UNITED LABORATORIES, INC., Petitioner, -versus- GLAXO GROUP LIMITED, Respondent-Patentee.	}	INTER PARTES CASE No. 3852 Petition for Compulsory Licensing: Patent No. 21761 Date Issued: February 18, 1988 Title: "Pharmaceutical Composition Containing Form 2 Ranitidine Hydrochloride & Process of Preparation Thereof" INTER PARTES CASE No. 3851 Petition for Compulsory Licensing: Patent No. 19489 Issued: May 14, 1986 Title: "Aminoalkyl Furan Derivatives” Decision No. 2001-32

DECISION

For decision are the consolidated Petitions filed by United Laboratories, Inc. against Glaxo Group, Ltd. for Compulsory Licenses under Philippine Patent No. 19489 for Aminoalkyl-Furan derivatives and Philippine Patent No. 21761 for Pharmaceutical Composition containing Form2 Ranitidine Hydrochloride and Process of Preparation thereof.

On December 8, 1991, United Laboratories, Inc. filed a Petition For Compulsory Licensing docketed as IPC No. 3851 under Patent No. 19489, for Aminoalkyl Furan Derivatives, invented by Derek Leslie Crookes and assigned to Glaxo Group, Limited, London, England, on the ground that the patented invention relates to medicine. (Sec. 34 (e), Republic Act 165, as amended by P.D. No. 1263.

Petitioner relied on the following facts to support its petition:

> "1. Philippine Patent No. 19489 sought to be licensed was granted on May 14, 1986, more than two (2) years prior to the filing of this Petition.
>
> "2. Philippine Patent No. 19489 relates to medicine more particularly, to Form 2 ranitidine hydrochloride, useful as an H2-antagonist.
>
> "3. Petitioner is a domestic corporation with an authorized capital stock of P2, 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 composition in the manufacture of useful products in pharmaceutical dosage forms."

Another case for compulsory licensing was filed on the same date by United Laboratories, Inc. against Glaxo Group Limited, as assignee of Patent No. 21761, for Pharmaceutical Composition containing Form 2 Ranitidine Hydrochloride and its process of

preparation and docketed as IPC No. 3852, likewise, based on the ground that the patented invention relates to medicine. (Sec. 34 (e), Republic Act 165, as amended by P.D. No. 1263.

Petitioner relied on the following facts to support its petition:

"1. Philippine Patent No. 21761 sought to be licensed was granted on February 16, 1988, more than two (2) years prior to the filing of this petition.

"2. Philippine Patent No. 21761 relates to medicine, more particularly, to a pharmaceutical composition composing Form 2 ranitidine hydrochloride and the process for 16 production of said compound, ranitidine hydrochloride being useful as an H2-antagonist.

"3. Petitioner is a domestic corporation with an authorized capital stock of P2, 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 composition in the manufacture of useful products in the pharmaceutical dosage forms."

Respondent-Patentee seasonably filed its Answer in Inter Partes Cases Nos. 3851 and 3852, adopting the same affirmative allegations and defenses in both pleadings, to wit:

"1 Respondent- Patentee has no actual direct knowledge of the size of the business organization and the technical/manufacturing capabilities of petitioner for the manufacture of any of the patented compounds and/or the finished pharmaceutical products using any of the patented compounds.

Petitioner has no experience and expertise in the manufacture of pharmaceutical formulation, and more importantly on the technical uses of the compounds covered by the patent claims necessary to ensure their efficacy and the safety of their users. Technical and clinical data necessary for the manufacture and sale of such a major pharmaceutical product could not be in petitioner's possession.

Petitioner has obtained from respondent-patentee a compulsory license under Philippine Patent No. 13540, which covers a "Ranitidine" product. However, to date, petitioner has not been able to exploit said patent and come up with a finished product due to its lack of technical know-how necessary to manufacture such a pharmaceutical product. Having thus failed, petitioner cannot now claim that it is capable of exploiting Patent No. 19489 which protects an ingredient similar to the active substance(s) covered by respondent-patentee's basic Patent No. 13540.

"2. The petition is likewise improper because the respondent-patentee has never been informed whensoever of the desire for a voluntary license by the petitioner. Respondent-patentee submits that a petition for a compulsory license is only proper where the patentee refuses, without valid reason or justification, to grant a voluntary license and/or to supply patented active ingredients.

"3. There is no legal or economic justification for the grant of the compulsory license, in view of the fact that the market/industry demands for the finished pharmaceutical products containing the active ingredient covered by the patent is sufficiently met by the local affiliate of respondent-patentee.

"4. The grant of the compulsory license will unduly deprive respondent-patentee of its property and property rights of the patent claims."

The pre-trial conference of the cases were initially set on May 13, 1993 for IPC Case No. 3851 and June 24, 1993 for IPC Case No. 3852 and reset on June 29, 1993.

In the meantime, on June 3, 1993, Petitioner's Motion to Consolidate IPC Nos. 3851 and 3852 was received by this Office which Motion was given due course under Order No. 93-394 dated June 12, 1993.

On June 29, 1993, respondent moved for a hearing on its affirmative defense arguing that before an applicant may be granted a compulsory license it must have been refused a voluntary license by the patentee. Thus, Order No. 94-78 dated January 29, 1994 was issued ruling against the respondent and confirming that it is not required that an applicant for a compulsory license be refused a voluntary license before it can file and be granted a compulsory license.

