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NEW JERSEY INTELLECTUAL PROPERTY LAW ASSOCIATION - NJIPLA

January Dinner Meeting

Biopharma IP Issues in Emerging Markets: Brazil and India

Wednesday, January 18, 2012 6:00 p.m.

Newark Club, 1085 Raymond Blvd., Newark

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1. Exclusive Marketing Rights

Exclusive Marketing Rights – EMRs are foreseen in Article 70.9 of the Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS. EMRs would be granted by countries where pharmaceutical and agrochemical products are temporarily not possible to be protected by patent (such protection is one of the World Trade Organization – WTO members' obligation) from the date when TRIPS came into force (i.e., January 1, 1995). In this sense, the applicants seeking patent protection for this sort of products can file its application before the local patent office for priority purposes, while a new Intellectual Property Law in accordance with

the TRIPS Agreement does not come into force in that Member, procedure known as mailbox system. It is important to highlight that EMRs are not available for inventions comprising agrochemical and pharmaceutical processes, but only products.

According to Article 70.9, EMRs should last for 5 (five) years from the date when such product obtained the marketing approval in that country or until a decision regarding its patentability is rendered by its national patent office, whichever happens first. It is important to stress, however, that EMR can only be granted after the pharmaceutical or agrochemical invention has already been patented in other country and obtained the corresponding marketing approval there.

Note that EMRs are set out in the TRIPS Agreement as a transitional rule for the countries that had not protected inventions in the agrochemical and pharmaceutical fields. In fact, while this group of countries had not updated its IP law, the mailbox system and consequently the EMR were available in the legislation of these countries (for instance, India had up to 10 years to apply TRIPS' provisions regarding the patentability of this kind of inventions) . As a matter of fact, such understanding was reinforced by the Appellate Board of WTO Dispute Settlement Body during the dispute WT/DS50 (US vs. India):

> "By its terms, Article 70.9 applies only in situations where a product patent application is filed under Article 70.8(a) [mailbox system]. Like Article 70.8(a), Article 70.9 applies 'notwithstanding the provisions of Part VI'. Article 70.9 specifically refers to Article 70.8(a), and they operate in tandem to provide a package of rights and obligations that apply during the transitional periods contemplated in Article 65. It is

obvious, therefore, that both Article 70.8(a) and Article 70.9 are intended to apply as from the date of entry into force of the WTO Agreement."

A simple scheme of EMRs protection is available below:

- A mailbox application for a pharmaceutical/agrochemical invention is filed in a country A;
- A patent application for the same invention is filed before the patent office of country B;
- The country B grants a patent for it and, afterwards, its corresponding marketing approval;
- EMRs must be approved for this same product in the country A.

  Provided that on January 1, 1995:
  Country A does not comply with provisions for in Article 27, TRIPS
  Country B has an IP law already in accordance with TRIPS

Some companies filed lawsuits against ANVISA seeking the granting of EMRs. They argued that, since in the Brazilian system of Law international treaties have the same status as ordinary laws passed by the Brazilian Congress, there was no need of further regulations. In fact, at some point, the BPTO even granted certifications indicating that the patent applicant complied with EMR requirements under TRIPS rules.

However, Brazilian Industrial Property Law no. 9,279 was enacted on May 14, 1996 and its transitional period started on January 1, 1995 (when TRIPS came into force) and ended on May 14, 1997 (as the Braz. IP Law came into force on May 15, 1997). As per provisions of Section 229, sole paragraph, of Law no. 9,279, patent applications for pharmaceutical and agrochemical products filed during the transitional period were analyzed in

accordance with the new provisions, which already granted protection for this sort of products. Therefore, some scholars understand that the mailbox system has never been available in Brazil, since the applications filed during the transitional period were analyzed in accordance with the new law, reason why there was no need of EMRs being available in Brazil.

Furthermore, EMRs have never been regulated in Brazilian Law and, according to WTO's understanding, "the TRIPS Agreement is different from other covered agreements in that most of its provisions requires Members to take positive action; in this particular case to grant exclusive marketing rights pursuant to Article 70.9" (WT/DS50).

