MERCK, INC.
Opposer,
- versus -

SONIX PHARMACEUTICALS, INC.
Respondent-Applicant.
x----------x

IPC 14-2004-00082

Opposition to:
TM Application No. 4-2000-05313
(Filing Date: 27 June 2000)

TM: "DIANORM"

Decision No. 2006-153

DECISION

This pertains to the VERIFIED NOTICE OF OPPOSITION to the application for registration of the trademark "DIANORM" for oral hypoglycaemic tablet covered by Class 5 under Application Serial No. 4-2000-05313 lodged by Sonix Pharmaceuticals, Inc. and published for opposition in the Intellectual Property Office (IPO) Gazette, Volume VI, No. 16, Page 107 which was officially released for circulation in the April 20, 2004 issued of said publication.

Opposer Merck, Inc. is a corporation organized and existing under the law of the Philippines with business address at 24/F GT Tower International 6813 Ayala Corner H.V. Dela Costa Street, Salcedo Village, 1227 Makati City, Philippines.

The grounds for opposition are as follows:

1. Opposer is a domestic drug manufacturer duly licensed by the Bureau of Food and Drugs (BFAD);

2. In accordance with the requirements of the BFAD, opposer sought and was granted a Certificate of Product Registration (CPR) No. DR-XY25565 for its Gliclazide 80 mg. Tablet under the brand name or trademark "DIANORM", which CPR was issued on October 8, 1999 with validity until October 8, 2004;

3. Opposer is the owner of the trademark "DIANORM" by virtue of its propriety and continuous use of the mark since May 8, 2000 in the Philippines;

4. Opposer applied for registration of the mark "DIANORM" on July 13, 2000 with the IP Phil. for goods in Class 5, i.e., "pharmaceutical product Oral Hypoglycaemic Agent" under Application Serial No. 4-2000-005827;

5. The BFAD in its Resolution dated June 27, 2003 in BFAD Case No. DM-00-161 initiated by opposer for the cancellation of the registration for the brand name "DIANORM" in respondent-applicant's name essentially declare that said "Office resolves to recall Respondent's CPR for its Glibenclamide ("Dianorm") 5 mg. Tablet and deny its application for renewal of the expired CPR (No. 23387) of Dianorm 2.5 Tablet, the same being covered by a previous valid registration of Petitioner"; advised respondent-applicant "to change the brand name of "Dianorm" for its drug products subject of this controversy"; and directed that until a change is made as regards its brand name, Respondent is hereby directed to cease and desist from introducing its products subject of this controversy in the market in the interest of the general public";

6. The registration of the mark "DIANORM" in respondent-applicant's name will undoubtedly cause grave and irreparable damage and injury to opposer who has been granted a CPR by the BFAD to use the subject mark exclusively in the Philippine market;

7. Opposer has the exclusive right to use the mark "DIANORM" in the Philippines for pharmaceutical products by reason of its being the exclusive holder of a valid CPR covering the

said trademark issued by the BFAD, the government authority that regulates the manufacture, importation, distribution, and sale of all pharmaceutical products in Philippine trade and commerce;

8. The product marketed by opposer under the "DIANORM" trademark has been certified safe and fit for sale to the public only after it has passed through a thorough and stringent study and analysis by the technical experts of the BFAD;

9. Opposer's "DIANORM" trademarks which has been in the Philippine market continuously for the last four (4) years has already earned for itself the reputation of being a high-quality product and has gained the confidence of consumers for which reason the registration of the mark "DIANORM" in favor of respondent-applicant would surely have disastrous consequences in the market as the confusion to the buying public would be unprecedented given that the marks of opposer and that of respondent-applicant are virtually identical;

10. The registration of the mark "DIANORM" in respondent-applicant's name may have grave consequences to the health and safety of the general public who have relief on opposer's product marketed under said mark for years;

11. Opposer has invested tremendous amount of resources in the research, manufacture, quality assurance, improvement, marketing and distribution of its "DIANORM" product and the registration of the same mark in respondent-applicant's name would cause grave and irreparable loss, injury, and damages to opposer; and

12. The registration of the mark "DIANORM" in respondent-applicant's name will undoubtedly violate opposer's rights and interest in its trademark "DIANORM", cause confusion between opposer's and respondent-applicant's businesses and products, and will most assuredly result in the dilution and loss of distinctiveness of opposer's "DIANORM" trademark.

