UNITED LABORATORIES Petitioner, - versus - JAN HEERES, ET.AL., Respondent-Patentees.	)))))))))))))))	INTER PARTES CASE NO. 1907 PET. FOR COMPULSORY LICENSING Letters Patent No. 14635 Issued on : October 12, 1981 Patentee/s : Jan Heeres, Leo J.J. Backx and Joseph H. Mostmans assignor to Janssen Pharmaceutical N.V. Beerse, Belgium Title : 1-(1, 3-DIOXOLAN-2-YLMENTHY) -1H-IMIDAZOLES AND 1H-1, 2, 4-TRIAZOLES Used on : Antifungal and antibacterial agents DECISION NO. 94-16 (PAT) February 14, 1994

x----------x

DECISION

This case pertains to a Petition filed by United Laboratories, Inc., a corporation duly organized and existing under laws of the Republic of the Philippines with principal offices at 66 United Street, Mandaluyong, Metro Manila, Philippines, seeking for the grant of the compulsory license under Philippine Letters Patent No. 14635 for 1-(1,3-Dioxolan-2-Ylmethyl)-1H-Imidazoles and 1H-1,2,4-Triazoles issued by the Philippine Patent Office on October 12, 1981 in the name of Janssen Pharmaceutica, N.V., a Belgian corporation with principal office at Beerse Belgium, which was served with summons through its then Philippine attorney of record, Messrs. Reyes, Santayana, Tayao and Molo, with offices of 3rd Floor, Zaragosa Building, 102 Gamboa Street, Legaspi Village, Makati, Metro Manila.

The grounds for this Petition for grant of Compulsory Licensing is as follows:

"That the patented invention relates to medicine (Sec. 34 (e), Republic Act No. 165, as amended."

To support the Petitioner presented and relied on the following facts, to wit:

"1. Philippine Patent No. 14635 herein sought to be licensed was granted on October 12, 1981 and, therefore more than two (2) years have elapsed prior to the filing of this petition.

"2. The chemical compound or compounds comprising the invention and which are covered by the claims of Patent No. 14635 are antifungal and antibacterial agents and are therefore useful as medicine.

"3. Petitioner, which has been engaged in the business of manufacturing and selling pharmaceutical products for more than thirty (30) years, possesses the necessary financial resources, technical expertise, machinery and equipment and manpower that render it fully capable of making dosage formulations containing the compound or compounds covered by Patent No. 14635 or otherwise making use of the patented product in the manufacture of a useful product."

Respondent-Patentees, through Counsel, filed their Answer and interposed the following affirmative defenses:

"5. Petitioner has no capability to work the patented product or make use of the patented product in the manufacture of a useful product.

"6. Petitioner has not made definitive allegations on how it intends to work the patented product or how it will make use of the patented product in the manufacture of a useful product. Petitioner should allege clearly and definitely what it proposes to do with the invention subject of Letters Patent No. 14635. Otherwise, petitioner may merely import the subject invention and engage only in a packaging activity contrary to the intent of Presidential Decree 1263. Importation does not constitute working under Sec. 34(3) of the Patent Law as amended by P.D. 11263.

"7. The grant of compulsory license is improper and will not redound to the public interest and welfare because:

a. The subject invention is being presently distributed, detailed or retailed adequately throughout the Philippines.

b. The Philippine market for antifungal and antibacterial agents or products is sufficiently and adequately covered.

"8. Unless petitioner intends to synthesize the patented product locally (as required by the Patent Law as amended by P.D. 1263) rather than merely to import the same, the grant of a compulsory to petitioner will prejudice the interests of the assignee, in particular, and the economy of the country in general.

"9. Assignee is adequately equipped to produce and/or market any amount or quantity of pharmaceutical products or medicines containing the patented invention which the Philippine market or the public may need or demand.

"10. The grant of a compulsory license to petitioner will not promote public safety of public health; the petition is designed only for the enhancement of pecuniary interests of the petitioner who obviously intends to take advantage of successful development efforts of assignee in establishing marketability of the invented products in the Philippines.

