

HON. ALFREDO R.A. BENGZON, IN HIS CAPACITY AS SECRETARY OF HEALTH, HON. CATALINA C. SANCHEZ, IN HER CAPACITY AS THE DIRECTOR OF FOOD AND DRUGS OF THE NATIONAL DRUG COMMITTEE OF ...

G.R. No. 82568. May 31, 1988

Ponente: GRIÑO-AQUINO. J.

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GRIÑO-AQUINO. J.

The petitioner filed on April 5, 1988 a petition for review on certiorari of the writ of preliminary injunction that was issued on March 3, 1988 by the Court of Appeals (Tenth Division) in CA-G.R. No. 13859 entitled, “BOIE-TAKEDA CHEMICALS INC., Petitioner versus DEPARTMENT OF HEALTH, HON. ALFREDO R.A. BENGZON, in his capacity as Secretary of Health, et al., Respondents.”

“enjoining respondents and all persons acting under them from enforcing and/or giving effect to Regulation No. 1 dated 1 April 1987 (Annex “B”, Petition), Regulation No. 1-A dated 10 April 1987 (Annex “C”) and to the order dated 1 February 1988 (Annex “Q”) and from conducting further proceedings, which shall issue upon petitioner’s bond for P250,000.00 executed to the respondents to the effect that petitioner will pay such damages as they may sustain and prove by reason of the writ if it should finally be decided that petitioner is not entitled thereto.”

The petitioners pray that the said writ of preliminary injunction be annulled and set aside and that its enforcement be temporarily restrained during the pendency of this case.

Respondent Boie-Takeda Chemicals, Inc. (hereafter referred to as “BOIE-TAKEDA” for brevity) filed a motion to dismiss the petition, and an opposition to the application for a writ of preliminary injunction.

Treating the motion to dismiss and opposition as the respondents’ comment or answer to the petition, We decided to immediately resolve the merits of the petition.

Under Republic Act No. 3720 of June 22, 1963, the petitioner Secretary of Health is charged with the duty and vested with authority “to insure safe and good quality supply of drugs and to regulate the production, sale, and traffic for the same to protect the health of the people.” (Sec. 2) To implement this policy, the Government shall:

“(a) Establish standards and quality measures for food, drug, and cosmetic.

“(b) Adopt measures to insure pure and safe supply of food, drug, and cosmetic in the country.”

As amended by Executive Order No. 175 dated May 22, 1987, the statute now empowers the Department of Health to:

“(a)

Establish standards and quality measures for foods, drugs and devices and cosmetics.

“(b)

Adopt measures to ensure pure and safe supply of foods and cosmetics, and pure, safe, efficacious and good quality drugs and devices in the country.

“(c)

Adopt measures to ensure the rational use of drugs and devices, such as, but not limited to, banning, recalling or withdrawing from the market drugs and devices which are not registered, unsafe, inefficacious or of doubtful therapeutic value, the adoption of an official National Drug Formulary, and the use of generic names in the labelling of drugs.

“(d)

Strengthen the Bureau of Food and Drugs.”

Respondent Boie-Takeda is a Philippine corporation which is engaged in the manufacture, distribution, and sale of drugs, among them “Danzen” a tablet which contains serrapeptase, an OPE (oral anti-inflammatory proteolytic enzymes) which it has been licensed to manufacture and sell in the Philippines since 1970. This drug is also being sold in other countries such as Japan and in the Federal Republic of Germany. However, it is not sold in the United States.

Based on a decision dated May 30, 1985 of the U.S. Food and Drug (FDA) Commissioner, and affirmed by the U.S. Court of Appeals on April 1, 1986, which determined that “oral anti-inflammatory proteolytic enzymes (OPE) which are labeled for use, in controlling edema and inflammation associated with surgical, obstetrical, or dental procedures or accidental trauma to any part of the body or infections or allergic manifestations, have not been shown to be effective for such uses,” the petitioner Catalina C. Sanchez, as Director of the Bureau of Food and Drugs, with the approval of petitioner Alfredo R.A. Bengzon, as Secretary of Health, “in the interest of consumer protection,” issued on April 1, 1987 BFAD Regulation No. 1 s. 1987, ordering that:

“1. The registration of all pharmaceutical preparations containing anti-inflammatory proteolytic enzymes, as listed in ANNEXES ‘A,’ ‘A-1,’ ‘A-2’ and ‘B,’ ‘B-1’ and ‘B-2’ hereof are hereby ordered recalled, which means that these drugs should no longer be marketed in the Philippines.

“2. For the orderly phasing out of stocks which have been distributed to outlets prior to the issuance of this Order, all stocks should have been recalled and withdrawn by the manufacturer and distributor by October 30, 1987.” (Annex ‘A’ of Petition.)

After a week, as an addendum to BFAD Regulation No. 1, the petitioners issued BFAD Regulation No. 1-A s. 1987 dated April 10, 1987, including in the list of banned pharmaceutical preparation Boie-Takeda’s Danzen tablet, 5 mg. with serratio-peptidase 10,000 U. (Annex B, Petition.)

Boie-Takeda filed with the Secretary of Health a request for reconsideration of BFAD Regulation No. 1-A on the grounds that:

“1. Serrapeptase was never registered in the United States and as a consequence, data related to this enzyme was not part of the review made by the US FDA.

“2. Since there has been no hearing called in connection with oral proteolytic enzyme by the Bureau of Food and Drugs, the Philippine regulatory authority, there has been no opportunity to submit data relating to serrapeptase.

