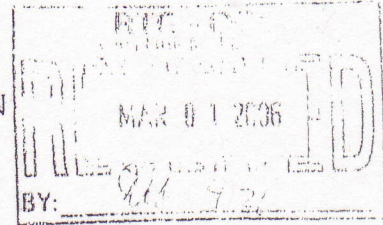


REPUBLIC OF THE PHILIPPINES
REGIONAL TRIAL COURT
NATIONAL CAPITAL JUDICIAL REGION
MAKATI CITY, BRANCH ____



PFIZER LIMITED (United Kingdom)
and PFIZER, INC. (Philippines),
Plaintiffs,

-versus-

Civil Case No. _____
For: Patent Infringement, Damages,
and Injunction with applications
for temporary restraining
order and/or preliminary
injunction and preliminary
mandatory injunction

THE PHILIPPINE INTERNATIONAL
TRADING CORPORATION, BFAD
DIRECTOR LETICIA BARBARA B.
GUTIERREZ, BFAD LICD OFFICER-
IN-CHARGE EMILIO L. POLIG, JR.
and the BUREAU OF FOOD AND
DRUGS,

Defendants.

x-----x

COMPLAINT

Plaintiffs, by counsel, respectfully state:

Parties

1. Plaintiff Pfizer Limited (hereafter, "Pfizer 'UK'") is a foreign corporation duly organized and existing under the laws of the United Kingdom, with principal offices at Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS 2900. Pfizer UK is not doing business in the Philippines and is, therefore, exempt from obtaining a license therefor. It does not maintain any office in this country, nor does it have any agent or representative in the Philippines upon whom summons may be validly served. However, notices and

processes in connection with, and exclusively limited to this case, may be served upon Pfizer UK through undersigned counsel.¹

2. Plaintiff Pfizer, Inc. (hereafter, "Pfizer Phils.") is a domestic corporation with principal offices at the 23rd Floor, Ayala Life-FGU Center, 6811 Ayala Avenue, Makati City. It may be served notices, orders, and other processes, as well as the final judgment of this Honorable Court in this case, through undersigned counsel.

3. Defendant Philippine International Trading Corporation (hereafter, "PITC") is a government-owned international trading corporation primarily tasked to export, import, and market a wide range of commodities, industrial products and consumer goods. PITC's principal office is located at the National Development Company Building, 116 Tordesillas Street, Salcedo Village, Makati City, where it may be served summons and other processes of this Honorable Court.

4. Defendant Leticia Barbara B. Gutierrez (hereafter, "Director Gutierrez") is the current Director of the Bureau of Food and Drugs ("BFAD"), a government regulatory agency under the Department of Health, created pursuant to Executive Order ("E.O.") No. 851 to administer and supervise the implementation of the provisions of R.A. No. 3720, otherwise known as the "Food, Drug and Cosmetic Act." Director Gutierrez holds office at Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City, where she may be served summons and other processes of this Honorable Court.

5. Defendant Atty. Emilio L. Polig, Jr. (hereafter, "Atty. Polig") is the Officer-In-Charge of the Legal, Information and Compliance Division ("LICD") of the BFAD and holds office at Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City, where he may be served summons and other processes of this Honorable Court.

¹ A copy of the Special Power of Attorney dated 3 February 2006 in favor of undersigned counsel in connection with this Complaint is herewith attached as Annex "A."

6. Defendant BFAD is a government regulatory agency under the Department of Health, created pursuant to Executive Order ("E.O.") No. 851. Its principal office is located at Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City, where it may be served summons and other processes of this Honorable Court.

Allegations Common to All Causes of Action

7. Pfizer UK is the registered owner of the invention called "*Improvements in Pharmaceutically Acceptable Salts of Amlodipine*," evidenced by Philippine Letters Patent No. 24348 issued on 13 June 1990 by the Intellectual Property Office ("IPO").² Pursuant to R.A. No. 165, the law then in force, Pfizer UK's product patent is valid for 17 years, or until 13 June 2007.

