Brief Technical Review of Brazil's Proposed Patent Law Reforms

Limiting patent terms to 20 years with no extensions is TRIPS compliant:

Article 2 of Bill No. H.R. 5402/2013 limits patents to 20-year terms by revoking Article 40 of Law no. 92790 of 14 May 1996.[1] Article 33 of the TRIPS Agreement merely requires that "The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." There is no requirement in TRIPS that there be patent term extensions to compensate for regulatory delays either in the granting of a patent or in the registration/marketing approval of a medicine. In fact, the term of 20 years was adopted in substantial part to compensate for customary periods of regulatory delay. Accordingly, Article 40 of the current Patent Law, which grants patent protection beyond 20 years whenever the date of granting a patent exceeds 10 years, can properly be revoked.

As explained in the Report, a patent applicant in Brazil has an expectation of eventual patent grant and a right to seek retroactive damages from persons who infringe the pending patent once a patent has been granted. Thus, in a practical sense, patent applicants have de facto exclusive rights even during periods of delay. Admittedly, the Brazilian Patent Office should develop more capacity so that it may reduce its patent application backlog[2] and increase the quality of issued patents, where warranted, on a more reasonable time table.[3] Despite its current delays and stretched capacity, TRIPS does not require patent term extensions such as those in Article 40 of Brazil's Patent Act.

Disallowing patents on new uses or new forms of existing medicines is TRIPS compliant:

Article 3 of Bill No. H.R. 5402/2013, seeks to amend the Patent Law to add Article 10.X and XI in the following way:

> Art. 10. [The following are not considered to be inventions or utility models:]
> X – any new property or new use of a known substance, or the mere use of a known process, unless this known process results in a new product;
> XI – new forms of known substances that do not result in an improvement in the known efficacy of the substance.
>
> For the purposes of this Article, salts, esters, ethers, polymorphs, metabolites, pure form, size of particles, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they significantly differ in terms of properties regarding efficacy.

[1] "The term shall not be less than 10 (ten) years for patents and 7 (seven) years for a utility model, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial dispute or for reasons of *force majeure*."

[2] The TRIPS Agreement Article 62.2 does require some reasonable degree of timeliness in rendering patent decision:

> Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

[3] It should also be noted that delays can result from applicant behavior, such as aggressive seeking of patents of poor quality, which require lengthy review and narrowing in the application process.

This provision mirrors one that has been in place in India for eight years, and that has been upheld against challenge by the multinational pharmaceutical industry in Indian courts. The stated purpose of these provisions is to prevent the practice of evergreening, the granting of new 20-year patent monopolies on the basis of minor or trivial changes to a known substance or on the basis of easily discovered new uses of existing substances. The "efficacy" standard suggests that there may be an inventive step worth patenting if the product shows significant or dramatic improvement in therapeutic efficacy.[4]

Article 27.1 sets for the basic standards of patentability under TRIPS: "[P]atents 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* (emphasis added)."

The terms new, inventive step and industrial application are not further defined and Members are granted substantial interpretive freedom to adopt loose or strict standards of patentability according to their own needs and circumstances, subject only to meeting the treaty's minimum requirements. Indeed there is substantial variation in precise patenting standards between Europe, the U.S. and other WTO Members, and many countries overtly limit the scope of patentability in various ways. (See, for example, the recent US Supreme Court case, *Association for Molecular Pathology v. Myriad Genetics* (2013), which held that US law forbids patents on genes.). Members' interpretive freedom is expressly set forth in Article 1.1 of the TRIPS Agreement, which states that: "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." This interpretative freedom is amplified by Articles 7[5] and 8[6], dealing respectively with mutual advantages for owners and users of IP and the right to promote public interest and public health and to prevent abuse of IPRs. These provisions were further amplified by the Doha Declaration on the TRIPS Agreement and Public Health, which confirmed that Members to prioritize public health and access to medicines for all:

> 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. [7]

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[4] Whether Brazil intends that this provision incorporates the Indian requirement that there be enhanced therapeutic efficacy in the treatment or prevention of human disease is unclear, but the Novartis v. Government of India decision by the Supreme Court of India has been referenced favorably in the report.

[5]

> 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.

[6]

> 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.
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> 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 technology.