The GEMZAR® case

In 2001, a lawsuit was filed before the 16th Civil Trial Court of Brasília against ANVISA seeking EMR for GEMZAR® (gemcitabine). The Judge initially denied the injunction relief requested by Eli Lilly stating that (i) there is no statute regulating exclusive marketing rights in Brazil, and (ii) the patent application that grounded the filing of the lawsuit claims a pharmaceutical process – not a product. Eli Lilly filed an interlocutory appeal challenging this decision and the Reporting Judge Fagundes de Deus (from the Federal Court of Appeals for the 1st Circuit) granted the interlocutory appeal, thus preventing ANVISA from granting marketing approval for similar drugs. Nevertheless, the decision rendered by Reporting Judge Fagundes de Deus was subsequently overruled by the Superior Court of Justice (Superior Tribunal de Justiça – STJ), which understood that such decision was contrary to public interest.

Due to the filing of the aforementioned lawsuit, as well as other measures that were taken by Eli Lilly to prevent the local industry from manufacturing

and trading generic drugs (which Eli Lilly understood that were infringing its rights), Eli Lilly is currently under investigation of SDE – Secretaria de Direito Econômico (Ministry of Justice's body which is similar to the Antitrust Division of the U.S. Department of Justice) for allegedly practicing sham litigation. By the way, we are aware that other pharmaceutical companies are under investigation for the same reasons as well, namely: Abbot, Genzyme and Lundbeck.

2. Data Package Protection in Brazil

In light of the TRIPS Agreement, data package is the undisclosed information set obtained through research and development activities (usually comprising a new substance) which is necessary to be submitted before a regulatory agency in order to obtain the corresponding marketing approval. The protection of such kind of information is set out in Article 39(3), TRIPS, as follows:

> "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."

It is important to be noted that the TRIPS Agreement imposes an obligation on the Members to grant protection for data packages, but it does not specify what would be this protection. While some scholars state that such protection should be made through an exclusivity right, other ones assert

that TRIPS did not expressly establish a new intellectual property for test data and such protection should be made through the general rules related to unfair competition and trade secrets.

According to the aforementioned TRIPS provision, Mmeber-Countries are obliged to grant: (i) protection for undisclosed data package comprising new chemical entities against unfair commercial use; (ii) protection for such data against disclosure, except where necessary to protect the public; (iii) data package protection against disclosure, unless steps are taken to ensure that the data are protected against unfair commercial use.

In Brazil, data package exclusivity – DPE is set out in Law no. 10,603/2002, Article 1st of which establishes that "this Law regulates the protection against unfair commercial use of information concerning the results of tests or other undisclosed data submitted to the competent authorities as a condition to adopt or maintain the record for the marketing of pharmaceutical products for veterinary use, fertilizers, pesticides, and their related components." Therefore, DPE for pharmaceutical products for human use was not expressly included in the Law at stake.

The requirements for DPE are set out in Section 2, of Law no. 10,603/2002, as follows:

> Section 2 - It is considered undisclosed information the one that up to the date of the application:
> I - are not easily accessible to people who normally deal with the kind of information in question, whether as a whole or in the precise configuration and assembly of its components, and
> II - has been subject to effective maintenance of its confidentiality by the person lawfully responsible for its control.

The terms of DPE are defined by Section 4, of the Law in question, namely:

> Section 4 - The term of protection referred to in Section 3 shall be:
> I - for products using new chemical or biological entities, ten years from the granting of registration or until the first release of information in any country, whichever occurs first, assuring at least one year of protection;
> II - for products not using chemical or biological entities, five years from the granting of registration or until the first release of information in any country, whichever occurs first, assuring at least one year of protection;
> III – for new data required after the granting of registration of the products mentioned in items I and II, the remaining period granted by the registration or one year as of the presentation of new data, whichever occurs last.

With regard to human drugs, the data package protection is solely (since it is not regulated in any other Law) based on the rules of unfair competition. In this connection, Law no. 9,279/1996, Brazilian Industrial Property Law, sets forth in its Section 195, item XI, that unfair competition crime is committed by the one who "divulges, exploits or uses, without authorization, the results of tests or other undisclosed data, which involves a considerable effort and have been presented to government entities as a condition of approving the marketing of products." As can be seen, Brazilian Law adopted a similar text to the one available in the TRIPS Agreement.

