UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

CV 02 6094

COLLAGENEX PHARMACEUTICALS, INC.,

Plaintiff,

v.

WEST-WARD PHARMACEUTICAL CORPORATION,

Defendants.

COMPLAINT AND JURY DEMAND

ROSS, J.

MANN, M.J.

COMPLAINT SEEKING RELIEF FROM INFRINGEMENT OF U.S. PATENT NO. 4,666,897 AND RE-ISSUE PATENT RE 34,656

Plaintiff, CollaGenex Pharmaceuticals, Inc. ("CollaGenex"), for its Complaint against Defendant, West-Ward Pharmaceutical Corporation ("WPC"), alleges as follows:

THE PARTIES

1. CollaGenex is a publicly traded corporation organized under the laws of the state of Delaware and having a principal place of business at 41 University Drive, Newtown, Pennsylvania 18940.

2. Upon information and belief, WPC is a corporation organized under the laws of the state of Delaware, and having a principal place of business at 465 Industrial Way West, Eatontown, New Jersey 07724.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §1331 and 1338(a).

4. This Court is empowered to provide declaratory judgment as a remedy in this action pursuant to 28 U.S.C. §2201 and §2202.

5. On information and belief, WPC has engaged in conduct as follows:

i) Does business in New York generally;

ii) Employs and/or engages agents and/or representatives in New York to perform services on its behalf;

iii) Has substantial sales of pharmaceutical products in New York; and

iv) Advertises in trade journals or other written and/or printed materials in hard copy and/or electronically directed to residents and companies in the state of New York.

6. Thus, on information and belief, WPC either separately or in cooperation with other companies and/or its agents has a presence in the state of New York amounting to a continuous course of conduct in New York such that of assertion of *in personam* jurisdiction over WPC comports with the requirements of due process and notions of fairness.

7. Venue is proper in this district pursuant to 28 U.S.C. §1391(b), §1391(c) and §1400(b).

COLLAGENEX PHARMACEUTICALS, INC.

8. CollaGenex is a specialty pharmaceutical company which focuses on providing innovative medical therapies for targeted disease classes. CollaGenex currently services the dental and dermatology markets. CollaGenex' flagship product is Periostat®, an oral enzyme suppressing-agent. Periostat® provides the first and only systemic pharmaceutical treatment for adult periodontitis, which works by inhibiting the enzymes which destroy periodontal support tissue(s).

9. CollaGenex is a publicly traded company which is primarily based around a core technology originating from research conducted at the laboratories of the State University of New York at Stony Brook by Dr. Lorne M. Golub. Dr. Golub, et al. discovered certain unique properties of tetracycline compounds, such properties being the subject of a series of U.S. patents (assigned to the Research Foundation of the State University of New York) which are exclusively licensed to CollaGenex.

10. Over the years, CollaGenex has invested over 20 millions of dollars in the development of Periostat® as an FDA (Food and Drug Administration)-approved, ADA (American Dental Association)-accepted, prescription drug for use in the treatment of periodontitis, and has actively engaged in marketing and sales of Periostat® throughout the world.

11. Periostat® is CollaGenex' primary product, and the (i) commercial reputation, (ii) maintenance of primary income stream, and (iii) value of the company reside in sustaining the premier market position of Periostat®.

PERIOSTAT®

12. Periostat® works by reducing the activity of the enzymes which destroy tooth and gum tissue.

13. Periostat® is available only by prescription from a dentist or periodontist or physician.

14. Periostat® is a tablet containing 20mg of doxycycline hyclate. This tablet is administered twice a day by the patient. Most importantly, extensive research conducted by Dr. Golub and CollaGenex established that this dose and dosage regimen delivers a sub anti-microbial dosage of the active ingredient doxycycline hyclate, which unexpectedly, is both safe and effective for long term administration to patients. Periostat® differs fundamentally from other formulations of tetracycline and its derivatives in that it is a tetracycline compound and dosage form proven safe for long term administration; and, as demonstrated through extensive clinical trials, does not affect the numbers of resident microflora of the body and does not contribute to the development of antimicrobial resistance.

15. On the basis of these trials, CollaGenex obtained approval from the FDA based on the method of treatment covered in the patents obtained by Dr. Golub, et al.

PATENTS COVERING PERIOSTAT®

16. The use of the Periostat® product for the treatment of, among other things, adult periodontitis, is covered by U.S. Patent No. 4,666,897 (Exhibit A) and Re-Issue Patent RE 34,656 (Exhibit B) referred to herein collectively as the "patents in suit." The `897 patent does not expire until May 19, 2004; and the `656 patent does not expire until July 5, 2007.