[7] WT/MIN(01)/DEC/2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

There are additional justifications concluding that patents on new uses and new methods of use are not required by TRIPS. As explained in the Report, the inventions forbidden by the new proposed provision are, and should be expressly understood, as mere codifications of longstanding requirements of patent law. The proposed provisions thus represent the considered view of the drafters that new uses and new forms of existing substances (without significantly enhanced efficacy) should not be considered "inventions" per se due to lack novelty and/or inventive step.

New uses are ordinarily discovered through routine/obvious investigations of existing, not new, substances and thus lack novelty and/or inventive step. New uses and methods of use may be considered more in the form of abstract ideas than of a new industrial product. Finally, TRIPS Article 27.3(a) allows Member to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans … ." A new use of a known medical substance is a new therapeutic use and thus can be excluded from patentability.

With respect to denying patents on new forms of existing chemical entities, Brazil is following in the shoes of section 3(d) of the India Amended Patents Act 2005, including an exception where the new form results in a significant improvement in the known efficacy of the product. Here again, the listed variations in form are often pre-existing, e.g., in polymorphs, or they are mere discoveries routinely made in the process of trying to optimize the active pharmaceutical entity in terms of stability, solubility, etc.

Heightening the inventive step requirement is also TRIPS compliant:

Article 3 of Bill No. H.R. 5402/2013, seeks to amend the Patent Law Article 13: "The invention carries inventive activity when, for a person skilled in the art, it does not derive in an obvious or evident manner from the state of the art, and provided it represents *a significant technical advance in regards to the state of the art*." For the reasons outlined in the discussion above, Brazil may adopt heightened standards for inventive step just as it proposes to do with respect to excluding new uses and new form of known substances from being inventions. Jurisdictions around the world, including the Supreme Court in the United States,[8] are taking steps to tighten up inventive step analysis so as to avoid granting 20-year monopolies on minor or trivial advances in the art.

Adopting opposition procedures is fully TRIPS compliant:

Article 3 of Bill No. H.R. 5402/2013, seeks to amend Patent Law Article 31 to allow full-fledged opposition procedures:

> From the publication of the patent application until the end of the exam, any interested party may file an opposition.
>
> > § 1 The applicant shall be notified of the opposition through publication in the official gazette, and may respond within 60 days from the publication of the opposition.
> >
> > §2 In cases where an opposition to a patent application is filed, the Brazilian Patent Office may commission technical opinions from the Public Administration, from

[8] *See, e.g., KSR Intern. Co. v. Teleflex Inc*., 127 S.Ct. 1727, 1741-43 (2007) (increasing the obviousness standard in the U.S.); see also *Pfizer v. Apotex, Inc*., 480 F.3d 1348, 1362 (U.S. Fed. Cir. 2007) (invalidating a new form salt patent as obvious, and suggesting that most salt selection patent are obvious under U.S. law).

> organizations recognized by the Government as consultancy bodies, and from university professors and students.
> § 3 After the opposition is filed, the examiner may, upon justified demand, application any additional clarification he/she deem necessary, as well as the presentation of supplementary documents.
> § 4 The examiner shall mandatorily respond to each filed opposition, indicating the reason by which he/she accepts or rejects the arguments presented.

Article 4 of Bill No. H.R. 5402/2013 seeks to the amend the Patent Law to add Articles 31-A also dealing with opposition procedures by allowing electronic submissions of relevant information:

> Art. 31-A. The Brazilian Patent Office shall offer an intuitive electronic channel, of easy access, connected to the Internet, for any person to present, free of charge, evidence or proof of previous existence, in Brazil or abroad, of the related invention or state of the art.
> It shall be allowed the presentation of evidence or proof of prior existence, in Brazil or abroad, of the related invention or state of the art, even after a patent is granted, and especially during the opposition and the post-grant opposition procedures.

The TRIPS Agreement indirectly references Members' rights to have opposition proceedings in Article 62.4:

> Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and inter partes procedures such as *opposition*, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41 (emphasis added).

