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PHARMACEUTICALS SUPPLEMENT 1994

Historically, the patent and trade mark protection of chemical products and processes, particularly pharmaceutical products and process for preparing them, have been subject to periodical cycles of protection and non-protection in Mexico.

THE 1976 ACT

The Mexican Patent Law, enacted in 1976, established that chemical products and chemical pharmaceutical products were not patentable and that the only way to protect them was by means of certificates of invention. The most important difference between a patent and a certificate of invention was that the owner of a patent had an exclusive right to the patented invention, while the owner of a certificate of invention indeed had the right to work the invention himself but was also under an obligation to grant a non-exclusive licence to any third party who wished to use the invention.

As a result of the provisions of the 1976 Patent Law, many foreign pharmaceutical companies ceased filing patent application in Mexico.

At that time, the maximum duration of a patent and of a certificate of invention was 10 years from the date of grant.

THE 1987 AMENDMENTS

On 17 January 1987 very important amendments were introduced to the 1976 Law. For example, the duration of patents and of certificates of invention was extended up to 14 years, also from the date of grant. The following, previously unpatentable, became patentable;

processes for the obtainment, modification or application of chemical products or mixtures of them, with the exception of biotechnological process;

processes for the obtainment of alloys, pharmaceutical products, medicines in general, foods and beverages for animal consumption, fertilizers, pesticides, herbicides or fungicides.

With these amendments, the term of patents was increased and at least processes for preparing pharmaceutical products became patentable – a small step in the right direction.

#### THE 1991 REFORM

Finally, in 1991 a great change was made and a new law was put in operation on 28 June. First of all, the old certificates of invention were removed. The patent term was further extended for up to 20 years, counted from the filing date, and the concept of patentability was broadened to include:

plant varieties (however, plant species remained unpatentable);

inventions relating to microorganisms, such as inventions involving their use, inventions that are applied to microorganisms or inventions that result from them, covering all types of micro-organisms, such as bacteria, fungi, algae, viruses, microplasm, protozoa and, in general, cells that do not reproduce sexually;

pharmaceutical chemicals, medicines in general, foods and beverages for human or animal consumption, fertilizers, pesticides, herbicides, fungicides or products with biological activity, such as vaccines and hormones.

biotechnological processes for obtaining any of the preceding products.

#### PIPELINE AND TRANSITIONAL PROVISIONS

Besides the above, “pipeline” protection was provided by means of Transitional Articles which allowed the recovery of protection for inventions already patented in other countries but which had not yet been produced or imported into Mexico; such inventions now qualify for a national patent. Pipeline protection was granted to the original applicant of the patent abroad, provided be presented and application in Mexico within a year following the date the new Law came into effect. This patent protection was available in the case of chemicals, pharmaceuticals and biotechnological processes and products.

Besides this improvement in the term of patents and the broadening of patentable inventive concepts, this new Law included a three year extension in the term of Patents related to pharmaceutical chemicals or pharmaceutical products or processes for obtaining them, provided that their owner granted a licence for the use of the invention to any legal entity the majority of whose capital is controlled by Mexican parties.

#### THE 1994 AMENDMENTS

As of 1 October 1994 the 1991 Law will incorporate substantial amendments to further strengthen patent protection for pharmaceutical patents and to satisfy the NAFTA provisions without discrimination as to:

the field of technology,

the territory of the three parties in which the invention was made and whether products are imported or locally produced.

Regarding plant varieties, Transitional Article 5 provides that, until the Law that complies with the substantive provisions of the International Agreement for Protection of Vegetable Obtentions 1978 is enacted (on or before 17 December 1994) or with the provisions of the International Convention for the Protection of New Plant Varieties, 1991 (UPOV), the applications from plant obtainers for varieties in all plant genera and species will be received by a new administrative authority. This authority will replace the Patent and Trademark Office with a new office named the Mexican Institute of Intellectual Property, (IMPI), starting from the effective date of the Decree of Amendments (1 October 1994) and in due course will remit them to the competent authority for further processing. From the above, it is quite evident that only the items mentioned under Article 16 may not be subject of patents in Mexico; all other inventive concepts are patentable, including second medical uses of known pharmaceutical products and compounds.