It is important to highlight that the Brazilian Health Surveillance Agency – ANVISA is under the obligation to keep secret the data package submitted to it for the concession of marketing approvals, as established by Section 30, Presidential Decree no. 3,029/1999:

> Section 30 - The Agency will treat as confidential technical, operational, financial and accounting information that it requests from companies and people who produce or trade products or render services comprising in the National Health Surveillance System, provided such disclosure is not directly necessary for preventing discrimination of consumer, producer, service provider or trader or the existence of circumstances of health risk of the population.

The LEXAPRO® Case

Up to the present moment, few lawsuits seeking data protection exclusivity for human drugs have been brought before Brazilian Courts. In fact, we are aware of one filed by LUNDBECK A/S against the Brazilian Health Surveillance Agency – ANVISA seeking to prevent ANVISA from using its data package for the concession of marketing approval for generic and similar drugs containing escitalopram (LEXAPRO®).

The Seventh Federal Trial Court of Brasília rendered a decision granting LUNDBECK's request and, therefore, determined that "ANVISA refrain from issuing registrations to third parties that are non-authorized by the Plaintiffs to use the results from the tests and data available in the dossier submitted by LUNDBECK BRASIL for obtaining the sanitary registration of LEXAPRO medicine (registration no. 1.0475.0044), as well as to declare the nullity of every and any sanitary registration issued with basis on this dossier, specially sanitary registrations nos. 0573.0379, 1.0573.0380 e 1.1213.0402..."

Nevertheless, the Brazilian Superior Court of Justice (Superior Tribunal de Justiça – STJ) has recently rendered a decision suspending the immediate

effects of this merits decision, based on the fact that, on the occasion of the conversion of Provisional Measure No. 69/2002 into Law No. 10,603/2002, the Brazilian Congress sought to suppress provisions for DPE for human drugs. STJ also understood that the DPE for human drugs could jeopardize the generic drugs program in Brazil.

The merits decision has been challenged before the Federal Court of Appeals for the First Circuit, but, up to the present moment, such appeal is still pending of decision.

3. Patent Infringement and Invalidity Actions

Patent Infringement

According to Brazilian Industrial Property Law, a patent infringement is committed by anyone who:

- manufactures a product which is the subject matter of a patent without the authorization of the owner of the patent;
- uses a means or a process that is the subject matter of a patent, without the authorization of the owner of same;
- exports, sells, exhibits or offers for sale, holds in stock, conceals or receives for use for a commercial purposes, a product manufactured in infringement of a patent, or that was obtained by patented means or process; or
- imports a product that is the subject matter of a patent or which is obtained by a means or process patented in the Country, for commercial purposes, and that has not been placed in the external market directly by the owner of the patent or with his consent.

Civil patent infringement actions must be filed before State Courts, remedies of which may include the cease of infringement and compensatory damages.

It is important to underline that patent infringement acts are all criminal offences punishable with imprisonment. Statutory felonies for patent infringement are set out in Sections 183 to 186, of the IP Law.

In case of infringement, the civil remedies available are (i) the cease of the patent violation under the payment of a daily fine and (ii) search, seizure and destruction of the counterfeit products.

With regard to compensatory damages, the criteria are set out in Section 210, of the IP Law, as follows:

- the benefits that the patent owner would have obtained if the violation had not occurred;
- the benefits obtained by the patent infringer;
- the remuneration that the infringer would have paid to the patent owner in order to become a licensee of the patent in question.

Section 210 expressly states that damages "shall be determined using the most favorable criterion" to the plaintiffs, but it is still very difficult to obtain awards of damages in sizable amounts.

Invalidity/Annulment Action

After the publication of the issuance of a patent in the Official Gazette, a 6(six)-month term opens for any interested party to request the administrative annulment of a patent. The Brazilian Patent and Trademark

Office – BPTO may also start such proceeding ex officio. As per Section 50, of the Brazilian IP Law, the nullity of a patent will be declared whenever:

- any of the statutory requirements (i.e., novelty, inventive step, and industrial application) have not been met;
- the claims are not well supported by the description or does not define clearly and precisely the subject matter for which the protection is sought (insufficiency of disclosure);
- the subject matter of the patent extends beyond the contents of the application as originally filed;
- any of the formalities essential for issuance were omitted during prosecution.

An annulment lawsuit can also be brought before courts by the BPTO or by any party having a legitimate interest. Such action can be filed with basis on any of the aforementioned reasons at any time during the term of a patent. Moreover, the annulment action must be filed against the patent owner and the BPTO. Considering that latter is a federal agency, such lawsuit must be filed before a Federal Court (usually in Rio de Janeiro, where the BPTO has its headquarters).

