Governments engaged in bilateral and regional trade and investment treaties** should ensure that these agreements do not include provisions that interfere with their obligations to fulfil the right to health. As a first step, they **must undertake public health impact assessments**. These impact assessments should verify that the increased trade and economic benefits are not endangering or impeding the human rights and public health obligations of the nation and its people before entering into commitments. Such assessments should inform negotiations, be conducted transparently and made publicly available.

Brazil co-sponsored the recommendations of the HLP as an agenda item for the WTO TRIPS Council meeting alongside China, India and South Africa encouraging Members to share their views on the final report for the first time.

15 WTO Members including **Brazil**, **China**, **India**, **South Africa**, the **European Union**, **Japan**, **Switzerland** and the **United States of America** delivered Statements on the HLP. Followed by Statements of 5 intergovernmental organizations (including **WTO**, the **World Health Organization** and the **United Nations Conference on Trade and Development**)

United Nations Secretary General's High-Level Panel on Access to Medicines

Statements on the WTO TRIPS Council meeting

Brazil stated that it has a strong commitment to the improvement of public health and mentioned the agreement between Mercosur Members to procure essential medicines through PAHO's fund as an innovative mechanism aimed at helping countries to cope with high prices of pharmaceuticals.

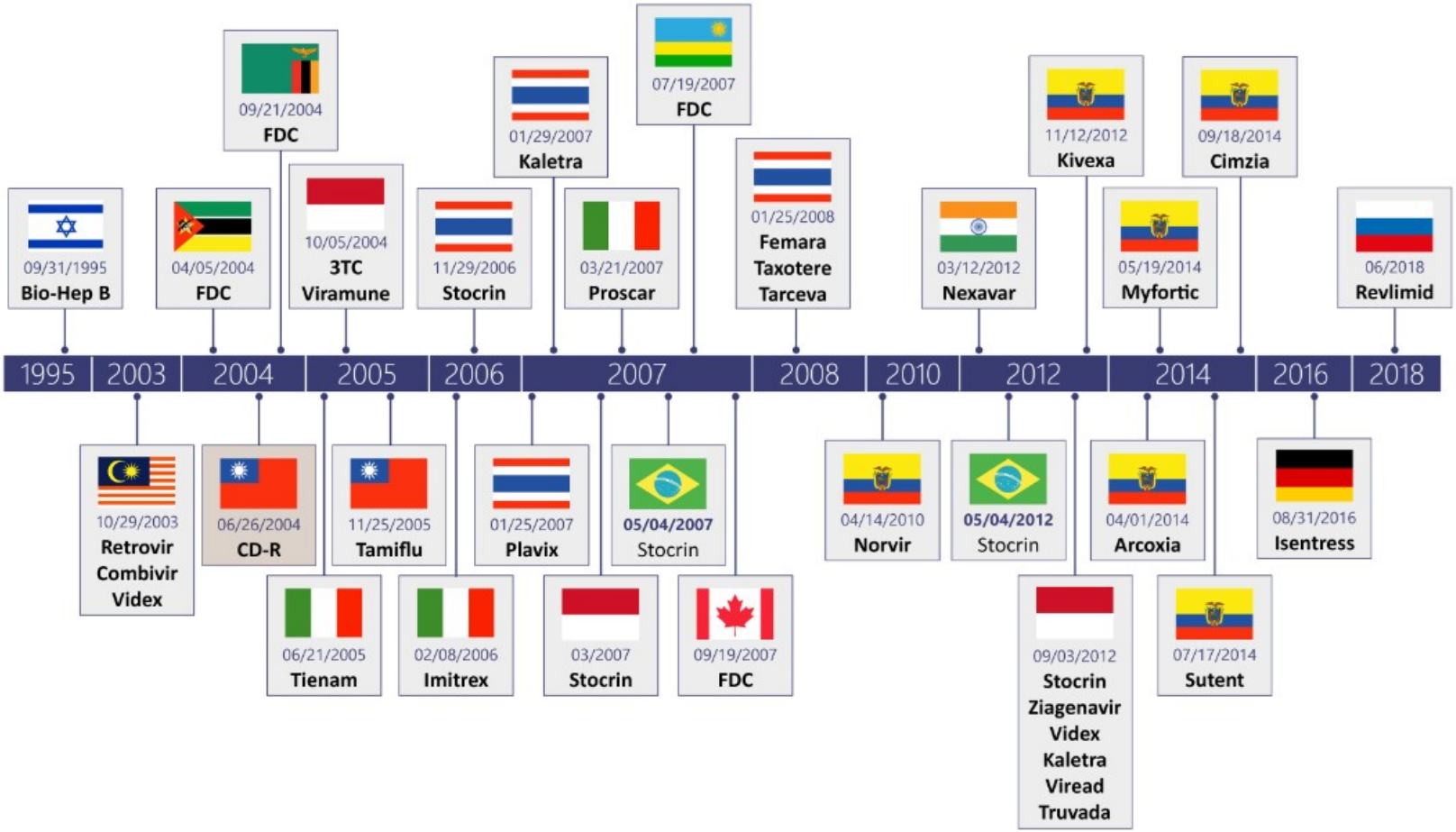
India expressed its concern over the special compulsory license system stating that "the Paragraph 6 System is too complex, cumbersome and administratively unwieldy for further use". To support this India referred to Apotex statement that it will not venture into supplying and CIPLA's statement that it will never come forward to manufacture under the system.

The **European Union** does not share the HLP's assumption that there was a **"policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health"**

For the **European Union** the Report underplays significant investment and long-term research, clinical trials and regulatory approval procedures required for the development of new drugs and that the right conferred by a patent is an important incentive for innovator pharmaceuticals to invest into R&D.

The **WHO** supports the HLP Report recommendations encouraging WTO Members to make full use of TRIPS flexibilities, supporting governments in applying patentability criteria that are sensitive to public health concerns and moving towards more transparency in patent information.

Recent examples of compulsory license



Examples of post-TRIPS compulsory licenses

ISRAEL

Bio-Hep B (recombinant vaccine, Biogen)
Issued: September 31st, 1995, until patents expiration
Type: Exclusive to BTG-Israel
Royalty rate: ?

MALAYSIA

Retrovir (zidovudine, GSK)
Issued: October 29th, 2003, for two years
Type: Exclusive to local company Syarikat Megah Pharma (importing from india, CIPLA)
Royalty rate: 4%

Combivir (lamivudine + zidovudine, GSK)
Issued: October 29th, 2003, for two years
Type: Exclusive to local company Syarikat Megah Pharma (importing from india, CIPLA)
Royalty rate: 4%

Videx (didanosine, Bristol-Myers Squibb)
Issued: October 29th, 2003, for two years
Type: Exclusive to local company Syarikat Megah Pharma (importing from india, CIPLA)
Royalty rate: 4%

MOZAMBIQUE

FDC (lamivudine + stavudine + nevirapine, GSK, Bristol-Myers Squibb and Boehringer-Ingelheim)
Issued: April 5th, 2004, until patents expiration or unneeded
Type: Exclusive to local manufacturer Pharco Moçambique
Royalty rate: maximum of 2%

TAIWAN

CD-R Compact Disc-Recordable (Philips)
Issued: July 26th, 2004, until patents' expiration
Type: Exclusive to local company Gigastore
Royalty rate: ?

Examples of post-TRIPS compulsory licenses

ZAMBIA

FDC (lamivudine + stavudine + nevirapine, GSK, Bristol-Myers Squibb and Boehringer-Ingelheim)
Issued: September 21st, 2004, until patents expiration or unneeded
Type: Exclusive to local manufacturer Pharco Ltd
Royalty rate: maximum of 2.5%

INDONESIA

3TC (lamivudine, GSK)
Issued: October 5th, 2004, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Viramune (nevirapine, Boehringer Ingelheim)
Issued: October 5th, 2004, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

ITALY

Tienam (imipenem cilastatina, Merck)
Issued: June 21st, 2005
Type: Exclusive to local company ACS Dobfar (trade sanction)
Royalty: ?

TAIWAN

Tamiflu (oseltamivir, Gilead licensed to Roche)
Issued: November 25th, 2005, for two years
Type: Government non-commercial use (non-exclusive)
Royalty rate: ?

Examples of post-TRIPS compulsory licenses

ITALY

Imitrex (sumatriptan succinate, GSK)
Issued: February 8th, 2006
Type: Exclusive to local company Fabbrica Italiana Sintetici (trade sanction)
Royalty: ?

THAILAND

Stocrin (efavirenz, MSD Merck)
Issued: November 29th, 2006, for five years
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Plavix (clopidogrel, Sanofi)
Issued: January 25th 2007, until patent expiration or unneeded
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Kaletra (lopinavir + Ritonavir, Abbott)
Issued: January 29th, 2007, for five years
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

ITALY

Proscar (finasteride, MSD Merck)
Issued: March 21st, 2007, until patent's expiration
Type: Non-exclusive for manufacturing and marketing in Italy (trade sanction)
Royalty rate: ?

INDONESIA

Stocrin (efavirenz, MSD Merck)
Issued: March, 2007, extended in 2012 until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: ?

Examples of post-TRIPS compulsory licenses

BRAZIL

Stocrin (efavirenz, MSD Merck)
Issued: May 4th, 2007, for five years, extended for five years on May 4th, 2012.
Type: Government non-commercial use (non-exclusive)
Royalty rate: 1.5%

RWANDA

CANADA

FDC (lamivudine + nevirapine + zidovudine, Bristol Myers Squibb, Boehringer Ingelheim and Shire BioChem Inc)
Issued: July 19th, 2007, for two years
(Canada authorized Apo-TriAvir's production on September 19, 2007)
Type: Paragraph 6, Rwanda importing from Canada, APOTEX
Royalty rate: Patent holders waived compensation

THAILAND

Femara (letrozole, Novartis)
Issued: January 25th, 2008, until patent expiration or unneeded
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5% to 5%

Taxotere (docetaxel, Sanofi-aventis)
Issued: January 25th, 2008, until patent expiration or unneeded
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5% to 5%

Tarceva (erlotinib, Roche)
Issued: January 25th, 2008, until patent expiration or unneeded
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5% to 5%

Examples of post-TRIPS compulsory licenses

ECUADOR

Norvir (ritonavir, Abbott)
Issued: April 14th, 2010 and May 11, 2013 both until patents expiration
Type: Exclusive to local companies Eskegroup (CIPLA) and Acromax
Royalty rate: 5%

INDIA

Nexavar (sorafenib, Bayer)
Issued: March 12th, 2012, until patents expiration
Type: Exclusive to local company Natco Pharma
Royalty rate: 7%

INDONESIA

Ziagenavir (abacavir, Glaxo Group Limited)
Issued: September 3rd, 2012, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Videx (didanosine, Bristol-Myers Squibb)
Issued: September 3rd, 2012, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Kaletra (lopinavir + Ritonavir, Abbott)
Issued: September 3rd, 2012, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Examples of post-TRIPS compulsory licenses

INDONESIA

Viread (tenofovir, Gilead)
Issued: September 3rd, 2012, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

Truvada (tenofovir + emtricitabine, Gilead)
Issued: September 3rd, 2012, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: 0.5%

ECUADOR

Kivexa (abacavir + lamivudine, ViiV, JV lead by GSK)
Issued: November 12th, 2012 until patents expiration
Type: Exclusive to local company Acromax
Royalty rate: 5%

Arcoxia (etoricoxib, Merck Frosst)
Issued: April 1st, 2014, until patents expiration
Type: Exclusive to local company Acromax
Royalty rate: 5%

Myfortic (mycofenolate sodium, Novartis)
Issued: May 19th, 2014, until patents expiration
Type: Exclusive to local company Ginsberg Ecuador
Royalty rate: 5%

Sutent (sunitinib, Pfizer)
Issued: July 17th, 2014, until patents expiration
Type: Exclusive to local public Company ENFARMA
Royalty rate: ?