8. Generally, the invention relates to the *besylate* salt of *amlodipine* for use in treating ischaemic heart disease, especially angina, or hypertension, in a human being. The invention arose out of a discovery that *amlodipine* was best administered in the form of a salt of a pharmaceutically acceptable acid, which must satisfy four physiochemical criteria: (a) good solubility; (b) good stability; (c) non-hygroscopicity; and (d) processability for tablet formulation. Based on various rigid tests, the *besylate* salt showed a unique combination of the foregoing, thereby making it outstandingly suitable for the preparation of pharmaceutical formulations of *amlodipine*. *Amlodipine besylate* is chemically described as 3-Ethyl -5-methyl(±)-2-[(2-aminoethoxy) methyl] -4-(2-chlorophenyl) -1,4-dihydro-6-methyl -3,5-pyridinedicarboxylate, monobenzenesulphonate.

9. *Amlodipine besylate* is a revolutionary pharmaceutical preparation for the treatment of hypertension, which works by slowing down the flow of calcium through muscle cells found in the walls of blood vessels. Since calcium is

² Attached herewith as Annex "B."

required for muscle cells to contract, blood vessels dilate and relax, thereby allowing blood to flow more easily through the body.

10. Since *amlodipine besylate* first became available in 1990, plaintiffs and their worldwide affiliates have exclusively used the same generally under the brand name *Norvasc*,[®] which has helped many people around the world improve their lives. Since its launch, the efficacy and safety of *amlodipine besylate* have been studied in over 800 clinical trials involving at least 400,000 patients, thereby fortifying the drug's innovative and ground-breaking effects.

11. The Philippines and the United Kingdom are parties-signatories to the Paris Convention for the Protection of Industrial Property ("Paris Convention"),³ the Patent Cooperation Treaty, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")⁴ of the World Trade Organization ("WTO") and are members of the WTO and the World Intellectual Property Organization, which were all intended, *inter alia*, for the protection of industrial property.

³ Article 2 of the Paris Convention plainly provides for the national treatment of non-nationals as regards the protection of patents, to wit:

- (1) *Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.*
- (2) *However, no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union for the enjoyment of any industrial property rights.*
- (3) *The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property are expressly reserved. (Emphases supplied)*

⁴ Article 28 of the TRIPS confers the following rights on a patent holder, thus:

1. A patent shall confer on its owner the following exclusive rights:
 - (a) *where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;*
 - (b) *where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.*
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts. (Emphasis supplied)

12. Pfizer UK brings the instant action pursuant to Section 2, Article II of the Philippine Constitution, which provides that the Philippines adopts, among others, the generally accepted principles of international law as part of the law of the land and adheres to the policy of peace, equality, justice, freedom, cooperation and unity with all nations. Furthermore, Section 3 of Republic Act ("R.A.") No. 8293, otherwise known as the "Intellectual Property Code of the Philippines" (the "IP Code"), grants a right in favor of Pfizer UK to seek redress before Philippine courts insofar as it states that:

International Conventions and Reciprocity – Any person who is a national or who is domiciled or has a real and effective industrial establishment in a country which is a party to any convention, treaty or agreement relating to intellectual property rights or the repression of unfair competition, to which the Philippines is also a party, or extend reciprocal rights to nationals of the Philippines by law, shall be entitled to benefit to the extent necessary to give effect to any provision of such convention, treaty or reciprocal law, in addition to the rights to which any owner of an intellectual property right is otherwise entitled by this act.

13. Pfizer Phils. is the exclusive licensee of Pfizer UK to import, market, distribute and sell various Pfizer products in the Philippines, particularly *amlodipine besylate*,⁵ under the brand name *Norvasc*. By virtue of Certificates of Product Registration ("CPR") Nos. YZ-015552 and YZ-016930 issued by BFAD,⁶ Pfizer Phils.' *amlodipine besylate* (*Norvasc*) is marketed and sold in the Philippines in 5 and 10 mg. tablet forms. Pfizer Phils. has been promoting *amlodipine besylate* in the Philippines since 1991, and had been distributing the same through the Zuellig Pharma Corporation.

14. On 21 September 2005, Pfizer Phils.' Medical and Regulatory Affairs Division discovered, through the BFAD website, that an application for product registration was filed by PITC for *amlodipine besylate*, using the brand name *Norvasc*.⁷ In an attempt to forestall any infringement of Pfizer UK's patent,

⁵ Attached herewith as Annex "C" is a Letter of Authorization granted by Pfizer UK to Pfizer Phils.