Remarks:

- Before the issuance of the patent, an infringement lawsuit may only be filed with basis on the unfair competition rules and the plaintiff must produce evidence that the consumers are likely to confuse one product by the other.

- Injunction relief is possible in both lawsuits, but the plaintiff must demonstrate the presumption of legal basis (fumus boni juris) of the

request and the danger of a possible delay (periculum in mora) in suspending the patent violation or the validity of the patent (in case of an annulment action). Injunction reliefs are usually refused when they may cause irreparable hardship to the defendants, without a countervailing benefit to the patent owner.

- In both actions, an expert is usually appointed by the judge for helping him/her to assess whether there is an infringement or if the invention in question complies with the patentability requirements.

- Partial nullity is possible when the remaining claims constitute subject matter patentable themselves (Section 47).

- In an infringement action, the nullity of the patent can be raised as an argument by the Defendants, but a patent can only be revoked through an annulment lawsuit filed against the patentholder and the BPTO before a Federal Court.

Sample decisions awarding damages:

1) Rio Grande do Sul State Court – 5th Board of Civil Appeals – Appeal no. 70022424089/2007 - SEMATO S/A INDUSTRIA E COMERCIO vs. GROSS COMERCIO IMPORTACAO E EXPORTACAO DE PECAS AUTOMOTIVAS – Judgment date: July 30, 2008.

"In light of the patent claims in question, it was demonstrated that the defendants were producing and trading the plaintiff's patented product, without the corresponding authorization and the payment of royalties, reason why they must pay damages. The manufacturing, trade and storage of one of the components of the product, which is protected by plaintiff's

patent, is what we understood as counterfeiting, that is, an usurpation of a invention idea. Damages are determined by the benefits that the patentholder would have obtained if the violation had not taken place, including the exploitation in the period between the publication date of the patent and its issuance date."

2) Rio Grande do Sul State Court – 10th Board of Civil Appeals – Appeal no. 70037172160/2010 - SEMEATO S/A INDUSTRIA E COMERCIO vs. GIHAL INDUSTRIA DE IMPLEMENTOS AGRICOLAS LTDA – Judgment date: June 30, 2011.

"It is not possible to assert that the Invention Patent no. 9101896-0 does not comply with the novelty and inventive step requirement. Moreover, there is no doubt that the plaintiff is the inventor of the subject matter of patent 9101896-0, as well as that the patent is legitimate and regular, and it complied with the requirements established by the BPTO for its issuance.

The evidence is conclusive and leaves no doubt that the defendant produced and traded straw cutting machines using identical device to the one patented by the plaintiff, which demonstrates the counterfeiting.

The compensation based on the full value of the machinery produced using the counterfeit technology can lead to unjust enrichment, which is incompatible with Section 210, of Law 9.279/96. That is why production cost cannot be disregarded.

Such amount will be determined during the liquidation phase, with basis on the criterion most beneficial to the plaintiff."

4. Access to public health, consumer's rights and the sanitary surveillance: citizen's petitions against the approval of sanitary registration of substandard drugs

The Brazilian Public Health Care System (SUS)

Article 196, of the Federal Constitution, states that "Health is everyone's right and it is the duty of the state to guarantee, through social and economic policies, to reduce the risk of disease and other health problems, and provide universal and egalitarian access to actions and services for its promotion, protection and recovery."

In this sense, the Unified Health System – SUS was created in 1990 as an universal health care system, which provides health services for the entire population no matter whether the person is poor or not. However, most middle and upper class Brazilians rely on private medical insurance, which is often subsidised by employers.

The regional healthcare network is a unified system, organised according to the following principles (Article 198, of Federal Constitution; Law No. 8,080, dated September 19, 1990; and Law No. 8,142, of December 28, 1990):

- Decentralisation, with a single management in each sphere of government.
- Full service, with priority given to preventive activities;
- Universal access to health services at all levels of care;
- Participation of the community;
- Right of information.

This Unified Healthcare System – SUS is statutorily defined as comprising "health activities and services, provided by public and federal entities and

institutions, both by states and counties, of the direct and indirect administration of the foundations maintained by the government."

Maintained by the federal, state and county executive governments and with the costs paid from the revenue obtained with taxes, SUS relies on publicly owned facilities, though private owned entities are permitted to provide services through SUS in some situations.

