

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF COLUMBIA

COLLAGENEX PHARMACEUTICALS, INC.,)
)
Plaintiff,)
)
)
v.)
)
TOMMY G. THOMPSON,)
DEPARTMENT OF HEALTH AND)
HUMAN SERVICES,)
MARK B. MCCLELLAN,)
and)
FOOD AND DRUG ADMINISTRATION,)
)
Defendants,)
)
and)
)
IVAX PHARMACEUTICALS, INC.,)
)
Intervenor-Defendant.)

CIVIL ACTION
NO. 03-1405 (RMC)

DECLARATION OF COLIN W. STEWART

I, COLIN W. STEWART, declare as follows:

1. I am the President and Chief Executive Officer of CollaGenex Pharmaceuticals, Inc. ("CollaGenex"). As President and Chief Executive Officer, I oversee the activities of CollaGenex including the commercial and scientific development of its products. I am familiar with the marketing of drug products in general, with the marketing and prospects for CollaGenex's product Periostat® (doxycycline hyclate 20 mg), and with the Food and Drug Administration ("FDA") regulatory process. This declaration is based upon my personal knowledge and the records maintained by CollaGenex in the course of its regular business activity.

2. I succeeded Brian M. Gallagher as President and Chief Executive Officer of CollaGenex in December 2003 and have been elected to its Board of Directors. I have a Master of Science degree from Durham University Business School, UK. Prior to joining CollaGenex, I served for five years as the President and Chief Executive Officer of Muro Pharmaceuticals, Inc., a specialty pharmaceutical company with a portfolio of branded respiratory and allergy products. Prior to that, I served ten years with the ASTA Medica Group, where I managed several business units in the United Kingdom and internationally. I began my career in sales and marketing for Winthrop Laboratories, Ltd. and subsequently held a number of positions of increasing responsibility within the Sterling-Winthrop Group.

3. I am familiar with the Declaration of Brian M. Gallagher, submitted in support of CollaGenex's motion for a preliminary injunction. The information contained in the Gallagher Declaration remains accurate and correct, and is updated below.

CollaGenex's Patents

4. CollaGenex licenses U.S. Patent RE 34,656 ("the '656 patent") from the Research Foundation of the State University of New York. The '656 patent does not expire until May 15, 2007.

CollaGenex's Assertion of Patent Infringement

5. As part of my responsibilities as President and Chief Executive Officer of CollaGenex, I have become familiar with the patents licensed by CollaGenex, the basis for the patents and the patent litigation in which CollaGenex has been involved. Based on this information, as well as the advice of patent counsel, I believe a claim of patent infringement of the '656 patent could reasonably be asserted against a person who made, used, or sold a generic version of Periostat. In fact, CollaGenex has twice filed claims for patent infringement against generic drug manufacturers to enforce its patents, including the '656 patent. CollaGenex did so based on the clear understanding that the generic drug manufacturers infringed the '656 patent. While both cases were settled prior to reaching a court decision on the merits, they were

vigorously contested, discovery was underway at the time of settlement, and CollaGenex was prepared to pursue both cases to conclusion if it was necessary to do so. CollaGenex was successful in reaching settlements with both companies in which each admitted, in a final judgment, that the manufacture, use, sale, importation or offer to sell a generic version of Periostat infringes the '656 patent.

6. On November 18, 2002, CollaGenex filed suit against West-ward Pharmaceutical Corp. ("West-ward") for infringement of the '656 patent and U.S. Patent No. 4,666,897 ("the '897 patent"). A copy of the Docket Sheet in CollaGenex Pharmaceuticals, Inc. v. West-ward, No. 1:02-cv-06094-ARR-RLM (E.D.N.Y.), is attached as exhibit 1.

7. In this litigation, West-ward argued, among other things, that the '656 patent did not cover the use of Periostat for the treatment of periodontitis. CollaGenex presented evidence, establishing that the '656 patent claims a method of using Periostat; that is, CollaGenex's evidence established that the claims of the '656 patent cover a method of treatment of periodontitis using Periostat in accordance with the package insert approved by FDA.

8. In November 2003, the case against West-ward was resolved by agreement of the parties, in the midst of discovery. As part of the resolution, West-ward agreed to the entry of judgment.

9. In the final judgment resolving the West-ward patent litigation, see attached exhibit 2, West-ward, and other defendants, admitted they had infringed claims of the '656 patent in connection with West-ward's efforts to obtain approval of an ANDA for a generic version of Periostat. West-ward also admitted that the '656 patent is valid and enforceable and West-ward was enjoined from infringing the claims of the '656 patent by the manufacture, marketing, sale and offer for sale of a generic form of Periostat without a license from CollaGenex during the duration of the life of the patents, absent any determination by a court that the relevant claims of the '656 patent are invalid or unenforceable. West-ward made parallel admissions regarding the '897 patent.

10. On July 8, 2003, CollaGenex filed suit against Mutual Pharmaceutical Company, Inc. ("Mutual") for infringement of its patents, including the '656 patent. A copy of the Docket Sheet is attached as exhibit 3.