⁶ Attached herewith as Annexes "D to D-1."

⁷ Attached herewith as Annex "E" is a computer print-out of an electronic message dated 21 September 2005, as well as the attachment thereto, which is the table appearing on the BFAD website listing all applicants for product registration for the first 2 weeks of September 2005, bearing the application of PITC for *amlodipine besylate*.

Pfizer Phils. immediately wrote a letter dated 21 September 2005 to PITC,⁸ informing the latter that the *amlodipine besylate* pharmaceutical compound is covered under Letters Patent No. 24348; hence, PITC's application for product registration of *amlodipine besylate* with the BFAD constitutes patent infringement.

15. PITC replied through a letter dated 26 September 2005, denying such allegations.⁹ Through a letter dated 6 October 2005,¹⁰ Pfizer Phils. reiterated its demand for PITC to immediately withdraw its BFAD application for product registration. Pfizer Phils.' letter, however, went unheeded.

16. Director Gutierrez and Atty. Polig, as Officer-In-Charge of the LICD, were well apprised of the ensuing dispute between Pfizer Phils. and PITC concerning the right to use *amlodipine besylate* under the *Norvasc* brand, inasmuch as copies of the foregoing letters were vigilantly furnished them. Director Gutierrez is the highest ranking officer tasked to provide overall management, direction, supervision and control over BFAD. The key functions of BFAD LICD include rendering legal advice in the enforcement of relevant laws and regulations and preparing recommendations, resolutions and other administrative issuances pertaining to drug regulation. Notwithstanding such duties, Director Gutierrez and Atty. Polig did not offer any reply, comment or explanation, written or otherwise.

17. Instead, upon information, BFAD Director Gutierrez granted PITC's application for product registration, by issuing Parallel Import Drug Registration ("PIDR") Nos. 2141 (for 5 mg. tablets) and 2140 (for 10 mg. tablets), effective 8 December 2005 until 30 December 2010.

18. In a meeting held on 11 January 2006, PITC assured Pfizer Phils. that a written response from the Office of the Government Corporate Counsel ("OGCC") will be forthcoming by 13 January 2006, and that the same would

⁸ Attached herewith as Annex "F."

⁹ Attached herewith as Annex "G."

¹⁰ Attached herewith as Annex "H."

comprise an undertaking on PITC's part not to import, sell, market or otherwise distribute *amlodipine besylate* products until after the patent thereon has expired.

19. In a letter dated 17 January 2006,¹¹ Pfizer UK and Pfizer Phils., through undersigned counsel, sent a final demand to PITC to (1) desist from utilizing the CPRs (PIDRs) for whatever purpose, including the importation and distribution of *amlodipine besylate* during the effectivity of Pfizer UK's patent; and (2) execute an undertaking to such effect and to surrender the foregoing CPRs (PIDRs) to the BFAD; otherwise, a patent infringement case will be filed against PITC. BFAD Director Gutierrez was furnished a copy of this letter.

20. In a letter dated 24 January 2006,¹² PITC simply informed undersigned counsel that it has referred the matter to the OGCC "for review/study and appropriate action/reply." In a letter dated 7 February 2006,¹³ the OGCC insisted that there was no infringement of Pfizer UK's patent. Although the OGCC said that PITC would "respect" plaintiffs' intellectual property rights, it refused to have PITC execute the requested undertaking.

21. In a letter dated 19 January 2006,¹⁴ Pfizer Phils. implored BFAD Director Gutierrez to take appropriate action in invalidating the issuance of CPRs (PIDRs) in favor of PITC, considering the far reaching legal and other implications thereof on the level of protection accorded to intellectual property rights in the Philippines. BFAD Director Gutierrez, however, merely ignored Pfizer Phils.' concerns.

22. All in all, PITC, Director Gutierrez and Atty. Polig of the BFAD were all clearly apprised of the infringement of Pfizer UK's patent over *amlodipine besylate*, which plaintiffs vigilantly intend to protect. PITC, Director Gutierrez and Atty. Polig of the BFAD, however, unjustly and wantonly disregarded plaintiffs' valid and lawful demands.

¹¹ Attached herewith as Annex "I."

¹² Attached herewith as Annex "J."

¹³ Attached herewith as Annex "K."