The health activities and services provided by SUS are organised regionally and hierarchically. SUS has a unified management structure, exercised by each government sphere of the following institutions:

- In relation to the Federal Union, by the Ministry of Health.
- In relation to the states, Federal District and municipalities, by the respective health offices.

SUS is also in charge of National Drug Policy - which was established by the Ordinance GM/MS nº 3,916, dated of October 30, 1998, and approved by the Ministry of Health.

The guidelines of the National Drug Policy are:

1) Adoption of a list of essential medicines: This list is called “RENAME”, and comprises the medicines considered basic and essential to meet the majority of population’s health problems. By using this list, the Ministry of Health deems the standardization of prescription and supplying of drugs, and also to reduce costs by chosen the medicines that have the best cost-benefit. This list is available on internet, and it is periodically reviewed;

2) Sanitary regulation of medicines: Manly focused on pharmacovigilance actions. According to the National Drug Policy, the sanitary regulation has also the purpose of strengthen the use of generic drugs by the attendance of the following standards: (i) the mandatory adoption of generic names in bids, contracts and invoices, as well as requirements on quality of products; (ii) the mandatory adoption of generic names in the purchases of medicines done by the Government; (iii) the use of generic names on the packages, labels, leaflets, brochures, texts and other promotion and information materials;

3) Reorientation of pharmaceutical care by privileging the purchase of medicines that meet the following requirements: (i) diseases that constitute public health problems, which affect and endanger the community, and whose control is focused on treatment; (ii) diseases that, despite achieving a small number of people, require a long and expensive treatment; (iii) diseases whose treatment requires medicines that are not available in the market;

4) Promotion of the rational use of medicines;

5) Support of innovation by encouraging a better coordination of research institutes with the pharmaceutical sector;

6) Promoting the production of drugs by the government owned laboratories;

7) Ensuring the safety, quality and efficacy of the drugs;

8) Training of human resources.

Brazilian Consumers Rights

Article 5th, section XXXII of Brazilian Constitution – The State shall promote consumer's rights.

Brazilian Consumer's Rights Act – Law # 8,078 of 1990.

Some consumer's basic rights:

- Right to adequate, clear and correct information about products and services, as well as their risks;
- Right of petition before Courts and administrative authorities in order to assure both individual and collective rights;
- Protection against misleading practices;
- Protection of life and health;
- Appropriate and effective provision of public services.

Legal remedies that may be used by the consumers against medicines that do not meet sanitary requirements, and also to assure the inclusion of new medicines in RENAME:

- Individual actions with injunction relief request – There are a large number of individual actions seeking the provision of medicines that are not listed in RENAME;
- Class actions – Class actions may be filed by the prosecutors; public defenders; the Union, the States and the Municipalities; government owned companies; and associations of citizens (if filed some legal requirements);
- Writ of mandamus (both individual and collective) - There are a large number of individual actions seeking the provision of medicines that

are listed in RENAME, but are not actually provided by Public Administration. For instance, during a certain period, the State of Rio de Janeiro was not purchasing Interferon, although such medicine was listed in RENAME for the treatment of hepatitis C. Many patients filed writ of mandamus requiring the immediate purchase of Interferon, and they were successful.

The Supreme Court has already decided that the obligation to provide medicines is a joint obligation that can be enforced against the Union, the States and the Municipalities.

There are some cases that were brought to Courts requiring the replacement of substandard drugs for the reference ones:

Class Action nº 023.07.141197-9:

Filed by APAR (an association of renal patients) against the State of Santa Catarina before the 2nd Trial Court for Public Matters of Florianópolis requiring the substitution of the substandard drug “ALOIS” (manufactured by Brazilian laboratory Apsen Farmacêutica S/A) for the reference drug “PROGRAF” (Astellas Pharma) or its generic Tacrolimus (currently manufactured by Brazilian laboratories LIFAL, EMS, Fundação Oswaldo Cruz and Germed). Such drugs are used in immunosuppression following transplantation, and the Plaintiff states that the use of drug “ALOIS” is risky for transplant patients since there is not interchangeability between substandard drugs and the innovative ones. The Judge decided that the Union was a compulsory jointer party, and determined that the case must be ruled by a Federal Court. Then the Federal Judge decided that the Union should not be a compulsory jointer party, and determined that the case must be ruled by the State Court. Thus, the State Court determined

the production of technical evidence in order to verify the alleged risk of the use of substandard drug “ALOIS”.

