UNITED LABORATORIES, INC., Petitioner,	)	INTER PARTES CASE NO. 3098 PET. FOR COMPULSORY LICENSING
	)	Letters Patent No. 19373
	)	Granted on : April 2, 1986
	)	Patentee(s) : Kazayuki Nakagawa
	)	Kaoru Tanimura, &
- versus -	)	Shigeharu Tamad
	)	Title : CARBOSTYRIL
	)	DERIVATIVES AND
	)	PROCESS FOR
	)	PREPARING THE SAME
KAZAYUKI NAKAGAWA, ET.AL., Respondent-Patentees.	)	DECISION NO. 94-21 (PAT) February 15, 1994

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DECISION

This pertains to a Petition filed by United Laboratories, Inc., a corporation duly organized and existing under the laws of the Republic of the Philippines with principal offices at 66 United Street, Mandaluyong, Metro Manila, seeking for the grant of the compulsory License under Philippine Letters Patent No. 19373 for Carbostyril Derivatives and Process for Preparing the Same, issued by the Bureau of Patents, Trademarks and Technology Transfer on April 2, 1986 in the name of Kazuyuki Nakagawa, et al inventors, with Otsuka Pharmaceutical Co., Ltd., as assignee, a corporation of Japan, with principal offices at Chiyoda-ku, Tokyo, Japan, which may be served with processes through its Philippine attorneys of record, Messrs. Quasha, Asperilla, Ancheta, Valmonte, Pena & Marcos, with offices at Don Pablo Building, 114 Amorsolo Street, Makati, Metro Manila.

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

"1. That the patented invention relates to medicine, (Sec. 34 (e), Republic Act 165, as amended by P.D. No. 1263).

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

"1. Philippine Patent No. 19373 herein sought to be licensed was granted on April 2, 1986, more than two (2) years prior to the filing of this petition.

"2. Philippine Patent No. 19373 is directed to carbostyril and 3, 4-dihydrocarbostyril derivatives, including the compound procaterol which is particularly claimed in Claim 18 under its chemical name, said derivatives possessing B-adreno-receptor stimulating activity and being useful as medicine.

"3. Petitioner is a domestic corporation with an authorized capital stock of P1, 500,000,000 and has been in the business of manufacturing and selling pharmaceutical products since its incorporation on October 8, 1953.

"4. Petitioner possesses the financial, technical and manpower capability to make use of the patented compounds in raw material form in the manufacture of useful products in pharmaceutical dosage forms.

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

"7. The petitioner does not possess the necessary technical capability to manufacture and produce medicines or pharmaceutical preparations containing the patented compound.

"8. The petitioner does not intend to "work" the patented compound in accordance with Presidential Decree No. 1263 but merely to import the raw materials to be used in the manufacture of useful products in pharmaceutical dosage forms.

"9. Petitioner does not have the necessary facilities and sophisticated equipments to make use of the patented compound.

"10. Respondent-Patentees have spent time, effort and money in the experiment and perfection of its patented CARBOSTYRIL DERIVATIVES AND PROCESS FOR PREPARING THE SAME and it would be unfair to deprive them of the exclusive rights to use the patent.

"11. Furthermore, the application for the grant of a letters patent was filed on December 26, 1974 and letters patent was granted only on April 2, 1986 or after twelve (12) years of exchange of communications between the patentees and the Examiner of the then Philippine Patent Office. Thus, it would be unfair for petitioner to reap the fruits of the efforts of respondent-patentee by the mere expediency of filing a petition for compulsory licensing.

"12. Petitioner as licensee, has been in the business of manufacturing and selling pharmaceutical products useful as therapeutic agent such as bronchodilator, peripheral resodilator, an antihypertensive agent and the like, particularly for treating bronchial asthma and therefore the patent in question is being worked within the Philippines on a commercial scale and that the demand of the patented article in the Philippines is being met to an adequate extent and on reasonable terms.

"13. Petitioner has no valid cause of action against respondent-patentee and that the instant petition for compulsory licensing is clearly devoid of merit.

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

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 "I".

Dr. William Torres, in his Affidavit (Exh. "I") 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, United States of America
1980	- Doctor of Philosophy

	(Pharmaceutics), University Of Mississippi, USA
1969 to Present (with interruption)	- Instructor to Associate Professor, College of Pharmacy, University of the Philippines, Manila
1973 - 1980	- Asst. Researcher/Instructor, School of Pharmacy, University Of Mississippi, USA
1980 - 1981	- Consultant, PIACT/KABALIKAT, Inc., (POPCOM)
1981 - 1982	- Consultant, United Laboratories, Inc.
1982 - Present	- Scientist/Manager Product Research Department, United Laboratories, Inc.