¹⁴ Attached herewith as Annex "L."

Causes of Action against PITC

FIRST CAUSE OF ACTION:

Patent Infringement

Plaintiffs replead the foregoing and further state:

23. Section 71.1 of the IP Code echoes Section 28 of the TRIPS insofar as the former provides that a patent shall confer on its owner the following rights:

- (a) *Where the subject matter of the patent is a product, to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing that product; and*
- (b) *Where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.¹⁵*

24. As a consequence of such rights, Section 76.1 of the IP Code authorizes the filing of a civil action for infringement, thus:

Civil Action for Infringement. — 76.1. The making, using, offering for sale, selling, or importing a patented product or a product obtained directly or indirectly from a patented process, or the use of a patented process without the authorization of the patentee constitutes patent infringement.¹⁶

25. An individual or entity with a certificate of patent issued by the IPO has the exclusive right to make, use and sell the patented machine, article or product for the purpose of industry or commerce, throughout the territory of the Philippines for the term of the patent, and such making, using or selling by any person without authorization of the patentee shall constitute infringement of its patent.¹⁷

26. Administrative Order ("A.O.") No. 85, series of 2000, issued by the Department of Health prescribes the registration requirements for a government

¹⁵ Emphasis supplied.

¹⁶ Emphases supplied.

¹⁷ Del Rosario v. Court of Appeals, 255 SCRA 152, 163 (1996).

agency importing a pharmaceutical product with a registered counterpart brand in the Philippines, which includes the submission of commercial samples and "full laboratory testing by BFAD of every batch/lot number of product per importation."

27. The submission of commercial samples in support of PITC's BFAD application necessitates the actual use and importation of the patented product, without sufficient authority. Furthermore, the performance of experiments for a commercial purpose constitutes the act of "using" Pfizer UK's *amlodipine besylate* without authority from the patent holder and is, thus, a clear act of patent infringement.¹⁸ A patent is infringed where the essential or substantial features of the patented invention are taken or appropriated, or the device, machine or other subject matter alleged to infringe is substantially identical with the patented invention.

28. PITC's use of *amlodipine besylate*, without the knowledge, authority or consent of the patent owner, makes it liable for patent infringement under Section 76.1 of the IP Code.

SECOND CAUSE OF ACTION: *Injunction*

Plaintiffs replead the foregoing and further state:

29. Apart from the direct patent infringement that has already been consummated, Pfizer UK's patent stands to be continually breached by PITC on the strength of PIDRs issued in its favor. This Honorable Court should therefore perpetually enjoin PITC, its agents, representatives or assigns from making, using, offering for sale or distribution *amlodipine besylate* products to various hospitals and drugstores, governmental or otherwise, or to any other individual or entity in the Philippines, or from otherwise infringing Pfizer UK's patent, at least until Pfizer UK's patent expires.

¹⁸ Section 76, R.A. 8293.

30. Furthermore, the infringement of Pfizer Phils.' rights, as the sole and exclusive distributor of *amlodipine besylate* products in the Philippines, is imminent. Through years of exclusive sale, distribution and marketing of *amlodipine besylate*, Pfizer Phils. has established a formidable market share and has single-handedly created the vital goodwill and reputation necessary for the buying public in the Philippines, which undoubtedly entailed significant monetary investment, among others. This Honorable Court should therefore restrain PITC from importing, selling, offering for sale, or from otherwise distributing *amlodipine besylate* products in the Philippines, and prohibit it from violating Pfizer Phils.' exclusive distribution rights. The right to perform an exclusive distributorship agreement and to reap profits resulting from such performance are also propriety rights which a party may protect, and which may not otherwise be diminished by unauthorized parallel importation at the expense of the sole authorized distributor.¹⁹

31. Indeed, the commission or continuance of the acts complained of during the pendency of the instant action would work injustice to the plaintiffs and render the judgment in this case ineffectual.

