

The requirement of complete manufacture of a patent object in national territory

Article 68, 1st Paragraph, I, of Law # 9,279/96
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The requirement of complete manufacture of a patent object in national territory

The Article 68, 1st Paragraph, of Law # 9,279/96 establishes that the non-exploitation of a patent object in Brazilian territory as a result of the lack of manufacturing or of the incomplete manufacturing, or the failure to fully work a patented process is subjected to compulsory license.

The use of the provision may happen through three ways, very different from each other. The first one is through the effective request of a compulsory license on INPI, which has already occurred to the PI8704197-9.¹ The second is the use of the provision to subvert the negotiation balance between a potential licentiate and the patent owner. As recognized by a NGO report on this second way, “*the mere availability of a local working requirement strengthens the ability to negotiate*”.²

1. The *Revista da Propriedade Industrial* (RPI) # 1460, of 12/29/1998, published by INPI, notified that the company Vacuum Pack Services Limited requested compulsory license due to the non-manufacturing of the patent PI8704197-9, whose owner is Interprise-Brussels.
2. Oxfam GB, *Drug Companies vs. Brazil: The threat to public health*, 2001, p.15.

The third mean of use occurs as a defense resource in a patent breach legal action. Article 68, 1st Paragraph, I, becomes an instrument of pressure and threat for dissuading the patent owner to exert its rights, escaping from a judgment...³

All those three ways have already been used in Brazil, proving the evident damage to patent owners imposed by the provision of Law 9,279/96 discussed here. Thus, one cannot say that there is no harm or use.

The requirement of manufacturing a patent object in national territory is described by the eminent and longed-for Prof. Beier, from the Max Planck Institute in Munich, as the most protectionist doctrine in the international patents system. This doctrine is old-fashioned and unfair to those investing in technology and new products.

In a posthumous article, published by the *International Review of Industrial Property and Copyright Law* (IIC), Prof. Beier discusses, impartially, about the bankruptcy of the mandatory determination of local manufacturing, contrary to patent system and to the economic principles:

“it soon became clear that the national obligation to work a patent, the protectionist nature of which is evident, was contrary to the concept of international patent protection and reasonable economic principles. Compelling a patent holder to manufacture each protected product in every country, irrespective of the dimensions of the market concerned and the existence of the remaining framework conditions for economically sensible production or licensed production, would be utterly contrary to economic reason and to the principle of the international division of labor.

*In an age of increasing globalization of manufacture and distribution, an institution such as the national obligation to work a patent is more than nonsensical. Where the patent holder does not act unreasonably, but according to economic principles by producing at minimum expense at the best location, then he is not acting abusively: “Failure to work a patent is not an abuse to the extent that the patent is worked at all and insofar as the needs of the market are satisfied by imports.”*⁴

According to the lessons by Beier, the lack of local manufacture shall not be considered as an abusive exercise of the right to exclude third parties, or as an economic power abuse. The jurisprudence of CADE demonstrates that abuses of rights or of economic power may occur even when products are produced in national territory, which shows a total inexistence of a relationship between local manufacturing, economic power abuse and abusive exercise of a patent right.⁵

Similarly, should the marketing of a patented product does not meet the needs of the market, either if the product is imported or produced in Brazil, a compulsory license can be granted, according to Article 68, 1st Paragraph, II. It is clear that there is no subordination relationship between both possibilities of a compulsory license granting listed in the *caput* of Article 68 (abusive exercise of the rights and economic power abuse) and the others foreseen on the 1st Paragraph of the same article, such as the compulsory license resulting from the lack of complete manufacture of a patent object. Any interpretation suggesting a subordination relationship between the provisions of the 1st Paragraph of Article 68, such as the lack of complete manufacture of a patent object, and the *caput* thereof, disregards the interpretation and hermeneutic rules of the Brazilian Law.

Everybody knows that the compulsory license system in force up to January 1995, instituted by Law 5,772/71, the Industrial Property Code, had an identical legislative technique now under discussion.

The *caput* of Article 33, of Law # 5,772/71, sets forth that the holder of the privilege not effectively manufacturing the patent in the country was liable to grant an exploitation license for third parties.

3. Refer, for example, to the compulsory license of the patent PI7107076 achieved by Nortox Agro-Química S/A, through a release on RPI 710 of 05/29/84, page 86, process DIRCO/1649/83, after the holder Monsanto Company, notified the company for breaching the patent concerned.

4. Friedrich-Karl Beier, Exclusive rights, statutory licenses and compulsory licenses in patent and utility model law, 30 IIC 252 (1999), not underlined on the original text.

5. The Administrative Council of Economic Defense - CADE is a judging agency, created by Law # 4,137, of 1962. Among other attributions, CADE is responsible for caring for the free competition, disseminate competition culture by means of public information about the ways in which the economic order is violated and for deciding issues regarding those violations.

However, the 1st Paragraph of the same Article 33, additionally determined that, for public interests reasons, a compulsory license could also be granted. In case the interpretation rule currently advocated by some people prevailed, we would have a situation today in which the license for public interest's sake would be conditioned to the whether the patent object is worked in national territory or not. It is interesting that the same people advocating the dependence thesis of Article 68 *caput* for the application of its paragraphs, stated that the 1st Paragraph, Article 33, of Law 5,772/71 was not subordinated to the *caput*. In other words, this is the hermeneutics of the convenience.