"11. The provisions of P.D. 1263 amending the Patent Law, are unreasonable and arbitrary because it fails to consider valid substantial differences obtaining among various patent owners who, without consideration of these differences, are compelled to license the patented invention to third persons.

"12. The provisions of P.D. 1263 amending the Patent Law, in so far as it sets a maximum royalty of 5% of the net wholesale of the patented products, are likewise arbitrary and confiscatory and fails to take into consideration the many factors involved such as the huge expense incurred by the patentee in research, development, promotions and marketing of the patented product.

"13. The grant of a compulsory license covering the patented invention will not be in accord with the policies and guidelines relative to technology transfer in relation to national development, as formulated and implemented by the Technology Transfer Board or other governmental agencies, pursuant to P.D. 1520."

Issues having been joined, the case proceeded to trial after initial pre-trial conferences failed to produce an amicable settlement.

Petitioner presented Dr. William Torres and Atty. Teodoro B. Pison as witnesses.

On the issue of whether or not Petitioner has the capability to make use of the patented compound in the manufacture of a useful product, Petitioner presented the testimony of Dr. William Torres in Affidavit form marked Exhibit “F”.

Dr. William Torres, in his Affidavit (Exh. “F”) which was admitted as his direct testimony, stated that he is a pharmacist by profession with the following degrees, titles and job experiences as follows:

1967 – B.S. Industrial Pharmacy, University of the Philippines;

1971 – M.S. Pharmaceutical Chemistry, University of the Philippines;

1976 – M.S. Pharmacognosy, University of Mississippi, U.S.A.;

1980 – Doctor of Philosophy (Pharmaceutics), University of Mississippi, U.S.A.;

1969 – to present (with interruption) Instructor to Associate Professor, College of Pharmacy, University of the Philippines, Manila;

1973 – 1980 Assistant Research/Instructor School of Pharmacy, University of Mississippi, U.S.A.;

1980 – 1981 Consultant, PIACT/KABALIKAT, Inc., (POPCOM);

1981 – 1982 Consultant, United Laboratories Inc.;

1982 – Present Scientist/Manager Product Research Department, United Laboratories Inc.

He also narrated that United Laboratories, Inc. was incorporated on October 6, 1953 and has since then been engaged in the development, manufacture and sale of drugs and other pharmaceutical products, with its manufacturing facilities located at United Street, Mandaluyong, Metro Manila. It manufactures around 500 different dosage forms such as tablets, capsules, powders for suspension, liquids, suspensions, elixirs, syrups, drops, lotions, emulsions, parenteral preparations and pellets and of such categories as antibiotics, anti-TB, anti-asthma, anti-arthritic, anti-infectives, anti-ulcers, anti-bacterial, anti-fungal, cardiovascular drugs and other, some of which are listed in the Product Information Catalogue, marked as Exhibit “H”.

He further declared that he originally joined United Laboratories, Inc. in 1982 as a Scientist, in-charge of the Pharmacy Research and Development Group. He was involved in designing stability programs for all new products under development and existing products undergoing improvement. In 1983, he took over the Bioavailability Unit which was charge of conducting studies to monitor products in relation to their bioavailability/bioequivalence in human subjects. He also took charge of the Pre-formulation Department which was concerned with the physico-chemical studies of pure compounds and these compounds with all possible excipients/additives needed to develop solid, semi-solid or liquid dosage forms.

That at the time he testified, he was the Scientist/Manager of the Product Research Department which is one of the departments under the Pharmaceutical Research and Development and Analytical Chemistry Division of United Laboratories, Inc. This division develops new products and processes for the manufacture of various dosage forms and is

headed by an Assistant Vice-President, Ms. Estelita N. Garcia who has a Masters Degree in Pharmacy, major in Manufacturing, from Purdue University, U.S.A.

That he was aware that United Laboratories, Inc. has applied for the Compulsory Licensing of the drug generically known as KETOCONAZOLE in which Petitioner has not made definite allegations on how it intends to work the patented product in the manufacture of a useful product.