Cimzia (certolizumab, Union Chimique Belge)
Issued: September 18th, 2014, until patents expiration
Type: Government non-commercial use (non-exclusive)
Royalty rate: ?

Examples of post-TRIPS compulsory licenses

GERMANY

Isentress* (raltegravir, Shionogi)

Issued: August 31st, 2016, until patents expiration (pending final decision on the main proceeding)
Type: Exclusive to Merck Sharp & Dhome (MSD)
Royalty rate: Not set in the Preliminary Injunction

***Isentress is the brand name for MSD's raltegravir based integrase inhibitor product.** Shionogi does not have a raltegravir based product.

RUSSIA

Revlimid (lenalidomide, Celgene)

Issued: June, 2018 (decision can be appealed)
Type: Non-exclusive to Oleg Ratislovovich Mikhailov, who assigned it to Nativa
Royalty rate: 30%

Examples of post-TRIPS compulsory licenses

Isentress – Merck Sharp & Dhome vs. Shionogi

On **August 31st, 2016** the German Federal Patent Court (BPatG) granted MSD a temporary compulsory license of the patent DE 602 42 459 (EP 1 422 218).

BUNDES PATENT GERICHT

BPatG's decision is a **paradigm shift** after almost 10 years since the last compulsory license in a developed country (Italy's trade sanctions on MSD and Canada's aid to Rwanda under paragraph 6 system)

It was **the first time a compulsory license was granted in a Preliminary Injunction proceeding** in BPatG's 55-year history. The only other compulsory license was granted in 1991 but later revoked on appeal by the Federal High Court, establishing a high threshold for proving public interest of a compulsory license (*Polyferon*) .

Under *Polyferon*: a drug must **treat a serious disease that cannot be treated by a comparable product or only so with considerable side effects**. The BPatG found that this was the case with Isentress.

The compulsory license confers MSD the right to use the patented invention for its previously approved products (400mgfilm tablet, 25mg and 100mg chewable tablets, and 100mg for oral suspension).

It **does not prevent the company from filing an invalidity lawsuit** against the patent.

Examples of post-TRIPS compulsory licenses

Isentress – Merck Sharp & Dhome vs. Shionogi

To grant the compulsory license the BPatG considered that:

- EP 1 422 218 was granted in 2012 and, despite being challenged on appeal, should be considered valid.
- MSD is able to explore the patent and that it markets Isentress, with raltegravir as API, since 2007 in the US and EU.
- MSD unsuccessfully attempted to obtain a license from Shionogi under reasonable commercial terms, for two years.
- FRAND terms under Huawei v. ZTE do not apply to compulsory licenses under article 24 of the Patent Act.
- It met public interest under *Polyferon*. Raltegravir is the best integrase inhibitor, and Isentress the only product available.
- There was urgency in light of the infringement litigation brought by Shionogi. Isentress could be removed from the market.
- Compulsory licenses are available in preliminary injunctions due to public interest (articles 24 and 85 of the Patent Act).
- The compulsory license only grants MSD the right to use the patent for its previously approved products.

Brazilian legal framework

Nine Possibilities for Compulsory License

One statutory authorization to grant compulsory license as trade sanctions under WTO

1. Non-compliance with WTO obligations (Art. 2, IV of Statute #12,270, granted by CAMEX)

Five possibilities for private parties to seek compulsory licenses before the BRPTO

2. Abuse of patent rights (Art. 68 of Patent Statute, Law #9,279)
3. Abuse of economic power (Art. 68 of Patent Statute, Law #9,279)
4. Lack of local working (Art. 68, I of Patent Statute, Law #9,279)
5. Supply that does not meet market demand (Art. 68, II of Patent Statute, Law #9,279)
6. Dependent patents (Art. 70, I, II and III of Patent Statute, Law #9,279)

Two statutory authorizations for the Government to issue compulsory licenses for public use

7. National emergency (Art. 71 of Patent Statute, Law #9,279)
8. Public interest for public non-commercial use (Art. 71 of Patent Statute, Law #9,279)

Grant of compulsory licenses by Federal Courts upon request of Federal Prosecutor's Office

9. The lawsuit seeks the compulsory license of Roche's Herceptin patents.

Brazilian legal framework

Five possibilities before the BRPTO

DAY 1	**60-DAY** TERM	**30-DAY** TERM	**60-DAY** TERM	**60-DAY** TERM	**60-DAY** TERM
Third party notice of the compulsory license request. (office action #998 of the Industrial Property Gazette).	The patent owner may file a brief reply, refusing or accepting the request.	The BRPTO issues a decision granting or denying the request.	The patent owner can challenge the compulsory license through an appeal before the BRPTO.	The petitioner for the compulsory license may present counterarguments to the appeal.	The BRPTO may ask for complementary information and must issue a final decision, which can be challenged before Federal Courts.

After BRPTO's final decision the licensee has a one-year term to start the exploitation of the patent.

The BRPTO denied the only two requests for compulsory license ever filed under art. 68.

The BRPTO considers the administrative proceedings to seek a compulsory license as confidential.

Brazilian legal framework

Compulsory license procedure under Decree #3,201 as amended by Decree #4,830

Decree #3,201, as amended by Decree #4,830, regulates compulsory license for national emergencies and public interest.

The only objective requirement is that prior to granting a compulsory license the Government has to establish that the patent owner or licensee is not capable of meeting the public demands. (Art. 4)

The relevant Ministry for the subject matter of the patent must then issue a declaration of public interest of the patented invention. So far the Ministry of Health issued three Ordinances under this provision:

Ordinance #985 of June 24th 2005 – Kaletra (lopinavir + ritonavir, Abbott)
Abbott reached an agreement with the MoH to lower the price of Kaletra used in the treatment of 163 million HIV patients in Brazil. Abbott agreed on a 46% discount. Starting March 2006 each capsule would cost USD 0.64

Ordinance #886 of April 24th 2007 – Stocrin (efavirenz, Merck)
After issuing the declaration of public interest the Government granted Merck a 7-day period to offer a price reduction. The Government rejected the 30% discount offered by Merck and on May 4th, 2007, the Presidential Decree #6,108 granting the compulsory license

Ordinance #681 of April 8th 2008 – Viread (tenofovir, Gilead)
The MoH issued the declaration of public interest despite having signed a deal with Gilead for a 51% reduction to Tenofovir's price in May 2006. The deal was expected to save the Brazilian government USD 31.4 million with each pill costing USD 3.80.

Brazilian legal framework

Compulsory license procedure under Decree #3,201 as amended by Decree #4,830

The licensed patents must be exploited directly by the government in association with a laboratory of the Brazilian Association of Public Laboratories (ALFOB) or by a contracted third party. (Art. 9)

ALFOB gathers all 21 public laboratories that produce drugs distributed by the Public Healthcare System to the Ministry of Health assistance programs. The most important public laboratories are:

- Farmanguinhos - Institute of Technology in drugs - RJ
- Bio-manguinhos - Institute of Technology in Immunobiology/FIOCRUZ - RJ
- Instituto Butantan - Butantan Institute - SP
- FUNED - Ezequiel Dias Foundation - MG
- FURP - Foundation for Popular Medicine "Chopin Tavares de Lima" - SP

If no laboratory is able to exploit the patents at the time of the license **the government may resort to article 10 exception in order to procure the generic versions of Efavirenz from other countries**.

Compulsory license procedure under Decree #3,201 as amended by Decree #4,830

Although not enforced against Merck, Decree #3,201 has a controversial provision authorizing that the patent owner be compelled to "*transmit all the information necessary and sufficient for effective reproduction of the protected object and the other technical aspects applicable to the case [...]*" (article 5, paragraph 1).

All patents granted by the BRPTO are assumed to describe the subject matter clearly and sufficiently so as to enable a person skilled in the art to carry it out. Thus, the provision introduced by the Decree is in fact an obligation for the patent owner to "*babysit*" the laboratory responsible for the exploitation of the license.

Compulsory license of data package

The Brazilian law provides two possibilities for a compulsory license of undisclosed information in case of **public interest or abuse of economic power**. (Art. 8 of Statute #10,603 of 2002)

Despite being applicable only to agrochemicals and veterinarian products, a decision rendered by the Federal Trial Court of Brasilia in 2009 analogically applied Statute #10,603 of 2002 in order to limit the protection of a pharmaceutical product for human use.

Also, Statute #12,270 of 2010 allows the Brazilian Chamber of Commerce (CAMEX) to license any undisclosed information in case of noncompliance with the WTO obligations, as a trade sanction. (Art. 2, IV, f)

Brazilian legal framework: Procedure under Decree #3.201 of 1999

National Emergency and Public Interest

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6	STEP 7	TERM OF VALIDITY
Establish the necessity or emergency, and the impossibility or denial of the patent owner to comply with the terms proposed by the Goverment in negotiations. (Statute #9,279 of 1996)	Issuance of the Declaration of Public Interest by the relevant Ministry for the subject matter of the patent. (Statute #3,201 of 1999)	Government must determine a period for the patent owner to offer better terms and avoid the compulsory license. Except in cases of national emergency.	Grant by Presidential Decree, establishing the term of validity and possibility of extension of the compulsory license. (Statute #3,201 of 1999)	Royalty rate set by the BRPTO if undetermined by the Presidential Decree. (article 73, §3º and §4º of Patent Statute #9,279 of 1996)	Registration by the BRPTO of the compulsory license.	Public offer or Bid for the right to exploit the patent. (Statute #8,666 of 1993)	

Timeline for the compulsory license of Merck's Stocrin®

In November 2006, The Brazilian Government began the last round of negotiations with MSD seeking to reduce the cost of Stocrin®, antiretroviral drug used in the National HIV/SDT Program.	On April 24, 2007, The Ministry of Health issued the Ordinance #886 declaring public interest on the rights of Efavirenz patents seeking compulsory license for public non-commercial use.	MSD was granted 7 days to present a price reduction offer. The Government rejected the 30% discount offered.	On May 4th, 2007, the Brazilian government issued Decree #6,108 granting a five-year non-exclusive license of Merck's patents covering Stocrin®, for public non-commercial use. Royalties were set at 1,5%.	The royalty was set by the Decree 6,801 of 2007. There was no need for the BRPTO to intervene.	On October 24th, 2008 the BRPTO published the registration of the compulsory license for Merck's patents.	No public laboratory was able to produce Efavirenz at the time of the license. The first batch of generic Efavirenz was procured through the United Nations Fund for UNICEF and arrived on July 2nd, 2007.	On May 4th, 2012, President Dilma Rousseff issued Decree #7,723 extending the compulsory license for five more years, in light of public interest, for both patents.

Merck's PP1100250-6 expired on August 7th, 2012 and PI9608839-7 expired on May 21st, 2016.

Brazilian legal framework

Requests before Federal Courts

The Federal Prosecutors Office argues that Roche is abusing its IPR and violating the economic order by maximizing profits. The lawsuit seeks:

- 52% Reduction in **the price** of Herceptin (trastuzumab) sold **to public entities** matching MoH´s deal
- **A declaration of public interest of Herceptin (trastuzumab) for the purposes of a compulsory license** (Art. 71 of Patent Statute, Law #9,279)
- The immediate grant by the BRPTO of a **compulsory license for the patent covering trastuzumab for government non-commercial use**
- BRPTO's grant of a **compulsory license** for the patent covering trastuzumab **due to abuse of economic power**, allowing the government to produce the drug through **PDPs** (Art. 68 of Patent Statute, Law #9,279)
- The **immediate parallel importation** of Herceptin as well as all raw materials needed for the local production by the government, until the MoH partner Labs (PDPs) are ready for full production
- On August 22nd, 2018 the 6th District Court for the Federal District rejected the Federal Prosecutors' arguments. The decision can be appealed.