Just as a reminder, the Complementary Law 95/88, a specific statute, which is designed to determine rules for the interpretation of national laws, contains legal commands in a paragraph, the *caput* of which has been integrally forbidden, just as the 2nd Paragraph, Article 2 has been also forbidden. That is to say, in our system, even the specific law addressing its own interpretation counts on paragraphs with no *caput*. If the proposed subordination thesis was true or right, examples such as this could not simply occur.⁶

Furthermore, it is always worthy to remember that the text of 1st Paragraph, Article 68 determines that “gives, equally, an opportunity to compulsory license”, clearly demonstrating that additional possibilities exist to those two listed on article's *caput*.

The requirement of complete manufacture of a patent object in national territory: a detrimental injustice to Brazilian consumers

Much is said about the requirement of complete manufacture of a patent object in national territory without an effective knowledge of the meaning of this legal liability. Erroneously, many people advocate the requirement of local manufacture “of the product” without the understanding that, most of the times, there is no direct relationship between an available product and a specific patent.

Firstly, the requirement foreseen on Article 68, 1st Paragraph, I, of Law 9,279/96, obliges a patent holder in Brazil to manufacture, in national territory, products that may potentially infringe each of the independent claims of a patent.⁷ No matter how many claims exist in the patent letter. This is much more than requiring the manufacture of a specific product.

INPI has agreed in this sense in a little more than four hundred decisions to be expired, all of them previously to the implementation of the Uruguay Round. The interpretation repeatedly expressed by INPI about the requirement of “effective work” of a patent object in national territory, foreseen on Article 33, 3rd Paragraph of the former Industrial Property Code (Law 5,772/71), was that the holder of the patent to expire should work the patent in all its extension. That is, the legal liability is the same, however, whereas in Law 5,772/71, the penalty was patent expiration; today, the penalty is compulsory license, according to Article 68, 1st Paragraph, of Law 9,279/96.

Just to illustrate, we can mention the deferral report of the expiration request for patent PI 6677387, (RPI 1693, of 01.13.1984), due to the failure to work only one among many independent claims. In the report, the DIQUOR chief at that time mentioned that “the invention must be used as described in the report and claims, and that the exploitation must apply to the patent object itself”.⁸

As outlined in the report, the patent PI 6677387 was granted to protect compositions (Claims 1-4); Production process (Claim 5); and process for controlling systems (Claim 6). The patent holder proved, according to the provisions of Article 33, 3rd Paragraph, of Law 5772/71 the effective work of the patent, except for a single claim. That is, among six claims, five have been worked in national territory through local and concurrently production. Only one was not being manufactured in the country.

Aiming to suppress expiration due to the failure to work a single claim, the patent holder alleged a major force reason, based on the “difficulty of locally working the process due to the need of high complex plants, requiring huge investments and long time for execution, impossible to be solved in the short term as established by letter ‘a’, Article 49 of Law 5,772/71.” However, this argumentation was refused by INPI, which, upon the absence of proofs of patent effective exploitation - only regarding Claim 5 - determined the

expiration of the patent PI 6677387 as a whole, concluding that “the holder was obliged to work the patent in all its extension”. There are many other examples as Draconian as the one described here.⁹

6. Complementary Law # 95, of February 26th, 1998, addressing the preparation, text, change and establishment of laws, according to the provisions of the sole paragraph, Article 59, of the Federal Constitution.

7. Article 25 of Law 9,279/96 determines that the claims shall be based in a descriptive report, featuring the individualities of the request, and defining, in a clear and accurate way, the matter object to protection.

8. DIQUOR (Organic Chemistry, Biotechnology and Related Areas Division) is a division of the INPI's Patents Board, which is responsible for granting the Patent Letters and Registrations of Industrial Designs. DIQUOR is now responsible for examining pharmaceutical substances patents.

9. In the same context is the decision engraved in the Appellate Review in Injunction # 77,429-RJ by the 1st Panel of the extinguished Federal Court of Appeals, through which the determination of the expiration of a patent was confirmed, based on the lack of its exploitation according to the provisions of Article 49 of the former Industrial Property Code. A similarly expressive legal decision in this context was engraved by the 5th Panel of the same Federal Court of Civil Appeals # 58,205-RJ. In that decision, the Court confirmed the determination of patent expiration and did not accept, for expiration suppression purposes, the allegation of major economic force of the patent holder.

Maybe the major example is the decision of the Federal Court of Appeals, where the requirement of manufacturing all separate claims in a patent was confirmed to suppress expiration was also applicable to the compulsory license system.¹⁰

In elegant appellee reasons (pages 359-368 of records), based on the opinion of the President's assistant at the time, Nelida Jessen (pages 107-113), INPI supported that:

“A patent shall always be unique and indivisible, in the legal sense, without the need of productive process unity (...) If, sometimes, it is possible – technically and physically – a partially worked patent, in the legal context, this shall never be possible, since this implies on the illegal use of the monopoly granted (...) Indeed, as clearly determined on the Industrial Property Code, a partial use is never, in any circumstance, an effective use, neither for expiration effects, nor for license effects.