He further stated that United Laboratories, Inc., was incorporated on October 8, 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 pharmaceutical products in different dosage forms such as tablets, capsules, powders for suspension, liquid 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-bacterials, anti-fungal, cardio-vascular drugs and others, some of which are listed in the Product Information Catalogue, marked as Exhibit “H”;

That the company has around 2,600 employees, of which more than 200 are of managerial rank who are holders of various degrees (chemists, pharmacists, chemical engineers, mechanical engineers, etc.); around 500 are supervisors, and the rest are rank-and-file workers, many of whom are also professionals and holders of various degrees. A bio-data of some key personnel is attached as Annex “A”;

That on June 2, 1982, he joined United Laboratories, Inc, as Scientist, in charge of the Stability Unit of Pharmacy Research and Development Group. He was involved in designing stability programs for all new products under development and existing products for improvement. In 1983, he was also made in charge of Bioavailability Unit and Preformulation Department. Bioavailability Unit is in charge of conducting studies to monitor product development and marketed products as to their bioavailability/bioequivalence in human subjects. Preformulation Department is involved in the physiochemical studies of pure compounds and these compounds with all possible excipients/additives needed to develop either solid, semi-solid or liquid dosage forms;

That his department, Product Research Department, is one of the several departments under the Pharmaceutical Research and Development and Analytical Chemistry Division of United Laboratories, Inc., the others being the Liquids and Semi-solids Department, Solids Department, Packaging Research and Development Department, Analytical Research Department, and Bioanalytical Research Department. The primary objective of this division is to develop new products and processes for the manufacture of various dosage forms and to improve formula and process of existing drug products. It is headed by an Assistant Vice-President, Ms. Estelita N. Garcia, who has a Masters Degree in Pharmacy, major in manufacturing from Purdue University, USA, Her experience in the pharmaceutical industry

covers the period from 1955 to the present, and she has been involved in all aspects of product development, quality control and manufacturing;

That he is aware that United Laboratories, Inc. has applied for the compulsory licensing of the drugs described in and covered by Patent No. 19373. One of the drugs covered by said patent is generically known as PROCATEROL, a substance which possesses B-adrenoreceptor stimulating activity and, therefore useful as a therapeutic agent, particularly as a bronchodilator. It is presently marketed in tablet and syrup forms. The development of the tablet and syrup forms of PROCATEROL is within the technical capability of United Laboratories, Inc. considering its technical expertise, experienced manpower, financial resources and manufacturing facilities, some of which are shown in the brochure “Research and Development at United Laboratories, Inc.” marked as Exhibit “G”;

That in the process of developing a tablet 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/Liquids & Semi-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. These are done to elucidate other physiochemical properties of the drug not specified in the supplier’s specifications. Stability studies are also conducted on the drug per se and the formulated dosage form and to be able to assign expiry date and to optimize the formula and process. United Laboratories, Inc. possesses the required equipments and expertise necessary for producing all pharmaceutical dosage forms mentioned in paragraph 2 hereof. Bioavailability studies are also conducted by Product Research Department to determine the acceptability of the formulation versus an established standard product;

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;

That after they have established that the dosage format complies with all product specifications and is completely free from defects, they turn over all date on manufacturing procedures to the Manufacturing Division which is headed by a Vice-President, Jose Pascual, for production of demonstration batches and 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 he products.

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

c. Complete essay procedure of the finished product.

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

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

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

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

That upon approval by the Bureau of Food and Drugs, full commercial production is commenced;

That their Division constantly words hand in hand with other divisions and groups in the company, particularly the Quality Control Group, under an Assistant Vice-President, Remedios Sanchez, and the Manufacturing Division. The Quality Control Group is charged with duty of assuring compliance with technical specifications of raw materials, packaging materials, products in process of manufacture and finished products. In short, no products are related into the market unless they conform to quality control standards the market unless they conform to quality control standards.