Class Action nº 0014707-63.2008.4.05.8100:

Filed by the Public Defender of the Union against the Union, the city of Fortaleza, ANVISA and the laboratory LIFAL before the 7th Federal Court of Fortaleza, state of Ceará. The Plaintiff challenges the replacement of reference drug “PROGRAF” in the RENAME list for its substandard “LIFTALTACROLIMUS” (manufactured by Brazilian laboratory LIFAL). The Plaintiff alleges that the efficiency of the substandard drug was not proved during the proceeding for sanitary approval, and seeks an injunction relief to determine the defendants to refrain from using LIFALTACROLIMUS substandard drug in the treatment of transplant patients within the State of Ceará until it proves the effectiveness of the first control rejection of transplanted organs. Meanwhile, the Plaintiff requests the return to the use of PROGRAF (reference drug). The pleading was fully granted, but the Defendants appealed to the Federal Court of Appeals for the 5th Circuit.

Class action nº 0020587-22.2009.404.7100:

Filed by Public Defender of the Union against the Union, the State of Rio Grande do Sul and the laboratory LIFAL before the 6th Federal Court of Porto Alegre, state of Rio Grande do Sul. The Plaintiff challenges the replacement of “PROGRAF” in the RENAME list for its substandard “LIFTALTACROLIMUS” (manufactured by laboratory LIFAL). The Plaintiff alleges that the efficiency of the substandard drug was not proved during the proceeding for sanitary approval, and seeks an injunction relief to determine the defendants to refrain from using LIFALTACROLIMUS substandard drug in the treatment of transplant patients within the State of

Rio Grande do Sul until it proves the effectiveness of the first control rejection of transplanted organs. Meanwhile, the Plaintiff requests the return to the use of PROGRAF (reference drug). The case is still pending of decision.

Important note about Tacrolimus cases: The Superior Court of Justice has decided that, since the proceeding for sanitary registration of LIFALTACROLIMUS followed the rules that were in force at that time, there is not any legal obstacle to the commercialization of LIFALTACROLIMUS (Special Appeal nº 1022258/DF).

Class Action nº 0011053-91.2009.4.02.5101:

Filed by the Federal Prosecutor against the Union and the State of Rio de Janeiro requiring the inclusion of medicines Bosentan ("TRACLEER", manufactured by Actelion Pharmaceuticals) and sildenafil ("REVATIO", manufactured by Pfizer) in the RENAME list. Both drugs are used in the treatment of pulmonary arterial hypertension. The Defendants alleged that the medicines Digoxin (manufactured by GSK), Warfarin, Amlodipine (manufactured by Pfizer) and Verapamil (manufactured by Nordisk), among others, were already listed in RENAME for the treatment of such disease, and the choices of the Public Administration were based upon the National Drug Policy. They also presented a report showing evidence that the cost-benefit of including Bosentan ("TRACLEER") and sildenafil ("REVATIO") in the RENAME list was not worth. Although the Plaintiff eventually got an injunction, this decision was later overruled by the Federal Court of Appeals for the 2nd Circuit. The case was later dismissed since the Public Administration established adopted a protocol for the treatment of pulmonary arterial hypertension which included the use of sildenafil

("REVATIO") and iloprost (manufactured by Bayer Schering Pharma AG) – but not Bosentan ("TRACLEER").

Individual Cases

Individual cases that were brought to Court in order to include the reference drug "CEREZYME" (manufactured by Genzyme) in RENAME: During the year 2009, the production of CEREZYME® (Imiglucerase), a reference drug which is used in the treatment of Gaucher's disease, was interrupted because of rumors of contamination with Vesivirus 2117. Considering that such medicine was the only one listed in RENAME for the treatment of Gaucer's disease and the imminent risk of shortages, SUS decided to replace this drug for a substandard drug manufactured in Israel that only had marketing approval in France. Some patients have filed lawsuit requiring the maintenance of CEREZYME® in RENAME. According to those patients, the security and efficiency of the substandard drug had not been proven. Furthermore, they alleged that the substandard drug was not indicated for pediatric patients. We are aware that 3 (three) pediatric patients have gotten injunctions.

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