International legal framework

Paris Convention, article 5A

(1) **Importation by the patentee into the country** where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses **to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.**

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; **it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive** [...]

International legal framework

WTO TRIPS Agreement article 31

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is annex 1-C of the Marrakesh Agreement Establishing the World Trade Organization (WTO) of **April 15th 1994**.

The Agreement provides for the possibility of limited exceptions to the rights conferred by a patent.

> Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, **including use by the government or third parties authorized by the government**, the following provisions shall be respected:
>
> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. **This requirement may be waived by a Member in the case of […] public non-commercial use. […]**
>
> (c) the scope and duration of such use shall be limited **to the purpose for which it was authorized** […]
>
> (d) such use shall be non-exclusive; […]
>
> (f) any such use shall be authorized **predominantly for the supply of the domestic market of the Member authorizing such use**;

International legal framework

WTO TRIPS Agreement article 31

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. **The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances**;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, **taking into account the economic value of the authorization**;

(i) 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;

(j) 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; [...]

International legal framework

Defining public non-commercial use

Public non-commercial is largely viewed as "government use" or "any use relating in some way to a nation's citizens that is not for business or profit related purposes." (Gold & Lam)

However, it **should not be interpreted as limitless justification for compulsory licensing.**

Such a reading broadens the possibilities of compulsory license in a way that renders superfluous the other restrictive terms in Article 31(b) "national emergency" and "circumstances of extreme urgency".

To this day no clarification was offered by the WTO.

International legal framework

Doha Declaration on TRIPS and Public Health

On **November 14th 2001** the Doha Declaration on the TRIPS agreement and Public Health was adopted by the WTO providing that the TRIPS Agreement:

- Does not prevent Members from taking measures to protect public health
- Should be interpreted as supporting Members right to protect public health and to promote access to medicines

The declaration also recognizes that **each Member has the right to grant compulsory licenses** and the freedom to determine the grounds upon which such licenses are granted.

> **Paragraph 6**. We recognize that **WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.** We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

On **August 30th 2003**, Members agreed to implement paragraph 6 of the Doha Declaration addressing the needs of WTO Members with insufficient manufacturing capacity **enabling them to import drugs under compulsory license.**

International legal framework

Protocol amending the TRIPS Agreement

On **December 6th 2005** the General Council decided to amend the TRIPS agreement adding **article 31bis** and providing the **paragraph 6 system** with legal status.

The system **waives the obligation put forth in article 31(f)** allowing the exporting Member's use of the authorization to supply the importing Member's market to the extent of its needs.

The exporting Member shall pay adequate remuneration to the patent holder taking into account the economic value of the authorization to the importing Member. **No remuneration is due by the importing Member.**

Members **shall take reasonable measures to prevent re-exportation** of products imported under the system.

The system became permanent on January 23rd, 2017 after Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam formally notified their acceptance of the protocol, reaching the **2/3 threshold to formally bring the amendment into TRIPS**. Brazil approved the protocol in 2008 and has already notified its acceptance.

Paragraph 6 system does not apply when:

- affordable supplies are already available from countries where no patent is in force
- prices for the product can be reduced through negotiation
- when the company agrees to grant a voluntary license to a generic producer

The system created by Paragraph 6

The use of the system is described by the annex introduced by the amendment to the TRIPS agreement:

The importing Member has to issue a notification that:

- Specifies the names and expected quantities of the products needed
- Confirms that it has insufficient or no manufacturing capacities in the pharmaceutical sector
- Confirms that it has granted or intends to grant a compulsory license in accordance with articles 31 and 31bis

The exporting Member has to issue the compulsory license under specific conditions conditions:

- Only the amount necessary to meet the importing Member needs may be produced under the license
- Products under the license shall have specific labelling or marking
- The licensee shall disclose on a website the quantities supplied and the distinguishing features of the product
- The exporting Member shall notify the WTO of the grant of the license, including the abovementioned conditions

International legal framework

Effects of TRIPS amendments and Doha's paragraph 6 system entry into force

After only two days, the entry into force of the paragraph 6 system had already caused impact in policy making.
On **January 25th, 2017**, Chilean Congress passed **Rule #798** calling on the government to **implement compulsory licenses on drugs for cancer and other diseases**.
The goal is to have the Ministry of Health **create protocols for compulsory licensing of pharmaceutical patents to address high drug prices and increase access**.
Rule #798 also requests the Ministry of Economic Development and Tourism to update regulations for the **expedited processing of compulsory licenses**.
On **March 17th, 2017** members of the Chilean Congress and patients submitted a petition to the Ministry of Health seeking compulsory licenses of any patent covering enzalutamide (Xtandi, Astellas) a prostate cancer drug, and sofosbuvir (Sovaldi, Gilead) for Hepatitis C.
The system **waives the obligation put forth in article 31(f)** allowing the exporting Member's use of the authorization to supply the importing Member's market to the extent of its needs.
The exporting Member shall pay adequate remuneration to the patent holder taking into account the economic value of the authorization to the importing Member. **No remuneration is due by the importing Member**.
Members **shall take reasonable measures to prevent re-exportation** of products imported under the system.
The system became permanent on January 23rd, 2017 after Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam formally notified their acceptance of the protocol, reaching the **2/3 threshold to formally bring the amendment into TRIPS**. Brazil approved the protocol in 2008 and has already notified its acceptance.

Paragraph 6 system, a tool against substandard drugs and corruption

WTO Members showed concern that the system could be used as an instrument to pursue industrial or commercial policy objectives rather than protect public health.

Also, Members recognized that the purpose would be defeated if products supplied under this Decision were diverted from the markets for which they were intended.

To prevent diversion, the exporting Members **must produce the exact amount necessary to meet the needs of eligible importing Members and the entirety of this production shall be exported to that Members.**

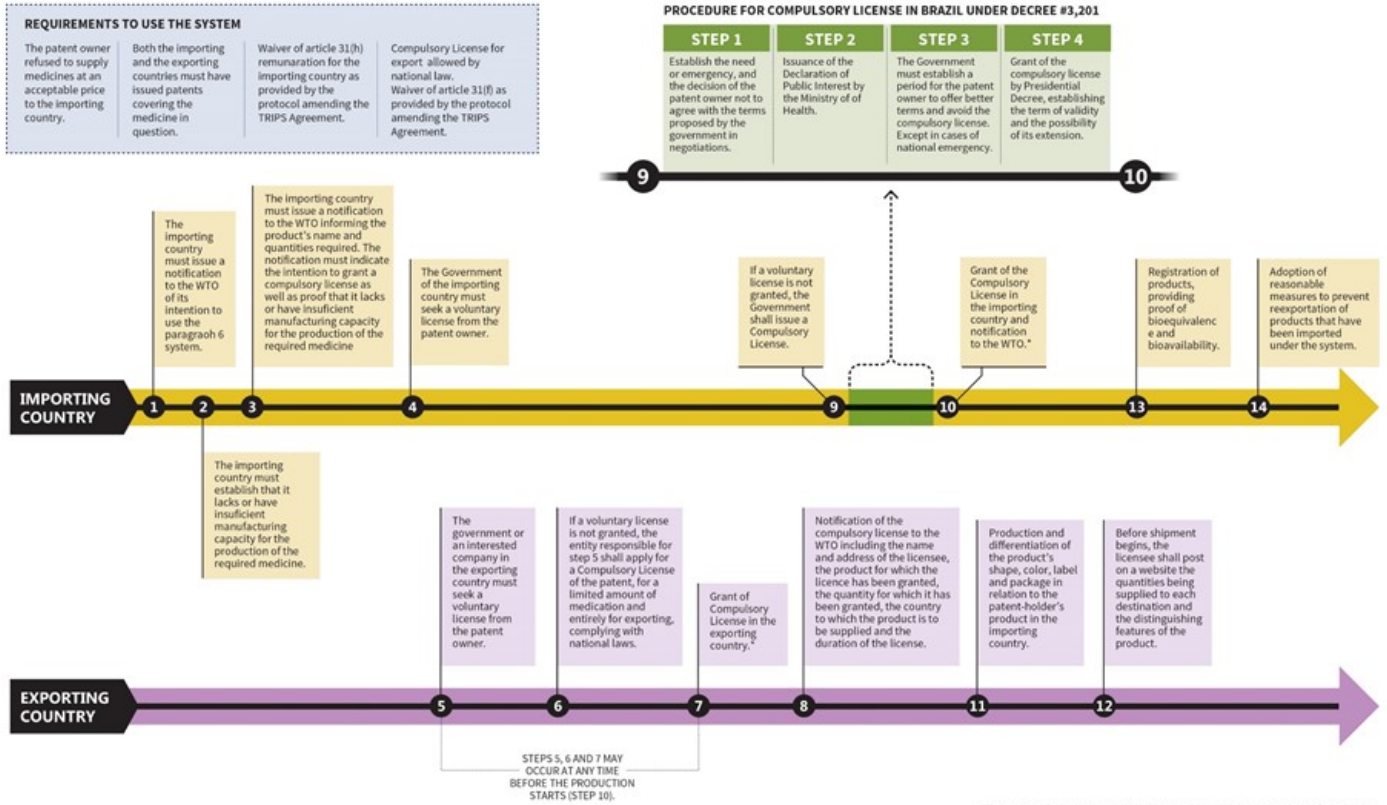
In 2000, Brazilian Congress published the final report on the investigation over quality of drugs produced in Brazil with **alarming conclusions regarding the lack of control over importation of API`s and substandard drugs.**

Other means to implement compulsory license may lead to improper means to manufacture the products leading to low quality API's and the marketing of substandard drugs.

The paragraph 6 system provides the importing Member with better quality drugs, GMP and in a timely manner. It also helps to fight corruption.

International legal framework

Workflow of the Paragraph 6 system



Licks
ATTORNEYS

Thanks!

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

Brics negotiates agreement to cheapen expensive medicines

O Globo – October 9, 2016

Brics negotiates agreement to cheapen expensive medicines (O Globo – October 9, 2016)

The Brazilian government began to negotiate an agreement between Brics (group formed by Brazil, Russia, India, China and South Africa) to produce, market and reduce the cost of drugs. The focus is on high-cost drugs, like those who treat chronic diseases such as AIDS. According to sources heard by GLOBO, the five countries discussed how to break patents (compulsory license) and make the drugs at a lower cost.

This is one of the topics that will be held in the 8th Summit of the BRIC countries, which will be held next week in Goa, India. Countries should discuss what types of drugs can enter into a free trade agreement. The discussion is not simple. After all, every nation tries to protect its own production. This agreement is still in early stages and should be concluded at the meeting.

"It is a discussion that is at its early stages, but it is very important and can mean a revolution for the distribution of high cost drugs among the BRICs. But we still have a long way in this negotiation "said a senior source from the Brazilian government.

Affecting up to ten drugs

Initially, the compulsory license agreement includes a limited number of drugs. It would be between five and ten drugs that are not produced by BRICS countries. In case it works, each country will be responsible for manufacturing one or two items and shall provide it to the other members of the group.

The idea of this arrangement for the exchange of technology between countries was introduced by Brazil during the United Nations (UN) meeting in New York. The conversations have been conducted by the Minister of Foreign Affairs, José Serra, who has experience in the subject.

