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MEXICO'S HEALTH LAW THREATENS DRUG TRADEMARKS

Over the past six years, the world's pharmaceutical companies have been faced with new and steadily increasing trademark troubles. Their difficulties began on May 12, 1993, when the World Health Assembly announced resolution WHA 46.19[1].

This resolution was intended to end the confusion caused by the marketing of generic drugs under trademarks and brand names derived from the drugs' international non-proprietary names. Such use could "compromise the safety of patients by creating confusion in prescribing and dispensing medicines and by interfering with the orderly development of nomenclature for international non-proprietary names[2]".

Accordingly, the World Health Organization (WHO) declared there was an urgent need to discourage the use of trademarks that are derived from international non-proprietary names (INNs)[3]. WHO asked Member States to enact appropriate rules and regulations to ensure that pharmaceutical manufacturers will be encouraged to create and market generic drugs (after the appropriate patent terms have expired), manufacturers will be pressured to rely on their corporate name and INNs, rather than on trademarks, in their labeling and marketing of drugs; manufacturers will use and prominently display the INNs of their products; and manufacturers will be discouraged from using of trademarks derived from INNs – particularly marks containing established INN stems[4].

This WHO resolution was not well received among the world's pharmaceutical laboratories, especially those that devote considerable efforts in the difficult task of researching, developing, marketing and promoting their patented drugs through trademarks and other distinctive symbols. The WHO resolution would

not only place a burden on the use of trademarks for generic drugs, it also would impose limitations on the generally accepted industry practice of using trademarks derived from the common stem of INNs[5].

The pharmaceutical industry recognized that WHO's objectives were, to a certain extent, reasonable. The use of INN stems in trademarks had made it difficult to choose distinctive brand names for generic drugs.

However, the industry thought it was unreasonable and harmful to avoid using trademarks on generic products, and instead, force manufacturers to market the drugs under their corporate names. The industry also objected to any requirements that the INN be prominently displayed.

As commentators have noted, "after patent protection expires, the trademarks is the most valuable asset a product often carries in the marketplace,[6]" "So pharma companies need brands, lots of them. Brands that patients will remember and associate with their condition.[7]"

Distinctive trademarks can also help patients, increasing the likelihood that they get the right drug for their condition. "While in other areas avoiding confusion is very important, with pharmaceuticals, you could be talking about life or death[8]".

The pharmaceutical industry has further argued that it is necessary to clarify the term "common stem", or else the "industry will not know which trademarks are acceptable and which unacceptable to individual trademark authorities.[9]"

Industry representatives have suggested that all future common stems should be suffixes and should contain at least five letters, and that all future variable parts of generic names should be prefixes and should contain at least four letters[10]. Under this suggestion, Health Authorities throughout the world could make a more objective decision on whether to accept or reject trademark applications for drugs[11].

MEXICO RESPONDS

On May 7, 1997, the Congress of Mexico amended the country's 1984 Health Law and opened the market to generic pharmaceuticals. Before this amendment, the manufacture and distribution of generic drugs was restricted to specific areas within the government and public health sectors.

However, one part of 1997 amendments were clearly written in order to comply with resolution WHA 46.19. Article 225 of the Health Law states, in part, that

“pharmaceuticals, for use and commercialization, must be identified by their generic and distinctive names.[12] Use of the generic name shall be mandatory”.

Article 225 goes on to prohibit the drug’s distinctive name from explicitly or implicitly mentioning the composition of the drug or its therapeutic action. The provision also prohibits the distinctive name from containing anything related to a disease, syndrome, symptom, anatomic data, or physiological phenomena. However, this latter prohibition does not apply to the names of vaccines and biotechnological products.

Finally, Article 225 authorizes government officials to issue regulations on how generic and distinctive drug names are to be used, including in prescriptions, publicity, and labeling of the drugs.

Mexico’s pharmaceutical companies strongly objected to Article 225[13], but they did not wind up accepting a few of the statute’s requirements without too much complaint. For instance, they basically acquiesced in Article 225’s prohibition on the use of INN stems in trademarks.