On cross-examination Dr. Torres testified among others, that:

Petitioner manufactures different anti-asthma products and that his company have the classic formula known as Asthmalon tablets which contains Theofillin. They have also Salbutamol which is called Librintin in the market and that is the brand name. There are also other products not specifically for asthma, but it can be used for asthma also. (See TSN 9-4-89, pp/ 9-10)

The patent for which compulsory license is sought covers an anti-asthma drug which is also a bronchodilator and is used as an anti-allergy preparation and that it is homologous to Salbutamol which respondent is now manufacturing is called Procaterol. Procaterol is available in tablet and syrup forms and is marketed in the Philippines by Marsman for Otsuka of Japan. (TSN, 9-4-89; pp. 10, 11 and 12)

That if Petitioner is granted a license, it will manufacture the tablet and syrup dosage forms of Procaterol, the same formats being produced by Marsman, but probably with different excipients. Since Procaterol is similar to Salbutamol, the use of excipients such as starch, magnesium state and lactose, will be considered in producing the syrup and tablet forms, (TSN, 9-4-89; pp. 15-17)

When asked why Petitioner is interested in Procaterol considering that it has other anti-asthma drugs in the market, Dr. Torres explained that “This is actually a new drug that is more effective than what we have right now, Salbutamol. This is one you need only from 10 to 50 micrograms of the active material in the tablet to give the same effect as let us say 84 Salbutamol to about 40 to 80 to be more effective than Salbutamol. So it is a very potent drug and it is longer lasting than the existing one that we have.” (TSN, 9-4-89; pp. 29-30)

Dr. Torres finally testified that Procaterol will not by synthesized by Petitioner which will only buy the same as an active ingredient, to be formulated in tablet or syrup form. He further testified that, “for the tablet, the formulation will be, the active which is Procaterol Hydrochloride in 10 to 50 micrograms. Then we will have the excipients which will aid in the formation of the tablet, like we will have the binder so we can form the compact tablet. We will have a disintegrant to make sure that when it is swallowed it will disintegrate in the stomach. We will have the lubricant which will facilitate tabletting of the formulation, some other additives like flavor, color if it is needed. x x x For the syrup dosage form, we prepare the base which is water plus sugar if it is syrup plus some preservative, and to this when it has cooled down you add now the additive, probably a flavor, so probably just one simple method of mixing one into another with the aid of sugar and water.” (TSN, 9-4-89; pp. 33, 35)

Petitioner thereafter formally offered Exhibit “A” to “I” including their respective sub-markings as well as the testimony of its lone witness, Dr. William Torres, which Exhibits were admitted as evidence for the Petitioner for whatever they are worth, per Order 90-220 dated April 10, 1990.

Respondent-Patentee in turn presented the testimony of Joselito O. Goco, Marketing Manager of Otsuka Pharmaceutical marked Exh. "I" to show among others, the organization, business, products, and facilities of the Respondent-Patentee and its Philippine Licensee; different agreements entered into by the Respondent in connection with the manufacture, sale and distribution of the patented product subject of this petitioner, the capability of the Respondent thru its licensee to manufacture and distribute the patented products in the Philippines in sufficient and steadily increasing quantities; and to prove that there is no necessity for an involuntary license to be issued to the herein petitioner.

Respondent-Patentee likewise formally offered Exhibit "1" to "8" as their evidence, the purposes of which are as follows:

Exh. "2" – Company Brochure of Otsuka Pharmaceutical Co. Ltd. consisting of 39 pages.	To show the company profile of the Respondent-Patentee, which includes among others, its history, clinical research activities, facilities, branches in different countries of the world, various pharmaceutical products, and promotional activities making it highly capable of supplying the world market of its products.
"3" – Agreement between Respondent and Marsman Laboratories, Inc. consisting of 14 pages.	To show that Respondent has licensed a reputable & competent local company as the exclusive manufacturer and distributor in the Philippines of the patented product.
"4" – Brochure of Marsman & Co., Inc. consisting of 9 pages.	To show the company profile of Marsman Co., to prove that Marsman as the licensee of the Respondent has more than sufficient facilities, manpower and technology of producing the patented products.
"5" – Memorandum between Respondent and Marsman Laboratories dated June 1, 1989.	To show the transfer of the manufacture of Respondent's specialties, which include the patented product from Marsman to Interphil Laboratories, one of the biggest, most well-equipped and most experienced pharmaceutical manufacturing company in the Philippines; also to show that there is no need to license petitioner to manufacture the patented product.
"6" – Memorandum of Agreement between Marsman Co., Inc. and Respondent-Patentee.	To show the creation of Otsuka Marsman Organization which is 100% devoted to the development of the Pharmaceutical specialties of Respondent in the Philippines.
"7" – Organizational Chart of Otsuka Marsman	To show the organizational structure of Otsuka Marsman Organization as 100% devoted in the development of the pharmaceutical specialties of the Respondent.
"8" – Organigram of Marsman Distributor Group as the distributing arm	To show that Otsuka Marsman Organization is wholly supported by the whole infrastructure of the distributing arm of

of Otsuka Marsman Organization. Marsman and Co.