In 2001, amid a price war with laboratories, Serra threatened to break patents of drugs for HIV, but did not need to annul it. When they saw that scientists of Manguinhos were able to develop the products, the responsible pharmaceutical companies started negotiating price reductions. At the time, Serra was the Minister of Health of Brazil when Fernando Henrique Cardoso was in office. According to sources heard by GLOBO, he has used the Brazilian experience as an example.

The patent grants the inventor of a product the reproduction and marketing rights for his invention. In Brazil, the patent can be broken in the event of national interest.

Brazil also wants to export the model of generic drugs. However, there are major differences between the health models of the countries. In India, for example, there are no public laboratories as there are in Brazil. This makes drugs more expensive for the population, because there is no incidence of taxes on public goods.

Proposal depends on India's approval

A great deal has to be done before it is approved. What must be signed in Goa is a memorandum of understanding on the cooperation and regulation of pharmaceutical products between the National Health Surveillance Agency (Anvisa) and the corresponding agency in India. After much negotiation, the memorandum is ready and waiting for the approval of India to be finalized. It is the first step for the trade agreement and investment in the pharmaceutical area.

Adjustments are agreed on by a team of diplomats and representatives of Anvisa. The initial goal is to establish cooperation with India, but the dealings have not been easy.

Since 2013, the Indian government has wanted to move forward in the proposal for an agreement with Brazil. This is one of the priorities of India in the relationship between the two countries. With the political crisis and the lack of definition of what would be the government structure in Brazil, the dialogue was suspended.

The conversations were resumed in June, already in the interim government of President Michel Temer. Three drafted memorandums of understanding were presented by India in the areas of traditional medicine and homeopathy, medicinal plants and university cooperation. An Indian medical chair must be created in **Brazil.** The Ministry of Health presented a counterproposal, but just before the bilateral meeting, there was still no response from India.

Brazil is a major importer

Brazil is interested in the agreement and considering strategy by Anvisa because of the profile of India´s pharmaceutical industry, particularly in the generics sector, of which Brazil is a major importer. With the arrangement, it would be possible to facilitate the inspection process and promote the recognition of approved inspections.

Temer's team must finalize the bilateral agreement at the beginning of next week. A meeting between the Brazilian President and Prime Minister Narendra Modi should seal the agreement. The two countries have much in common: both seek to implement structural reforms to enhance competitiveness.

The meeting between the two heads of state will take place after the meeting of the Brics. It is the eighth meeting of the group. Since 2012, initiatives have been announced as the creation of a development bank and a contingent reserve. Since India assumed the presidency of the group, there's been some noise among members.

"There is interest in India to move forward on issues of which there is no consensus" says a source in the Foreign Ministry.

In this sense, the summit in Goa is seen as a chance to establish new understandings.

http://oglobo.globo.com/economia/brics-negocia-acordo-para-baratear-remedios-de-alto-custo-20262275

Brics negocia acordo para baratear remédios de alto custo (O Globo – 9 de outubro de 2016)

O governo brasileiro começou a negociar um acordo entre o Brics (grupo formado por Brasil, Rússia, Índia, China e África do Sul) para produzir, comercializar e baratear medicamentos. O foco são os remédios de alto custo, caso daqueles que tratam doenças crônicas como a Aids. Segundo fontes ouvidas pelo GLOBO, os cinco países discutem como quebrar patentes e fabricar os medicamentos com um custo menor.

Esse é um dos temas que estarão nas conversas da 8ª Cúpula do Brics, que será realizada no próximo fim de semana em Goa, na Índia. Os países devem debater quais tipos de medicamentos podem entrar em um acordo de livre comércio. A discussão não é simples. Afinal, cada nação tenta proteger a sua própria produção. Esse acordo ainda está em fase inicial e não deve ser concluído no encontro.

— É uma discussão que está no início, mas que é muito importante e pode significar uma revolução para a distribuição de medicamentos de alto custo entre o Brics. Mas ainda temos um longo caminho de negociação — disse uma alta fonte do governo brasileiro.

Efeito em até dez medicamentos

Inicialmente, um acordo de quebra de patente incluiria um número limitado de medicamentos. Seria algo entre cinco e dez remédios que não são produzidos pelos países do Brics. Se vingar, cada país será responsável pela fabricação de um ou dois itens e deve fornecer para os demais integrantes do grupo.

A ideia desse acerto para a troca de tecnologias entre os países foi levada pelo Brasil ao encontro da Organização das Nações Unidas (ONU), em Nova York. Nos bastidores, as conversas têm sido conduzidas pelo ministro das Relações Exteriores, José Serra, que tem experiência no assunto.
Em 2001, em meio a uma guerra de preços com laboratórios, Serra ameaçou quebrar patentes de medicamentos para a Aids, mas não precisou cassar a licença. Ao verem que os cientistas de Manguinhos tinham condições de desenvolver os produtos, os laboratórios farmacêuticos responsáveis passaram a negociar reduções de preços. Na época, Serra era ministro da Saúde do governo Fernando Henrique Cardoso. De acordo com fontes ouvidas pelo GLOBO, ele tem usado a experiência brasileira como exemplo.

A patente garante ao inventor de um produto os direitos de reprodução e comercialização de seu invento. No Brasil, a patente pode ser quebrada em caso de interesse nacional.

O Brasil também quer exportar o modelo de genéricos. No entanto, há grandes diferenças entre os modelos de saúde dos países. Na Índia, por exemplo, não há laboratórios públicos como no Brasil. Isso encarece o remédio fornecido para a população, porque sobre o produto público não há incidência de impostos.

Proposta depende de aval de indianos

Um grande acordo como esse tem um longo caminho a percorrer antes de ser fechado. O que deve ser assinado na cúpula de Goa é um memorando de entendimento em cooperação e regulação de produtos farmacêuticos entre a Agência Nacional de Vigilância Sanitária (Anvisa) e o órgão correspon-dente na Índia. Após muita negociação, o texto está pronto e espera o aval dos indianos para ser fechado. É o primeiro passo para o acordo de comércio e investimentos na área de medicamentos.

Ajustes são acordados por uma equipe de diplomatas e representantes da Anvisa. O objetivo inicial é firmar a cooperação com os indianos, mas a tratativa não tem sido fácil.

Desde 2013, o governo indiano quer avançar na proposta de um acordo com o Brasil. Essa é uma das prioridades da Índia no relacionamento entre os dois países. Com a crise política e a indefinição de qual seria o governo no Brasil, o diálogo foi suspenso.

As conversas foram retomadas em junho, já no governo interino do presidente Michel Temer. Foram apre-sentadas três propostas de memorandos de enten-dimento pelo governo indiano, nas áreas de medicina tradicional e homeopatia, plantas medicinais e cooperação universitária. Uma cátedra de medicina indiana deve ser criada no Brasil. O Ministério da Saúde apresentou uma contraproposta, mas, pouco antes da reunião bilateral, ainda não havia resposta dos indianos.

Brasil é grande importador

O Brasil tem interesse no acordo, considerado estratégico pela Anvisa por causa do perfil da indústria farmacêutica indiana, sobretudo no setor de genéricos, dos quais o Brasil é grande importador. Com o acerto, seria possível facilitar o processo de inspeção e promo-ver o reconhecimento de inspeções homologadas.

A equipe de Temer deve fechar o acordo bilateral no início da semana que vem. Uma reunião entre o presidente brasileiro e o primeiro-ministro Narendra Modi deve selar o entendimento. Os dois países têm muito em comum: ambos buscam implementar reformas estruturais para aumentar a competitividade.

O encontro entre os dois chefes de Estado acontecerá após a reunião do Brics. É o oitavo encontro do grupo. Desde 2012, já foram anunciadas iniciativas como a criação de um banco de desenvolvimento e um contin-gente de reservas. Desde que a Índia assumiu a presi-dência do bloco, há alguns ruídos entre os membros.

— Há interesse da Índia em avançar em assuntos nos quais não há consenso — diz uma fonte do Itamaraty.

Nesse sentido, a cúpula em Goa é vista como uma chance de estabelecer novos entendimentos.

http://oglobo.globo.com/economia/brics-negocia-acordo-para-baratear-remedios-de-alto-custo-20262275

Licks
ATTORNEYS

WTO IP rules amended to ease poor countries' access to affordable medicines

WTO IP rules amended to ease poor countries' access to affordable medicines

An amendment to the agreement on intellectual property entered into force today (23 January) securing for developing countries a legal pathway to access affordable medicines under WTO rules.

The amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement marks the first time since the organization opened its doors in 1995 that WTO accords have been amended.

The WTO Secretariat has received in recent days notifications from five members that they have ratified the protocol amending the WTO TRIPS Agreement. These notifications — from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam — brought to two-thirds the number of WTO members which have now ratified the amendment. The two-thirds threshold was needed to formally bring the amendment into the TRIPS Agreement.

Members took the decision to amend the TRIPS Agreement specifically to adapt the rules of the global trading system to the public health needs of people in poor countries. This action follows repeated calls from the multilateral system for acceptance of the amendment, most recently by the United Nations General Assembly High-Level Meeting on Ending AIDS in June 2016.

"This is an extremely important amendment. It gives legal certainty that generic medicines can be exported at reasonable prices to satisfy the needs of countries with no pharmaceutical production capacity, or those with limited capacity. By doing so, it helps the most vulnerable access the drugs that meet their needs, helping to deal with diseases such as HIV/AIDS, tuberculosis or malaria, as well as other epidemics. I am delighted that WTO members have now followed through on their commitment and brought this important measure into force," said WTO Director-General Roberto Azevêdo. In video statements available here, some of the key players share their thoughts on the TRIPS amendment.

Unanimously adopted by WTO members in 2005, the protocol amending the TRIPS Agreement makes permanent a mechanism to ease poorer WTO members' access to affordable generic medicines produced in other countries. The amendment empowers importing developing and least-developed countries facing public health problems and lacking the capacity to produce drugs generically to seek such medicines from third country producers under "compulsory licensing" arrangements. Normally, most medicines produced under compulsory licences can only be provided to the domestic market in the country where they are produced. This amendment allows exporting countries to grant compulsory licences to generic suppliers exclusively for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.

"As important as trade policy is, health and well-being must take precedence," said Amina Mohamed, Kenya's Foreign Minister who chaired the WTO General Council at the time when the amendment was approved in December 2005. "WTO members recognise this and have proven how seriously they take health issues by ratifying and putting into force an amendment to WTO rules which will facilitate access to essential medicines in low income countries."

The amendment provides a secure and sustained legal basis for both potential exporters and importers to adopt legislation and establish the means needed to allow countries with limited or no production capacity to import affordable generics from countries where pharmaceuticals are patented. More and more WTO members are taking practical steps to implement the system in their laws. The bulk of global medicine exports is covered by laws enabling exports under this system, opening up new options for potential beneficiaries to access a wider range of potential suppliers and enabling new, innovative procurement strategies.

Background

Flexibilities such as compulsory licensing are written into the TRIPS Agreement — governments can issue compulsory licences to allow companies to make a patented product or use a patented process under licence without the consent of the patent owner, but only under certain conditions aimed at safeguarding the legitimate interests of the patent holder.

Some governments were unsure of how these flexibilities would be interpreted, and how far their right to use them would be respected. At the Doha Ministerial Conference in November 2001, WTO members struck a deal which clarified the accords and provided governments in the developing world with greater clarity and certainty that protection of patents does not and should not prevent members from taking measures to protect public health.

But one more element was needed — how to guarantee that countries lacking the capacity to produce generic drugs could still procure them affordably. Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health recognized that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement", and instructed the Council for TRIPS to find an expeditious solution to this problem.