That in the process of developing a dosage form, Product Research Department, upon receipt of the experimental raw material sends it to either Analytical Chemistry Group or Quality control Group for clearance based on suppliers/UL's specification and other information in the literature or generated through in house tests and development. Once cleared the raw material is forwarded to Solids Department where it undergoes the described process in Annex "B", to evolve into the final dosage format. Other activities conducted in the Product Research Department are thermogravimetric analysis and chromatographic analysis. These are done to elucidate other physicochemical properties of the drug not specified in the supplier specifications. Stability studies are also conducted on the drug per se and the formulated dosage form and to be able to assign expiry date to optimize the formulation/process;

That somewhere along the Scale-up and Pilot stages indicated in Annex "B", samples of the developed drug are given to the Medical Affairs Division, headed by a Vice-President, Dr. Conrado Dayrit, for clinical testing to determine the bioavailability, safety, efficacy and other effects of the drug on patients;

After having established that the dosage format complies with all product specification and its completely free from defects, we turn over all date on manufacturing procedures to the Manufacturing Division which is headed by a Vice-President, Jose Pascual, for production of commercial batches.

That at about the same time, the product is registered with the Bureau of Food and Drugs, which requires the following documents, among others:

"a. List of amount and technical specifications of all ingredients used as components of the products.

"b. Technical specifications or physical description of the finished product.

"c. Complete essay procedures of the finished product.

"d. Stability studies of the product, to justify expiration date.

"e. Full description of the methods of use, the facilities and controls in the manufacture, processing, packaging of the product.

"f. Full report of investigation in man to show efficacy and safety.

"g. Sufficient samples (in market or commercial presentation) for laboratory analysis.

Upon approval by the Bureau of Food and Drugs, full commercial production is commenced.

He finally testified that his Division constantly works hand in hand with other divisions and groups in the company, particularly the Quality Control Group, under an Assistant Vice-President, Remedios Sanches, and the Manufacturing Division. The Quality Control Group is charged with the duty of assuring compliance with technical specification of raw materials,

packaging materials, products in process of manufacture and finished product. In short, no products are released into the market unless they conform to quality control standards."

On cross-examination, Dr. Torres declared that his company has done some literature research and has small amounts of the product for laboratory test and experiment. The company also has other anti-fungal products in the market which, while being chemically different from Ketoconazole, is also an imidazole derivative, and "once you know the basic chemistry of imidazole the reaction would be fairly the same" (TSN, July 17, 1989, pp. 8, 9, 17). Ketoconazole itself will be imported from abroad because there is no capability in the Philippines to synthesize the compound. Once a sample is secured, it undergoes all the tests in the laboratory as to purity and all the physical and chemical properties that can be determined. These can be compared with references from the US Pharmacopoeia and if the materials pass the tests then they will be accepted. (TSN July 17, 1987, pp. 12, 26 to 30). In the pre-formulation stage, one of the units under Dr. Torres' department will study Ketoconazole as a pure drug to know its physical properties. Once this is done, it will, be combined with common excipients normally used in drugs, like starch and lactose, to find out which ones are compatible with the drug. After the compatible excipients are determined, a selection of what to add to the drug will be made. After the studies are completed, the procedure goes to the product screening stage where the formulators will conduct a product screening and try to prepare the tablet. Studies are then conducted on efficacy and stability (Ibid, pp. 13-16). Dr. Torres further stated that the capability to manufacture a dosage form with Ketoconazole as an active ingredient "is not an assumption, from our experience it is as I mentioned before, this compound is similar to what we are doing now, with the chemistry known, I do not see any problem."

Petitioner thereafter formally offered Exhibits "A" to "K" and submarkings which were all admitted for whatever they are worth with Respondent's comments and objections thereto being made part of the records of this case to be considered in the fair adjudication of this case.

Respondent-Patentee in turn, presented its evidence which consisted of the Affidavit of Mr. Wilfred Patty (Exh. "I") and the Affidavit of Mr. Gustaf Van Kesteren (Exh. 2).