Causes of Action against BFAD

FIRST CAUSE OF ACTION:

Inducement of Patent Infringement

Plaintiffs replead the foregoing and further state:

32. Apart from direct patent infringement, Section 76.6 of the IP Code likewise proscribes the inducement of patent infringement by making such individual or entity jointly and severally liable with the infringer, thus:

Anyone who actively induces the infringement of a patent or provides the infringer with a component of a patented product or of a

¹⁹ Yu v. Court of Appeals, 217 SCRA 328, 332 (1993).

product produced because of a patented process *knowing it to be especially adopted for infringing the patented invention and not suitable for substantial non-infringing use shall be liable as a contributory infringer and shall be jointly and severally liable with the infringer.*²⁰

33. By allowing the submission of samples of, conducting experimentation on, and issuing the PIDRs in favor of PITC for *amlodipine besylate*, despite having full knowledge of Pfizer UK's valid and existing patent thereon, BFAD Director Gutierrez and Atty. Polig committed *ultra vires* acts, outside the scope of their duties in BFAD, insofar as they actively induced and facilitated PITC's infringement of the subject patent. The PIDRs do not in any way indicate that such may only be used as authority for market distribution upon the expiration of the patented compound. On the strength of the BFAD's PIDRs alone, PITC can immediately proceed to import, market, sell and distribute Pfizer UK's *amlodipine besylate*.

34. By having issued the PIDRs erroneously, if not unlawfully, in PITC's favor, BFAD Director Gutierrez and Atty. Polig induced the infringement of Pfizer UK's patent. This Honorable Court should order BFAD to align the acts of its recalcitrant officers and recall, revoke or otherwise invalidate the PIDRs of PITC.

SECOND CAUSE OF ACTION:

Injunction

Plaintiffs plead the foregoing and further state:

35. As of the period starting from 25 January 2005 to 15 February 2006, but only insofar as Pfizer Phils. has gathered from the BFAD website, www.bfad.gov.ph, a total of 19 applications for product registration for *amlodipine besylate* have been filed by 11 entities apart from PITC with the BFAD.²¹ Despite Pfizer Phils.' demand to 10 of these 11 entities, copies of which

²⁰ Emphases supplied.

²¹ Attached herewith as Annex "M" is a computer print-out of a table summarizing the 21 applications for product registration of *amlodipine besylate*, which were listed on the BFAD website, as of the period 25 January 2005 to 15 February 2006.

had been furnished BFAD,²² such applicants refused to cease and desist from proceeding with their respective applications. Neither has the BFAD restrained itself from entertaining and processing the same, nor has it expressed any intention to do so having been copied of these demand letters.

36. Sections 5 and 6, Article III, of A.O. No. 2005-0001 provide that the BFAD may be restrained from entertaining such applications by an order of injunction, thus:

5. In the event that any interested party notifies BFAD in writing of any alleged prior or existing intellectual property right over the said product, BFAD shall immediately respond to said party, in writing, that intellectual property matters are beyond the legal mandate of BFAD and that *their proper recourse should be from the IPO or the appropriate courts of competent jurisdiction.*

6. *Under no circumstance shall the filing of any such notification or the posting of any new application in the BFAD website be the reason or cause to suspend, delay, or otherwise adversely affect the processing of the application for, and the issuance of the CPR until and unless BFAD is restrained or enjoined by the proper authorities from doing so.* In this instance, "proper authority" shall only pertain to the IPO or courts of law with competent jurisdiction over the said subject matter.²³

37. Unless this Honorable Court restrains BFAD from entertaining the other applications for product registration of *amlodipine besylate*, Pfizer UK's patent shall continually be breached. Despite the clear right of Pfizer UK over its patent, BFAD Director Gutierrez and Atty. Polig allowed PITC to use the patented product in the course of its application and had even issued the PIDRs in PITC's favor. As regards the pending applications currently being accommodated by the BFAD, there is no indication whatsoever that BFAD and/or its officers will disallow the use of Pfizer UK's patented drug in the course of its registration procedures. Considering the material and substantial invasion of the right sought to be protected, which rights are clear and unmistakable, there is an urgent and paramount necessity for the issuance of an injunction to prevent serious damage and injury to plaintiffs.²⁴

²² Attached herewith as Annexes "N" to "N-9."

²³ Emphases supplied.

²⁴ *Arcega v. Court of Appeals*, 275 SCRA 176 (1997).

*Cause of Action for Damages against PITC,
BFAD Director Gutierrez, and Atty. Polig*

Plaintiffs replead the foregoing and further state:

38. Based on the foregoing acts of patent infringement, Pfizer UK's rights must be recognized and vindicated. PITC, BFAD Director Gutierrez and Atty. Polig should be jointly and severally assessed the amount of ₱500,000.00 as and by way of nominal damages.