INPI acted correctly, as of Right and Law, in granting the license. The emeritus Judge *a quo* performed very well when maintained the granting act...

Regarding the odd thesis of compulsory license granting only for the portion not worked, at no moment legal rules could admit such a hypothesis”.

In pharmaceutical industry, a patent request shall be written and filed long before the beginning of clinical studies, or of a definition for the best formulation and use of a “promising molecule” in a pharmaceutical product. Patents are filed and granted almost 10 years before any product reaches the market. Many independent claims may be not “produced in Brazilian territory” due to the lack of conclusive safety and efficacy studies. On the other hand, other claims may be not “produced” exactly because of the existence of studies performed after a patent is granted, showing additional technical problems that could not be solved yet.

Almost all patent-protected pharmaceutical products are produced after commercialization approval issued by ANVISA.¹¹ As required by ANVISA, in order to determine the safety and efficacy of a product, tests that take approximately 10 years must be completed, therefore, no patent can meet the legal requirements of complete manufacture of the object in the country within the foreseen term. This is only one of the reasons for the indignation of patent holders, which see this legal obligation as unfair and potentially harmful to Brazilian consumers. Additionally, independent claims in a same patent may be manufactured in Brazil, but not simultaneously.

Thus, if a particular pharmaceutical patent contains a claim for an ethical product and another claim for an unrestricted sale (OTC) product, the legal obligation of Article 68, 1st Paragraph, I, would only be met if the patent holder marketed both products at the same time, and if the claimed elements were all manufactured in national territory.

The requirement established by law is so difficult to comply with, that not even the patent of a well-known sterilization system (PI8302255), a product invented by the genius of a Brazilian citizen, Alintor Fiorenzano

Jr., and marketed under the brand *Sterilair*, would be able to comply with the law, because it would not have all independent claims manufactured continuously and simultaneously within the established terms.

According to the definition comprised in Article 68, 1st Paragraph, I, the manufacturing, import and distribution, even if almost integrally, of the patented object are not sufficient to meet the requirements of Law. The manufacturing of a great part of the product does not also meet the requirements of Law, according to the practice of INPI and to the judgments of the Judiciary.

It is interesting to note that this requirement in Article 68, 1st Paragraph, I, disagrees with any other law on origin rules, determining which percentage of a product shall be produced in Brazil in order to be considered a national or Mercosul product.¹²

10. Injunction appeal # 106,155-RJ, judged in May 28th, 1996, the judgment of which was entered by Minister Ilmar Galvão, was published on the Justice Gazette of 08/21/1996.

11. The National Sanitary Surveillance Agency was created by Law # 9,782, of January 26th, 1999. The institutional purpose of the Agency is to promote population's health by means of the sanitary control over products and services production and marketing submitted to sanitary surveillance, including their environments, processes, inputs and related technologies.

12. In Brazil, origin rules agreed in the scope of the Asunción and Montevideo Treaties have been internalized through the Decrees #3,325 of 12/30/99, and # 1,568, of 07/21/95. One of the major criteria for defining an origin rule is a product's added value so that competitiveness could be maximized through drawback system. In Mercosul, it is required 60% of Regional Content, being allowed the use of at most 40% of raw materials sourced by other countries. ALADI allows the use of up to 50% of raw materials.

The requirement on Article 68, 1st Paragraph, I, precludes any possibility of using the drawback system for assuring a better competitiveness for Brazilian products with a high added value and protected by a patent.¹³

The competitiveness risk for Brazilian exports is evident. By taking into account that the production of each “element” in a claim could mean a cost increment – due to exchange rates, scaled economy, or lack of electric power – the requirement is potentially harmful both for exporters and currencies and for the end consumer, who shall buy the product with a higher price in order to recover the higher production costs. It seems that those encumbrances to the Country have been identified by the Itamaraty in the early 1990's, long before the completion of Uruguay Round. After all, the Article 73, 2nd Paragraph of the Bill 824, originated by the Presidential Message # 192, of April 30th, 1991, which contained the Bill “ruling rights and obligations over industrial property”, already determined that the import should be considered as a way of effective work. The Bill 824 counted with the support of the Brazilian ambassador to GATT at that time, Rubens Ricupero. In summary, if the holder of a patent having ten different claims produces only nine of them in national territory, that patent would be subjected to compulsory license due to the lack of local manufacturing of only one of the claims. By the practices adopted by INPI, all those 10 claims should be licensed – those nine being manufactured plus the only one that was not – because INPI does not grant partial licenses. On the other hand, if a compulsory license is granted due to the lack of local production of one of the claims, the “compulsory” licensed may not have the same obligation as the patent holder of manufacture locally all the claims. This is because, according to Article 68, 2nd Paragraph of Law # 9,279, the licensed is only obliged to “perform the efficient work of the patent object”. This uneven treatment pattern of the law is another reason for the indignation of the patent owners, who see this legal obligation as unfair and potentially harmful to foreign investments.