There is nothing in TRIPS otherwise referencing or limiting the adoption of opposition procedures – indeed TRIPS Article 62.1 allows Members to require certain procedures and formalities. Here, relying on favorable precedent elsewhere,[9] Brazil has proposed to adopt eminently reasonable opposition procedures that (1) allow pre-grant opposition by any interested party until the end of the patent examination, (2) allow the patent applicant to respond with 60 days of the publication of the opposition, (3) allow the commission of expert technical opinions, (4) may require clarifications from the patent applicant, and (5) mandates written and reasoned response to each filed opposition. Such procedures are desirable to add to the quality of patent examinations by securing inputs and analysis that can help deter and appropriately reject unmeritorious patent applications.

Rejecting data exclusivity is TRIPS compliant:

Article 3 of Bill No. H.R. 5402/2013 seeks to amend the Patent Law Article 195 to add § 3: "The provision set forth under item XIV does not apply to the use, by government bodies, of test results or other undisclosed data, for market approval of products equivalent to the product for which they were initially presented."

Article 39.3 of the TRIPS Agreement provides for data protection, but not data exclusivity/monopoly:

[9] WIPO, Standing Committee on the Law of Patents, Opposition Systems, SCP/17/19 (Oct. 31, 2011), available at http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_17_9.pdf.

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Brazil's Patent Law Article 195.XIV fully provides for these limited degrees of protection both with respect to unfair commercial use and unlawful disclosure:

> A crime of unfair competition is perpetrated by anyone who:
>
> > XIV. divulges, exploits, or utilizes, without authorization, results of tests or other undisclosed data whose preparation involves considerable effort and that were submitted to government agencies as a condition for obtaining approval to commercialize products.

Unfortunately, Brazilian courts have begun to interpret this limited provision as essentially requiring data exclusivity instead of data protection. To correct this misinterpretation, Article 3 of Bill No. H.R. 5402/2013 seeks to clarify that the acts of government bodies may lawfully use or rely on undisclosed data for the purpose of granting market approval or equivalent products. This interpretation is fully consistent with the state practice of many countries and with the weight of expert commentary on this subject.[10]

Involving ANVISA in the patent examination process and requiring its prior consent is TRIPS compliant:

Article 3 of Bill No. H.R. 5402/2013, seeks to amend the Patent Law Article 195 to add Article 229-C:[11]

> The granting of patents for pharmaceutical products and processes shall depend on the prior consent from the National Sanitary Agency - ANVISA, that shall examine the object subject to the patent application in light of public health.
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> § 1 A patent application shall be considered as contrary to public health, according to further regulation, where:
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> > I-the product or pharmaceutical process in the patent application present a health risk, or

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[10] *See*, *e.g.*, World Health Organization, *Briefing note: access to medicines. Data exclusivity and other TRIPs-plus measures* (2006), available at http://209.61.208.233/LinkFiles/IPT_Briefing_note2_Data_exclusivity.pdf; Carlos Correa. *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement*. *South Centre, University of Buenos Aires and Department of Essential Drugs and Medicines Policy of the World Health Organization* (2002), available at http://www.who.int/medicines/areas/policy/protection_of_data.pdf; Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303-344 (2008)

[11] Article 5 of Bill No. H.R. 5402/2013 also would amend Law no. 9782 of 26 January 1999 with respect to the duties of ANVIA:

> The Sanitary Agency shall implement and enforce the provisions set forth under sections II through VII of Art. 2 of this Law, and the Agency shall:
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> > XXVIII – participate in the process of examination of patent applications for pharmaceutical products and processes, including the analysis of the patentability requirements and the other criterion set forth under the specific legislation.

II - the patent application for pharmaceutical product or pharmaceutical process is of interest to an access to medicines policy or to a pharmaceutical care program under the National Health System - SUS, and provided that it does not meet the patentability requirements and the other criteria established by this law.

§ 2 Following the prior consent examination and after the decision is published, ANVISA shall return the application to the Patent Office, that shall examine the approved application, and definitely archive the application that has not been approved.

As discussed above in the section on pre-grant oppositions, Brazil has freedom under the TRIPS Agreement to design its own mechanisms for examining and granting patents and need not do so under the auspices of a single administrative agency, i.e., a patent office. We anticipate that this provision might be challenged as out of compliance with the requirements of the TRIPS agreement, particularly the provisions of TRIPS Article 27 that ban discrimination by field of technology and that require that patents "shall be available" for any new inventions "provided that they are new, involve an inventive step and are capable of industrial application." We think such a challenge would be unmeritorious.

