UNITED LABORATORIES, INC., Petitioner, -versus- BAYER AKTIENGESELLSCHAFT Respondent-Assignee.	}	Inter Partes Case No. 2085 For Compulsory Licensing: Patent No. : 18803 Date Granted: 27 September 1985 Title : 1-Cyclopropyl-6-Fluoro-1, 4-Dihydro-4Oxo-Piperazino-Quinoline-3-Carboxylic Acids Antibacterial Agents Containing These Compounds Inventor : Klause Grahe, et al. Assignee : Bayer Aktiengesellschaft Decision No. 2002 – 15

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DECISION

This is a verified petition for the compulsory licensing of Patent No. 18803 issued to assignee Bayer Aktiengesellschaft, a corporation organized and existing under the laws of Germany with principal office address at D-5090 Leverkusen, Bayerwerk, Germany.

On October 27, 1987, United Laboratories, Inc., a corporation duly organized and existing under the laws of the Republic of the Philippines, with a principal office address at 66 United Street, Mandaluyong, Metro Manila, filed a verified petition for compulsory licensing of Patent No. 18803 in its favor. Petitioner relied on the following grounds for the grant of its petition as hereunder quoted:

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

In support of its quest for compulsory license, Petitioner relied on the following facts:

> "1. Philippine Patent No. 18803 herein sought to be licensed was granted on September 27, 1985 more than two (2) years prior to the filing of this petition.
>
> "2. Philippine Patent No. 18803 is directed to:
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> a. 1-Cyclopropyl-6-Fluoro-1,4-Dihydro-4Oxo-Piperazino-quinoline-3-carboxylic acids, including the compound ciprofloxacin chemically named in claim 2, which are useful as antibacterial agents; and
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> b. antibacterial pharmaceutical composition medicament and feed additive comprising the above-named compounds as active ingredient, all which are useful as, or relate to, medicine.
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> "3. Petitioner is a domestic corporation with an authorized capital stock of Php. 1,500,000,000 and has been in the business of manufacturing and selling pharmaceutical products since its incorporation on 8 October 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-Assignee filed its Answer on April 6, 1988 after requesting an extension thereof. In its answer Respondent-Assignee denied all the material allegations in the petition except the preliminary matters therein relative of its being holder-assignee of the subject patent which relates to medicine and its existence.

In its defense Respondent-Assignee posited the following averments by way of Special and Affirmative Defenses:

"5. The patented product (CIPROFLOXACIN) is being manufactured / worked and adequately made available in the Philippines on commercial scale since October 1986 thru the manufacturing and marketing agents of Respondent-Patentee. And, the present demands for the use of the patented products by the public does not warrant or justify the grant of a compulsory license to Petitioner since such demands has been fully and adequately met by the current production, distribution and marketing of the same in the Philippines.

"6. The Petitioner is not in a position to develop the laboratory scale process required for the production of the patented product (CIPROFLOXACIN) and neither is Petitioner in a position to produce sufficient amounts of the patented products of such purity, high quality and safety standards set by the Food and Drug Administration (FDA) for the registration of the patented product since it (CIPROFLOXACIN) is produced in a very complicated multi-stage processing very special devices, which Petitioner certainly does not possess. Thus, Petitioner has no capability to manufacture, produce and/or even import, the patented products (CIPROFLOXACIN) in such amounts and quantity as to satisfy or meet the demands;

"7. Petitioner did not specifically set forth or alleged in the petition the ultimate facts showing its capability to work and make use of the patented product, such as the method or technical know-how/process to be used to manufacture and/or formulate the patented product, the raw materials to be used in the manufacture of the patented products and the test methods which are to be used to insure that the raw material and final product meet the standard quality and safety of CIPROFLOXACIN.

"8. The Petitioner did not further allege with sufficient definiteness or particularity to support its claim that it possesses the 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.

"9. Petitioner is not entitled to grant of a compulsory license under Section 34 of the Patent Laws since it does not possess the necessary technical know-how and capability to work the patented product or to make use of the patented product in manufacture of a useful product.

"10. The denial of the present petition will not result in a monopoly of trade and business in respect of the production and distribution of the patented product since Respondent-Assignee has an existing manufacturing and marketing agents and did not exclusively exercise all the rights conferred by the letters patent.

"1.. The grant of the compulsory license to Petitioner will not promote nor guaranty public safety or public health by reason of the technical scale process, know-how, and the high quality and safety standards involved in the manufacture, formulation and/or use of the patented product (CIPROFLOXACIN).

The parties filed their respective Pre-Trial Brief on July 8, 1988 interposing the main common issue to which this office is now task to resolve on whether or not Petitioner has the capability of working or making use of the patented product subject of this instant case, thus entitled to the grant of compulsory license.