In August 2003, WTO members decided to remove an important obstacle to affordable drug imports by waiving the limitation in the TRIPS Agreement to predominantly supply the local market. The decision says that if the importing country could not secure access to needed medicines at affordable prices, these medicines could be produced under compulsory licence by drug makers in third countries, and be imported to poorer countries unable to manufacture the medicines themselves.

Two years later, WTO members agreed on 6 December 2005 to permanently incorporate the 2003 waiver decision into the TRIPS Agreement subject to the acceptance of two-thirds of WTO members. Through the entry into force of the amendment, the flexibility to protect public health becomes an integral part of the TRIPS Agreement.

Against concerns some have voiced that use of this option may be challenged politically, the amendment provides legal certainty that any member can export the entirety of pharmaceutical products made under a compulsory licence to countries confronted with limited domestic capacity.

The up-to-date list and map of members that have accepted the protocol amending the TRIPS Agreement are available here. The rate of acceptance has picked up significantly in recent years, as members familiarize themselves with the practical implications of the TRIPS amendment: some 37% of instruments of acceptance were deposited in the last two years alone, following a review in the WTO General Council of the benefits of entry into force. Members who are yet to accept the TRIPS amendment currently have until end December 2017 to do so. In the meantime, they can refer to the 2003 waiver decision to access affordable medicines from third country sources.

The WTO TRIPS Council recently discussed the TRIPS public health amendment. A range of delegations urged WTO members that are yet to accept the amendment to do so expeditiously and called for work to make it operational. During related discussions on the UN High Level Panel Report on Access to Medicines, one delegation also recalled the Panel's recommendation to revise the system of compulsory licences for export.

More information on the issue of TRIPS and public health is available here.

Licks
ATTORNEYS

Paris Convention for the Protection of Industrial Property [Excerpt]

[…]

Article 5

A. Patents: Importation of Articles; Failure to Work or Insufficient Working; Compulsory Licenses

[…]

A.

(1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

(2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

(3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

(5) The foregoing provisions shall be applicable, mutatis mutandis, to utility models.

[…]

Licks
ATTORNEYS

WTO TRIPS Agreement [Excerpts]

Part I - General Provisions and Basic Principles

[...]

Article 7. Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8. Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of SECTION 5: PATENTS

[...]

Part II - Standards Concerning the Availability, Scope and use of Intellectual Property Rights

[...]

Section 5: Patents

Article 27. Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.1 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The technology provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

[...]

Article 29. Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

Article 30. Exceptions to Rights Conferred Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31. Other Use Without Authorization of the Right Holder Where the law of a Member allows for other use2 of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
(a) authorization of such use shall be considered on its individual merits;
(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
(c) the scope and duration of such use shall be limited to the purpose for which it was authorized,

[1] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.
[2] "Other use" refers to use other than that allowed under Article 30.

and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) 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;

(j) 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;

[...]

Part III - Enforcement of Intellectual Property Rights

[...]

Section 2: Civil and Administrative Procedures and Remedies

Article 44. Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

[...]

Licks
ATTORNEYS

Declaration on the Trips Agreement and Public Health of November 14, 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. 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.
In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.
6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Licks
ATTORNEYS

Implementation of Paragraph 6 of the Doha Declaration On the Trips Agreement and Public Health of August 30, 2003

Decision of 30 August 2003[3]

The General Council,
Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");
Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;
Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;
Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;
Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;
Decides as follows:
1. For the purposes of this Decision:
(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[4];
(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[5] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[6] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.
2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived 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 below in this paragraph:
(a) the eligible importing Member(s)[7] has made a notification[8] to the Council for TRIPS, that:
(i) specifies the names and expected quantities of the product(s) needed[9];
(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[10];
(b) the compulsory licence issued by the exporting Member under this Decision 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 set out in this Decision through specific

[3] This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.
[4] This subparagraph is without prejudice to subparagraph 1(b).
[5] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
[6] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.
[7] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.
[8] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.
[9] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.
[10] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

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[11] 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;
(c) the exporting Member shall notify[12] the Council for TRIPS of the grant of the licence, including the conditions attached to it.9 The information provided shall include 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. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.
3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement 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 be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.
4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member 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.
5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.
6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:
(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;
(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.
7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.
8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

ANNEX

[11] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

[12] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.
For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:
(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR
(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Draft Chairman's Statement
Of August 21, 2003

The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems identified in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasise that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

First, Members recognise that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.

Second, Members recognise that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable steps should be taken to prevent and discourage such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.

In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programs. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes. Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.

Third, it is important that Members seek to resolve and issues arising from the use and implementation of the Decision expeditiously and amicably.

To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.

Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.

If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilize the good offices of the DG or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have decided to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

Some other Members, including the following, have agreed that they would only use the solution as importers in situations of national emergency or other circumstances of extreme urgency: Chinese Taipei; Hong Kong; China; Israel; Republic of Korea; Kuwait; Macao; China; Mexico; Qatar; Singapore; Turkey; and United Arab Emirates.

Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agree that they may only use the solution as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will not use the solution as importers.

"BEST PRACTICES" GUIDELINES

Companies have often used special labelling, colouring, shaping, sizing etc to differentiate products supplied through donor or discounted pricing programs from products supplied to other markets. Examples of such measures include the following:

- Bristol Myers Squibb used different markings/imprints on capsules
- supplied to sub-Saharan Africa.
- Novartis has used different trademark names, on (Riamet®) for an antimalarial drug provided to developed countries, the other (Coartem®) for the same products supplied to developing

countries. Novartis further differentiated the products through distinctive packaging.
- GlaxoSmithKline (GSK) used different outer packaging for its HIV/AIDS medications Combivir, Epivir and Trizivir supplied to developing countries. GSK further differentiated the products by embossing the tablets with a different number than tablets supplied to developed countries, and plans to further differentiate the products by using different colours.
- Merck differentiated its HIV/AIDS antiretroviral medicine CRIXIVAN through special packaging and labelling, i.e., gold-ink printing on the capsule, dark green bottle cap and a bottle label with a light-green background.
- Pfizer used different colouring and shaping for Diflucan pills supplied to South Africa.

Producers have further minimized diversion by entering into contractual arrangements with importers/distributors to ensure delivery of products to the intended markets.

To help ensure use of the most effective anti-diversion measures, Members may share their experiences and practices in preventing diversion either informally or through the TRIPS Council. It would be beneficial for Members and industry to work together to further refine anti-diversion practices and enhance the sharing of information related to identifying, remedying or preventing specific occurrences of diversion.

Licks
ATTORNEYS

Amendment of The TRIPS Agreement
of December 6, 2005

The General Council;
Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");
Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;
Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;
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;
Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;
Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);
Noting the consensus to submit this proposed amendment to the Members for acceptance;
Decides as follows:
1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.
2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

Attachment protocol amending the TRIPS agreement

Members of the World Trade Organization;
Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");
Hereby agree as follows:
1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.
2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.
3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.
5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.
6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.
Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

Annex to the Protocol Amending the TRIPS Agreement

Article 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.
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.
3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be

exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.
4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.
5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

Annex to the TRIPS Agreement

1. For the purposes of Article 31bis and this Annex:
(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[13];
(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[14] to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members[15] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.
2. The terms referred to in paragraph 1 of Article 31bis are that:
(a) the eligible importing Member(s)[16] has made a notification[17] to the Council for TRIPS, that:
(i) specifies the names and expected quantities of the product(s) needed[18];
(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex[19];
(b) 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[20] 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;
(c) the exporting Member shall notify[21] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[22] The information

[13] This subparagraph is without prejudice to subparagraph 1(b).
[14] It is understood that this notification does not need to be approved by a WTO body in order to use the system.
[15] Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.
[16] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.
[17] It is understood that this notification does not need to be approved by a WTO body in order to use the system.
[18] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.
[19] This subparagraph is without prejudice to Article 66.1 of this Agreement.
[20] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.
[21] It is understood that this notification does not need to be approved by a WTO body in order to use the system.
[22] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

provided shall include 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. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.
3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member 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.
4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.
5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.
6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.
7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

Appendix to the Annex to the TRIPS Agreement

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.
For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:
(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or
(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

Licks ATTORNEYS

Drecree #9,289
of February 21, 2018

Published in The Federal Register of February 22, 2018

The PRESIDENT OF THE REPUBLIC, in its atributons granted by Artcle 84, item IV, of the Consttuton, and
Considering that the Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights was adopted by the General Council of the World Trade Organizaton on December 6, 2005;
Considering that the Brazilian Government fled the instrument of ratfcaton of the Protocol Amending the Agreement with the Director-General of the World Trade Organizaton on November 13, 2008;
Considering that the Protocol Amending the Agreement entered into force to the Federatve Republic of Brazil, regarding the external juridical feld, on January 23, 2017;
DECREES:
Article 1. The Protocol Amending the Agreement on Trade-Related Aspects of Intellectual Property Rights adopted by the General Council of the World Trade Organizaton on December 6, 2005, annex to this decree, is hereby enacted.
Article 2. Acts that may result in the review of the Protocol Amending the Agreement, and adjustments that entail charges or onerous compromises to the natonal patrimony, under artcle 49, item I of the Consttuton, are subject to approval by the Natonal Congress.
Article 3. This Decree enters into force at the date of its publicaton.
Brasilia, February 21, 2018; the 197th of independence and 130th of the Republic.

MICHEL TEMER
Aloysio Nunes Ferreira Filho

PROTOCOL AMENDING TRIPS AGREEMENT

The members of the World Trade Organizaton;
Having regarded the decision from the General-Council in document WT/L/641, adopted in accordance with Artcle X, paragraph 1, of the Marrakesh Agreement consttutng the World Trade Organizaton ("The WTO Agreement");
Agree as follows:
1. in the entering into force of the Protocol, under paragraph 4, the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") will be amended as established by the Annex to this Protocol with the inclusion of Artcl 31bis following Artcle 31, and by the inclusion of the Annex to the TRIPS Agreement following Artcle 73.
2. No reservatons regarding the provisions of this Protocol are permited without consent from the other Members.
3. This Protocol shall be open for acceptance by Members untl December 1, 2007 or such later date as may be decided by the Ministerial Conference.
4. The Protocol shall take effect in accordance with the provisions of Artcle X, paragraph 3, of the WTO Agreement.
5. This Protocol shall be deposited with the Director-General of the World Trade Organizaton, which will promptly provide each Member with a certfed copy and a notce of each acceptance of the Protocol, in accordance with paragraph 3.
6. This Protocol shall be registered in accordance with the provisions from Artcle 102 of the United Natons Charter.
Prepared in Geneva in the sixth of December of 2005, in a single copy in English, French and Spanish, each text being authentc.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Artcle 31bis
1. The obligatons of an exportng Member under Artcle 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of producton of a pharmaceutcal product(s) and its export to an eligible importng Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.
2. Where a compulsory licence is granted by an exportng Member under the system set out in this Artcle and the Annex to this Agreement, adequate remuneraton pursuant to Artcle 31(h) shall be paid in that Member taking into account the economic value to the importng Member of the use that has been authorized in the exportng Member. Where a compulsory licence is granted for the same products in the eligible importng Member, the obligaton of that Member under Artcle 31(h) shall not apply in respect of those products for which remuneraton in accordance with the frst sentence of this paragraph is paid in the exportng Member.
3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitatng the local producton of, pharmaceutcal products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Artcle XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differental and More Favourable Treatment Reciprocity and Fuller Partcipaton of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Natons list of least developed countries, the obligaton of that Member under Artcle 31(f) shall not apply to the extent necessary to enable a pharmaceutcal product produced or imported under a compulsory licence in that Member to be exported to the markets of those other