First, we read section 1(I) above to implement the TRIPS Article 27(3) authorization to exclude from patentability any invention that "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."[12] Second, section 1(II) permits ANVISA to reject certain classes of patents that fail to meet "the patentability requirements and the other criteria established by this law" if, in addition, the invention is determined to be "of interest to an access to medicines policy or to a pharmaceutical care program under the National Health System." This provision thus sets up a different system for examining medicines patents than exist for other types of inventions, which we understand merely to select certain patents for careful review, and not to apply anything beyond the usual substantive requirements for the grant of those patents. Here, Brazil confirms a historic national judgment that the expertise of ANVISA is a useful guarantor of patent quality in the pharmaceutical context, and the reasonable view that patent quality is particularly important with respect to medicines that are central to Brazil's access to medicines policy and its pharmaceutical care program. In this regard it should be noted that a WTO panel has held that the word "discrimination" in TRIPS Article 27 does not ban all differentiation by field of technology.[13] It permits differentiation that has a reasonable justification and this provision may pass muster as long as Brazil can adequately document that justification, as it has by relying on ANVISA's special expertise.[14]

Adopting clear guidance for government use (public, non-commercial use) is fully TRIPS compliant under Article 31:

Article 3 of Bill No. H.R. 5402/2013, seeks to amend the Patent Law to add Article 43-A:

[12] To bolster this interpretation, the legislation might consider amendments to more clearly apply this authorization, such as stating in section 1(I) that ANVISA may reject an application -- "the prevention of the commercial exploitation of which in Brazil is necessary to protect human health."

[13] *Canada – Pharmaceutical Products*, WTO Dispute DS114 (2000), available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

[14] It should be noted that Doha Agreement on TRIPS and Public Health itself singles out pharmaceuticals for special treatment by TRIPS members, condoning policies needed to promote "access to medicine for all." U.S. policy as well frequently singles out pharmaceuticals for special and favorable patent treatment, including through special patent extensions and particular rules of data protection applicable only to that field of technology.

The Government, by Ordinance from the Minister of State concerned, may use the subject matter of a patent or of a patent application, for non-commercial purposes, without consent or authorization from the patent holder or patent applicant, directly or upon contract or authorization to third parties, for public interest purposes, including national defense and social interest.

§ 1 Should the invention be a process, the public non-commercial use of the patent or patent application shall include the use in relation to any product that may be obtained by the process that is protected by the patent or the patent application;

§ 2 The Government shall notify the patent holder or patent applicant upon public non-commercial use;

§ 3 Public non-commercial uses shall meet the following conditions:

I – not hinder the full exercise of the other rights of the patent holder or patent applicant;

II – be non-exclusive, and not admit sub-licensing;

III – be undertaken exclusively to serve the goals of the Ordinance that authorized it, resting assured that any other use that, without the character of public non-commercial use, would constitute an infringement of Art. 42 of this Act, is hereby prohibited;

§ 4 The remuneration for public non-commercial use shall be set by the Government, taking into account the circumstances of each use, shall take into account the percentage that would customarily incur upon a voluntary license between independent parties, applied over the cost for the Government resulting from the use of the subject matter of a patent or patent application, and weighed according to the collaboration supplied by the patent holder in the transfer of technology;

§ 5 In the case of patent applications, the remuneration shall be legally deposited until the granting of the patent;

§ 6 The Judiciary shall not, in regards of public non-commercial use, decide whether public interest purposes apply;

§ 7 Public non-commercial uses shall not be lifted, limited or interrupted by legal appeal over the appointed remuneration.

Brazil's proposed adoption of an explicit mechanism for granting government use licenses is fully legal under Article 31 of the TRIPS Agreement. Article 31 directly references the right of "involuntary use" for "public, non-commercial uses" such as those described in proposed Article 43-A. In such instances, Article 31 does not require that the government or its proposed licensee engage in prior negotiations with the patent holder seeking commercially reasonable terms and instead merely requires notification and eventual payment of adequate remuneration, a requirement amply fulfilled by § 4. Moreover, the adoption of remuneration guidance, like that contained in § 4 is permissible under TRIPS.[15] In addition to providing for proper purposes, notification to patent holders/applicants, and payment to right holders, the Brazilian proposal also follows requirements with respect to continued use of the patent by the patent-holder, non-exclusivity, and disallowance of sub-licensing.

