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A LACK OF COORDINATION BETWEEN MEXICO'S MINISTRY OF HEALTH AND THE MEXICAN INSTITUTE OF INDUSTRIAL PROPERTY HAS MEANT PHARMACEUTICAL PRODUCT REGISTRATION HEADACHES FOR MULTINATIONAL DRUG LABORATORIES FOR YEARS. BUT RECENTLY PUBLISHED AMENDMENTS LOOK SET TO PROVIDE AT LEAST A PARTIAL CURE.

On September 19 2003, a decree amending the Regulations of the *Health Law* (Health Law Regulations) and the *Regulations of the Law on Industrial Property* (Regulations to the LIP) was published in the Official Gazette of the Federal Government of Mexico. The purpose of the amendments is to establish coordination rules between the Ministry of Health and the Mexican Institute of Industrial Property (IMPI), in connection with the granting of pharmaceutical product registrations for marketing approval, when the making and/or selling of said product might trigger the infringement of a patent.

PRODUCT REGISTRATION

Under the amendments, applicants for product registrations relating to "substances or active ingredients" will have the obligation to indicate if they own a patent or have a licence for the product. In the event that an applicant does not have a patent or a licence, it will be required to declare under oath that the product (substance or active ingredient) is in "compliance with the patent laws". In such cases, the health authorities will request technical assistance from the IMPI, which will carry out a patent clearance procedure within 10 working days. If the IMPI search reveals that the product subject to the registration falls within the scope of any patent, the Ministry of Health will give the applicant a chance to show that it has a right to make and sell that product. In the absence of convincing evidence, the application will be dismissed.

A party will be entitled to apply for registration of a product relating to a

“substance or active ingredient” covered by a patent owned by another party, if the application is filed no more that three years before the expiration of the patent. This provision, supported by the “Roche Bolar Exception” theory, would allow the applicant to start performing tests and expermiments in order to be ready to enter the market as soon as the patent has expired. Obviously, the Ministry of Health will not grant the product registration until the expiration date of the relevant patent.
The amendments to the Regulations to the LIP will impose upon the IMPI an obligation to publish a special gazette that lists those patents relating to allopathic drugs, and their correspondence to a non proprietary name. This special gazette will include patents that cover “substances or active ingredients”, but exclude other types of patents such as those covering processes.

BENEFITS TO PATENTS OWNERS

The newly adopted regime will be of benefit to patent owners. Under Mexican health laws, laboratories are required to have a registration to make or sell a medical product, including any sales made to the government by virtue of a tender or otherwise. Product registrations are thus of great importance. In the past, the Ministry of Health issued a number of registrations relating to products covered by patents to parties other than the patentee, producing confusion or conflict. Laboratories having a registration had considered themselves eligible to manufacture and sell a product, regardless of whether such action could lead to the infringement of patent rights. However, holders of patents expressed their understandable disappointment that the Mexican government was issuing registrations relating to patented products, when such registrations were being used as vehicles for infringing patent rights. The fact was that the Ministry of Health was granting registrations for products without checking with the competent authorities to determine if the marketing of the products would lead to an infringement of patent rights. Patent owners were thus require to bring costly court actions that clearly could have been avoided.
Protests by multinational laboratories were elevated to a governmental level under the framework of international treaties such as the North American Free

Trade Agreement and the Agreement on Trade related Aspects of Intellecutal Property Rights. Mexico was, in fact, included in the Special 301 Watch List of 2003 largely on the basis of this very issue-the result of a lack of coordination between the health authorities and the IMPI, and the related problem of the protection of confidencial information submitted to the Ministry of Health by patent owners in order to obtain product registrations of their own. The decree of amendment under discussion is being routed as a positive response by the Government of Mexico to the protests of multinational companies as well as certain governments, particularly US government.

OUTSTANDING ISSUES

As mentioned above, the steps taken by the Government of Mexico to resolve this issue can undoubtedly, be regarded as good ones. That said, however, there are still issues that are likely to require further analysis. For example, the language “substances and active ingredients” is vague since it would appear to indicate that the coordination system will only apply in cases where products infringe patents protecting molecules. Similarly, the amended provision does not property address the topic of the protection of dossiers containing confidential data on innovative products and, as a result, Mexico could still be defaulting on obligations imposed by international treaties.

The limited time allowed for the IMPI to respond to the queries of the Health Department is also worrying. It will be extremely difficult for IMPI to meet these deadlines, and failure to do so could become problematic as the provision implies that in such cases the product registration will be granted as if there was no relevant patent.

Lastly, the Health Law Regulations now state that the patent licences that applicants rely on is seeking approval for product registrations must have been recorded with the IMPI and that such applications will be refused if the licence has not been so recorded. Laboratories – especially those that have licensed their patents to a subsidiary or other licensees- are thus strongly encouraged to keep this requirement in mind since failure to record their patent licences could create problems when filing applications for product