The text of articles and the controversy

As previously seen, one of the seven possibilities of compulsory license for a patent, according to Law 9,279/96, is the “failure to work a patent object in Brazilian territory **due to the lack of manufacture or to the incomplete manufacture** of a product, or, also, the **lack of integral use** of the patented process.”

According to the provisions of the Law, any exploitation but the complete manufacture of the patent object subjects the patent owner to a compulsory license.

The Article 5A(2) of the Paris Convention, a long-lasting treaty that is still in force, allows the option of granting compulsory licenses by lack of patent exploitation.¹⁴

In Brazil, a thesis is advocated in the sense that the Paris Convention determines the requirement of complete manufacture of an object of patent in national territory. This is not correct. Paris Convention determines that a country may require the exploitation. There is no article in the treaty determining that only a local production should be considered as exploitation. Exploitation is not necessarily a complete manufacture of a patent object. The requirement of complete manufacture of a patent object exists on Law 9,279/96, but it does not exist in any article of Paris Convention.

Bodenhausen, the most famous commentator of the Convention, understands that “*the member States are also free to define what they understand by failure to work.*”¹⁵

The difference between the option provided by Article 5A(2) of Paris Convention and the Article 68, 1st Paragraph, I, of Law 9,279/96 is obvious, since national laws determine only a single way in which a patent can be worked. Although some may understand that the non-literal interpretation of the Paris Convention allows for the definition of “work” as a complete manufacture of a patent object, this is not exhibited in the Convention text. Furthermore, Article 5A(2) does not address an obligation, but an option.

13. “Drawback is the return, total or partial, of the rights charged on the entrance of foreign products partially manufactured that shall be used for the production of national manufactured articles to be exported.” (Ratti, Bruno, *Comércio internacional e câmbio*, 1994, p. 372).

14. In the original text in English, article 5A(2) exhibits the following text: “Each country of the Union shall have right to take legislative measures providing for the Grant of compulsory licenses to prevent abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work”.

15. G.H.C. BODENHAUSEN, *Guide to the application of the Paris Convention for the Protection of Industrial Property as revised at Stockholm in 1967*, BIRPI, Swiss, 1968, p. 71.

The difference between manufacture and work is so evident and unquestionable that Article 33, 2nd Paragraph of Law 5,772/71 had to restrictively define the term work: “The industrialization being replaced or supplemented by importation shall not be considered as effective work”. Thus, Article 27.1 of TRIPS determines that “patent rights shall be enjoyable with no distinction... **regardless if the goods are imported or locally produced.**”¹⁶

Thus, a member State of the Paris Convention and of WTO – remains with the option granted by Article 5A(2), provided its definition does not differentiate from “patent work” regarding the fact that patented products are imported or locally produced. The patent work should be performed through local manufacture or importation.

The requirement of local manufacture in a free market treaty: an incongruence

We should not forget that the preface of the major agreement in WTO, to which TRIPS is subordinated (annex 1C), determines as main objectives of that Organization the expansion of the international trade and the optimal use of world’s resources. Thus, by analyzing the obligations and options in Brazil, we should remember the objectives justifying the existence of the WTO.

Aiming to develop the free trade of goods and services, TRIPS has incorporated superior standards to those existing in Paris Convention. The incongruence of the thesis defending the requirement of local production is evident when analyzed in the light of a system aiming the international flow of goods and services. Thus, once the international trade is important for the development of nations, one cannot defend progress by suggesting the removal of patent-protected products. As explained in the report about TRIPS published by UNCTAD, “*the patentee’s bundle of exclusive rights must include the right to supply the market with imports of the patented products.*”¹⁷

Otherwise, how could we possibly make compatible an international effort for the development of trade and the reduction of tax and non-tax barriers with a requirement that is contrary to the international trade itself, applying penalties to patent holders?

Nuno Pires de Carvalho, consultant to the Intellectual Property Division of the World Trade Organization at that time, and now a member of the World Intellectual Property Organization (WIPO), with an authority

exerted by someone who is also a patent-expert lawyer in Brazil, has alerted to the need to analyze the requirement of local production in the light of the most general precepts and conjectures of WHO:

“The discrimination regarding the fact that products are imported or locally produced has been addressed with a certain emotion in Brazil (...) About this matter, it is worthy to clarify that the WTO Agreement and its attachments shall be seen as a whole, since they have been negotiated and accepted by all WTO members as a “pack”, that is, an indivisible and harmonic set of principles and rules. Thus, in order to understand the scope of TRIPS provisions, we have to consider rules existing in other agreements of the WTO, which help to clarify their meanings.

In fact, the biggest difference existing between the TRIPs Agreement and the other administrative treaties by WIPO is in the fact that the TRIPs Agreement is, as any other agreement in the WTO, a mechanism resulting in markets’ access to products and services. Unfortunately, there is a certain likelihood to forget this point, which is essential for understanding the real meaning of the TRIPs.

The general perception is that TRIPs have only completed a phase in the enhancement of the levels of intellectual property. This is not true. The truth is that, by completing this phase, TRIPs included the intellectual property in the rules referring to the free trade of goods and services.