39. By way of example or correction for the public good, with the objective of promoting respect for the intellectual property rights of Pfizer UK and others who may be similarly situated, and to prevent others from committing the same acts done by PITC and the foregoing officers of BFAD, PITC, BFAD Director Gutierrez and Atty. Polig should be jointly and severally assessed at least ₱500,000.00 in exemplary damages.

40. On account of the willful and deliberate refusal of PITC, BFAD Director Gutierrez and Atty. Polig to respect Pfizer UK's rights, plaintiffs were constrained to engage the services of undersigned counsel and institute the instant action to protect their interests. Due to the intricacies of this case, plaintiffs expect to incur attorneys' fees and litigation expenses of not less than ₱400,000.00.

*Application for Temporary Restraining Order,
Preliminary Injunction and Preliminary Mandatory Injunction*

Plaintiffs replead the foregoing in support of their application for a temporary restraining order, preliminary injunction and preliminary mandatory injunction, and further state:

41. As registered owner of the patent relating to the preparation of *amlodipine besylate*, Pfizer UK may prevent anyone, including PITC, from using the same in its business without Pfizer UK's consent in writing.

TEMPORARY RESTRAINING ORDER AND
WRIT OF PRELIMINARY INJUNCTION
AGAINST THE PITC

42. Apart from the right to recover damages, attorneys' fees and expenses for litigation, Section 76 of the IP Code pertinently provides:

76.2 Any patentee, or anyone possessing any right, title or interest in and to the patented invention, whose rights have been infringed, may bring a civil action before a court of competent jurisdiction, to recover from the infringer such damages sustained thereby plus attorney's fees and other expenses of litigation, and *to secure an injunction for the protection of his rights.*

...

76.5. The court may, in its discretion, order that the infringing goods, materials and implements predominantly used in the infringement be disposed of outside the channels of commerce or destroyed, without compensation.

43. As held in *H. H. Robertson Co. v. United Steel Deck, Inc.*:²⁵

In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement. . . . This presumption derives in part from the finite term of the patent grant, for patent expiration is not suspended during litigation, and the passage of time can work irremediable harm. The opportunity to practice an invention during the notoriously lengthy course of patent litigation may itself tempt infringers The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude.

44. Not only has PITC succeeded in infringing Pfizer UK's patent by submitting samples of, and conducting experiments on, the patented compound, PITC, unless otherwise restrained by this Honorable Court, stands to commit acts that would further infringe Pfizer UK's property right.

45. Similarly, the infringement of Pfizer Phils.' right as exclusive distributor of *amlodipine besylate* products in the Philippines is clearly within reach.

²⁵ 820 F.2d 384, 390.

46. Having secured the necessary PIDRs, PITC can immediately forge ahead, import and market *amlodipine besylate* and carve its share in the Philippine market for a product which PITC did not, in any way, formulate or develop. Through its illegal acts, PITC aims to unjustly enrich itself at the expense of plaintiffs, thereby significantly eroding the market shares, revenues, profits and goodwill which Pfizer Phils. painstakingly built throughout the years at tremendous costs and effort.

47. Upon the filing of this complaint and before the matter can be heard on notice, or upon proper hearing, PITC should be restrained from utilizing the PIDRs in its favor and from otherwise engaging in acts involving *amlodipine besylate*. Unless the temporary restraining order and/or writ of preliminary injunction prayed for is granted by this Honorable Court, plaintiffs would suffer great or irreparable damage or injury in that Pfizer UK would be deprived of its right, among others, to use the patent to the exclusion of others and derive benefits or reap profits it rightfully deserves, considering the amount of investments in research, technology and development it has placed just to come up with this revolutionary product. Similarly, Pfizer Phils. will be deprived of its right to distribute *amlodipine besylate* products to the exclusion of others despite having invested substantial time and millions of pesos to market the same in the Philippines.