Both patents in suit were included in the New Drug Application (NDA) filed at the FDA for approval of Periostat®; and they are printed on the package insert for Periostat® whereby notice under 35 U.S.C. § 287 is provided.

17. Both of these patents have been issued to Dr. Golub, et al. and have been assigned to The Research Foundation of the State University of New York.

18. These patents and other patents relating to Dr. Golub's technology are exclusively licensed to CollaGenex. Under the license from The Research Foundation CollaGenex has the authority to enforce the rights provided by the patents in suit.

THE INFRINGER

19. On information and belief, WPC is a generic drug company which provides to the marketplace generic drugs.

20. On information and belief, WPC is a wholly owned subsidiary of Al Hikma Pharmaceuticals, a Jordanian pharmaceutical company.

21. On information and belief, the generic drugs which WPC provides to the commercial marketplace include, without limitation, the following: Acetominephen, Aminophylline, Ascorbic Acid, Aspirin, Butalbital, Hyosophen, Isolin, Idenal, Butalgen,

Atropine Sulfate, Belladonna, Alkaloids with Phenobarbital, Bisacodyl, Calcium Lactate, Calcium Gluconate, Dioctyl with Casanthranol, Antispasmodic, Butabarbital Sodium, Chloral Hydrate, Chlordiazepoxide HCl, Chloroquine Phosphate, Chlorothiazide, Chlorpheniramine Maleate, Colchicine, Dimenhydrinate, Diphenylhydramine, Dioctyl Sodium Sulfosuccinate, Ephedrine Sulfate, Ferrous Fumurate, Flurazepane, Folic Acid, Hydralazine, Hydrochlorothiazide, Imipramine, Isoniazid, Isosorbide Dinitrate, Isoxsuprine HCl, Methocarbamol, Niacin, Oxytetracycline, Oxytetracycline HCl, Phenobarbital, Prednisone, Procainamide HCl, Propantheline Bromide, Propoxyphene HCl, Pseudoephedrine HCl, Triprolidine w/Pseudoephedrine, Actamine, Triafed, Pyridoxine HCl, Quinidine Sulfate, Quinine Sulfate, Sulfisoxazole, and Tetracycline HCl.

INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2)(A)

22. The patents in suit cover the use of Periostat® to treat patients with adult periodontitis.

23. Specifically, the two patents cover the treatment of patients by use of Periostat® since it reduces a pathological excess of collagenolytic enzyme activity in patients in need thereof and since it enhances bone protein synthesis in patients with bone deficiency disorders, such as periodontitis.

24. On information and belief, on August 30, 2001, WPC submitted an abbreviated new drug application ("ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act for doxycycline hyclate capsules, 20mg, based on the fact that the WPC drug and use is duplicative of the Periostat® drug and use.

25. Therefore, WPC has committed an act of infringement and continues to infringe under 35 U.S.C. § 271(e)(2)(A) which states as follows:

"§ 271…

…(e)…

(2) It shall be an act of infringement to submit–

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act…for a drug claimed in a patent or the use of which is claimed in a patent,

• • •

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. "

INFRINGEMENT UNDER 35 U.S.C. § 271(b) OR § 271(c)

26. Under § 505(j) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), FDA will approve West-ward's ANDA if West-ward has shown, *inter alia*, that the active ingredient in its capsules is the same as the active ingredient in Periostat's® capsules and is bioequivalent, and the labeling (package insert) is the same as the labeling for Periostat®

capsules. On information and belief, West-ward's ANDA states that these requirements are met.

27. Since the patents in suit cover methods of treating, *inter alia*, patients, infringement of the patents in suit also occurs under 35 U.S.C. §271(b) and/or (c) based on unauthorized (i.e., unlicensed) sale and offer for sale of a generic form of Periostat® for the same treatment as Periostat®.

28. Thus WPC, as the supplier of the generic form of Periostat® to patients, will be, liable as an inducer of infringement under 35 U.S.C. §271(b) and/or as a contributory infringer under 35 U.S.C. §271(c).

COLLAGENEX WARNS WPC

29. WPC has solicited the State Formulary of New Jersey to enlist it as a source, for a generic replacement for Periostat®. And WPC has been listed on the formulary for the State of New Jersey for the sale of a generic replacement for Periostat®. See Exhibit C.