16. The initials “TRIPS” is used in this text as originally employed in English to name the agreement. TRIPs constitutes the annex 1C of the Marrakech Constitutive Agreement of WTO, one of the documents of the Final Minutes that incorporates the Results of the Uruguay Round of GATT’s Multilateral Business Negotiations, signed by Brazil in Marrakech in 04/12/1994. The Final Minutes was approved by the Legislative, according to Article 49 I of the Constitution, by the Decree # 30, of 12/15/1994, published in the Brazilian Official Gazette in 12/19/1994. The ratification filing instrument was filed in 12/21/1994. The Final Minutes was subsequently enacted and published according to the Decree # 1,355, of 12/30/1994, and published in the Brazilian Official Gazette of 12/31/1994.

17. United Nations Conference on Trade and Development, The TRIPs Agreement and developing countries, UNCTAD/ITE/1, New York and Geneva, 1996, p. 30.

The issue of local work is one of the points in which the function of enabling access to markets, achieved by TRIPs, is more evident. The 1st Paragraph of Article 27 does involve the principle of national treatment, but not of the national treatment applicable to people, in the terms of Paris and Berne Conventions, but to what applies to goods, in the terms of Article III, 4th paragraph, of the 1994’s GATT Agreement, as follows:

“Products from the territory of any contractor party imported in the territory of any other contractor party shall not be less favored than similar products of national origin in terms of any law, rule or prescription that may affect sales, availability for sale, purchase, transport, distribution, or use of such products in the internal market”.

In other words, those WTO members imposing the burden of patent work cannot give to imported products a less favorable treatment than they do to locally manufactured products to be used as a proof of work.”¹⁸

Therefore, if we remember WTO’s objectives, we can conclude that there is an incongruence in the requirement of local manufacture, *per se* antagonist to the free trade.

The pacific interpretation in the world

Article 27.1 of TRIPS is categorical when it establishes that patents are available and the patent rights are enjoyable without differentiation, regardless of the invention site, its technological area, and if goods are imported or locally produced. We can see, thus, that - at least apparently - a conflict exists between article 27.1, of TRIPS, and article 68, 1st paragraph, I, of Law 9,279/96. It is exactly this discord of the national patent law to TRIPs that gave the opportunity to the implementation of a panel in the Controversy Solving Body of WTO. There are several technical and impartial studies commenting or interpreting TRIPs. Those studies show the most accepted reading and the expectations of the international community. Among all publications, Lars Anell, chairman of the TRIPs negotiation team during the Uruguay Round, pointed out the work by Prof. Daniel Gervais entitled: *The TRIPs Agreement: Drafting History and Analysis* as a guide for future negotiations and for the decision of WTO panels. Prof. Gervais, in his work about TRIPs considers that

article 27.1 restrain the options granted by article 5A(2) of Paris Convention, just as supported by WTO panel, with the following words:

*“In determining the (...) enjoyment of patent rights Article 27(1) also prohibits discrimination based on whether the invention is locally produced or imported, (...) This concerns working requirements and possible compulsory licenses which, before the TRIPS Agreement, were regulated only by the narrowly-drafted Article 5A of the Paris Convention, which (...) left contracting States free to impose compulsory licenses for failure to work after a prescribed delay.”*¹⁹

We can see that Prof. Gervais understands that article 27.1 of TRIPs limits the option granted by article 5A(2) of Paris Convention, prohibiting the requirement of local production intended to maintain the rights of a patent holder.

The opinion of Prof. Gervais could not, by far, be considered separately. Almost all reports published worldwide about TRIPs agree with the judgment of the English professor. The vast majority of opinions found in international community discredit the thesis of maintaining the option granted by article 5A(2) of Paris Convention, which seem to be defended by those suggesting the maintenance of the provision discussed in Brazil. In the United States, Prof. J. H. Reichman, from the Law School at the Vanderbilt University, a well-known expert in intellectual property, describes, in an article published by the International Lawyer - one of the most traditional journals in international law area - that the option of requiring local manufacture as per article 5A(2) of Paris Convention, is derogated. Prof. Reichman is emphatic in saying:

18. Nuno T. P. Carvalho, “TRIPs – Questões controvertidas na área de patentes”, in XIX Seminário Nacional de Propriedade Intelectual, ANAIS 1999, ABPI, Rio de Janeiro, 1999, p.92. Nuno Carvalho has a PhD degree in Economic Law by UFMG and in Law by Washington University in St. Louis, EUA.

19. Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, London, Sweet & Maxwell, 1998, p.148.

*“The patentees’ bundle of exclusive rights must include the right to supply the market with imports of the patented products. Logically, the obligation to work patents locally under article 5A of the Paris Convention appears overridden by the right to supply imports.”*²⁰

Prof. Ruth L. Gana - PhD by the well-known Law School at Harvard University, professor at the University of Oklahoma and licensee researcher of the Max Planck Institute in Munich - agrees entirely with that. Prof. Ruth Gana demonstrates that the relationship between Paris Convention and TRIPs is not one of coexistence, but of derogation of the provisions of Paris Convention conflicting with TRIPs. Prof. Gana’s opinion is clear when establishes the prohibition of the local production requirement by TRIPs, derogating the option granted by article 5A(2) of Paris Convention:

“At first glance, the TRIPs Agreement seems to rely substantially on the Paris Convention. Indeed, some scholars have concluded that the two agreements may successfully, if not happily, coexist. Closer examination, however, shows that the Paris Convention simply provides a context for the TRIPs Agreement and not a standard. The Agreement, in reality, derogates from the effects of the Paris Convention.

