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Newsletter

No. 154

May, 2001

Re.: Amendments to Brazilian Patent Law:

- **Regulatory review exception to patent rights; and**
- **Pharmaceutical patent applications have a new patentability requirement: the prior approval by Brazilian Health Authorities**

LAW 10,196 AMENDS THE BRAZILIAN PATENT LAW AS OF FEBRUARY 16, 2001, INCORPORATING CHANGES PREVIOUSLY MADE BY PROVISIONAL RULING 2,105-15.

Law 10,196, of February 14, 2001, effective as of February 16, 2001, has amended the Brazilian patent law (Law 9,279), incorporating changes brought about by Provisional Ruling 2,105 (see our Newsletters 151 and 151a).^{*} The 10,196 statute creates a new patentability requirement for applications claiming pharmaceuticals, statutorily rejects many pending applications that would potentially benefit from articles 70.2 and 70.7 of the WTO's TRIPS

^{*} *Provisional Rulings are de facto laws enacted by the President and subject to subsequent ractification by Congress (when a law is enacted to substitute the Provisional Ruling, such as Law 10,196 commented herein). Provisional Ruling 2,105 was initially numbered 2,006, then 2,014 (with several re-editions), terminating with Provisional Ruling 2,105.*

Agreement and further limits the patent owner exclusive rights by creating a regulatory review exception to the patent rights.

According to the new section VII of article 43, the country's patent law has now a regulatory review exception to the exclusive rights granted by a Brazilian patent, providing that acts done by unauthorized third parties relating to the patented invention carried exclusively to produce information, data and test results to seek market approval in Brazil or abroad, in order to exploit or commercialize the patented product after the term set by article 40 has expired shall not constitute infringement of the patent owner exclusive rights.

It is important to remember that the Brazilian regulatory review exception was implemented without any consideration to a system of restoration of patent term due to delays in the pioneer drug approval process.

Also introduced into the patent law by the new statute is a fourth requisite of patentability, in addition to novelty, industrial applicability and inventive step. This new requisite applies exclusively to patent applications claiming pharmaceutical products or processes. Article 229-C now establishes that any patent claiming pharmaceutical products or processes might only be issued after receiving approval from the national sanitary agency (ANVISA). The new statute does not establish any standard that pharmaceutical patent applicants shall meet in order to obtain the mandatory prior approval, making the grant of the prior consent for a pharmaceutical patent a discretionary act.

According to the Official Notice 02/2001 (annexed) published on April 17, 2001, by the Brazilian Director of Patents of the BPTO, this new requirement applies to both regular pending applications as well as the remaining pending pipeline applications not yet issued.

The Brazilian PTO has established that after the conclusion of the technical examination, the examiner will not publish a notice of allowance of an application claiming pharmaceutical product or process but a notice stating the technical examination has been concluded and that the patent application meets the requirements established by articles 8 to 36 of the patent law. The notice will further condition the notice of allowance and issuance of the application to the consent required by article 229-C of the Law 9,279/96, as amended by the herein commented Law 10,196.

After the publication of said notice, the entire file will be sent to ANVISA, for the Agency's prior approval. ANVISA has never examined patent applications before but has hired approximately 30 people to analyze the applications. ANVISA staff has been hired partially with funds from the United Nations Development Program and has received more than 30 days of training into patent law, prosecution, classification and examination.

Law 10,196 has further altered article 229 of the patent law to consider statutorily denied all pending applications filed before December 31, 1994, claiming products or processes for obtaining or modifying pharmaceutical products/medicaments, or processes for obtaining or modifying alimentary products. Applications withdrawn and re-filed under the pipeline provisions (arts. 230 and 231 of Law 9,279/96) are excluded from this statutory rejection.

Comments already made in our previous Newsletters 151 and 151a are still valid and applicable. The main practical implications of this amendment to the patent law are:

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- 1 No application filed after May 15, 1997 will be affected by this Law, as far as patentable subject matter is concerned;
 - 2 A new patentability requirement for pharmaceutical patents has been created, as per Article 229-C: "The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from the National Sanitary Supervision Agency (Agência Nacional de Vigilância Sanitária - ANVISA)." ANVISA is the Federal regulatory agency that approves pharmaceutical products for marketing;
 - 3 Applications claiming pharmaceutical products, medicaments, alimentary products, as well as the respective processes for obtaining them, filed before December 31, 1994, not converted into "pipeline" applications by May 15, 1997, will be considered rejected;
 - 4 Applications filed between January 1st 1995 and May 15, 1997, claiming pharmaceutical products or products for use in agriculture (Art. 70.8 of the TRIPs), will be analyzed as per Law 9,279/96;
 - 5 Applications filed between January 1st 1995 and May 15, 1997, claiming processes for obtaining/modifying pharmaceutical products, medicaments and alimentary products will be considered rejected;
 - 6 Applications claiming chemical products not comprehended in the previous paragraphs, filed before May 15, 1997, not converted into "pipeline" applications, will be considered rejected.

We call your special attention to item 5, above. Applications claiming such subject-matter, filed in such time-interval, will be rejected, even if they have been re-filed under the pipeline provisions.

Our comments reflect a possible interpretation to be given to Law 10,196. However, no official statement was issued by the BPTO before this newsletter was sent to print in addition to the Official Notice 02/2001 from the Office of the Director of Patents of the BPTO.

Should you need further information, please contact any of our attorneys or email us at momsen@leonardos.com.br.

**Ministry of Development, Industry and Foreign Trade
Brazilian Patent and Trademark Office
Office of the Director of Patents**

OFFICE OF THE DIRECTOR OF PATENTS

April 2, 2001

Official Notice 02/2001 from the Director of Patents of the BPTO:

Article 229-C of the Law 9.279/96, amended by Law 10,196, of 2001, establishes that:

“Art. 229-C. The granting of patents claiming pharmaceutical products or processes shall be dependent on prior consent from the National Sanitary Surveillance Agency – ANVISA)”

In order to enact the provision above, the BPTO must examine patent requests for pharmaceutical products or processes on a normal basis, until the final conclusion. On this stage, the requirements shall be made and the applicant parties shall be officially called to present their usual reply.

When the BPTO decides for the granting of the patent, the corresponding notice 9.1 (granting) of the BPTO Gazette shall not be published and notice 7.4 - “Notice related to article 229-C of the Industrial Property Law”, now implemented, shall be published instead. The BPTO Gazette will publish:

“The technical examination concluded that the patent application meets the requirements established by articles 8 to 36 of the Industrial Property Law. The granting of the patent depends on the consent described in art. 229-C of Law 9.279/96, as amended by Law 10,196/2001”.

Then, the application shall be sent to ANVISA and, after it returns to the BPTO, the appropriate notice, such as the “granting” of item 9.1, shall be published.

When the BPTO decides for the granting of the patent application that were filed according to article 229 to 231 of the Industrial Property Law (“pipeline”), the corresponding notice 23.13 of the BPTO Gazette shall not be published and notice 23.17 “Notice related to article 229-C of the Industrial Property Law”, now implemented, shall be published instead. The BPTO Gazette will publish:

“The technical examination concluded that the patent request meets the requirements established by articles 229 to 231 of the Industrial Property Law. The granting of the patent depends on the consent described in article 229-C of Law 9.279/96, as amended by Law 10,196/2001”.

Then, the request will be sent to ANVISA and, after it returns, the appropriate notice, such as the “granting” of notice 23.13, shall be published.

(signed):

Luiz Otávio Beaklini
Director of Patents