On July 30, 2001, respondent-applicant filed his VERIFIED ANSWER specifically denting the allegations in the VERIFIED NOTICE OF OPPOSITION and alleging the following affirmative defenses:

1. Opposer cannot claim exclusive use of the brand name "DIANORM" though it may have a CPR for its Gliclazide product with "DIANORM" for its brand because respondent-applicant also has an existing CPR for its Glibenclamide product carrying the same brand name "DIANORM";

2. The BFAD Resolution dated June 27, 2003 upon which opposer relies has not yet become final as respondent-applicant has timely filed his motion for reconsideration and opposer has filed its comment;

3. Proof that the BFAD Resolution dated June 27, 2003 has not yet become final in view of the motion filed is respondent-applicant's CPR, the dorsal portion of which shows the extension of the CPR's validity to November 2004;

4. BFAD's approval of the use of name "DIANORM" as the branded version of the drug product Glibenclamide 5 mg. was proper and justified: Records of BFAD show continuous and uninterrupted registration of the drug product Glibenclamide since 1993 up to present;

5. In 1996, starting with 2.5 mg., this product Glibenclamide was distinguished by its proprietary name "DIANORM";

6. While the registration of Glibenclamide ("DIANORM") 2.5 mg. Expired in August 1998, the BFAD registration of the Glibenclamide product was not interrupted because the registration of its Glibenclamide 5 mg. was subsisting, as in fact it still is;

7. The brand “DIANORM” has already been attached to the drug product Glibenclamide;

8. Pursuant to the “one brand for one formulation policy”, the drug product Glibenclamide must continue to carry the same brand name “DIANORM”, this time for its 5 mg. increased dosage;

9. The Guideline for the Evaluation of Brand Names for Products to be Registered with the Bureau of Food and Drugs states that only one brand name shall be allowed for a given pharmaceutical registered in the name of every manufacturer, trader, and distributor-importer/exporter; and that a brand name that has been used for a given formulation must not be used for a new formulation with a different active ingredient or additional active ingredient;

10. The remarks in respondent-applicant’s CPR No. YZ-005157 BFAD Reg. No. XY23533 for its “DIANORM” Glibenclamide 5 mg. with RSN 94A-2708 states that the CPR became effective on November 24, 1997;

11. Respondent-applicant is the one that has long been damaged and prejudiced by opposer’s appropriation of its brand name “DIANORM”; Respondent-application withheld the launch of its drug product Glibenclamide despite BFAD’s grant of CPR in its favor and in good faith waited for BFAD to resolve the issue of whose CPR prevails; respondent-applicant proceeded and launched its drug product Glibenclamide with the brand name “DIANORM” when it had become apparent that the resolution of the case was not forthcoming; Zuellig Pharma Corporation, respondent-applicant’s exclusive distributor for its pharmacological products and the same contract distributor of opposer, refused to release respondent-applincat’s Glibenclamide (“DIANORM”) despite receipt of subsequent purchase orders; respondent-applicant still has in its warehouse a substantial amount/number of its drug product Glibenclamide (“DIANORM”); and respondent-applicant is having a hard time with its distribution as it is bound by its contract for exclusive distribution with Zuellig;

12. All CPRs issued by the BFAD contains the special condition that nothing in the registration of the product shall be interpreted as an indorsement or representation by the BFAD, the registrant has the right or privilege to the use of the name or brand so registered;

13. When respondent-applicant questioned opposer’s appropriation of the brand name “DIANORM” in a letter dated June 29, 2000 addressed to the BFAD, BFAD’s Director declared the issue to be within the jurisdiction of the IP Phil.;