Exh. "1" was presented by Respondent-Patentee to show that the manufacture of a drug formulation containing Ketoconazole (the subject patented substance) involves special chemical expertise needed in handling the difficult synthesis of Ketoconazole, special technical skill and experience, highly specialized chemical manufacturing equipment needed particularly in the various purification steps needed to obtain Ketoconazole of acceptable purity, tight supervision by highly skilled engineers who have the required expertise; consequently, to show that Petitioner does not have the required capability to manufacture the drug formulation in question.

Exh. "2" was presented to show a compulsory license should not be granted to Petitioner because it will not redound to the benefit of the Philippine drug industry since the Philippine drug market is more than adequately served by the present marketing network and the corresponding supply of the subject patented drug by Respondent.

Respondent thereafter formally offered Exh. "1" and "2" as evidence which were admitted for whatever they are worth with Petitioner's comments and objections being made part of the records of this case.

In order to deal with the main issue as well as the corollary issues in the instant case, this Office has to refer to the pertinent law particularly the specific provisions of Republic Act 165 as amended by Presidential Decree No. 1263 as the determination of said issues revolves around Sec. 34-1(e) and Section 2 thereof.

Sec. 34 provides as follows:

> "SEC. 34. Ground for compulsory licensing. (1) Any person may apply to the director for the grant of a license under a particular patent <u>at any time after</u>

the expiration of two years from the date of the great of the patent, under any of the following circumstances:

xxx

(e) In any of the above cases, a compulsory license shall be granted to the Petitioner provided he has proved his capability to work the patented product or to make use of the patented product in the manufacture of a useful product. Or to employ the patented process.

xxx"

(Underscoring supplied)

What can be clearly gleaned from the aforequoted provisions are the requirements which Petitioner has to comply in order to be granted a compulsory license, to wit:

1. The petition for compulsory license must be filed after the expiration of two years from date of grant of the patent;

2. The patented invention relates to medicine; and

3. The Petitioner has the capability to make use of the patented product in the manufacture of a useful product.

Emphasis must be placed on the fact that as records and the evidence will show, subject Letters Patent No. 14635 was issued on October 12, 1981 and has been in effect for more than two years when the instant petition for compulsory licensing was filed on February 15, 1985.

There is likewise no question that subject patent relates to medicine.

As to the third requirement which relates to Petitioner's capability to use the patented product in the manufacture of a useful product or substance, there is ample evidence to show that Petitioner possesses such capability, having been in the drug manufacturing business for more than thirty three years, with varied lines of products including antibiotics, anti-TB, anti-asthma, anti-arthritics, anti-infectives, anti-ulcers, anti-bacterial, anti-fungal, and cardiovascular drugs. (See Affidavit of Dr. William Torres, par. 2 Exh. "F")

Petitioner has likewise established that it was incorporated way back on October 8, 1953 (Exh. "C") and its authorized capital stock has since been increased to ONE BILLION FIVE HUNDRED MILLION PESOS (Exh. "C-1"). It has been granted the license to operate Pharmaceutical Laboratory by the Bureau of Food and Drugs (Exh. "D"). It has also been granted the Certificate of Compliance attesting to the compliance with technical requirements for operation of a pharmaceutical laboratory by Bureau of Food and Drugs (Exh. "E").

Petitioner also possesses the necessary machineries and equipment for producing in capsule or tablet form, such as balances, Stokes/Manesty and Glen Mixers, V blender, oscillating granulators, Fitzmill comminuting machines, BB-B Tabletting Machine, Manesty Accela-COTA 24, and others. (See Affidavit of Dr. Torres, Exh. "F", Annex "B")

On personnel capability, Petitioner employees around 2,600 employees, of which 237 are holders of various degrees (Chemists, Pharmacists, Chemical Engineers, Mechanical Engineers and others). A list of ranking personnel with degrees ranging from Ph. Ds to Chemiste and Pharmacists, has been attached as Annex "A" to Exhibit "F".