developing or least developed country partes to the regional trade agreement that share the health problem in queston. It is understood that this will not prejudice the territorial nature of the patent rights in queston.
4. Members shall not challenge any measures taken in conformity with the provisions of this Artcle and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Artcle XXIII of GATT 1994.
5. This Artcle and the Annex to this Agreement are without prejudice to the rights, obligatons and flexibilites that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Artcle 31, including those reafrmed by the Declaraton on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretaton. They are also without prejudice to the extent to which pharmaceutcal products produced under a compulsory licence can be exported under the provisions of Artcle 31(f).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Artcle 31bis and this Annex:
(a) "pharmaceutcal product" means any patented product, or product manufactured through a patented process, of the pharmaceutcal sector needed to address the public health problems as recognized in paragraph 1 of the Declaraton on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that actve ingredients necessary for its manufacture and diagnostc kits needed for its use would be included(1);
(b) "eligible importng Member" means any least-developed country Member, and any other Member that has made a notfcaton(2) to the Council for TRIPS of its intenton to use the system set out in Artcle 31bis and this Annex ("system") as an importer, it being understood that a Member may notfy at any tme that it will use the system in whole or in a limited way, for example only in the case of a natonal emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members(3) and that some other Members have stated that, if they use the system, it would be in no more than situatons of natonal emergency or other circumstances of extreme urgency;
(c) "exportng Member" means a Member using the system to produce pharmaceutcal products for, and export them to, an eligible importng Member.
2. The terms referred to in paragraph 1 of Artcle 31bis are that:
(a) the eligible importng Member(s)(4) has made a notfcaton2 to the Council for TRIPS, that:
(i) specifes the names and expected quanttes of the product(s) needed(5);
(ii) confrms that the eligible importng Member in queston, other than a least developed country Member, has established that it has insufcient or no manufacturing capacites in the pharmaceutcal sector for the product(s) in queston in one of the ways set out in the Appendix to this Annex; and
(iii) confrms that, where a pharmaceutcal product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Artcles 31 and 31bis of this Agreement and the provisions of this Annex(6);
(b) the compulsory licence issued by the exportng Member under the system shall contain the following conditons:
(i) only the amount necessary to meet the needs of the eligible importng Member(s) may be manufactured under the licence and the entrety of this producton shall be exported to the Member(s) which has notfed its needs to the Council for TRIPS;
(ii) products produced under the licence shall be clearly identfed as being produced under the system through specifc labelling or marking. Suppliers should distnguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distncton is feasible and does not have a signifcant impact on price; and
(iii) before shipment begins, the licensee shall post on a website(7) the following informaton:
— the quanttes being supplied to each destnaton as referred to in indent (i) above; and
— the distnguishing features of the product(s) referred to in indent (ii) above;
(c) the exportng Member shall notfy(8) the Council for TRIPS of the grant of the licence, including the conditons atached to it.(9) The informaton provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantty(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duraton of the licence. The notfcaton shall also indicate the address of the website referred to in subparagraph (b)(iii) above.
3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importaton, eligible importng Members shall take reasonable measures within their means, proportonate to their administratve capacites and to the risk of trade diversion to prevent re-exportaton of the products that have actually been imported into their territories under the system. In the event that an eligible importng Member that is a developing country Member or a least-developed country Member experiences difculty in implementng this provision, developed country Members shall provide, on request and on

mutually agreed terms and conditons, technical and fnancial cooperaton in order to facilitate its implementaton.

4. Members shall ensure the availability of effectve legal means to prevent the importaton into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufcient for this purpose, the mater may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitatng the local producton of, pharmaceutcal products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Artcle 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperaton in accordance with Artcle 67 of this Agreement, including in conjuncton with other relevant intergovernmental organizatons.

6. Members recognize the desirability of promotng the transfer of technology and capacity building in the pharmaceutcal sector in order to overcome the problem faced by Members with insufcient or no manufacturing capacites in the pharmaceutcal sector. To this end, eligible importng Members and exportng Members are encouraged to use the system in a way which would promote this objectve.

Members undertake to cooperate in paying special atenton to the transfer of technology and capacity building in the pharmaceutcal sector in the work to be undertaken pursuant to Artcle 66.2 of this Agreement, paragraph 7 of the Declaraton on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functoning of the system with a view to ensuring its effectve operaton and shall annually report on its operaton to the General Council.

1. This subparagraph is without prejudice to subparagraph 1(b).
2. It is understood that this notfcaton does not need to be approved by a WTO body in order to use the system.
3. Australia, Canada, the European Communites with, for the purposes of Artcle 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.
4. Joint notfcatons providing the informaton required under this subparagraph may be made by the regional organizatons referred to in paragraph 3 of Artcle 31bis on behalf of eligible importng Members using the system that are partes to them, with the agreement of those partes.
5. The notfcaton will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.
6. This subparagraph is without prejudice to Artcle 66.1 of this Agreement.
7. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.
8. It is understood that this notfcaton does not need to be approved by a WTO body in order to use the system.
9. The notfcaton will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT

Assessment of Manufacturing Capacites in the Pharmaceutcal Sector Least-developed country Members are deemed to have insufcient or no manufacturing capacites in the pharmaceutcal sector.

For other eligible importng Members insufcient or no manufacturing capacites for the product(s) in queston may be established in either of the following ways:

(i) the Member in queston has established that it has no manufacturing capacity in the pharmaceutcal sector;

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufcient for the purposes of meetng its needs. When it is established that such capacity has become sufcient to meet the Member's needs, the system shall no longer apply.

Licks ATTORNEYS

Patent Statute #9,279
of May 14, 1996 [Excerpts]

Regulates rights and obligations relating to industrial property

Preliminary Provisions

Article 1. This statute regulates rights and obligations relating to industrial property.
Article 2. The protection of rights relating to industrial property, taking into account the interests of society and the technological and economic development of the country, is effected by means of:

I. the grant of patents of invention and utility model patents;

II. the grant of industrial design registrations;

III. the grant of trademark registrations;

IV. the repression of false geographical indications; and

V. the repression of unfair competition.

Article 3. The provisions of this statute also apply:

I. to an application for a patent or registration originating from abroad and filed in this country by a person having protection guaranteed by a treaty or convention in force in Brazil; and

II. to nationals or persons domiciled in a country that guarantees reciprocity of identical or equivalent rights to Brazilians or persons domiciled in Brazil.

Article 4. The provisions of treaties in force in Brazil are applicable, in equal conditions, to natural and legal persons that are nationals or domiciled in this country.
Article 5. For all legal effects, industrial property rights are considered to be chattels.
[...]

§III. Compulsory Licenses

Article 68. A patentee will be subject to have his patent licensed compulsorily if he exercises the rights resulting therefrom in an abusive manner or by means of it practices abuse of economic power that is proven under the terms of the law by an administrative or court decision.

¶1. The following may also result in a compulsory license:

I. the non-exploitation of the subject matter of the patent in the territory of Brazil, by lack of manufacture or incomplete manufacture of the product or, furthermore, by lack of complete use of a patented process, except in the case of non-exploitation due to economic unviability, when importation will be admitted; or

II. commercialization that does not meet the needs of the market.

¶2. The license can only be requested by a party with legitimate interest and that has the technical and economic capacity to carry out the efficient exploitation of the subject matter of the patent, that should be destined predominantly for the internal market, suppressing, in this case, the exception provided for in item I of the previous ¶.

¶3. In the case that a compulsory license is granted due to abuse of economic power, a period of time, limited to that provided for in article 74, will be guaranteed to the licensee proposing to manufacture locally, to proceed with the importation of the subject matter of the license, provided it has been placed on the market directly by the patentee or with his consent.

¶4. In the case of importation to exploit a patent and in the case of importation provided for in the previous ¶, the importation by third parties of a product manufactured according to a process or product patent will equally be allowed, provided it has been placed on the market directly by the patentee or with his consent.

¶5. A compulsory license, to which ¶1 relates, may only be requested after 3 (three) years from grant of the patent.

Article 69. A compulsory license will not be granted if, at the date of the request, the patentee:

I. justifies non-use for legitimate reasons;

II. proves that serious and effective preparations for exploitation have been carried out; or

III. justifies lack of manufacture or commercialization due to legal obstacles.

Article 70. A compulsory license will also be granted when the following hypotheses are shown to exist cumulatively:

I. a situation of dependency of one patent on another is characterized;

II. the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent; and

III. the patentee does not come to an agreement with the patentee of the dependent patent for the exploitation of the earlier patent.

¶1. For the purposes of this article, a dependent patent is considered as the exploitation of which depends obligatorily on the use of the subject matter of the earlier patent.

¶2. For the purposes of this article, a process patent may be considered as dependent on a patent for the respective product, as also a product patent may be dependent upon a process patent.

¶3. The proprietor of a patent licensed under the terms of this article will have the right to a compulsory cross license under the dependent patent.

Article 71. In cases of national emergency or public interest, declared in an act of the Federal Executive Authorities, insofar as the patentee or his licensee does not meet such necessity, a temporary ex officio non- exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee.

Sole ¶ The act of grant of the license will establish its term of validity and the possibility of extension.

Article 72. Compulsory licenses will always be granted without exclusivity, sublicensing not being permitted.

Article 73. An application for a compulsory license must be formulated by indicating the conditions offered to the patentee.

¶1. Once the application for a license has been filed, the patentee will be notified to respond within a period of 60 (sixty) days, at the end of which, in the absence of a response from the patentee, the proposal will be considered as accepted under the conditions offered.
¶2. An applicant for a license who alleges abuse of patent rights or abuse of economic power must file documentary proof.
¶3. If a compulsory license is requested on the basis of lack of exploitation, it will rest with the patentee to prove exploitation.
¶4. If there is a request for reconsideration, the BRPTO may take the necessary steps, including the establishment of a committee that may include specialists that are not part of the BRPTO, with a view to arbitrating the remuneration that will be paid to the patentee.
¶5. The organs and entities of the direct or indirect, federal, state and municipal public administration will provide the BRPTO with such information as is requested with a view to assisting the arbitration of remuneration.
¶6. In arbitrating remuneration, the circumstances of each case will be considered, taking into account obligatorily the economic value of the license granted.
¶7. Once the process is duly filed, the BRPTO will come to a decision regarding the grant and the conditions of the compulsory license within a period of 60 (sixty) days.
¶8. Appeals against decisions granting a compulsory license will not have staying effects.
Article 74. In the absence of legitimate reasons, the licensee must initiate exploitation of the subject matter of the patent within a period of 1 (one) year from the grant of the license, interruption for an equal period being permitted.
¶1. The patentee may request revocation of the license if the provisions of this article are not met.
¶2. The licensee will be vested with all powers to act in defense of the patent.
¶3. After grant of a compulsory license, the assignment thereof will only be permitted when effected together with the assignment, transfer or leasing of that part of the undertaking that exploits it.
[...]
Brasilia, May 14, 1996

FERNANDO HENRIQUE CARDOSO
Nelson A. Jobim
Sebastião do Rego Barros Neto
Pedro Malan
Francisco Dornelles
José Israel Vargas

Licks ATTORNEYS

Decree #3,201 of October 6, 1999 as amended by Decree #4,830

This Presidential Executive Order governs the ex officio grant of compulsory permit in the cases of national emergency and public interest under Article 71 of the Statute #9,279 of May 14, 1996.