“3. Voluminous data on Serrapeptase has, on 20 April 1987, been submitted to the BFAD, including what might be considered carefully designed double-blind studies of serrapeptase against placebo, studies demonstrating intestinal absorption of serrapeptase by measurable quantities of the enzyme in lymph, arterial blood and venous blood, by radio-immunoassay techniques.

“4. In addition, a considerable number of additional clinical studies showing clinical effectiveness of serrapeptase in various conditions, done in West Germany, France, Italy and other countries, are available and can be submitted to the BFAD.

“5. Serrapeptase is registered and approved drug in some 20 countries, including the ASEAN nations, and most recently in the Federal Republic of Germany.

“6. There is evidence that serrapeptase has demonstrable effectiveness not only as an anti-inflammatory drug, which was the indication for which oral proteolytic enzymes were registered in the United States, but also as a mucolytic and as an agent that enhances penetration of antibiotics and other chemotherapeutic agents into the sites of pathology. Documentation regarding these uses has been submitted to the BFAD and additional material can be supplied if necessary.

“7. Additional studies are still being conducted in various parts of the world, the results of which, we anticipate, will further augment the evidence demonstrating the effectivity and uses of serrapeptase.” (Annex C, Petition.)

After a 15-minute hearing before the members of the Technical Advisory Committee on Registration of Products (TACORP), Director Sanchez of the Bureau of Food and Drugs denied Boie-Takeda’s request for reconsideration (Annex E).

Boie-Takeda appealed to the Secretary of Health (Annex F) who referred the appeal to the National Drug Committee (NDC) which granted the appellant a 20-minute hearing where it submitted voluminous documentation proving the efficacy and safety of its product (Annex M), but to no avail. On February 1, 1988 Secretary Bengzon informed Boie-Takeda that the National Drug Committee confirmed the recall and cancellation of registration of “Danzen” tablets and directed the company “to discontinue marketing the said product effective as of receipt of this notice.” (Annex N.)

Alleging that the cancellation of the registration of its product was done without due process of law, Boie-Takeda filed in the Court of Appeals a petition for certiorari and prohibition with preliminary injunction (CA-G.R. SP No. 13859 entitled, “Boie-Takeda Chemicals Inc. versus Department of Health, Hon. Alfredo R.A. Bengzon, et al.”) praying, among other reliefs, that a writ of preliminary injunction be issued to restrain the Secretary of Health from enforcing BFAD Regulation No. 1-A pending the determination of the case.

Upon receipt of the petition, the Court of Appeals issued a temporary restraining order and set the hearing of the application for preliminary injunction on February 22, 1988. After oral arguments at the hearing, the parties submitted their respective memoranda.

On March 3, 1988, the Court of Appeals granted the writ prayed for (Annex A, p. 98, Rollo).

This resolution of the Court of Appeals was elevated to Us by the Secretary of Health on a petition for certiorari and prohibition with preliminary injunction alleging grave abuse of discretion in issuing the same.

As the issuance of a writ of preliminary injunction is an exercise of the Court’s sound discretion, the only point of

inquiry in the petition before Us is whether the Court of Appeals committed a grave abuse of discretion in issuing the writ. The matter of whether the respondent herein, Boie-Takeda (petitioner in the Appellate Court) was denied due process of law in the proceedings before the administrative bodies, namely, the Secretary of Health, the Bureau of Food and Drugs (BFAD), the National Drug Committee (NDC), and the Technical Advisory Committee on Registration of Products (TACORP), is not for Us to determine as it is still pending adjudication in CA-G.R. SP No. 13859.

A writ or preliminary injunction, as an ancillary or preventive remedy may only be resorted to by litigant for the preservation or protection of his rights or interests, and for no other purpose, during the pendency of the principal action. (*Calo vs. Roldan*, 76 Phil. 445)

Here, the writ was issued to protect and preserve the right or license of the private respondent Boie-Takeda to market its product “Danzen” in the Philippines, which it has been doing since 1970 or for the past 17 years. Hence the object of the writ is to preserve the status quo, or the last actual peaceable uncontested status which preceded the pending controversy (*Rodulfa vs. Alfonso*, 76 Phil. 225) which, as correctly noted by the Court of Appeals, “is the status before the withdrawal order” was issued. The status quo before the ban or withdrawal order was issued, was that Boie-Takeda’s product, “Danzen” tablets, was registered and being sold in the Philippines under proper license from the Bureau of Food and Drugs. That status quo is what the writ of preliminary injunction seeks to preserve pending a final determination of the merits of Boie-Takeda’s petition in CA-G.R. SP No. 13859.

Significantly, the writ was granted after a hearing where both parties were given an opportunity to present their arguments which they amplified with memoranda. Said hearing rejects any suggestion that the issuance of the writ grave abuse of discretion (*Republic Flour Workers Associations vs. Reyes*, 18 SCRA 796). As a general rule, this Court should refrain, in certiorari proceedings, from interfering with the lower court’s exercise of its discretion in issuing a writ of preliminary injunction except in cases of manifest abuse (*Rodulfa vs. Alfonso*, 76 Phil. 225; *Agno River Gold Dredging Co. vs. De Leon*, 61 Phil. 190; *Detective & Protective Bureau, Inc. vs. Cloribel*, 26 SCRA 255).

We rule, therefore, that respondent Court of Appeals did not commit a grave abuse of discretion in issuing a writ of preliminary injunction ordering the petitioners to desist from enforcing and implementing the withdrawal order (BFAD Regulation No. 1-A dated April 10, 1988) at least while the aggrieved party’s petition for judicial review of the administrative proceedings is still pending determination by that Court.

WHEREFORE, the petition for certiorari and prohibition is denied.

SO ORDERED.

Narvasa, Cruz, Gancayco and Medialdea, JJ., concur.

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