It is important to mention that the provision regarding the three-year extension in the term of patents related to pharmaceutical chemicals or pharmaceutical products or processes was deleted by the amendments to the Law, both because it was optional for Mexico under the NAFTA and also in order to avoid certain discriminatory treatment of Mexican nationals.

## TRADE MARKS

In the field of trade marks, Mexican Law grants pharmaceutical marks the same type and level of protection and regulations that it offers to trade marks or service marks in other industrial sectors, without making any distinctions. As in other countries, Mexican Law considers marks registrable if they are inherently distinctive, that is, marks that are suggestive, fanciful and arbitrary. On the other hand, it prohibits registration of generic and descriptive marks and, in this latter case, does not recognize protection even if a descriptive mark has acquired a secondary meaning.

Some pharmaceutical trade marks share in common the characteristic that they combine distinctive elements with other elements of a generic or descriptive

nature. Such generic or descriptive element usually consists of a prefix or suffix that is used to give a slight or indirect idea of the active ingredient in the pharmaceutical product identified under the particular trade mark. Mexican trade mark law has granted protection for these marks without the need for the generic or descriptive element to be disclaimed and has allowed the co-existence of registrations for trade marks that include the same prefixes or suffixes, as long as the overall impression of the marks remains distinctive.

#### PARALLEL IMPORTS

Mexican Law appears to allow parallel imports in a fairly broad form. In fact, a provision was introduced in the 1991 Law in terms so broad that they practically permit any form of grey marketed goods. The regulations to the Law that are expected to be published in October 1994, will impose control measures aiming at ensuring that not every single form of parallel import will be permitted in Mexico. This limitation will be focused on protecting the consumer and the goodwill of trademarks by imposing a burden on behalf of the importer to introduce into the Mexican market parallel imported goods of the same quality to those circulating in the territory of this country. In addition, it will have to comply with product standards and regulations and consumer law provisions.

#### OMISSIONS

Nothing appears to be provided in the regulations in connection with repackaging and relabeling of the grey marketed products. It can however be expected that, if repackaging or relabeling of products is used as a means of misleading the consumer, for example as to quality or origin of the products, such acts will constitute a bar to the right of the importer to bring they grey market product into Mexico.

In 1991 the Mexican Trade Mark Law abolished the grant of compulsory licences, which was adopted in the Law of Inventions and Trade Marks of 1976. The 1976 Law gave authority to the Trade Mark Office to declare compulsory registration and use of marks or even prohibit it when the use of the mark was considered to be associated with monopolistic practices or used for distorting or blocking production and commercialization of goods and services, when that practice was conducted by a particular industrial sector. Unfortunately, under the Law such authority still subsists. These rules are applicable to all industrial sectors without distinction, including of course the pharmaceutical industry. From all the above it may be concluded that the patent and trade mark

protection of pharmaceutical products and processes has been highly improved in Mexico in recent years.

THE 1994 AMENDMENT: ARTICLE 16

ARTICLE 16 PROVIDES THAT INVENTIONS THAT ARE NEW, THE RESULT OF AN INVENTIVE ACTIVITY AND SUSCEPTIBLE OF INDUSTRIAL APPLICATION ARE ELIGIBLE FOR PATENT PROTECTION EXCEPT:

PROCESSES THAT ARE ESSENTIALLY BIOLOGICAL FOR THE PRODUCTION, REPRODUCTION AND PROPAGATION OF PLANTS AND ANIMALS;

BIOLOGICAL AND GENETIC MATERIAL AS FOUND IN NATURE;

ANIMAL BREEDS;

THE HUMAN BODY AND THE LIVING PARTS THAT COMPOSE IT AND

PLANT VARIETIES