**WRIT OF PRELIMINARY MANDATORY
INJUNCTION AGAINST THE BFAD**

48. In the same vein, not only has BFAD Director Gutierrez and Atty. Polig facilitated the infringement of Pfizer UK's patent by granting the PIDRs in favor of PITC, their continued refusal to remedy the actual violation of Pfizer UK's patent paves the way for PITC to continue acts of patent and trademark infringement. On the strength of the PIDRs alone, PITC can immediately proceed to import, market, sell and distribute Pfizer UK's *amlodipine besylate*.

49. BFAD should therefore be ordered, through a *writ* of preliminary mandatory injunction, to recall, revoke or otherwise invalidate the PIDRs issued in the name of PITC, lest Pfizer UK's patent rights and Pfizer Phils.' right to exclusivity in the Philippine market be continually breached. Unless this Honorable Court issues the *writ* of preliminary mandatory injunction against BFAD, PITC, on the strength of the BFAD PIDRs, will continue to infringe the subsisting patent on *amlodipine besylate*, to which PITC has no right whatsoever, and realize profits from its acts of thievery and infringement to the damage and prejudice of plaintiffs.

TEMPORARY RESTRAINING ORDER AND
WRIT OF PRELIMINARY INJUNCTION
AGAINST THE BFAD

50. Furthermore, the BFAD, by an express mandate under Section 6, Article III, of A.O. No. 2005-0001, may be restrained from processing applications for product registration through a court of law.

51. Given the clear inclination of the foregoing BFAD officers to process applications despite their knowledge that a patent on the product applied for exists, as they did as regards PITC's application, there exists an unmistakable threat that BFAD will once again allow its officers to do the same. Upon the filing of this complaint and before the matter can be heard on notice, or upon proper hearing, BFAD should be restrained from further entertaining other applications for product registration of *amlodipine besylate*, lest the infringement of Pfizer UK's patent thereon be surely committed.

52. To exemplify plaintiffs' insistence on the gravity of PITC's unlawful infringement of their rights and the BFAD officer's complicity to, and inducement of, infringement, as well as the urgency of the relief prayed for, plaintiffs are willing to post a bond, in such amount as may be fixed by this Honorable Court, conditioned upon payment to PITC and/or the BFAD officers

for damages which the latter may sustain by reason of the injunction, should this Honorable Court finally decide that plaintiffs were not entitled thereto.

53. In compliance with Rule 58 of the Revised Rules of Civil Procedure, the affidavits of plaintiffs' witnesses in support of the issuance of the temporary restraining order, *writ* of preliminary injunction and *writ* of preliminary mandatory injunction are attached herewith as Annexes "O," "P" and "Q."

RELIEF

WHEREFORE, plaintiffs respectfully pray that this Honorable Court:

(a) Immediately upon the filing of this action, issue an *ex parte* order and subsequently after due notice and hearing, an order temporarily restraining:

(1) PITC its agents, representatives and assigns from making, using or offering for sale or distribution *amlodipine besylate* products to various hospitals and drugstores, governmental or otherwise, or to any other individual or entity in the Philippines, or from otherwise infringing Pfizer UK's Philippine Letters Patent No. 24348, imported in the Philippines by Pfizer Phils., at least until Pfizer UK's patent thereon expires; and

(2) BFAD, its officers, employees, and agents from entertaining the applications for product registration for *amlodipine besylate*, or such other applications submitted therewith now or in the future related to any *amlodipine besylate* product, covered by Pfizer UK's Philippine Letters Patent No. 24348 and imported in the Philippines by Pfizer Phils, at least until Pfizer UK's patent thereon expires.

(b) After notice and hearing, issue a *writ* of preliminary injunction enjoining:

(1) PITC, its agents, representatives and assigns from making, using or offering for sale or distribution *amlodipine besylate* products to various hospitals or drugstores, governmental or otherwise, or to any other individual or entity in the Philippines, or from otherwise infringing Pfizer UK's Philippine Letters Patent No. 24348, imported in the Philippines by Pfizer Phils., at least until Pfizer UK's patent thereon expires; and

(2) BFAD, its officers, employees, and agents from entertaining the applications for product registration for *amlodipine besylate*, or such other applications submitted therewith now or in the future related to any *amlodipine besylate* product, covered by Pfizer UK's Philippine Letters Patent No. 24348 and imported in the Philippines by Pfizer Phils, at least until Pfizer UK's patent thereon expires.

