

DOCTOR'S PHARMACEUTICAL, INC., Petitioner,	)	INTER PARTES CASE NO. 2058 Pet. For Compulsory Licensing
	)	
	)	Letters Patent No. 12207
	)	Issued on : November 29, 1978
	)	Patentee : Graham John Durant, John Collin Emmett and Charon Robin Ganellin, assignor to Smith Kline & French Laboratories Ltd.
- versus -	)	
	)	Title : DERIVATIVES OF HETEROCYCLITHIO OR LOWER ALKOXY OR AMINO LOWER ALKYL THIOUREA, UREAS AND GUANIDINES
	)	
	)	
	)	
SMITH KLINE & FRENCH LAB. LTD., Respondent-Patentee.	)	<u>DECISION NO. 94-20 (PAT)</u> February 14, 1994
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DECISION

This pertains to a Petition filed by Doctors Pharmaceutical, Inc., a corporation organized and existing under and by virtue of the laws of the Philippines, with principal office at 345 B. San Diego Street, 10<sup>th</sup> Avenue, Grace Park, Caloocan City, Metro Manila, seeking for the grant of the compulsory license under Philippine Letters Patent No. 12207 entitled DERIVATIVES OF HETEROCYCLITHIO OR LOWER ALKOXY OR AMINO LOWER ALKYL HIOUREA, UREAS AND GUANIDINES, issued by the Bureau of Patents, Trademarks and Technology Transfer on November 29, 1978 in the name of Smith Kline & French Overseas Company as assignee, with place of business at Welwyn Garden City, England, which may be served with orders and other processes of this through its Philippine representative Smith Kline & French Overseas Company with office at Victoria Valley Blvd., Cainta, Metro Manila.

The ground for this Petition for grant of Compulsory License is as follows:

"1. That the patented inventions relate to medicines or is necessary for public health or public safety."

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

"1. That the patented invention is an antacid and therefore, relates to medicine and/or is necessary for public health or public safety;

"2. That the date of the grant of Philippine Letters Patent No. 12207 is on November 29, 1978, and therefore, the filing date of this petition for compulsory licensing is well after the expiration of the two years period provided for under Section 34 of Republic Act No. 165, as amended by Presidential Decree No. 1263;

"3. That the petitioner is and has been lawfully engaged in the business of manufacturing and distributing pharmaceuticals products;

“4. That petitioner is duly registered with the Bureau of Food and Drugs and has the capability to work the patented product or make use of the patented product in the manufacture of medicine and its distributions thereof.”

Respondent-Patentee, through counsel, filed an Answer which was thereafter amended and interposed the following affirmative defenses:

“6. The petition states no legal/factual ground to merit consideration and therefore lacks cause of action;

“7. Petitioner lacks the 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;

“8. Petitioner has not made any definitive allegation on how it intends to work the patented invention or how it will make use of the patented product in the manufacture of a useful product. Petitioner should clearly and unequivocally allege what it proposes to do with the invention subject of Letters Patent No. 12207. Otherwise petitioner may merely import the patented product and engage only in packaging activity contrary to the intent and purpose of the amendatory provision of Presidential Decree No. 1263. Mere importation of the invention covered by Letters Patent No. 12207 does not constitute “working” under Section 34(3) of R.A. No. 165 as amended by Presidential Decree No. 1263;

“9. Respondent-Patentee’s conversion, production, manufacture, marketing, detailing and distribution of the invention covered by Letters Patent No. 12207 are so extensive and in such quantity that the demands of the Philippine market are fully met by medical preparations covered by the patented invention;

“10. Respondent-patentee’s marketing arms are adequately equipped to produce and/or market any amount or quantity of the medicine covered by the patented invention to satisfy the Philippine market or public need;

“11. The grant of compulsory license to petitioner will not promote public safety or public health as the petition is evidently designed for the enhancement of the pecuniary interests of the petitioner.”

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

To support its allegation in the Petition for Compulsory Licensing, Petitioner was able to establish the fact that it has sufficient, adequate, machines and equipment, to manufacture cimetidine. Likewise, it was able to establish that it is financially capable of importing from a foreign source, the materials sought to be patented. It also established that the petitioner has the laboratory and competent staff of Medical Personnel who are graduates of well known universities and passed the Board. Thus in the hearing, the following witnesses were presented namely: Milagros Villarba, Edna Ursolino and Ofelia A. Natividad, who testified substantially in their respective field of special technical jobs in the Doctor’s Pharmaceutical, Inc. Petitioner likewise presented Messr. Ramos and Gregorio Alcobao as witnesses.