[15] James Love, Remuneration Guidelines for Involuntary Use of Medical Technologies, WHO and UNDP, Health Economics and Drugs, TMC Series No. 18 (2005), available at http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf.

Brazil has adopted some unique and highly desirable additional provisions, all of which, in our judgment, are TRIPS compliant. First, it allows a government use license during the period of patent examination and before the patent is granted, conditioned on the legal deposit of remuneration pending grant of the patent. Article 31 does not directly discuss pre-grant government use licenses, nor does it prevent them. With this provision, Brazil has confirmed that government use licenses may, as a measure of extra security, be issued even before patent status is determined, so that the uncertainty during the pendency of a patent examination is not a barrier to Brazil's sovereign right to implement a government use license. Second, Brazil confirms that the public-interest grounds of the license – public, non-commercial use alone suffices – are a matter for the elected branches to determine, and are not subject to substantive review by the judiciary. The law also does not allow courts to enjoin or interrupt the government use during the course of review of the amount of remuneration, a measure that is also TRIPS compliant under TRIPS Article 42.

Conclusion:

Although this is a necessarily brief examination of Brazil's proposed patent law reform, this technical review does confirm the TRIPS compliance of the measures discussed herein. Granting fewer and higher-quality patents, limiting patent terms, avoiding data monopolies, and guaranteeing the right of government use will go a long way in ensuring that Brazil is able to meets its human rights obligations while gaining technological expertise, building its industrial base, increasing skilled employment, and becoming more innovative and self-reliant with respect to knowledge goods.

ANNEXES

ANNEX I

BILL NO. H.R. 5402/2013
(DR. NEWTON LIMA, AND DR. ROSINHA)

Amends the Patent Act no. 9279/96, of 14 May 1996, to revoke the sole paragraph of Art. 40, modify Articles 10, 13, 14, 31, 195 and 229-C, and add Articles 31-A and 43-A; and amends Article 7 of Law no. 9782, of 26 January 1999.

The National Congress enacts:

Art. 1 This law revokes the sole paragraph of Art. 40; amends Articles 10, 13, 14, 31, 195 and 229-C; and adds Articles 31-A and 43-A, all in Law no. 9279/96, of 14 May 1996; and amends Art. 7 of Law no. 9782, of 26 January 1999.

Art. 2 The sole paragraph of Art. 40 of Law no. 9279 of 14 May 1996 is revoked.

> [Sole Paragraph. The term shall not be less than 10 (ten) years for patents and 7 (seven) years for a utility model, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial dispute or for reasons of *force majeure*.]

Art. 3 Articles 10, 13, 14, 31, 195 and 229-C of Law no. 9279 of 14 May 1996 shall be amended as follows:

"Art. 10. [The following are not considered to be inventions or utility models:]

.....

X – any new property or new use of a known substance, or the mere use of a known process, unless this known process results in a new product;

XI – new forms of known substances that do not result in an improvement in the known efficacy of the substance.

Sole paragraph. For the purposes of this Article, salts, esters, ethers, polymorphs, metabolites, pure form, size of particles, isomers, mixtures of isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they significantly differ in terms of properties regarding efficacy." (new text)

"Art. 13. The invention carries inventive activity when, for a person skilled in the art, it does not derive in an obvious or evident manner from the state of the art, and provided it represents a significant technical advance in regards to the state of the art." (new text)

"Art. 14. The utility model carries inventive activity when, for a person skilled in the art, it does not derive in a common or vulgar fashion from the state of the art, and provided it represents a technical advance in regards to the state of the art." (new text)

"Art.31. From the publication of the patent application until the end of the exam, any interested party may file an opposition.

§ 1 The applicant shall be notified of the opposition through publication in the official gazette, and may respond within 60 days from the publication of the opposition.

§2 In cases where an opposition to a patent application is filed, the Brazilian Patent Office may commission technical opinions from the Public Administration, from organizations recognized by the Government as consultancy bodies, and from university professors and students.