Petitioner proceeded to present its evidence consisting of the testimony of one Mr. William D. Torres, Assistant Vice President, Product Research, PR & D United Laboratories, Inc. and an ocular inspection at the United Laboratories, Inc on September 11, 1995. The documentary evidence submitted by Petitioner consisted of:

1. Copy of Philippine Patent No. 19489 and Philippine Patent No. 21761.
2. Petitions for compulsory licensing IPC 3851 and IPC 3852.
3. Copy of the Certificate of Filing of Amended Articles of Incorporation of Petitioner.
4. Copy of catalogue containing products manufactured, sold and distributed.
5. Copy of brochure entitled Research and Development at United Laboratories, Inc.
6. Certificate of the Director of Human Resources.
7. Affidavit of William Tomas.

In turn, Respondent presented the testimony of one Romualdo L. Umali, Product Manager of Glaxo Wellcome Philippines, Inc. The documentary evidence of respondent consisted of the sworn affidavit of Romualdo Umali, actual sample of Form 2 Ranitidine "Zantac", package literature and sample tablet.

In resolving the case, Chapter VIII, Article 2 of Republic Act 165 applies, the pertinent portions of which we shall reproduce hereunder for ready reference:

"Section 34.: Grounds 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:

(a) If the patented invention is not being worked in the Philippines on a commercial scale although capable of being so worked, without satisfactory reason;

(b) If the demand for the patented article in the Philippines is not being met to an adequate extent and or reasonable terms;

(c) If, by reason of refusal of the patentee to grant a license or licenses on reasonable terms, or by reason of the conditions attached by the patentee to the licensee or to the purchase, lease or use of the patented article or working of the patented process or machine for production, the establishment of any new trade or industry in the Philippines is prevented, or the trade or industry herein is unduly restrained;

(d) If the working of the invention within the country is being prevented or hindered by the importation of the patented article; or

(e) 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.

(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 in the manufacture of a useful product, or to employ the patented process. x x x" *(Underscoring Supplied)*

It appears that upon the filing of a petition for compulsory license on 8 December 1991, the subject Letters Patent No. 19489 issued on May 14, 1986 and letter Patent No. 21761 issued on February 18, 1988 have both been in effect for more than two years.

Likewise, a careful scrutiny of the records shows that the patented invention, compounds and compositions are used in the treatment of ulcer, hence, both patents relate to medicine.

It bears emphasis that when a patented invention relates to medicine under Sec. 34 (e) and that the application for compulsory licensing has been made after the expiration of two years from the grant of the patent the condition for the filing of a compulsory license has perforce been fulfilled.

The Supreme Court quoted the Director of Patents in the case of Parke Davis and Co. vs. Doctor's Pharmaceutical, Inc. et. al. *(G.R. No. L-22221. August* 31, 1965), in explaining that.

"x x x Compulsory licensing of a patent on food or medicine without regard to other conditions imposed in Section 34 is not an undue deprivation of proprietary interests over a patent right because the law sees to it that even after 3 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 x x x."

Having established that both invention patents relate to medicine and that the same have been issued after two years from the grant of subject patents, the only issue left to be resolved by this Office is whether Petitioner has capability to work the patented product in the manufacture of a useful product or to employ the patented process.

In connection with the issue of capability of the Petitioner to work the patented product, the records undeniably show that Petitioner is in a position to carry out such objective. Petitioner has been involved in the business of manufacturing sale and distribution of medicine and pharmaceutical products as early as 1953 as shown in its Articles of Incorporation.

Likewise, Petitioner was able to establish that it has adequate number of personnel managed by competent and well-trained individuals. Research and development appears to be modern, innovative and specialized. The sheer volume of medicinal preparation in its catalogue *(Exhibit "D")* alone suggest that petitioner has acquired as expertise in its affair, having manufactured and sold several formulations.

In all, this Office is convinced that the Petitioner was able to sufficiently establish its entitlement to the licenses under Philippine Patent No. 19489 entitled Aminoalkyl-Furan derivatives and Philippine Patent No. 21761 for Pharmaceutical Composition containing Form2 Ranitidine Hydrochloride and Process of Preparation thereof.

IN VIEW THEREOF, the Petitions for Compulsory Licensing are, as they are hereby, *GRANTED.* Respondent-Patentee is ordered to grant compulsory license to herein Petitioner with respect to Letters Patent No. 21761 for Pharmaceutical Composition Containing Form2 Ranitidine Hydrochloride & Process of Preparation Thereof and Letters Patent 19489 for Aminoalkyl-Furan derivatives under the following terms and conditions:

1. That the 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-Patentee's patented invention which is disclosed and claimed in Letters Patent No. 19489 and Letters Patent No. 21761;

2. That the license granted herein shall be for the remaining life of said Letters Patent No. 19489 and Letters Patent No. 21761 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 A HALF PERCENT (2.5%) of the net sales in Philippine Currency. The term "net sale" means the gross amount billed for the product pertaining to Letters Patent No. 19489 and Letters Patent No. 21761, 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:

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

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'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 Petitioner;

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 the agreement which are to be performed by the 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 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 *(then Bureau of Patents, Trademarks and Technology Transfer).*

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 and to the successors and assigns of the Petitioner, and

11. This license takes effect immediately.

SO ORDERED.

Makati City, 19 December 2001.

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