Trial on the merits ensued there having no amicable settlement arrived by the contending parties. On September 7, 1992, Petitioner formally offered its evidence consisting of exhibits "A" to "P" inclusive of sub-markings. The same were admitted over the objection of the other party. On the other hand, Respondent-Assignee formally offered its evidence on July 10, 1994 consisting of Exhibits "1" inclusive of sub-markings. Said Exhibits were admitted over the objection of the Petitioner as per Order No. 94-469. Thereafter, the parties were directed to file their respective Memorandum within thirty (30) days from receipt of said Order.

Accordingly, Respondent-Assignee filed its Memorandum on October 17, 1994 while Petitioner did its part on January 21, 1997 through its new counsel Atty. Cesar C. Sandiego of Sioson, Sandiego & Associates after the withdrawal of Petitioner's former counsel on December 20, 1994, while the present counsel entered its appearance on the same date.

Section 34(1)(e), 2 and 3 of the Republic Act No. 165, as amended by Presidential Decree No. 1263, requires that Petitioner for a compulsory license must show that patented article relates to medicine and the patent was granted at least two (2) years from the grant of patent (Sec. 34-1[e], 2 and 3). This provision provides that:

> "Grounds for compulsory license. – (1) Any person may apply to the Director for the grant of license under a particular patent <u>at any time after the expiration of two (2) years from the date of the grant of the patent, under any of the following circumstances:</u>
>
> x x x
>
> "(e) <u>If the patented invention or article relates to food or medicine or manufactured products or substances which can be used as food or medicine, or is necessary for public health or safety.</u>

> "(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 employ the patented process.
>
> "(3) The term "work" or "working" as used in the sections means the manufacture and sale of the patented article or the patented machine, or the application of the patented process for production, in or by means of a definite and substantial establishment or organization in the Philippines and on scale which is reasonable and adequate under the circumstances. Importation shall not constitute "working"."
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> x x x

From the foregoing provisions, it is clear that Petitioner must safety the following requirements before it can be granted a compulsory license, to wit:

1. The petition for the compulsory license must be filed after two (2) years from the date the subject patent was granted;

2. The patented invention must relate to food or medicine;

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

Delving now into the issued, the records show that Letters Patent No. 18803 subject matter of this case was issued on September 27, 1985; that said patent relates to medicine and that this petition for compulsory license was filed on October 27, 1987 or more than two (2) years after the issuance of the subject matter of this case. Therefore, the instant petition for compulsory license filed by herein Petitioner complied with the first two requirements of the law as above stated.

Having resolved the first two issues, the main issue now left to be resolved is whether or not Petitioner has the capability to make use of the patented product in the manufacture of a useful product or pharmaceutical dosage forms.

The evidence on record showed that Petitioner was incorporated on October 8, 1953 (Exhibit "C") with an authorized capital stock of ONE BILLION FIVE HUNDRED MILLION (Php 1, 500,000,000.00) PESOS (Exhibits "C" and "C-1"). It has been granted a License to Operate Pharmaceutical Laboratory by the Bureau of Food and Drugs (Exhibit "D"). It has also been granted a Certificate of Compliance by the Bureau of Food and Drug relative to the technical requirements for operation of pharmaceutical laboratory in pursuant to Section 4(e) or Republic Act No. 3720 (Food, Drug and Cosmetic Act) (Exhibit "E"). Likewise, a Certificate of Accreditation was issued in its favor by the Bureau of Food and Drug relative to its compliance of Drug Quality Control Laboratory as inspected (Exhibit "F"). Subsequent inspections were conducted by the representatives of the Bureau of Food and Drug on Petitioner's premises and operational requirements, which yields a satisfactory result in its favor (Exhibits "K" to "N" inclusive of sub-markings).

The records also show that Petitioner possesses indispensable machineries and equipment in the production of its various products in capsule or tablet forms, which include among others Strokes/Manesty and Glenn Mixers, V and Ribbon Blenders, Oscillating Granulators, Fitzmill Comminuting Machines, tabletting machines and other equipment which are

indispensable in drug manufacturing (Exhibits “G” and “I”). It has also employed around 2,600 employees majority of whom are professionals in their respective fields related to pharmaceutical operation. These profession include Doctor of Medicine, Chemist, Pharmacist and Engineer (Exhibit “I”).

In its bid to controvert Petitioner’s stand, Respondent-Assignee presented the affidavit of its foreign witness Dr. Ekkehard Beyer, who testified that Petitioner is not equipped with the required technical know-how and lacks the adequate facilities in the production of the patented product in its finished form/product of the subject patent and the fact that it lacks adequate quality control procedures (Exhibit “1” inclusive of sub-markings). These matters have been dealt with adequately and fully in Petitioner’s documentary evidences and its witness testimony as above mentioned which disclosed that it possesses the necessary financial resources, technical expertise, machinery and equipment and manpower that render it fully capable of making dosage formulation containing the compound or compounds covered by the patent under consideration or other useful product derive therefrom. Quality control is part and parcel of drug manufacturing operation, which is one Petitioner’s qualifications, being a grantee of several compulsory licenses, as testified to by its witness.