Milagros Villarba testified that she is the Administration Manager of the petitioner. That as Administration Manager, she testified on the different departments that make up the company namely, the Administration, Production and Sales department. She also testified on the number of personnel in each department namely: Production – 120; Sales – 3-; and Administration – 40; That three (3) sections directly under her are the following: Inventory Control Section, the Credit and Collection and Accounting Sections. She claimed that she also has access in production since she takes care of the purchasing of the materials that the production people use. She

presented several documents like LTO (Licensing to Operate issued by BFAD); Articles of Incorporation, Amended Articles of Incorporation, which were marked as Exhibits "A" to "G" correspondingly. She also testified that she is not a graduate of any technical course but she has attended some seminars pertaining to production and she has not in anyway performed an actual work in production. That with the list of machines she presented, some of them she is familiar with although she is not actually aware of their functions and operations. She further testified that she is aware that the Research and Development section has an on-going study on the production of cimetidine tablet. That Ms. Ursolino has submitted to her a copy of the status of this study. According to her, given the license to manufacture Cimetidine tablet formulation, they will be capable since the equipment required are already available in the plant. She also testified that it is not the first time that Doctor's filed for a Compulsory Licensing for a patented drug since they have acquired a permit to manufacture drugs containing patented active ingredients like ethambutol (Cyanamid), ampicillin and amoxicillin. That at one time she had a meeting with some of the sales force people and touched on the marketability of the said product. (TSN, October 14, 1987, pp. 5 to 25, TSN, February 9, 1988, p.5)

Witness Edna Ursolino testified on the technical side of the case. She testified that she was formerly the Quality Control Analyst and at present the Researcher and Development Officer of herein Petitioner; that as Research and Development Officer, she has been involved in the development of new product including its formulation and setting the manufacture and control procedures and also improvement of product and finding ways of solution in product form, also of registration of the same with the Food and Drugs Administration. She presented exhibits marked as Exhibit "I", "I-1" to "I-6" which pertains on the studies of Cimetidine Hydrochloride Tablet Manufacturing Procedure which included in the specifications of cimetidine as raw materials and the different tests that have to be conducted on the material (cimetidine), the manufacturing procedure which included the different steps in each stage of processing, the equipment and utensil requirements necessary and their specifications, the physical description as well as other characteristics of a finished dosage form was also discussed. Likewise emphasis was given on where and how the active material (cimetidine) used in the experiment was procured during the direct and cross-examination. The witness also explained the use of the required equipments and machines are already available at the DPI PLANT; that this is not the first time that Doctor's Pharmaceutical, Inc. would be manufacturing compresses tablet. (TSN, October 14, 1987, pp. 27-38; TSN February 14, 1988, pp. 2-28)

Another witness Ofelia A. Natividad testified that she is the Quality Control Supervisor of the Petitioner. She also testified on her expertise as quality control supervisor; that she is a B.S. Pharmacy graduate at the University of the Philippines in the year 1981 and passed the Pharmacy Licensure Examination in the same year; that she was connected with Doctor's Pharmaceutical, Inc. since January 3, 1983; that she has undergone special trainings on the different establishments like Veterans Hospital (Dispensing), and same company where she is employed right now in Doctor's Pharmaceutical, Inc. where she got to be exposed in the different areas such as production, quality control (analysis/inspection) and research and development. She also testified that she also had a part in developing the procedure in the manufacture of cimetidine tablet since she initiated it and turned it over to Ms. Ursolino when she took over as research and development pharmacist in 1987. (TSN, April 14, 1988, pp. 3-12)

Petitioner thereafter formally offered Exhibits "A" to "L-4", inclusive, and the testimonies of Petitioner's witness Ofelia A. Natividad, Edna Ursolino, Milagros Villarba, Melchor Ramos and Georgia Alcobao, which exhibits were admitted as evidence for the Petitioner for whatever they are worth, per Order No. 89-858 dated October 31, 1989.

Respondent-Patentee in turn presented and formally offered the following exhibits together with the purposes for which they were offered:

<u>EXHIBITS</u>	<u>NATURE</u>	<u>PURPOSE</u>
"1"	Transcript of Stenographic	To prove that (a) Cimetidine is the

Notes of the hearing of March 9, 1990 consisting of 38 pages, containing the direct examination of BELINDA MOLINA, respondent-patentee's Chief Analyst.

subject matter of Letters Patent No. 12207 and is used in the manufacture of tablets, capsules and liquid under the brandname of TAGAMET for the treatment of recurrent duodenal or benign gastric ulcer; (b) that Cimetidine is a raw material (not a product) and not locally available. Respondent-Patentee gets its supply of this raw material from Smith Kline Puerto Rico, which is a subsidiary of Smith Kline Beecham, Pennsylvania, USA, like respondent-patentee herein; (c) that it is not possible for any pharmaceutical firm in the Philippines or the Petitioner for that matter, to manufacture their own brand of medicine with Cimetidine since this raw material is not locally available.

"2"

Transcript of Stenographic Notes of the hearing of October 29, 1991 consisting of 82 pages, containing the direct and cross-examination of JULIETA LIM, respondent-patentee's Quality Philippines other than Assurance Manager.

To prove that

(a) Cimetidine is an active ingredient in the manufacture of Tagamet.

(b) That Smith Kline Puerto Rico is not supplying Cimetidine raw material to other companies in the Philippines other than Smith Kline Philippines

(c) That no other drug firm in the Philippines is manufacturing Tagamet with Cimetidine as the active ingredient.

(d) That respondent-patentee's quarterly supply from its sister company Smith Kline Puerto Rico is sufficient to supply its requirements for the manufacture of Tagamet for the people.