§ 3 After the opposition is filed, the examiner may, upon justified demand, application any additional clarification he/she deem necessary, as well as the presentation of supplementary documents.

§ 4 The examiner shall mandatorily respond to each filed opposition, indicating the reason by which he/she accepts or rejects the arguments presented.

……" (new text)

"Art. 195. [A crime of unfair competition is perpetrated by anyone who:]

……

> [XIV. divulges, exploits, or utilizes, without authorization, results of tests or other undisclosed data whose preparation involves considerable effort and that were submitted to government agencies as a condition for obtaining approval to commercialize products.]

§ 3 The provision set forth under item XIV does not apply to the use, by government bodies, of test results or other undisclosed data, for market approval of products equivalent to the product for which they were initially presented." (new text)

"Art.229-C. The granting of patents for pharmaceutical products and processes shall depend on the prior consent from the National Sanitary Agency - ANVISA, that shall examine the object subject to the patent application in light of public health.

§ 1 A patent application shall be considered as contrary to public health, according to further regulation, where:

I-the product or pharmaceutical process in the patent application present a health risk, or

II - the patent application for pharmaceutical product or pharmaceutical process is of interest to an access to medicines policy or to a pharmaceutical care program under the National Health System - SUS, and provided that it does not meet the patentability requirements and the other criteria established by this law.

§ 2 Following the prior consent examination and after the decision is published, ANVISA shall return the application to the Patent Office, that shall examine the approved application, and definitely archive the application that has not been approved." (new text)

Art. 4. Articles 31-A and 43-A shall be added to Law no. 9279 of 14 May 1996:

Art. 31-A. The Brazilian Patent Office shall offer an intuitive electronic channel, of easy access, connected to the Internet, for any person to present, free of charge, evidence or proof of previous existence, in Brazil or abroad, of the related invention or state of the art.

Sole paragraph. It shall be allowed the presentation of evidence or proof of prior existence, in Brazil or abroad, of the related invention or state of the art, even after a patent is granted, and especially during the opposition and the post-grant opposition procedures.

Art. 43-A. The Government, by Ordinance from the Minister of State concerned, may use the subject matter of a patent or of a patent application, for non-commercial purposes, without consent or authorization from the patent holder or patent applicant, directly or upon contract or authorization to third parties, for public interest purposes, including national defense and social interest.

§ 1 Should the invention be a process, the public non-commercial use of the patent or patent application shall include the use in relation to any product that may be obtained by the process that is protected by the patent or the patent application;

§ 2 The Government shall notify the patent holder or patent applicant upon public non-commercial use;

§ 3 Public non-commercial uses shall meet the following conditions:

I – not hinder the full exercise of the other rights of the patent holder or patent applicant;

II – be non-exclusive, and not admit sub-licensing;

III – be undertaken exclusively to serve the goals of the Ordinance that authorized it, resting assured that any other use that, without the character of public non-commercial use, would constitute an infringement of Art. 42 of this Act, is hereby prohibited;

§ 4 The remuneration for public non-commercial use shall be set by the Government, taking into account the circumstances of each use, shall take into account the percentage that would customarily incur upon a voluntary license between independent parties, applied over the cost for the Government resulting from the use of the subject matter of a patent or patent application, and weighed according to the collaboration supplied by the patent holder in the transfer of technology;

§ 5 In the case of patent applications, the remuneration shall be legally deposited until the granting of the patent;

§ 6 The Judiciary shall not, in regards of public non-commercial use, decide whether public interest purposes apply;

§ 7 Public non-commercial uses shall not be lifted, limited or interrupted by legal appeal over the appointed remuneration.

Art. 5. Article 7 of Law no. 9782 of 26 January 1999 shall be amended as follows:

"Art. 7. [The Sanitary Agency shall implement and enforce the provisions set forth under sections II through VII of Art. 2 of this Law, and the Agency shall:]

.....

XXVIII – participate in the process of examination of patent applications for pharmaceutical products and processes, including the analysis of the patentability requirements and the other criterion set forth under the specific legislation.

Art. 6. This law shall come into force within one hundred and twenty (120) days from the date of its publication.