14. Though opposer and respondent-applicant both have existing and valid CPRs from the BFAD and both have used the brand name “DIANORM” for their existing respective products, respondent-applicant is the first to file an application for registration of the mark “DIANORM” with the IP Phil, and is preferred under the First-Filer-Owner Rule pursuant to Sections 122 and 138 of the Intellectual Property (IP) Code;

15. Opposer took a risk when it appropriated the brand name “DIANORM” as its previous CPR for its Gliclazide 80 mg. product carried the brand name “Diabex” which was at the time when respondent-applicant’s Glibenclamide 2.5 mg. product already carried the brand name “DIANORM”, calculated the cost of such risk, and should alone bear the cost;

16. Opposer’s claim that the grant of respondent-applicant’s application will create confusion, will have disastrous consequences, and will be extremely dangerous to the consumers is not true. The consuming public will not get confused because Republic Act (R.A.) No. 6675 (Generics Law of 1988) requires the doctor’s drug prescription to specify the generic name and the milligram content of the drug prescribed, and both respondent-applicant’s Glibenclamide (“DIANORM”) 5 mg. and opposer’s Gliclazide (“DIANORM”) 80 mg. are prescription drug products which are not sold over the counter but are dispensed by a pharmacist based on a doctor’s prescription; and

17. There is no chance either for the pharmacist to commit error because in addition to the doctor's prescription, respondent-applicant's and opposer's respective products are presented distinctively and differently. Respondent-applicant's generic name Glibenclamide is distinctly different from opposer's generic name Gliclazide, both of which are presented dominantly in the outer packaging of the products; and Glibenclamide has 5 mg. presented in blister packs with twenty (20) tablets per pack and five (5) blister packs are contained in a wide and thick box colored white and rustic brown while Gliclazide has 80 mg. and presented in a bottle of thirty (30) tablets with an outer box colored brown and green.

Pre-trial on January 7, 2005 and was terminated. Opposer and respondent-applicant respectively presented and formally offered their evidence, which includes testimonial evidence on rebuttal and sur-rebuttal. Opposer filed timely its position paper while respondent-applicant did not file its position paper. The case is now deemed submitted for decision.

The issue to be resolved herein is who between opposer and respondent-applicant has a better right to the mark "DIANORM"

It is to be noted that a greater part of opposer's and respondent-applicant's respective arguments resolved in the issuance by the BFAD of their respective CPRs as basis for opposer's and respondent-applicant's respective claims to the right to the mark "DIANORM". Opposer claims that it was granted CPR No. DR-XY25565 for its Gliclazide 80 mg. Tablet under the brand name or trademark "DIANORM" on October 8, 1999 with validity until October 8, 2004, and which grant has given opposer the exclusive right to use the mark "DIANORM" in the Philippine market for pharmaceutical products in view of BFAD's Resolution dated June 27, 2003 in BFAD Case No, DM-00-161 declaring, among other, that the BFAD resolves to recall respondent-applicant's CPR for its Glibenclamide ("Dianorm") 5 mg. Tablet and deny its application for renewal of the expired CPR (No. 23387) of Dianorm 2.5 Tablet, as the same is being covered by a previous valid registration by opposer. Respondent-applicant, meanwhile, alleges the said Resolution has not yet become final as it filed a motion for reconsideration to which opposer filed a comment.

DOH Administrative Order No. 001-05, which is the Revised Policies and Guideline Governing Patent and Trade Secret Rights in Relation to the Registration of Pharmaceutical Products, clarifies role of the BFAD and the rationale for the registration therewith of pharmaceutical products vis-à-vis the role of the IP Phil. and the registration therewith of trade marks pursuant to intellectual property rights.

The DOH Administrative Order acknowledges that Section 15, Article II of the 1987 Constitution in relation to Sections 11 and 12, Article XIII of said 1987 Constitution is the foundation for the creation of an effective drug regulatory system.