With the cast resources of Petitioner in terms of manpower capitalization and plant facilities, coupled with the fact that it now actually produces more than 500 different dosage

forms of medicine under different brand names (Exh. “F”, par. 2), there is no doubt that Petitioner has sufficiently proved that it is capable of making use of the patented product, Ketoconazole, in the manufacturing of pharmaceutical dosage forms thereof. In fact, the capability of Petitioner to manufacture dosage forms of other drugs has been declared by this Office and affirmed by the Court of Appeals in the following cases: United Laboratories, Inc. v. Lawrence Henry, Charles Lants, et.al., CA-G.R. No. 10608-SP, September 28, 1981; United Laboratories, Inc. v. Eli Lilly & Co., et.al., CA-G.R. No. SP-06777, January 14, 1981; United Laboratories, Inc. v. Nippon Soda Kabushiki Kaisha, CA-G.R. No. 07437-SP, November 18, 1980, United Laboratories, Inc. v. Bristol-Myers Company, AC-G.R. SP No. 13375, March 30, 1983; United Laboratories, Inc. v. Frank Weisenborn et.al., CA-G.R. No. 13216-SP, January 13, 1983; United Laboratories, Inc. v. Fujisawa Pharmaceuticals Co., Ltd., CA-G.R. No. SP-11275-R, January 11, 1982; Pfizer Corporation v. The Hon. Demetrio Wendam, Director of Patents, and United Laboratories, Inc., CA-G.R. No. SP-13060, January 7, 1982; General Drug & Chemical Co., Inc. vs. Newport Pharmaceuticals, Inc., AC-G.R. No. SP-13410, November 22, 1983; Barry John Price, et.al. v. United Laboratories, Inc., G.R. No. 82542, September 29, 1988; and Graham John Durant, et.al. vs. Hon. Court of Appeals, et.al., G.R. No. 97247, January 31, 1991.

Petitioner definitely admitted that it seeks license to use the patented substance covered by Letters Patent No. 14635 as a raw material (which it will import from abroad) in the manufacture of pharmaceutical dosage form ready for use by patients.

The argument or issue thus posed does not militate against Petitioner’s action. But to facilitate proper understanding this Office once more ran through the whole gamut of jurisprudence relevant to the instant case.

In the case of General Drug and Chemical Co. Inc. vs. Newport Pharmaceuticals, Inc. et.al. (A.C. G.R. No. SP-13410, November 22, 1983), the Intermediate Appellate Court was confronted with the same issue. Aside from affirming the decision of the Director of Patents granting the compulsory license to the Petitioner to make use of the patented product in the manufacture of a useful product, the Intermediate Appellate Court cited the case of Parke Davis & Co. vs. Doctors Pharmaceuticals, Inc., L-22221, Aug. 31, 1965 (SCRA 1053) and quoted the Supreme Court’s pronouncements, in construing the original provisions of Republic Act 165 on compulsory licensing before its amendment by Presidential Decree No. 1263, that:

> “xxx In the first place, Section 24 of Republic Act No. 165 does not require the petitioner of a license to work the patented invention if the invention refers to medicine, for the term ‘work’ or ‘working’ used in said section does not apply to the circumstances mentioned in subsection (4), which relates to medicine or to one necessary for public health and public safety. Indeed, the Director of Patents has already correctly stated in previous cases that, in its strict sense, the term ‘worked’ or ‘working’ mentioned in the last paragraph of section 34 of the Patent Law has no applicability on those cited patented matters and the qualification of the petitioner to work the invention is immaterial, it being not a condition precedent before any person may place, it is not the intention of respondent to work or manufacture its brand of medicinal preparations containing such substance. And even if it be required that respondent should work itself the invention that it intends to use in the manufacture of its own brand of medicinal preparations said respondent would not be competent personnel and technicians; it has found wanting for it is staffed with adequate and several laboratories where medicines are prepared for safety and quality; it is equipped with machines for subdividing antibiotics; and it has capsule-filling machines and adequate personnel and facilities to test the quality of chloramphenicol.”