This Presidential Executive Order governs the ex officio grant of compulsory permit in the cases of national emergency and public interest under Article 71 of the Statute #9,279 of May 14, 1996.
In the exercise of the powers vested in him by Article 84, section IV of the Constitution and in view of Article 71 of the Statute #9,279 of May 14, 1996, the PRESIDENT OF THE REPUBLIC DECREES:
Article 1. The ex officio grant of a compulsory permit in cases of national emergency or public interest, in the latter case only for public non-commercial use, mentioned in Article 71 of Statute #9,279 of May 14, 1996, shall be made under this Decree.
Article 2. An ex officio compulsory patent permit may be granted in cases of national emergency or public interest, in the latter case only for public non-commercial use, if so declared by the Government, when it is found that the patentee, either directly or through a licensed party, does not meet these requirements.
¶1. National emergency is an imminent public danger, even if only in part of the national territory.
¶2. Public interest entails facts related to public health, nutrition, environmental protection, including others, as well as those of prime importance for the technological or social and economic development of the country.
Article 3. The Federal Executive Branch act declaring a national emergency or public interest will be practiced by the Minister responsible for the matter in question and must be published in the Official Gazette.
Article 4. In the event that the patentee or his licensee fails to meet the national emergency or public interest, the Government shall grant an ex officio compulsory license in a non-exclusive basis, and such act shall be immediately published in Official Gazette.
Article 5. The compulsory license granting act shall provide, among others, the following conditions:
The period of license validity and the possibility of extension; and
Those conditions offered by the Federal Government, in particular the holder's remuneration.
¶1. The act of granting compulsory license may also establish the obligation of the holder to transmit the information necessary and sufficient for effective reproduction of the protected object and the other technical aspects applicable to the case or otherwise meet the provisions of Article 24 and Title I, Chapter VI, of Statute #9,279 of 1996.
¶2. In determining the appropriate compensation to the holder, the relevant economic and market circumstances, the price of similar products and the economic value of the authorization shall be considered.
Article 6. The competent authority may request information necessary to support the granting of the license or to determine the compensation to the patent holder, as well as other relevant information, to federal, state and municipal government bodies and entities.
Article 7. In the case of national emergency or public interest characterizing extreme urgency, the compulsory license of this Executive Order, patent use may be implemented and made effective regardless of prior compliance with the conditions established in Articles 4 and 5 hereof.
Sole ¶. If the competent authority is aware, without conducting a search, that a patent is in force, the holder shall be promptly informed of such use.
Article 8. The exploitation of the patent compulsorily licensed herein may be initiated regardless of agreement on the conditions contained in Article 5.
Article 9. The use of a patent licensed herein may be held directly by the Government or by duly contracted or licensed third parties, and the reproduction of its object for other purposes remains precluded, under penalty of being considered illegal.
Sole ¶. Exploitation by third parties of compulsorily licensed patent shall be made with regard to the principles of Article 37 of the Constitution, subject to the other applicable legal standards.
Article 10. In cases where it is not possible to comply with situations of national emergency or public interest with the product placed on the domestic market or it proves impracticable to manufacture the patent by third parties of the object, or by the Government, the Government may carry out this importing of the object of the patent.
Sole ¶. In the cases referred to in this article, the Government shall acquire preferably the product that have been placed on the market directly by the holder or with his consent, provided that it does not hinder the license purposes.
Article 11. (Revoked by Decree 4,830 of September 4, 2003)
Article 12. Upon compliance with the national emergency or public interest, the competent authority shall terminate the compulsory license, subject to the terms of the contract with the licensee.
Article. 13. The competent authority shall inform the Brazilian Patent and Trademark Office (BRPTO), for recording purposes, the licenses for public non-commercial use as granted on the basis of Article 71 of Statute #9,279 of 1996, including any changes and termination of such licenses.
Article 14. This Executive Order enters into force on the day of its publication.
Brasilia, October 6, 1999

FERNANDO HENRIQUE CARDOSO
José Serra
Alcides Lopes Tápias

Licks ATTORNEYS

Decree #6,108
of May 4, 2007

This Presidential Executive Order grants compulsory license for public interest to patents related to Efavirenz, for public non-commercial use purposes.

This Presidential Executive Order grants compulsory license for public interest to patents related to Efavirenz, for public non-commercial use purposes.
In the exercise of the powers vested in him by Article 84, section IV of the Constitution and in view of Article 71 of the Statute #9,279 of May 14, 1996, and Article 4 of Presidential Executive Order #3,201 of October 6, 1999 the PRESIDENT OF THE REPUBLIC DECREES:
Article 1. It is hereby ex officio granted compulsory license for public interest to patents 1100250-6 and 9608839-7.
¶1. The compulsory license provided for in the main Section is granted public non-exclusive and non-commercial use under the National STD/AIDS Program, in accordance with Statute #9,313 of November 13, 1996, with the term of five years which may be extended for an equal period.
¶2. The compulsory licensing provided for in the main Section will be terminated by an act of the Health Minister, to cease the circumstances of public interest that determined it.
Article 2. Patentee remuneration referred to in Article 1 is fixed at a point five percent of the cost of drug product as made and finished by the Ministry of Health or the price of the medicine given.
Article 3. The holder of patents licensed in Article 1 is obliged to provide the Ministry of Health with all the information necessary and sufficient for effective reproduction of protected objects, and the Government shall ensure the appropriate protection of such information against unfair competition and deceptive trade practices.
Sole ¶. The provisions of Article 24 and Title I, Chapter VI, of Statute #9,279 of May 14, 1996 shall apply in the case of breach of obligation under the main Section.
Article 4. Exploitation of patents licensed under this Presidential Executive Order may be held directly by the Government or by duly contracted or licensed third parties, and the reproduction of their objects for other purposes remain precluded, under penalty of being considered illegal.
Article 5. Where the product placed on the domestic market fails to comply with public interest or where production of the objects of patents by the Federal Government or by third-party contractors or agreements proves unfeasible in whole or in part, the Government may import the product subject of patents, notwithstanding the remuneration provided for in Article 2.
Article 6. The Ministry of Health shall inform the Brazilian Patent and Trademark Office (BRPTO), for recording purposes, the licenses for public non-commercial use as granted herein, including any changes and termination of such licenses.
Article 7. This Executive Order enters into force on the day of its publication.
Brasilia, May 4, 2007

LUIZ INÁCIO LULA DA SILVA
José Gomes Temporão

Licks ATTORNEYS

Decree #7,723
of May 4, 2012

This Presidential Executive Order extends the effectiveness of compulsory license for public interest to patents related to Efavirenz, for public non-commercial use purposes under Presidential Executive Order #6,108 of May 4, 2007.

This Presidential Executive Order extends the effectiveness of compulsory license for public interest to patents related to Efavirenz, for public non-commercial use purposes under Presidential Executive Order #6,108 of May 4, 2007.
In the exercise of the powers vested in him by Article 84, section IV of the Constitution and in view of Article 71 of the Statute #9,279 of May 14, 1996 the PRESIDENT OF THE REPUBLIC DECREES:
Article 1. It is hereby extended for an additional five years the effectiveness of patents #1100250-6 and 9608839-7 related to Efavirenz, for public non-commercial use purposes under Paragraph 1 of Article 1 of Presidential Executive Order #6,108 of May 4, 2007.
Article 2. This Presidential Executive Order enters into force on the day of its publication.
Brasilia, May 4, 2012.

DILMA ROUSSEFF
Alexandre Rocha Santos Padilha

Licks ATTORNEYS

Statute #12,270
of June 24, 2010 [Excerpt]

This Statute regulates Brazil's staying measures of concessions or other obligations relating to intellectual property rights and others in cases of non-compliance with the Agreement Establishing the World Trade Organization.

This Statute regulates Brazil's staying measures of concessions or other obligations relating to intellectual property rights and others in cases of non-compliance with the Agreement Establishing the World Trade Organization.
THE PRESIDENT OF THE REPUBLIC - I hereby make known that the National Congress has decreed and I sanction the following Statute:
Article 1. This Statute regulates Brazil's staying measures of concessions or other obligations relating to intellectual property rights and others in cases of non-compliance with multilateral obligations by a Member of the World Trade Organization (WTO) when the Federative Republic of Brazil was authorized by the OMC's Dispute Settlement body to stay the enforcement for such concession Member or additional obligations under the OMC Agreements.
Article 2. For the purpose of this Statute, definitions are as follows:
The 1994 Agreement Establishing the World Trade Organization: the Treaty establishing the World Trade Organization, concluded in Marrakesh on April 12, 1994, included in the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations of the GATT, of April 12, 1994, incorporated into the Brazilian legal system by Decree #1,355, of December 30, 1994;
Agreement on Aspects of Intellectual Property Rights Related to Trade: the Agreement integrating Annex 1C of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations of the 1994 GATT, incorporated into the Brazilian legal system by Decree #1,355 of 30 December 1994;
Understanding on Dispute Solutions: understanding on Rules and Procedures on the WTO Dispute Solutions, part of Annex II of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations of the 1994 GATT, incorporated into the Brazilian legal system by Decree #1,355, of December 30, 1994; and
intellectual property rights: rights related to intellectual property of:
a. literary, artistic and scientific works;
b. performers, phonogram producers and broadcasting organizations;
c. computer programs;
d. brands;
e. geographical indications;
f. industrial designs;
g. patents and utility models;
h. cultivars or plant varieties;
i. topographies of integrated circuits;
j. confidential or undisclosed information; and
k. additional intellectual property rights established by the Brazilian legislation.
Article 3. In the enforcement of this Statute, the following measures may be adopted:
I. stay of intellectual property rights;
II. limitation of intellectual property rights;
III. change of measures for the enforcement of intellectual property rights protection standards;
IV. change of measures to obtain and maintain intellectual property rights;
V. temporarily blocking the remittance of royalties or remuneration for the exercise of intellectual property rights; and
VI. application of commercial rights on the remuneration of the intellectual property right holder.
Sole ¶. For the enforcement of the measures mentioned in this Article, the provisions related registrar procedures provisioned in the relevant legislation will be considered, respecting the powers of the Brazilian Patent and Trademark Office (BRPTO) and the Ministry of Agriculture, Livestock and Supply.
Article 4. The measures provided for herein may be applied to the following Parties to the Agreement on Aspects of Intellectual Property Rights Related to Trade:
I - Part II - on standards concerning the availability, scope and use of intellectual property rights with respect to:
a. copyright and related rights;
b. trademarks;
c. geographical indications;
d. industrial designs;
e. patents;
f. integrated circuit topographies; and
g. protection of confidential information and protection of non-disclosed information;
II. Part III - on the application of standards of protection of intellectual property rights; and
III. Part IV - on obtaining and maintaining intellectual property rights and related interparty procedures.
¶1. The intellectual property protection of computer programs, as per international obligations, is considered an integral part of line a of subsection I of the main Section of this article.
¶2. The protection of intellectual property cultivars or plant varieties as per international obligations is considered an integral part of the obligations under line a and subsection I of this Article, in accordance with line b of paragraph 3 of Article 27 of the Agreement on Aspects of Intellectual Property Rights Related to Trade.
Article 5. The measures provided for herein only apply to applicants, holders or licensees of intellectual property rights that are:
I. WTO Member nationals or domiciled under Article 1; or
II. Legal entities domiciled or established in a WTO Member, under Article 1.
[...]
Brasilia, June 24, 2010

LUIZ INÁCIO LULA DA SILVA
Celso Luiz Nunes Amorim
Nelson Machado
Miguel Jorge

Licks ATTORNEYS

BRPTO's Rule #80
of March 19, 2013

This Rule establishes the priority examination of patent applications regarding pharmaceutical products and processes, as well as devices and materials related to public health.