Relative to Petitioner’s capability to use the patented product in the manufacture of useful product or substance, there is ample evidence to show that Petitioner possesses such capability having been in drug manufacturing business for more than fifty (50) years and the fact that it produces various line of products including antibiotics, anti-TB, anti-asthma, anti-arthritic, anti-infections, anti-ulcer, cardio-vascular drugs and others (Exhibits “G”, “H” and “I”).

Petitioner likewise possesses the vast resources in terms of manpower, capitalization and plant facilities, as well as the fact that it now actually produces more than 500 different dosage forms of medicine under different brand names of different medical application (Exhibit “H”). Indubitably, Petitioner has sufficiently proven that it is capable of making use of the patented product known as CIPROFLOXACIN in the manufacture of dosage forms thereof. In fact, the records in this Office show that Petitioner has been a grantee of several compulsory licenses to manufacture various inventions which relates to medicine.

Respondent-Assignee advanced the argument that since Petitioner proposes to merely import the patented product without working the same, it cannot be granted a compulsory license. While Petitioner definitely admitted that it seeks the license to use the patented substance covered by Letters Patent No. 18803 subject matter of this case as a raw material which it will import from abroad and use the imported product for its manufacture of pharmaceutical dosage forms, this issue will not militate Petitioner’s action.

In the explanatory note of Bill No. 1156 which eventually became Republic Act No. 165 otherwise known as the Philippine Patent Law, the legislative intent in the grant of a compulsory license was not only to afford others an opportunity to provide the public with the quantity of the patented product but also to prevent the growth of monopolies (Congressional Records, House of Representatives, May 12, 1957, 998). Moreover, “xxx in the first place, Section 34 of Republic Act No. 166 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 dos not apply to circumstances mentioned in sub-section (d), which related to medicine or is one necessary to public health and public safety. Indeed, the Director of Patents has already correctly stated in previous cases that “worked” or “working” mentioned in the last paragraph of Section 34 of the Patent Law has no applicability on those cited patented matters and 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 the Respondent-Assignee to work or manufacture its brand of medicinal preparations containing such substance. And even if it be required that Respondent-Assignee should work itself the invention that it intends to use in the manufacture of its own brand of medicinal preparations said Respondent-Assignee 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 subdividing

antibiotics; and it has the capsule-filling machines and adequate personnel and facilities to test the quality of chloramphenicol." Parke Davis & CO., vs. Doctors Pharmaceuticals, Inc. 14 SCRA 1056.

In all, this Office is convinces that Petitioner was able to sufficiently establish its entitlement to the license under Letters Patent No. 18803 which pertains to 1-Cyclopropyl-6-Fluoro-1, 4-Dihydro-4Oxo-Piperazino-Quinoline-3-Carboxylic Acids Antibacterial Agents Containing These Compounds.

NOW THEREFORE, by virtue of the power vested in this Office by law, there is hereby issued a license in favor of the herein Petitioner, UNITED LABORATORIES, INC., under Letters Patent No. 18803 issued on September 27, 1985, 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-Assignee's patented invention which is disclosed and claimed in Letters Patent No. 18803;

2. That the license granted herein shall be for the remaining life of said Letters Patent No. 18803 unless this license is terminated in the manner herein after provided and that no right or license is hereby granted to the Petitioner under any patent to the Respondent-Assignee or other than recited herein;

3. By virtue of this license, Petitioner shall pay the Respondent-Assignee a royalty on all license products containing the patented substance made and sold by the Petitioner in the amount equivalent to TWO AND A HALF PERCENT (205%) of the net sales in the Philippine Currency. The term "net sale" means the gross amount billed for the product pertaining to Letters Patent No. 18803, less;

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

   (b) Trade, quantity or cash discounts and broker's or agent's or 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; and

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

   In case Petitioner's products 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:

$$\text{ROYALTY} = \frac{\text{Net Sales on Admixed Products (Value of Patented Substance)}}{\text{Value of Patented Substance (Value of Other Active Ingredients)}} \times 0.25$$

4. The royalties shall be computed after the end of each calendar quarter to all goods containing the patented substance herein involved, made and sold during the precedent 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-Assignee's authorized representative in the Philippines;

5. The Petitioner shall keep records in sufficient detail to enable the Respondent-Assignee 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-Assignee by a certified public accountant appointed by Respondent-Assignee 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 invoked;

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

8. The Respondent-Assignee 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 the agreement which are to be performed by Petitioner;

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

   (b) Any termination of this license as provided for above shall not in any way operate to deny Respondent-Assignee its right 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 Intellectual Property Office.

9. In case of dispute as to the enforcement of the provisions of this license, the matter shall be submitted for arbitration before the Bureau of Legal Affairs.

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

11. This license takes effect immediately.

SO ORDERED.

Makati City, 23 August 2002.

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