(c) After notice and hearing, issue a *writ* of preliminary mandatory injunction directing BFAD, its agents, representatives and assigns, to recall, cancel or otherwise invalidate Parallel Import Drug Registration Nos. 2141 (for 5 mg. tablets) and 2140 (for 10 mg. tablets) issued in favor of PITC for *amlodipine besylate*, or any other similar authority for importation, market distribution or sale of *amlodipine besylate* in the Philippines.

(d) After trial, render judgment:

(1) declaring that PITC and BFAD have infringed Pfizer UK's Philippine Letters Patent No. 24348 and the right of Pfizer Phils. to make, use, import, market, sell, or otherwise distribute *amlodipine besylate* products in the Philippines to

the exclusion of others, and that PITC has no right whatsoever over Pfizer UK's patent;

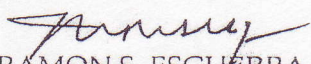
- (2) ordering PITC, BFAD Director Gutierrez and Atty. Polig to jointly pay plaintiffs the following amounts:
 - (i) at least ₱500,000.00 as nominal damages;
 - (ii) ₱500,000.00 as exemplary damages; and
 - (iii) ₱400,000.00 as attorneys' fees and litigation expenses;
 - (iv) costs of this suit.
- (3) ordering the condemnation, seizure or forfeiture of PITC's infringing goods or products, wherever they may be found, including the materials and implements used in the commission of patent infringement, to be disposed of in such manner as may be deemed appropriate by this Honorable Court; and
- (4) making the injunctions permanent, at least until Pfizer UK's Philippine Letters Patent No. 24348 expires.

Plaintiffs hereby also pray for other just or equitable relief.

Makati City, 28 February 2006.

ESGUERRA & BLANCO
Counsel for Plaintiffs
4th Floor, S&L Building
De la Rosa corner Esteban Streets
Legaspi Village, Makati City

By:

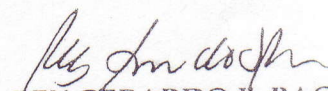

RAMON S. ESGUERRA
Roll of Attorneys No. 30183
PTR No. 4182721/1-03-06/Makati City
IBP No. 665181/1-03-06/Cavite Prov. Chap.

VERIFICATION/CERTIFICATION

I, **REY GERARDO E. BACARRO**, of legal age, Filipino, with office address at the 23rd Floor, Ayala Life-FGU Center, 6811 Ayala Avenue, Makati City 1200, subscribing under oath, hereby depose and state that I am the authorized representative of Pfizer Limited (United Kingdom) and Pfizer, Inc. (Philippines), the plaintiffs in this case and I caused the preparation of the foregoing complaint, the contents of which are true and correct of my own personal knowledge and based on authentic documents in my possession.

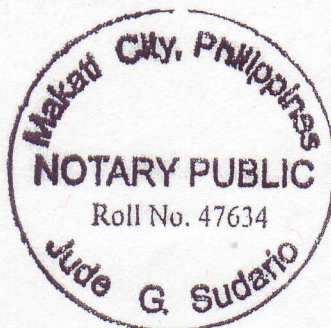
I hereby certify that the plaintiffs have not commenced any action or filed any claim involving the same issues in any court, tribunal or agency and, to the best of our knowledge, no other such action or claim is pending therein; if the plaintiffs should thereafter learn that the same or similar action or claim has been filed or is pending, we undertake to report this fact to this Honorable Court within five (5) days therefrom.


I am authorized to execute this verification and certification as evidenced by the Secretary's Certificate issued by Pfizer Limited (United Kingdom) and Pfizer, Inc. (Philippines), copies of which are attached hereto.


REY GERARDO E. BACARRO
 Affiant

SUBSCRIBED AND SWORN before me this MAR 01 2006 day of February 2006, affiant exhibiting to me his Community Tax Certificate No. 00005815 issued on Mar. 21, 2005 at Quezon City.

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 Series of 2006.




JUDE G. SUDARIO
 Commission No. 465
 Notary Public - City of Makati
 Until 31 December 2006
 Esguerra & Blanco Law Offices
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 Esteban Sts., Legaspi Village, 1229 Makati City
 PTR No. 4182725; 01/03/06; Makati City
 IBP No. 47634; 01/03/06/Makati City
 Roll No. 48265