The bite of Article 31 appears to be the curtailment of working requirements which, in the opinion of developed countries, undermine a patentee’s right. The TRIPs Agreement eliminates the use of working requirements as a condition to granting a patent.”²¹

It is worthy to notice that, although discussed in Brazil, the correct interpretation of TRIPs and the derogation of the option of the local manufacture requirement have never been object to doubts. Prof. Gervais, for instance, teaches in his work about TRIPs that article 2.2, when determining that nothing can derogate the existing obligations which the Members could have among each other, as a result of the Paris Convention, must be interpreted and applied in a much different way from that suggested only in Brazil:

“Article 2(2) thus confirms the fact that TRIPs is a “Paris-plus” agreement.... It is important to emphasize that Article 2(2) refers to obligations of Members, not to all provisions that have been incorporated into TRIPs. A number of those provisions allow contracting Parties to either limit the scope of a right or impose

formalities. These provisions do not create obligations for those Parties and may be derogated from in TRIPS."²²

Prof. Gervais, similarly to other impartial professors, certifies the error of the thesis created in Brazil for justifying the violation of the treaty.

At the other corner of the world, Prof. Michelle McGrath from the University of Sydney, Australia, has indeed demonstrated her disappointment in recognizing the thesis prevailing at the final text of TRIPS, but respecting its provisions:

"However, the major disappointment in this area is that under the combined effect of Articles 27 and 31, local working of the patent by the owner is not required so long as importation of patented products 'sufficient to meet local need' is provided."²³

Similarly, the work by Prof. Michael Blakeney, Chairman of the Law School at Murdoch University in Perth, Australia, also recognizes that the option comprised in article art. 5A(2) of Paris Convention is not available for TRIPS members, in the terms of articles 27.1 and 31:

"A contentious issue, which had been unresolved during the negotiations on the revision of Article 5A, was whether the importation of patented products could be considered to be a sufficient working of a patent. The Paris Convention in Article 5A(1) had disallowed the forfeiture of patents on the ground of importation by a patentee. Article 27 of the TRIPS Agreement attempts to resolve this issue by its insistence that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention ... and whether products are imported or locally produced"."²⁴

It is interesting to note that some theses trying to justify the legality of the local work requirement upon commitments undertaken by Brazil, with sovereignty, by occasion of TRIPS and WTO, suggest that the option granted by the non-literal interpretation of a provision of the Paris Convention is an unchangeable rule, which should prevail over any other, even if expressed and subsequent.

20. J.H. Reichman, *Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement*, 29 Int'l Law, 345, Summer 1995, p.352.

21. Ruth L. Gana, *Prospects for developing countries under the TRIPS Agreement*, 29 Vand. J. Transnat'l L. 735, 1996.

22. Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, London, Sweet & Maxwell, 1998, p.46.

23. Michelle McGrath, *The patent provisions in TRIPS: Protecting reasonable remuneration for services rendered – or the latest development in Western colonialism?* 7 EIRP 398 (1996).

24. Michael Blakeney, *Trade related aspects of intellectual property rights: A concise guide to the TRIPS Agreement*, London, Sweet & Maxwell, 1996, p.90-91.

Nevertheless, the UNCTAD representative in TRIPS negotiations, Abdulqawi A. Yusuf, clarifies that changes in international commitments undertaken in a treaty by another international treaty is a common occurrence in intellectual property area. According to Yusuf:

"It is not unusual of international agreements of a technical character to be often amended or revised. As stated earlier, the Paris Convention and the Berne Convention themselves have been revised on several occasions, each revision resulting in a new version of the original convention, which continued to exist. The states parties to the new version, or as it is called the most recent act of such a convention, are sometimes different from those that had subscribed to the original convention or to earlier versions.

What is unusual about the TRIPS Agreement is that not only one but several multilateral conventions are modified through the conclusion of a new treaty. Apparently, a basic objective of the proponents of a TRIPS Agreement was to avoid the time consuming amendment procedure of individual IPR conventions, and to work instead toward a comprehensive new agreement that would supplement and modify existing conventions. This has resulted in the conclusion of the most wide-ranging international agreement for the protection of intellectual property rights." ²⁵

Similar is the opinion of the chairman of the Intellectual Property Division of the World Trade Organization, Adrian Otten, the most graduated employee at WTO hierarchy, with technical responsibilities on the matter:

“The TRIPS Agreement adds a substantial number of additional obligations with respect to matters where the preexisting conventions were silent or were perceived as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Berne and Paris-plus agreement. While the TRIPS Agreement adds new obligations, it also aims to make more effective the application of the main preexisting conventions.” ²⁶

Hannu Wager, co-author of the article mentioned above, and also a graduated technician of WTO, has the same opinion. Both technicians of the World Trade Organization, impartial and experts in the matter, Adrian Otten and Hannu Wager, have determined, since 1996, the authentic and impartial interpretation of article 27.1:

*“Compulsory licensing and government use without the authorization of the right holder are allowed, but are made subject to fifteen conditions aimed at protecting the legitimate interests of the right holder. These conditions include the prohibition of discrimination in compulsory licensing as to the field of technology, the place of invention, and **whether products are imported or locally produced.**”*²⁷

During a specific presentation about some of the implications of TRIPs to pharmaceutical industry, Adrian Otten was even more incisive when said that:

*“Failure to meet the reasonable needs of the market can remain a ground for the grant of a compulsory license. But the compulsory licensing system must not provide for differential treatment according to whether the patent owner supplies the market through imports or local production.”*²⁸

This is an authentic, free, and unreserved interpretation of the most important technicians of the World Trade Organization about the TRIPs member States obligations. There is no doubt, according to the reports by Adrian Otten and Hannu Wager, that the requirement of local working, according to the provisions of article 68, 1st paragraph, I, of Law 9,279/96, infringes the international obligations contracted, in a sovereign and voluntary way, by Brazil within the international community.

The derogation of the option comprised in article 5A(2) of Paris Convention by article 27.1 of TRIPs has not surprised even those authors proven to be interested, who historically have profited from the inefficiency of the international system of intellectual property protection.

Even Carlos Correa, an Argentinean negotiator during the Uruguay Round and one of the most radical opponents to the international system of intellectual property protection, considered the current isolation position of Brazilian law, when he found in our law the only and sole post-TRIPs clause of local working requirement. Perceiving the imminent conflict, the author has extolled the WTO panel, now under discussion:

25. Abdulqawi A. Yusuf, *TRIPs: Background, principles and general provisions, in Intellectual property and international trade: The TRIPs Agreement*, Carlos M. Correa and Abdulqawi A. Yusuf Ed., United Kingdom, Kluwer Law International, 1998, p. 19-20.

26. Adrian Otten & Hannu Wager, *Compliance with TRIPs: The emerging world view*, Vand. J. Transnat'l L. Vol. 29:391, 1996, p.396.

27. Original text not underlined, Id., p. 401.

28. Adrian Otten - *GATT Secretariat, The implications of the results of the Uruguay Round for the protection of pharmaceutical inventions*, ALIFAR Annual International Forum on the Latin-American Pharmaceutical Industry, 12 May 1994, p.5. Please, note that the possibility demonstrated by the expert is foreseen on article 68, 1st Paragraph, II, of the Law.

“As commented above, article 27(1) of the Agreement (in accordance with which ‘patent rights shall be enjoyable without discrimination (...) whether the products are imported or locally produced’), has been interpreted as a prohibition of obligations requiring the industrial execution of the invention. Hence exploitation of the patent could be satisfied through importation.” ²⁹

*“The interpretation of this clause is debatable. Though Article 27.1 has been understood as prohibiting any obligation to execute a patented invention locally, this interpretation is not unanimous. Thus, the Brazilian Patent Law (1996) has included an obligation to exploit patented inventions locally. The interpretation of this article is likely to be finally settled under WTO procedures if a dispute thereon arises between WTO members.”*³⁰

It is important to highlight that the international community and Brazil were already aware of the pacific interpretation of article 27.1 of TRIPs, and of the limitation of local working requirement by the national system of a WTO member State.

In January 1995, the World Bank, through a specific publication by the technician in charge of topics related to intellectual property, who, ironically is a Brazilian citizen - Prof. Carlos A. Primo Braga, from USP – informed the correct interpretation of article 27.1. The World Bank's text informs that imports must be considered as patent exploitation, which cannot be bonded to local manufacture anymore:

*"In other words, importation should be accepted as meeting the obligation to work a patent. Accordingly, working obligations that require domestic execution of the invention - a common practice in developing countries - will not provide grounds for granting compulsory licenses anymore."*³¹

Thus, it is clear, according to the most renowned, impartial, and exempted international experts, that article 5A(2) of Paris Convention has been derogated by article 27.1 of TRIPs, discrediting the maintenance of complete manufacture of a patent object requirement in national laws of WTO member States, and, consequently, establishing the illegality of article 68, 1st Paragraph, I, of Law 9,279/96, according to WTO legal system.

The *Guide to the Uruguay round agreements*, an official publication by WTO Secretariat, widely used all over the world, well summarizes the matter: *"Compulsory licensing must also not discriminate between imports and local products."*³²

The correct interpretation in Brazil

Although the authors mentioned up to now are, most of them, from countries adopting the customary system (Common Law), Alberto Cerviño, from Spain, has come to the same conclusion.³³ That is, if the most classical lessons of continental and Brazilian law doctrines are applied, we would come to a similar result of such conflict analysis among legal provisions.

According to Hildebrando Accioly, *"in the hypothesis of incompatibility between two collective treaties, whose subscribers are the same, or when the second contains other subscribers, additionally to all of the first, naturally prevails the second"* (not underlined in the original text).³⁴

Therefore, we can say that Federal Senate law consultants understood quite well the extension of obligations comprised on articles 27.1 and 31 of TRIPs, as expressed by one of its members, Cícero Ivan Ferreira Gontijo, in an article published on the *Revista de Informação Legislativa*:

*"Regarding substantial points, GATT determines as follows: (...) g) preclude member States to require from patent holders the obligation of local production, by considering that imports must be sufficient to address the effective exploitation (art. 27.1)."*³⁵

29. Carlos A. Correa, *Patent Rights, in Intellectual property and international trade: The TRIPs agreement*, Carlos M. Correa and Abdulqawi A. Yusuf Ed., United Kingdom, Kluwer Law International, 1998, p. 208.