The companies also reluctantly accepted the requirement that drug labels and ads contain both the INN and distinctive names for a drug. Certainly, the companies were pleased that Article 225 did not require that INNs be displayed prominently – and so it set a lower standard that WHA 46.19.

The companies’ principal objection to Article 225 was that it failed to define when a drug could be labeled using the INN – i.e., when a drug can be considered to be a generic. The trouble is that even if two drugs contain the same active ingredients, the drugs’ composition and quality may not be identical. The two drugs could thus produce different effects.

Accordingly, the main flaw of Article 225 was that if did not guarantee the bioequivalence of generic pharmaceuticals. If bioequivalence were required, the generic product, to be considered an equivalent substitute for an “original” product, would be required to act in the human body, in the same degree and same strength as the “original” product[14].

The Mexican Government responded positively to these arguments by implementing new “Regulations for Health Expenditures[15]”. These 1998 regulations introduced a definition of “Interchangeable Generic Drug” which recognized the principle of bioequivalence and required generic drugs not only to have same active ingredient, but also the same pharmaceutical presentation, in identical concentration.

FORBIDDEN NAMES

The regulations require that government authorities must test and approve every generic drug in order to ensure that it is equivalent to the original drug. After approval, the drug is registered in the Catalag of Generic Interchangeable Drugs, under the appropriate INN[16].

Labels affixed on pharmaceutical products must include, inter alia, the drug's generic name and its distinctive name, unless the drug's name was published in the Catalog of Generic Interchangeable Drugs[17].

If the drug's name was published in the Catalog, a distinctive name cannot be used, since the drug is sold as a generic and only the generic name can be used. An exception is made for original products, however. They may continue to use their distinctive names.

The law is silent as to whether non-interchangeable generic products are required to be sold in its generic name only. Since there is no applicable legal prohibition, the correct interpretation seems to be that these type of generics can be sold using both generic and distinctive names.

Prescriptions must indicate the "generic denomination" when referring to products in the Catalog[18].

If a prescription is for a drug that does not have a generic version included in the Catalog, the doctor can write a prescription using just the drug's distinctive name or using both the generic and distinctive names[19].

CONFLICTING STANDARDS

In Mexico, as in other countries, pharmaceutical trademarks need to satisfy two different types of government examinations. The first examination is made by the Mexican Industrial Property Institute (IMPI), for trademarks registration purposes. The second examination is made by health authorities, for product registration purposes.

The Health Law now imposes restrictions on pharmaceutical trademarks that go beyond the restrictions of Mexico's Industrial Property Law (LIP)[20]. This is creating some problems for drug companies doing business in Mexico.

As mentioned above, the Health Law prohibits pharmaceutical trademarks based on the stem of a generic name. The LIP does not impose any such prohibition.

The regulations under the Health Law provide that trademarks submitted to Health authorities for approval must be distinct from other registered products' trademarks in "at least three letters[21]". The LIP contains no such limitations. The LIP states that a mark can be registered so long as it is inherendy distinctive, i.e., suggestive, fanciful, or arbitrary[22]. Generic and descriptive marks cannot be registered under the LIP23. Even a descriptive mark has acquired secondary meaning, it cannot be registered.

In the past, a large number of pharmaceutical trademarks registered under the LIP had prefix or suffixes that consisted in whole or part of the common stem of INN's. Many registered marks thus had the same (or similar) prefixes or suffixes as already existing marks24. These owner marks have often been allowed to coexist with preexisting registered marks even without the descriptive portion or stem having been disclaimed, as long as in their entirety or as a whole, the new marks were sufficiently distinctive and different from those preceding them25. The IMPI is charged with ensuring that any new marks are sufficiently different from existing marks so as to avoid consumer confusion26. However in the case of pharmaceutical marks, IMPI has not always carried out this duty as strictly as it should be27. After all, confusion in pharmaceuticals could easily be a matter of life and death28. Moreover, the risk of confusion is only present at the time that pharmaceuticals are purchased, but when the drugs are dispensed by people in hospitals, clinics, or their homes.