(e) That it is not possible to manufacture Tagamet tablets or liquids without Cimetidine as the active ingredients.

"3"

Transcript of Stenographic Notes of the hearing of November 25, 1991 consisting of 8 pages, containing the offer of evidence of the testimony of JOEY DOMINGUEZ, a respondent-patentee's Plant

To prove that the basic issues which Mr. Dominguez would have testified were admitted by Counsel for Petitioner.

Manager, if presented to testify.

“4”

Transcript of Stenographic Notes of the hearing of February 11, 1992 consisting of 15 pages, containing the direct examination of CARMENCITA GUTIERREZ, respondent-patentee's Director for Quality Assurance, Vaccines and External Affairs.

To prove that the offer of evidence on matters which Mrs. Gutierrez would have testified if presented to testify further was admitted by Counsel for Petitioner.

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 issued revolves around Sec. 34-1(e) and Section 2 thereof.

Sec. 34 1(e) provides as follows:

SEC. 34. Ground for Compulsory Licensing.

(1) Any person may apply top 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:

- a) xxx
- b) xxx
- c) xxx
- d) xxx
- e) If the patented invention or article related to fond or medicine or manufactured products or substances which can be used as food or medicine, or is necessary for public health or public safety.

xxx

(2) 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 the records and the evidence will show, subject Letters Patent No. 12207 was issued on November 29, 1978 and has been in effect for more than two years when the instant petition for compulsory licensing was filed on March 24, 1987.

Likewise, as shown on page 2, 2<sup>nd</sup> paragraph of the Specification, subject Letters Patent No. 12207 relates to compound and compositions used in inhibiting certain actions of histamine not inhibited by known antihistamines and therefore, relates to medicine.

Furthermore, as shown by no less than Exh. "1" and "2" of Respondent-Patentee and the purposes for which they were offered i.e. "to prove that (a) Cimetidine is the subject matter of Letters Patent No. 12207 and is used in the manufacture of tablets, capsules and liquid under the brandname of TAGAMET for the treatment of recurrent duodenal or benign gastric ulcer hence, the same undeniably 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 as has been discussed, there is ample evidence to show that Petitioner possesses such capability, having competent personnel, machines and equipment as well as permit to manufacture different drugs containing patented active ingredients such as ethambutol of American Cyanamid and Ampicillin and Amoxicillin of Beecham Groups, Ltd.

The claim that a compulsory license cannot be granted to respondent because the latter does not intend to work the patented invention itself but merely import it has no legal nor factual basis.

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 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 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 invention 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 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 equipped with machines for subdividing antibiotics; and it has capsule-filling machines and adequate personnel and facilities to test the quality of chloramphenicol. (See General Drug and Chemical Co. Inc. vs. Newport Pharmaceuticals, Inc. et.al., A.C.G.R. No. 13410, Nov. 22, 1983; Parkes Davis and Co. vs. Doctors Pharmaceuticals Inc., L-22221, August 31, 1965 SCRA 1053)

Likewise, the claim of Respondent-Patentee that a compulsory license cannot be lawfully granted under a patent if the invention is being worked by the patentee in the Philippines and has no basis law.

Sec. 34(a) of R.A. 165 Provides that the non-working of patentee of the patented invention is one of the several grounds for granting a compulsory license enumerated under Sec. 34 (a) to (e).

For emphasis, the ground for compulsory license in the instant case is based on Sec. 34(e) of R.A. 165 as hereinbefore discussed and therefore, has no applicability whatsoever to Sec. 34(a) of the same law.

Sec. 34(2) however explicitly states that –

(2) In any of the above cases, a compulsory license shall be granted to the petitioner provided that 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 enjoy the patented process;

hence the capability to work” the patented invention or to make use of the patented product in the manufacture of a useful product, or to employ the patented process is required.

On the claim that the subject invention is being presently distributed, detailed or retailed adequately throughout the Philippines by the Patentee who 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 ad that 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 I entitled to the exclusive use of the invention for a term which under the law extends to 17years, 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 a 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 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)”

Likewise, the claim that Sec. 34(d) as amended by P.D. 1263 is unconstitutional has likewise no basis on fact or in law as has been amply discussed in the preceding case of Parke Davis Co. vs. Doctors Pharmaceutical, Inc. Moreover the fact that the Phil. Adhered to the Convention of Paris for the protection of industrial property does not deprive the country the right to take legislative measures to provide for a compulsory license.

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 it’s 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 has 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 know 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. (Exh. “K-1”)

In voluntary licenses, the licensee is the recipient of technology transfer from the licensor in the form of licensing cases, however, the license 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 case 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. 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 his discretion in fixing the royalty at 2.5% that Appellee must pay to the Appellant; that considering the complicated nature and proven 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-B 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 sue of his sound discretion in fixing the percentage of the net wholesale price of the articles manufactured under 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 containing 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, Petitioner, 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 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, 1983; 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. 12207.

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. 12207 issued on November 29, 1978, 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. 12207;
2. That the license granted herein shall be for the remaining life of said Letters Patent No.12207 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. By 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. 12207, 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 or 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:

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

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 month 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