30. CollaGenex became aware of WPC's application for addition to the New Jersey formulary on/or about June 2002 and immediately placed WPC on notice of its patent protection. See Exhibit D. WPC was already on notice of CollaGenex's patent rights because

a patent notice is, and has been, printed on the Periostat® package insert (which WPC had to emulate as part of its ANDA).

31. Disingenuously, WPC requested the patent numbers from CollaGenex on June 10, 2002. See Exhibit E. And CollaGenex responded on June 13, 2002. See Exhibit F.

32. CollaGenex again warned WPC to respect its patent rights by letter of September 23, 2002. See Exhibit G. CollaGenex's counsel called WPC's attorney again on September 30, 2002 and was assured of WPC's continued investigation; and WPC's counsel called again the following week reporting WPC's continued investigation.

33. On October 31, 2002, CollaGenex sent a letter, Exhibit H, basically accusing WPC of intent to willfully infringe the patents in suit.

34. In response, WPC has unequivocally stated that it "… intends to commercialize its generic Periostat® as quickly as the Food and Drug Administration will allow." See letter from counsel for WPC to counsel for CollaGenex provided here as Exhibit I.

35. Furthermore, WPC expects to receive an approval from the FDA in the "…very near future." See again Exhibit I.

36. These letters evidence WPC's intent to willfully infringe the patents in suit imminently.

37. Thus, WPC has engaged in infringing activity under 35 U.S.C. § 271(e)(2)(A) and intends to further infringe under 35 U.S.C. § 271(b) and/or (c) as soon as it receives FDA approval; and has conducted such acts in the face of a charge by CollaGenex of willful infringement of the patents in suit. See Exhibits H and I.

INJURY

38. In accordance with 35 U.S.C. § 271(e)(4)(A) CollaGenex is entitled to an order from the Court requiring the date of approval of WPC's generic form of Periostat® be not earlier than the date of the last to expire of patents in suit, i.e., July 5, 2007.

39. Further in accordance with 35 U.S.C. § 271(e)(4)(B) CollaGenex is entitled to injunctive relief against WPC to prevent the commercial manufacture, use, offer to sell, and sale within the United States and importation into United States of a generic form of Periostat® in accordance with its label and package insert.

40. WPC is also poised to introduce product into the commercial marketplace which, in use, will infringe the CollaGenex patents and which will have irrevocable impact on the reputation, product and sales, and the very viability of CollaGenex as a company.

41. Unless enjoined by this Court, WPC intends to, and will continue a course of conduct which will, infringe the patents in suit. As a direct and proximate result of the acts of WPC, CollaGenex will suffer irreparable harm and sustain untold loss of revenue, reputation, and stock value. CollaGenex has not adequate remedy at large to redress such injuries that WPC intends to cause and will cause by its conduct.

42. CollaGenex is entitled to a preliminary and permanent injunction restraining WPC, its officers, agents, employees, and all persons acting in concert with WPC, from engaging in any further acts related to the infringement of the patents in suit.

PRAYER FOR RELIEF

WHEREFORE, CollaGenex prays for an order:

a. Making the effective date of any approval of the generic form of Periostat® by the FDA be not earlier than the date of expiration of the last to expire of the patents in suit; i.e., not earlier than July 5, 2007;

b. Imposing injunctive relief against WPC to prevent the commercial manufacture, use, offer to sell, and sale within the United States and importation into the United States of a generic form of Periostat® in the manner prescribed on the label and package insert;

c. Declaring that WPC will infringe U.S. Patent No. 4,666,897 and U.S. Patent RE 34,656 under 35 U.S.C. §271(b) and §271(c), by introducing the generic form of Periostat® to the marketplace upon FDA approval of the generic form of Periostat®;

d. Declaring that any of the acts of sales, offer for sale, and importation into the United States of a generic form of Periostat® for the prescribed use will infringe U.S. Patent No. 4,666,897 and U.S. Patent RE 34,656;

e. Preliminarily and permanently enjoining WPC, its officers, agents, servants, employees and attorneys and all those persons acting in concert or participation with WPC from infringing the patents in suit;

f. Awarding to CollaGenex any damages incurred by acts undertaken by WPC which are related to the infringement of the patents in suit, including attorneys fees;

g. Requiring WPC to take all actions necessary to prevent introduction of infringing product into commerce in the United States;

h. Awarding to CollaGenex as against WPC aggravated damages up to three times the amount assessed and the cost of the suit, including attorneys fees; and

i. Such other further relief as the Court deems just.

This the 18th day of November, 2002.

Respectfully submitted,

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JURY DEMAND

CollaGenex hereby demands a trial by jury on all issues triable to jury.

Respectfully submitted,

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