Buttressing the foregoing cases are the cases of United Laboratories, Inc. vs. Bristol Myers Company, AC-G.R. No. 13375, March 30, 1983, and Pfizer Corporation vs. Wendam and United Laboratories, Inc., AC-G.R. No. SP-13060, January 7, 1982. In the Bristol-Myers case it was held that:

"In the matter of capability of United in using Amikacin in the manufacture of a useful product, we quote with approval the Director of Patents in his decision, dated August 20, 1981:

As to issue raised by Respondent-Patentee Petitioner has failed to meet the requirement of the law on capability because successful manufacture of a product containing the patented substance has not been proved as required is not tenable. I do not subscribe to such interpretation. It is sufficient that the Petitioner possesses the necessary financial resources, technology, equipment and machinery and people with technical competence required in drug manufacture, all of which have been amply proved by the evidence on record. As aptly stated by Miss Garcia, there has been no instance where Petitioner was not able to produce a new product out of a new substance for reasons of technical difficulties in manufacturing. Gleaned from all the foregoing, I find that Petitioner has the capability to manufacture a useful product out of the patented product using pharmaceutical preparations containing the compounds covered by Patent No. 9589.

"On the other hand, Bristol maintains that in order to prove capability on the part of United to manufacture a product with Amikacin as an ingredient, the following factors should be established

a. a pharmaceutical formulation containing Amikacin as an active ingredients;

b. Procedures for manufacturing said pharmaceutical formulation;

c. quality control procedures for said pharmaceutical formulation; and

d. equipment necessary to carry out the manufacturing and quality control procedure for said pharmaceutical formulation.

"We agree with the argument of United to the effect that if we were to follow the theory of Bristol, we would require the actual production of the medicine itself and if that were so, the presidential decree in question should have required actual production, instead of mere capability."

On the claim that the subject invention is being presently distributed, detailed or retailed adequately throughout the Philippines, and that Patentees-Assignee is adequately equipped to produce and market any amount of pharmaceutical products containing the patented invention which the public may need, this Office would like to point out that such issue has already been threshed out and settled in the case of Parke Davis vs. Doctors Pharmaceuticals, Inc., 14 SCRA 1043, 1965, where the Supreme Court held that:

"Finally, we may add that it is not a valid ground to refute the license applied for the fact that the patentee is working the invention and as such has the exclusive right to the invention for a term of 17 years (Sections 20 & 21, Republic Act 165) as claimed for it being that the provisions permitting the grant of compulsory license is intended not only to give a chance to others to supply the public with the quantity of the patented articles but especially to prevent the building up of patent monopolies.

"The point is raised that the grant of the license is against public interest for it would force Parke Davis & Company to cease or stop manufacturing the

patented invention which would thereby adversely affect local employment and prejudice technology and chemical manufacturing and cut off the local supply of medicinal products. It should be noted to compete with Petitioner in the manufacture of chloramphenicol for it would either obtain the same from petitioner or would import whatever it may need in the manufacture of its own brand of medicinal preparations. But even assuming that the consequence the petitioner has envisioned may come true if the license is granted, still that should not stand in the way of the grant for that is in line with an express provision of our law. The grant of such license may work disadvantage on petitioner but the law must be observed until modified or repealed. On the other hand, there is the advantage that the importation of chloramphenicol might redound to the benefit of the public in general as it will increase the supply of medicines in our country containing chloramphenicol thereby reducing substantially the price of this drug.

xxx

"Finally, with regard to the contention that petitioner is entitled to the exclusive use of the invention for a term which under the law extends to 17 years, suffice it for us to quote what the Director of Patents says on this point:

The right to exclude others from the manufacturing, using or vending an invention relating to food or medicine should be conditioned to allowing any person to manufacture, use, or vend the same after a period of three years from the date of grant of the letters patent. After all, the patentee is not entirely deprived of any proprietary right. In fact, he has been given the period of three years to complete monopoly over patent. Compulsory licensing of a patent on food and medicine without regard to the other conditions imposed in Section 34 is not an undue deprivation of proprietary interest over a patent right because the law sees to it that even after three years of complete monopoly something is awarded to the inventor in the form of a bilateral and workable licensing agreement and a reasonable royalty to be agreed upon by the parties and in default of such agreement, the Director of Patents may fix the terms and conditions of the license. (See Sec. 36, Rep. Act 165)"