Thus the new, stricter rules under the Health Law should serve a good purpose and help consumer confusion over drugs. At the same time, these rules contradict trademark law principles, creating technical confusions in the law.

HOW TO SAVE YOUR TRADEMARK

As a result of the restrictive provisions of the Health Law and its implementing regulations, drug companies doing business in Mexico will have to change their branding and marketing strategies. This will become especially important in regard to generic drugs, as it will not be possible to continue selling them under word marks.

Fortunately the LIP does not limit its protection to word marks. The LIP also allows for the registrability of, inter alia: symbols, pictures, drawings, and three-dimensional forms29. Isolated letters, numbers, or colors are not registrable "unless they are combined or accompanied by elements such as symbols,

designs or denominations that give them a distinctive character30".
Reading this provision literally, one could conclude that a combination of two or more "isolated" colors can be receive trademarks protection, regardless of the form or surface on which the color combination is applied. This form could be the shape of a capsule, so that a capsule's color could be trademarked.
Notwithstanding this analysis, there are no reported cases addressing the issue of whether a combination of colors on capsules can be registered. From a practical standpoint, the IMPI is reluctant to grant trademark protection to color combinations. However, this position runs counter to several old Supreme Court decisions.
In the case, for instance, the Trademark Office (the IMPI's predecessor) refused to register a combination of three colors applied to the sides of certain denim textiles. The Supreme Court reversed, stating that the colors "produced a visual impression which was capable of functioning as trademarks31".
Moreover, commentators such as Professor David Rangel Medina strongly support the position that the LIP allows registration of color combination32.
Thus, there is good reason to think that manufactures of generic drugs can protect their goodwill by using colors, designs and other non-word trademarks. Manufacturers of "innovative" drugs that fall into the public domain after patent expiration can to continue using their old marks, including word marks, in connection with the innovative product. If the drug is then registered in the Catalog of Generic Interchangeable Drugs, the manufacturer of the innovative drug, and any third party fulfilling the legal requirements, will be entitled to make the generic product, although the third parties can't make use of the registered word mark.

A NEW FORM OF COMPETITION

The original manufacturer of a innovative drug may wish to use in connection with its generic product the designs and color combinations originally used on the capsules and packaging of its innovative products. But it is likely that third party competitors will wish to use the same designs and color combinations on their generic versions of the drug or on similar versions of the drug33. In fact, manufacturers of similar, non-interchangeable drugs have already started to mislead consumers into thinking that their drugs are approved substitutes for innovative drugs by doing such things as slipping the innovative drug's

trademark onto their labels. The ethical pharmaceutical industry is thus facing a powerful new form of competition.
In order to handle this competition, the ethical manufacturers will need support from IMPI. IMPI should, to be fair, protect the “original” marks against new competitors in the generic field whose trademarks are the same or similar to the “originals”.
In enacting Article 225 of the Health Law, Mexico’s Congress demonstrated that it was not fully aware of the needs of drug companies to protect their good name and their goodwill. It is to be hoped that the IMPI will be more sensitive to these concerns.

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[1] Resolution of the world Health Assembly, WHA 4619 of May 12, 1993. “Nonproprietary Names for Pharmaceutical Substances”, adopted at 46thWorld Health Assembly, Agenda Iten 18.2.

[2] WHA 4619, paragraph five.

[3] WHA 4619, paragraph seven.

[4] WHA 4619, point 1 (1) (2) and (3).

[5] For instance, the trademarks KEFTAR, ZOVABIN, DANTRON and ZEPOVIR, rely on stems that are widely used in many different marks Stepen R. James “Pharmaceutical Trademarks and Generic Drug Names, WHO’s right? “Trademark World, December/January 1994/1995, p. 29.

[6] PHRMA president Gerald Messingoff in correspondence on the Resolution WHA 4619 to Dr. Arpad Bogsch, ex-Director General of WIPO. Quoted by Nancy Dwyer Chapman, “WHO, WHA and why? The World Health Assembly’s Resolution on Nonproprietary Names for pharmaceutical substances”. Trademark World. December/January 1994/1995, p. 20.