THE VICE-PRESIDENT and the PATENT DIRECTOR of BRPTO, in the exercise of their assignments,
CONSIDERING Patent Statute #9,279 of May 14, 1996, establishing that the protection of the rights related to industrial property must reflect social interest and the technological and economic development of the country;
CONSIDERING the alignment of the BRPTO to the Greater Brazil Plan (Plano Maior Brasil), and to the public policy of health assistance provided by the Ministry of Health and to the development of the Industrial Health Complex;
CONSIDERING the needing to optimize the proceedings of examination of patent applications related to products, process, devices and materials regarding health sector, in particular those considered strategic to the National Healthcare System (SUS);
CONSIDERING the purpose of the BRPTO's Priority Program – Solution to the Patent Backlog in reducing the delay in the examination of patent applications at levels consistent with best international practices;
CONSIDERING the needing to optimize the proceedings of operation processing of patent applications in order to obtain an improvement of efficiency quality;
DETERMINE:
Article 1. This Rule establishes the priority examination of patent applications regarding pharmaceutical products and processes, as well as devices and materials related to public health.
¶1. The priority examination of the patent applications related to article 1 can be requested by the Ministry of Health, as detailed in Section I of this Regulation;
¶2. The priority examination of patent applications related to article 1 can be requested by any interested when they refer to diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), cancer or neglected diseases, as detailed in Section II of this Regulation.
Article 2. The patent applications submitted to the priority examination, as established in this Regulation, will be under the responsibility of the Board of Patents - DIRPA.
Sole ¶. The Priority Examination Committee, selected by the Board of Patents – DIRPA -, will analyze the request for priority examination of patent applications.

§I. Priorization of the examination of patent applications as per the request of the Ministry of Health

Article 3. The patent applications will be examined with priority when filed before the BRPTO, related products, processes, devices and/or materials used in health related to the National Policy of Pharmaceutical Assistance of the Ministry of Health and established as strategic to National Healthcare System.
§1. The patent applications are not limited to diagnosis, prophylaxis and treatment of the diseases listed in Annex 1 of this Rule;
§ 2. Patent applications must have been requested for technical examination, as provided in Article 33 of the Patent Statute.
Article 4. The list of patent applications submitted to priority examination request by the Ministry of Health will be established by the Committee of Priority Examination.
§1. The Board of Patents – DIRPA – will determine the grant or not of the prioritization of examination of patent applications;
§2. The list mentioned in article 4 can be established from the number of patent applications or from names or references to products, devices and/or materials for use in health related to the request of the Ministry of Health;
§3. In the case of names or references to products, devices and/or materials for use in healthcare, the BRPTO will identify their related patent applications.

§II. Priorization of examination of patent applications as per the request of the applicant or third parties

Article 5. The patent applications will be examined with priority when filed before the BRPTO, related products, processes, devices and/or materials used in health, directly related to the diagnosis, prophylaxis and treatment of Acquired Immunodeficiency Syndrome (AIDS), cancer or neglected diseases.
Sole ¶. Neglected diseases are listed by the Ministry of Health and the World Health Organization (WHO), as per the

Annex 1 of this Rule

Article 6. The prioritization of examination of patent applications by the request of the applicant or third parties will be analyzed by the Priority Examination Committee.
Sole ¶. The Board of Patents – DIRPA – will determine if the patent application examination will be granted priority;
Article 7. For the granting of a priority examination of a patent application, the patent application shall be published in the BRPTO's Gazette, as provided by Article 30 of the Patent Statute.
Sole ¶. The publication of the patent application can be anticipated as per the request of the applicant, as provided by ¶1 of Article 30 of the Patent Statute.
Article 8. For the granting of a priority examination of a patent application, it is necessary to have a request for technical examination, as provided by Article 33 of the Patent Statute.
Article 9. The request for priority examination for patent applications mentioned in Article 5 may be submitted by any interested party and by an application form. The application form (FQ009 - APPLICATION FOR PRIORITY EXAMINATION) is in PR Rule #63/2013.
Article 10. The acts of this Rule, when not practiced by the interested part, must be accompanied by POA,

as provided by ¶1 of article 216 of the Patent Statute.

§IV. Priority of examination – workflow

Article 11. The Commission of Priority Examination shall verify the patent applications meeting the following mandatory conditions for the granting of priority examination:
I. does not refer to the patent application whose examination is suspended for compliance with formal requirements previously formulated by the Board of Patents - DIRPA;
II. does not refer to a patent application of which has already been granted priority examination;
III. refers to the patent application that complies with the payment obligations of the annuities mentioned in Article 84 of the Patent Statute.
Article 12. The Board of Patents shall notify, in particular publication at the BRPTO's Gazette, whenever the priority examination of the patent application has been granted.
Article 13. The Board of Patents shall notify, in particular publication at the BRPTO's Gazette, whenever the priority examination of the patent application has been rejected.

§V. General rules

Article 14. Article 4 of Rule #68 of March 18, 2013 is revoked.
Article 15. The priority examination mentioned in this Rule occurs without any charge for the interested.
Article 16. This Rule will enter into force on the date of its publication at the Official BRPTO Gazette.

JÚLIO CÉSAR CASTELO BRANCO REIS MOREIRA
Patent Director
Ademir Tardelli
Vice-President

Annex 1. List of neglected diseases
Neglected diseases list

- Chagas Disease;
- Dengue / Dengue hemorrhagic;
- Schistosomiasis;
- Leprosy;
- Leishmaniasis;
- Malaria;
- Tuberculosis;
- Buruli ulcer;
- Neurocysticercosis;
- Echinococcosis;
- Bouba;
- Fascioliasis;
- Paragonimiasis;
- Filariasis;
- Rabies;
- Helminthiasis;
- Manifestations from intoxications or poisonings due to poisonous and venomous animals

Bill #5,994
of August 10, 2016

This Bill amends the Statute #9,782, of January 26, 1999, that "sets out the Brazilian Health Surveillance System, establishes the Brazilian Food and Drugs Administration (the ANVISA), and sets out additional provisions," as to set out the requirements to be enforced for exemption of marketing approval and incorporation of immunobiologicals, insecticides, drugs and additional strategic ingredients as purchased through international multilateral agencies to be used in public health programs by the Ministry of Health and its affiliated entities.

The NATIONAL CONGRESS
ENACTS:

Article 1. This statute sets out the requirements to be enforced for exemption of marketing approval and incorporation of immunobiologicals, insecticides, drugs and additional strategic ingredients as purchased through international multilateral agencies to be used in public health programs by the Ministry of Health and its affiliated entities.

Article 2. Article 8 of the Statute #9,782, of January 26, 1999 is now enforced with the following wording:

"Article 8

.....

¶5. The Agency may exempt all immunobiologicals, insecticides, drugs and additional strategic ingredients as purchased through international multilateral agencies to be used in public health programs by the Ministry of Health and its affiliated entities of marketing approval.

I - The requirements for the Agency to exempt the products in Brazil of marketing approval include:

a) A product duly registered in Brazil and having the same active ingredients is not available; or

b) A product approved and marketed in Brazil is unable to supply the demand.

II - The requirements for the Agency to incorporate the products exempted of marketing approval include:

a) The Agency's reviewing and issuing a final favorable opinion on proof of product safety, efficacy and quality.

b) Proof that the product has a marketing approval in the country of origin or in the country where it is being marketed; and

c) Proof that the supplier and holder of product marketing approval is in good standing of its legal rights.

¶5-A. Upon full compliance with the requirement that motivated the marketing approval, such exemption as provided in ¶5 of this Article is revoked."

Article 3. This Statute enters into force on the date of its publication.

JUSTIFICATION

Since the creation of the Revolving Fund for Strategic Public Health Supplies of the PAHO (Pan American Health Organization) also known as Strategic Fund on September, 2000 it has made the technical cooperation and support between American countries possible, and has assured access to strategic drugs with quality, security and efficacy, in addition to additional critical products for public health, such as insecticides and diagnostic kits.

Throughout those years, the Strategic Fund has proven critical for the fulfillment of specific demands of countries deprived of access to certain products, either because they are unavailable or due to shortage. Therefore, it has helped protect the population against the worst diseases known to humanity, such as polio, measles, yellow fever, rotavirus, HPV, and many others.

In this regard, it is important that the State be capable to enforce such privileges, be it to carry on, conserve or deploy the most differing public policies while aiming at protecting the population or improving its quality of life.

Thereby, Statute #9,782, of January 26, 1999, which establishes the Brazilian Food and Drugs Administration (ANVISA, in the Portuguese abbreviation), through amendment included by the Provisional Measure #2,190-34, of August 23, 2001, conferred the ANVISA power to exempt the marketing approval of immunobiologicals, insecticides, drugs and additional strategic ingredients when purchased through international multilateral bodies to be used in public health programs by the Ministry of Health and its affiliated entities.

The purpose of this forecast is to handle and solve endemic, pandemic and/or urgent public health issues that put the population in risk in exceptional situations and therefore are grounds for the ANVISA not to await for the completion of the product's marketing approval process.

The Ministry of Health, through the ANVISA, enforces such legal privilege, but the requirements for the Agency's dismissing the marketing approval and incorporating such products have not been set out.

Managers are increasingly required to abide by objective requirements in their decision-making processes due to the globalization of supply chains, growing product demand and the never-ending pursuit for transparency. The wording of the current statute, where amendment is herein suggested, lacks such requirements and contains scope for legal uncertainty over industries regularly established in Brazil, which are subject to one of the highest tax burdens around the world for purely economic reasons.

The lack of objective requirements practically overburdens the ANVISA, that ends up too busy reviewing quality, security and efficacy data of international products, however such reviews were made when the product was approved in Brazil.

This bill aims at filling the existing gap by setting out the requirements to be enforced for exemption of marketing approval and incorporation of immunobiologicals, insecticides, drugs and additional strategic ingredients as purchased through international multilateral agencies to be used in public health programs by the Ministry of Health and its affiliated entities.

Therefore, inclusion of items I and II and its respective subparagraphs to paragraph 5 is suggested, as well as the inclusion of paragraph 5-A, all of which to Article 8 of the Statute #9,782 of January 26, 1999, and the support of other congressmen is requested.

Chamber, August 10, 2016.

MARCUS PESTANA
Federal Representative

BRPTO's Directive #16
of March 18, 2016

This ordinance standardizes the procedures for registrating technology transfer contracts within the BRPTO.

[...]
Article 2. The BRPTO shall record or register, as appropriate, all technology transfer agreements, which is industrial property rights license agreements (patent exploration, industrial design exploration or use of trademarks), the technology skills acquisition agreements (providing technology and providing technical and scientific services), franchise agreements and the compulsory license agreements for patent exploration.
Sole ¶. The BRPTO shall also record industrial property rights assignment agreements (patent exploration, industrial design exploration or use of trademarks) when the holder of this right is domiciled abroad, as provided for in Article 3 of Annex III of BACEN Rule #3,844 of March 23, 2010.
Article 3. Agreements shall clearly state their purpose, the compensation or "royalties", the periods of validity and performance of the agreement, where applicable, and additional contractual terms and conditions.
Article 4. The application for record or registration should be submitted in proper form, by any of the contracting parties, along with the following documents:
a) certified copy of the agreement or representative instrument of the duly legalized act;
b) translation into Brazilian Portuguese when written in a foreign language;
c) explanatory letter justifying the agreement;
d) registration form of the transferee of technology transfer or franchise;
e) other documents at the discretion of the parties, as relevant to the legal business;
f) proof of payment of due remuneration, and
g) proxy, subject to the provisions of arts. 216 and 217 of the Brazilian IP Statute.
[...]

Rio de Janeiro • Sao Paulo • Brasilia • Curitiba • Tokyo
www.lickslegal.com | info@lickslegal.com | japan@lickslegal.com