Section 15, Article of the 1987 Constitution provides that it is the policy of the State to protect and promote the right to health of the people and instil health consciousness among them. Section II, Article XIII, meanwhile, mandates and State to adopt an integrated and comprehensive approach to health development which shall endeavour to make essential goods, health and other social services available to all the people at affordable cost while Section 12 of the same Article mandates the State to establish and maintain an effective food and drug regulatory system and undertake appropriate health, manpower development, and research, responsive to the country's health needs and problems

Republic Act No. 3720, as amended by Executive Order No. 175, otherwise known as the "Food, Drug and Devices and, Cosmetics Act"; and Republic Act No. 6675, otherwise known as the "Generics Act of 1988" were, thus, enacted.

Administrative Order No. 67, Series of 1989 was promulgated to provide the rules and regulations for the registration of pharmaceutical products.

Issues regarding intellectual property rights in the registration of pharmaceutical products, however, arose and have adversely affected the constitutional mandates. At this point, the DOH Administrative Circular recognized and affirmed the respective mandates of the BFAD and the IP Phil. when it declared:

> "It is clear, however, from the 1987 Constitution and the aforementioned laws, rules, and regulations that the Department through the Bureau of Food and Drugs (BFAD), is mandated only to ensure the safety, efficacy and good quality of pharmaceutical products applied for registration. It has no mandate at all to pass upon intellectual property matter since it does not have the legal authority, resources and competence to do so.
>
> Meanwhile, pursuant to Republic Act No. 8293, otherwise known as the Intellectual Property Code of the Philippines, issues pertaining to intellectual property rights, particularly patent rights, trademarks, trade names, copyrights, and unfair competition, are properly lodged with either the Intellectual Property Office (IPO) or a court of law with competent jurisdiction on the subject matter". (Underscoring supplied.).

Administrative Order No. 170, series of 2004 was issued on September 30, 2004 "to establish the policies and guideline governing intellectual property rights in relation to the registration of pharmaceutical products." DOH Administrative Order No. 001-05 was issued, however, in revision of Administrative Order No. 170, series of 2004 after the Department of Health (DOH) consulted with various stakeholders in the pharmaceutical industry. The current DOH Administrative Order No. 001-05 provides:

> "Henceforth, the purpose of this Order is to establish and revise the existing policies and guidelines governing intellectual property rights and the registration of pharmaceutical products in recognition of the respective mandate, authority, and jurisdiction of this Department, through BFAD, the IPO, and the court of law with competent jurisdiction over intellectual property rights disputes. In this Order, "intellectual property rights" means patents and trade secret rights over a pharmaceutical product."
>
> In issuing this Order, this Department, through BFAD, hereby reiterates and consistently adopts its mandate and responsibility to ensure the safety, efficacy and good quality or pharmaceutical products applied for registration." (Underscoring supplied.)"

It is very clear, that, the registration of pharmaceutical products with the BFAD is only for the purpose of ensuring the safety, efficacy and good quality of pharmaceutical products applied for registration therewith, not for the purpose of recognizing, representing, endorsing, and/or, much less, granting intellectual property rights and/or title over the pharmaceutical product applied for. In fact, this is explicitly recognized by the DOH in Part III, Paragraph 2 of the current DOH Administrative Circular, which provides:

> "The acceptance for CPR application by BFAD shall not be interpreted, nor construed, as an approval, endorsement, or representation that the applicant has legal right or title over any intellectual property attached to the pharmaceutical product applied for."

Issued pertaining to the determination of intellectual property right over a pharmaceutical product is within the jurisdiction of the IP Phil. Regardless of the registration of pharmaceutical products with the BFAD in terms of the time/period of filing, the status thereof, and other circumstances pertaining per se to the registration with said agency, this Office is bound neither by the pronouncements of said agency nor the circumstances or status of the registrations therewith. The yardstick within which to determine opposer's and respondent-applicant's rights in this case are the IP Code, and laws and jurisprudence pertinent thereto.

Section 123.1 of the IP Code provides:

"A mark cannot be registered if it:

(d) Is identical with . . . a mark with an early filing or priority date, in respect of:

(i) The same goods . . . , or
(ii) Closely related goods . . ."