Exhs. “1” to “8’ were admitted for whatever they are worth with Petitioner’s comments and objections being made part of the records of this case, per Order No. 91-193 dated February 25, 1991.

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 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 at any time after the expiration of two years from the date of the grant 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 form 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 the records and the evidence will show, subject Letters Patent No. 19373 was issued on April 2, 1986 and has been in effect for more than two years when the instant petition for compulsory licensing was filed on June 21, 1988.

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, and that it manufactures around 500 pharmaceutical products in different dosage forms such as tablets, capsules, powders for suspension, liquid suspensions, elixirs, syrups, drops, lotions, emulsions, parenteral preparations and pellets with varied lines of products including antibiotics, anti-TB, anti-asthma, anti-arthritic, anti-infectives, anti-ulcers, anti-bacterial, anti-fungal, and cardiovascular drugs and others, some of which, are listed in the Product Information Catalogue, marked as Exhibit “H”, (See Affidavit of Dr. William Torres, par. 2, Exh. “I”)

Petitioner has likewise established that it was incorporated way back on October 8, 1953 (Exh. “C”) and it 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 equipments for producing drugs in capsule or tablet form, such as balances, Stokes/Manesty and Glen Mixers, V blenders, oscillating granulators, Fitzmill comminuting machines, BB-3B Tabletting Machine, Manesty Accela-COTA 24, and others. (See Affidavit of Dr. Torres, Exh. “I”, Annex “B”)

On personnel capability, Petitioner employs around 2,600 employees, of which more than 200 are of managerial ranks who are holders of various degrees (chemists, pharmacists, chemical engineers, mechanical engineers, etc.); around 500 are supervisors, and the rest are rank-and-file workers, many of whom are also professionals and holders of various degrees. A bio-data of some key personnel is attached as Annex “A” of (Exh. “I-4”).

With the vast 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 brandnames (Exh. “I”, par.2), there is no doubt that Petitioner has sufficiently proved that it is capable of making use of the patented product, 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 and Supreme Court 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. 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. v. 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. v. 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. 19373 as a raw material (which it will import from abroad) in the manufacture of pharmaceutical dosage forms such as syrup and tablet.

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. (AC-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 or Parke Davis & Co. vs. Doctors Pharmaceuticals, Inc., L-22221, August 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 34 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 “worked” or “working” used in said section does not apply to the circumstance mentioned in subsection (d), which related 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 paragraph of Section 34 of the Patent Law “has no applicability to 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 apply for the grant of the license.” In the second place, it is not the intention of respondent to work or manufacture the patented invention itself but merely to 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 and of medicinal preparations said respondent would not be found wanting for it is staffed with adequate and competent personnel and technicians; it has several laboratories where medicines are prepared for safety and quality; it has been 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, Ins. 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 the issue raised by Respondent-Patentee that 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.
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> 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:
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> a. a pharmaceutical formulation containing Amikacin as an active ingredient;
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> b. procedure for manufacturing said pharmaceutical formulation;
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> c. quality control procedure 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 Patentee-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 1053, 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 for the invention for the terms of 17 years (Sections 20 & 21, Republic Act 165) as claimed in the third assignment of error, the reason 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 article 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, however, that respondent does not intend 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 on food and medicine without regard to the other conditions imposed on Sec. 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 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 started 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 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. v. Frank D. Weisenborn, et.al., CA-G.R. No. 13216, January 13, 1983; and General Drug and Chemical Company, Inc. v. Newport Pharmaceuticals, Inc. AC-G.R. 13410, November 22, 1983.

The 2.5% royalty rate has likewise been approved by the Supreme Court in the cases of Barry John Price, et.al. v. 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 the patented product covered by Letters Patent No. 19373.

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. 19373 issued on April 2, 1986, 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. 19373;

2. That the license granted herein shall be for the remaining life of said Letters Patent No. 19373 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. 19373, 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