30. Carlos M. Correa, *Intellectual property rights, the WTO and developing countries, The TRIPs agreement and policy option*, London, Zed Books, 2000, p.91.

31. Carlos Primo Braga, *Trade-related intellectual property issues: The Uruguay Round agreement and its economic implications*, International Trade Division, World Bank, January 1995, p. 23.

32. *Guide to the Uruguay round agreements*, The WTO Secretariat, The Hague, p.215, 1999.

33. Alberto C. Cervino and Begona Cerro Prada, *GATT y propiedad industrial*, Madrid, Tecnos, 1994.

34. Hildebrando Accioly, *Tratado de Direito Internacional Público*, 2a edição, Rio de Janeiro, 1956, p. 572.

35. Cícero Ivan Ferreira Gontijo, "O acordo sobre propriedade intelectual contido no GATT e suas implicações para o Brasil", *Revista de Informação Legislativa*, Brasília, 32, 125, jan./mar. 1995, p.183.

The correct interpretation and the resultant infringement of international obligations undertaken by Brazil, in a sovereign and free manner, were also emphasized by Nuno Carvalho, in 1999, during the annual ABPI Seminar, which counted on the official participation of the National Institute of Intellectual Property, INPI. Nuno Carvalho, technical consultant to WTO at that time, is very clear in his conclusions:

“There has been some doubts about how article. 27,1st paragraph of the TRIPs agreement would coexist with Paris Convention, because of the incorporation by reference of its articles. The answer is simple: Paris Convention shall be applied by WTO members as adopted in Stockholm, in 1967, with the legal advancements adopted by TRIPs. Thus, for WTO members, patent exploitation as referred to on the 2nd paragraph of letter A, article 5 of the Paris Convention can be proven if imported products became available to consumers.

Please, note that this was not the only redirection in the provisions of Paris Convention by TRIPs. Article 21 of TRIPs, for example, states that a trademark holder may assign it without the need of transferring the site to which it belongs. Thus, TRIPs modified the authorization, implicit on article 6 *quater* of Paris Convention, so that members could require the assignment to occur only upon transferring the site or trade fund to which the trademark belongs.”

It is worthy to remember that the International Law Committee of the United Nations has already adopted the following text about treaties rights:

“1 A bilateral or multilateral treaty, or any provision in a treaty shall be considered null if its execution involves a rupture of a treaty-bonded obligation previously undertaken by one or more contracting parties...

4 The rule provided on paragraphs 1 and 2 does not apply to subsequent multilateral treaties, having a generality level lending them a law character and properly reaching all international community members, or must be considered as concluded in the scope of international interests. They also do not apply to treaties reviewing multilateral conventions in conformity with their provisions or, in the absence of such provisions, by a substantial majority of the portions of the reviewed convention.”³⁶

Accordingly, we must also understand that, because TRIPS text has not expressly adopted the institute of compulsory license by lack of “local working”, TRIPs forbids it. This understanding is based also on the fact that the draft discussed before the final project of the treaty, of 1991, named Brussels Draft, contained in its article 34(o), a composition allowing for compulsory license if four years after the patent request filing, or three years after granting it, the patent object has not been worked .³⁷ As the final draft of December 1991 has not adopted this proposal, by removing article 34 (o), it should be understood that the members do not accept the institute.

Upon so many exempted and distinct opinions, the thesis that a WTO member State could have a law containing a requirement of complete manufacture of a patent object in national territory, subjected to a compulsory license penalty, obviously infringes the commitments undertaken, in an exempted and sovereign manner, with the international community.

Conclusion

The unanimous, exempted and free interpretation of technicians, professors and renowned experts, proves the illegality of article 68, 1st paragraph, I, of Law 9,279/96, upon the international commitments undertaken by Brazil in a sovereign way, as well as article 27.1 of TRIPS. Those authorities also demonstrate that article 2.2 of TRIPs does not support the defense of the provision under discussion.

In Brazil, technicians, experts and Government employees have also demonstrated an identical opinion.

In conclusion, the Country waits for a Bill that may revoke Item I of article 68, 1st paragraph of Law 9,279/96, in order to not jeopardize efforts to the promotion of foreign investments and exports increase due to misconceptions in political decisions or to those aiming to conquer votes for the next elections.

36. Lauterpacht Report, about treaties law (U.N., doc. A/CN. 4/87, p. 35).

37. Doc. No.MTN.TNC/W/35/Rev.1 (Dec. 3, 1990). This document was subsequently called Brussels Draft. Brazil presented a joint communication with other countries in which the proposal of local manufacture obligation was described on article 5(2)(iii). The communication, delivered by document MTN.GNG/NG11/W/71, of May 14th, 1990, has not been accepted.