Opposer filed Application Serial No. 4-2000-005827 on July 13, 2000 for Class 5 goods, specifically; pharmaceutical product Oral Hypoglycemic Agent while respondent-applicant filed Application Serial No. 4-2000-053131 on June 27, 2000 likewise for Class 5 goods, specifically, oral hypoglycemic tablet. Respondent-applicant is the first to file, thus, his application for registration or the mark "DIANORM" over the same class of goods as that applied for by opposer.

As to opposer's allegation that the public shall be confused between opposer's and respondent-applicant's respective pharmaceutical products, and that the confusion shall have negative consequences in terms of the public's health and safety, it must be emphasized that pharmaceutical products required a medical prescription before these could be obtained. A buyer must first secure from a licensed doctor the required prescription, present this is to the pharmacist who reads and then matches the pharmaceutical product to the prescription based on what is written on said product, and the buyer checks if the product given him is the one stated in the medical prescription. The margin of error is, thus, almost nil (Etepha v. Director of Patents, 16 SCRA 495 [1966]). Pharmaceutical products are not like articles of everyday use such as sugar or candies that are freely purchased and obtained anywhere.

Pharmaceutical products require, moreover, prescription in their generic names, not necessarily in their brand names or trademark. Section 6, Paragraph (b) of R.A. No. 6675, the Generics Act of 1988, provided:

"SECTION 6. Who Shall Use Generic Terminology. –

x x x

(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired.

Likewise, Paragraph (c) of the same Section requires that "(A) any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicine shall indicate prominently the generic name of the product. In the case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials." This requirement eliminates the likelihood of confusion.

The generic name of opposer's pharmaceutical products is "Gliclazide" while the generic name of respondent-applicant's pharmaceutical products is "Glibenclamide". These generic marks are distinct and different from each other. Not only are the generic names required to be prescribed but it is to be noted, too, that said generic names are presented dominantly in the outer packaging of the products: "Glibenclamide" 5 mg. is presented in blister packs with twenty (20) tablets per pack, and five (5) blister packs are contained in a wide and thick box colored white and rustic brown while Gliclazide 80 mg. is presented in a bottle of thirty (30) tablets with an outer box colored brown and green (Exhibits "F", "F-1", "4", "4-a", and "4-b"). Again, the likelihood of confusion is rendered the more remote.

Opposer claims first use of the mark "DIANORM" in May 8, 2000 as opposed to respondent-applicant's commencement of use of said mark on June 17, 2003. Considering however that both applications of Opposer as well as Respondent-Applicant for the registration of

the mark DIANORN were filed under the new law, R.A. 8293, the same law must govern the determination as to who between Opposer and Respondent-Applicant is entitled to the registration of the mark DIANORM.

Under Sec. 123.1 of the IP Code (R.A. 8293) a mark cannot be registered only if it is identical with a mark with an earlier filing date. As respondent-applicant was the first to file an application for registration of the mark “DIANORM” for Class 5 goods on June 27, 2000 and that Opposer’s identical mark DIANORM was only filed later on July 13, 2000, it cannot be cited against respondent-applicant’s Application Serial No. 4-2000-05313 hence, Respondent-Applicant’s application for the mark DIANORM having been filed earlier on June 27, 2000, must be given due course.

WHEREFORE, the VERIFIED NOTICE OF OPPOSITION is, as it is hereby DENIED. Accordingly, Application Serial No. 4-2000-05313 filed on June 27, 2000 for the registration of the mark “DIANORM” covering oral hypoglycaemic tablets under Class 5 is, as it is hereby, GIVEN DUE COURSE.

Let the filewrapper of DIANORM subject matter in this case together with a copy of this Decision be forwarded to the Bureau of Trademarks (BOT) for appropriate action.

SO ORDERED.

Makati City, December 22, 2006

ESTRELLITA BELTRAN-ABELARDO
Director, Bureau of Legal Affairs
Intellectual Property Office