[7] Tom Nicholson “In Search of Outstanding Branding”: Managing Intellectual Property, November 1998, P. 34.

[8] Lesley Edwards, Chair of PTMG, quoted by Tom Nicholson, id at P. 34.

[9] James supra, at note 5

[10] See Stephen James, supra. At p. 31. See also Nancy Chapman, supra. At p. 22.

[11] Daniel Boring. Irving A. Stein, and George Dr. Domildo. “United States: Trademark Trade Wrecks at FDA”, Trademark World July 1998, p. 29.

[12] Subsecuent regulations have defined “distinctive name” as the trademark that a laboratory uses to distinguís its drug from similar ones and which is used in connection with obtaining required approval and registration from health authorities and government officials Regulations for Health Expenditures, Article 2 (IV), published in the Oficial Gazette of February 4, 1998. These regulations have defined “generic name” as the name of a product identifying the drug or active ingredient that is internationally recognized and accepted by helath authorities. Id., Article 2 (V).

[13] Various pharmaceutical companies worked together in order to bring a constitutional actino against implementation of Article 225, but the companies lost on technical grounds.

[14] See Alejandro Perez Serrano, “Mexico to Open Pharmaceutical Market to Generic Products”, Novedades/News from the National Law Center for Inter.-American Free Trade, Volume 5, number 1, February 1998, P.1.

[15] Published at Oficial Gazette of February 4, 1998.

[16] Regulations, Article 2 (XIV) See also, id., Article 75 et seq. (concerning the nature, purposes and characteristics of catalog).

[17] Regulations Article 24.

[18] Id., Article 31 (I).

[19] Id., Article 31 (II).

[20] Published in the Oficial Gazette of June 27, 1991, and amended on August 2, 1994 (the amendments became effective on October 1, 1994).

[21] Regulations, Article 23 (I).

[22] LIP, Article 89 (I) and 90 (II), (III) and (IV).

23 Id. Article 90 (II), (III) and (IV).

24 For example class 5 registration for AZAPETINE coexist with registration for ACCEPTINE, OXOPOTINE, ACEPTIN, ZAPATIN, NOCEPTINE, HERCEPTIN, AZATINA, ASASANTIN, AZATIN, FUMETINEX, ASTRIMSIN, ANSIOPEPINE, EUCALIPTINE, MEPTIN, ASCRIPTIN AND AZAPURIN.

25 LIP. Article 90 (IV).

26 Id., Articles 113 et seq.

27 See Laboratorios Reforma SA., Tribuna Colegiados de Circuito, Tomo III administración, p. 370. Mayo Ediciones S. de R.L. Mexico D.F. 1977: Amparo en Revisión R.A. 262/74.

28 One commentator has argued that any confusión análisis requires a "curcunstantial" rather flexible approach, and that the degree of screen should be determined. See Jorge Otamendi. Derechos de Marcas P. 1 (Abeledo-Berrot, Argentina 1989).

29 LIP, Article 89 (I) and (II).
30 Id., Article 90 (V) (emphasis added).

31 Toca 74/40; ejecutoria form 30-XII-94 confirmed by 17-X-946, dictated by Supreme Court in Toca 263-1/41. See also Resolution of Supreme Court of Justice, published at "Semanario Judicial of la Federación", Tomo CV, p. 1290, No. Reg. 319,727; Amparo en revision 8593/49 of August 1950: Resolution of Supreme Court of Justice, published at "Semanario Judicial de la Federación Volumen XXXIIL Thrid Part, P. 32 No. Reg. 267,974; Amparo en Revisión 8009/57 of Marzo de 1960, filed by Parke Davis & Co.

32 See David Rangel Medina. Tratado de Derecho Mexicano pp. 361-365 (Mexico 1960).33 Pharmaceutical products manufacturers may validly produce an interchangeable drgs based on the same active ingredient as the products, without a bioequivalence in these cases the product will be called "similar" and be allowed to use a word mark. However, it will be possible for the manufacturers calling that product a "generic".