To cap it all, it must also be stated that the then Court of appeals also took the same stand in the case of United Laboratories, Inc. vs. Eli Lilly and Company CA-G.R. No. SP-06777, January 14, 1981, where it held:

"The provision embodied in Sections 34 to 36 of Republic Act No. 165 are designed to protect the public welfare against the disadvantages of monopoly resulting from a patent. But, a compulsory license may be granted only on the ground set forth in Section 34 and only after the expiration of three (3) years from the date of the grant of the patent. Under Section 34(d), any person may apply for a compulsory license if the patented invention relates to food or medicine or is necessary for public health or public safety. The legislature singled out food or medicine, since these items are vital to the survival and health of the people. If patented inventions on these items are completely controlled exclusively by the patentee, they may become instruments to injure and harm public interest. The legislative intent behind the provisions of Section 34(d) is to give a chance to others to supply the public with the quantity of the patented article, thereby increasing the supply of medicine inevitably leading to a reduction of the price thereof. xxx"

On the issue of royalty, it has been the policy of this Office to fix the same at the rate of 2.5% of the net wholesale price. This Office can take official cognizance of the practice of the Technology Transfer Board, which has been merged into what is now known as the Bureau of

Patents, Trademarks and Technology Transfer, in fixing the royalty rate at 3% of the net wholesale price in voluntary licensing cases.

In voluntary licenses, the licensee is the recipient of technology transfer from the licensor in the form of manufacturing procedures and other technical data. In compulsory licensing cases, however, the licensee is entitled only to the bare right of making use of the patented product in the manufacture of a useful product. The royalty rate of 2.5% has already been affirmed by the Court of Appeals in the cases of United Laboratories, Inc. vs. Frank D. Wisenborn, et.al. CA-G.R. No. 13216, January 13, 1983; and General Drug and Chemical Company, Inc. vs. Newport Pharmaceuticals, Inc., CA-G.R. No. 13410, November 22, 1983. In the latter case, the Court of Appeals held:

> "It is further claimed by Appellant in its fourth assigned error that the Director of Patents gravely abused hid discretion in fixing the royalty at 2.5% that Appellee must pay to the Appellant; that considering the complicated nature and proven effective usefulness of the patented complex or compound, the Director of Patents should have fixed the royalty which Appellee shall pay the Appellant at 5% of the net sales, the maximum allowed by par. (5) of Section 35-D of Presidential Decree 1263.
>
> "However, paragraph 3 of Section 35-B of Presidential Decree 1263 relied upon by Appellant provides that "royalty shall not exceed five percent (5%) of the net wholesale price (as defined in Section 35-A). Said provision thus grants the Director of Patents the use of his sound discretion in fixing the percentage of the net wholesale price of the articles manufactured under the license to be paid by the licensee to the Patentee so long as said royalty does not exceed 5% of the net wholesale price.
>
> "Considering that the Appellee in obtaining the license would only have the bare right to make use of the patented compound, without the Appellant's technical assistance in the manufacture of Appellant's pharmaceutical products using the patented compound; and considering that said pharmaceutical products of Appellee thus produced would only be used, distributed and disposed of in the Philippines (Par. 1, Prayer, Petition, Record, p. 2); and considering that the presumption of regularity attaches to the official actions taken by a public officer and in the absence of any evidence establishing a different conclusion, the royalty of 2.5% fixed by the Director of Patents must be accepted by this court as adequate and reasonable." (Underscoring supplied)

The 2.5% royalty rate has likewise been approved by the Supreme Court in the case of Barry John Price et.al. vs. United Laboratories, Inc., G.R. No. 82542, September 29, 1988; and Graham John Durant, et.al. v. Hon. Court of Appeals, et.al. G.R. No. 97247, January 31, 1991.

Thus, all the foregoing considered, this Office is convinced that the Petitioner deserves under the law and existing jurisprudence to be granted a compulsory license to make use of that product covered by Letters Patent No. 15877.

NOW THEREFORE, by virtue of the powers vested in this Office by Republic Act No. 165, as amended by Presidential Decree No. 1263, there is hereby issued a license in favor of the herein Petitioner, United Laboratories, Inc., under Letters Patent No. 14635 issued on October 12, 1981, subject to the following terms and conditions:

1. That Petitioner be hereby granted a non-exclusive and non-transferable license to manufacture, use and sell in the Philippines its own brands of pharmaceutical products containing Respondent's patented invention which is disclosed and claimed in Letters Patent No. 14635;

2. That the license granted herein shall be for the remaining life of said Letters Patent No. 14635 unless this license is terminated in the manner hereinafter provided and that no right or license is hereby granted to the Petitioner under any patent to the Respondent or other than recited herein;

3. Bu virtue of this license, Petitioner shall pay the Respondent a royalty on all license products containing the patented substance made and sold by the Petitioner in the amount equivalent to TWO AND ONE HALF PERCENT (2.5%) of the net sales in Philippines currency. The term "net sale" means the gross amount billed for the product pertaining to Letters Patent No. 14635, less:

(a) Transportation charges or allowances, if any, included in such amount;

(b) Trade, quantity or cash discounts and broker's or agent's distributor's commissions, if any, allowed or paid;

(c) Credits or allowances, if any, given or made on account of rejection or return of the patented product previously delivered;

(d) Any tax, excise or government charge included in such amount, or measured by the production, sale, transportation, use of delivery of the products; and

In case Petitioner's product containing the patented substance shall contain one or more active ingredients admixed therewith, said product hereinafter identified as admixed product, the royalty to be paid shall be determined in accordance with the following formula:

$$\text{ROYALTY} = \frac{\text{Net Sales on Admixed Product}}{\text{(Value of Patented Substance)} + \text{(Value of Other Active Ingredients)}} \times 0.025 \times \text{Value of Patented Substance}$$

4. The royalties shall be computed after the end of each calendar quarter for all goods containing the patented substance herein involved, made and sold during the preceding quarter and to be paid by the Petitioner at its place of business on or before the thirtieth day of the moth following the end of each calendar quarter. Payments should be made to Respondent's authorized representative in the Philippines;

5. The Petitioner shall keep records in sufficient detail to enable the Respondent to determine the royalties payable and shall further permit its books and records to be examined from time to time at Petitioner's premises during office hours, to the extent necessary to be made at the expense of Respondent by a certified public accountant appointed by Respondent and acceptable to the Petitioner;

6. The Petitioner shall adopt and use its own trademark or labels on all its products containing the patented substance herein involved;

7. The Petitioner shall comply with the laws on drugs and medicine requiring previous clinical tests and approval of proper government authorities before selling to the public its own products manufactured under the license;

8. The Respondent shall have the right to terminate the license granted to Petitioner by giving the latter thirty (30) days notice in writing to that effect, in the

event that Petitioner default in the payment of royalty provided herein or if the Petitioner shall default in the performance of other covenants or conditions of this agreement which are to be performed by the Petitioner:

(a) Petitioner shall have the right provided it is not in default to payment or royalties or other obligations under this agreement, to terminate the license granted to it, giving the Respondents thirty (30) days notice in writing to that affect;

(b) Any termination of this license as provided for above shall not in any way operate to deny Respondent its rights or remedies, either at law or equity, or relieve Petitioner of the payment of royalties or satisfaction of other obligations incurred prior to the effective date of such termination; and

(c) Notice of termination of this license shall be filed with the Bureau of Patents, Trademarks and Technology Transfer.

9. In case of dispute as to the enforcement of the provisions of its license, the matter shall be submitted for arbitration before the Director of Bureau of Patents, Trademarks and Technology Transfer or any ranking official of the Bureau of Patents, Trademarks and Technology Transfer duly delegated by him;

10. This License shall inure to the benefit of each of the parties herein, to the subsidiaries and assigns of the Respondent and to the successors and assigns of the Petitioner; and

11. The license takes effect immediately.

SO ORDERED.

IGNACIO S. SAPALO
Director