11. In this litigation Mutual argued, among other things, that the '656 patent did not cover the use of Periostat for the treatment of periodontitis. In the course of this litigation, CollaGenex presented evidence establishing that the use of Periostat as approved by FDA and reflected in the package insert infringes the claims of the '656 patent. See, e.g., Declaration of Maria Ryan, attached as exhibit 4.

12. This case was resolved in April 2004 by agreement of the parties, as part of which Mutual stipulated to the entry of an order for judgment.

13. In the final judgment Mutual admitted that CollaGenex's Periostat patents, including the '656 patent, are valid and would be infringed by the commercial manufacture, use, sale, importation or offer for sale of the generic version of Periostat for which Mutual submitted its ANDA. The Court entered a consent judgment enjoining Mutual from infringing CollaGenex's patents by making or selling a generic version of Periostat until the patents expire or are declared invalid or unenforceable by a court of competent jurisdiction. The judgment is attached as exhibit 5.

14. As asserted in the course of the patent infringement litigation, and specifically explained in the Declaration of Maria Ryan, attached as exhibit 4, the use of Periostat as for the treatment of periodontitis approved by FDA and reflected in the package insert, requires treating a patient utilizing the method claimed by the '656 patent.

15. When CollaGenex submitted its NDA to the FDA for Periostat capsules in 1996 and for Periostat tablets in 2000, CollaGenex filed with each application the patent number and expiration date of the '656 patent in the form required by FDA. A copy of the certification for the '656 patent is attached as exhibit 6. The '656 patent and the '897 patent are included on the labeling of Periostat.

16. Despite the fact that FDA filed the patent information required by Section 505(b) of the Food, Drug, and Cosmetic Act, FDA never published the patent information in the Orange Book.

Harm to CollaGenex From Dissolution of the Preliminary Injunction

17. IVAX Corporation is a multinational company engaged in the manufacturing and marketing of branded and generic pharmaceuticals in the United States and internationally. IVAX boasts of having one of the strongest pipelines in the generic pharmaceutical sector with 43 abbreviated new drug applications pending with FDA as of March 31, 2004. See <http://www.ivax.com/jsps/about/about.jsp> (last visited Sept. 1, 2004). As of July, 2004, Ivax holds approvals for 100 prescription drugs. FDA Electronic Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations, available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempah.cfm> (last visited Sept. 1, 2004). As of the end of 2003, IVAX Pharmaceuticals, a subsidiary of IVAX Corporation, manufactured and marketed approximately 63 generic drugs, and distributed an additional 164 generic and over-the-counter drugs and vitamin supplements. IVAX Corporation, SEC Form 10-K for the fiscal year ended December 31, 2003, at 6, available at <http://www.sec.gov/Archives/edgar/data/772198/022119312504040619/d10K.htm> (last visited Sept. 1, 2004). In 2002 alone, IVAX sold approximately 5.7 billion units of generic pharmaceuticals in the United States through its subsidiary, IVAX Pharmaceuticals, Inc. See <http://www.ivax.com/jsps/about/about.jsp> (last visited Sept. 1, 2004). IVAX's net revenues for 2003 were \$1.42 billion. IVAX Corporation Annual Report 2003, available at http://www.ivax.com/pdfs/2003_Annual_Report.pdf (last visited Sept. 1, 2004).

18. FDA's deprivation of CollaGenex's rights under Hatch Waxman and FDA's approval of an application for a generic version of Periostat would cause immediate and irreparable injury to CollaGenex. The magnitude of the harm to CollaGenex from approval of a

generic version of Periostat is no different now than it was in July 2003; the losses would be devastating and threaten the viability of CollaGenex.

19. As the Gallagher Declaration set forth, CollaGenex depends on the revenues from Periostat for its continued viability. CollaGenex is still at a critical point in its development; it is still building the market for Periostat, and it cannot yet finance its research and development program from sources other than Periostat's revenues. CollaGenex needs to be allowed to recoup its investment in Periostat. At this point, every penny of revenue is required to make the company secure, and losing it would irreparably injure CollaGenex.

20. CollaGenex's only significant revenue has come from sales of Periostat. During 1999, 2000, 2001 Periostat accounted for approximately 95%, 84%, and 87%, respectively, of the total revenues of CollaGenex. During the six months ended June 30, 2004, and for the years ended 2003 and 2002, Periostat accounted for approximately 90%, 82% and 82% respectively, of CollaGenex's total net revenues. CollaGenex experienced a net loss for each year through 2002.

21. CollaGenex achieved net income of \$1.2 million for the six months that ended June 30, 2004, and net income of \$4.8 million for the year ended Dec. 31, 2003. CollaGenex incurred losses every other year since its inception and has an accumulated deficit of \$67.9 million at June 30, 2004. Because CollaGenex still continues to incur significant expenses with respect to the marketing and sales of Periostat, new products and continuing clinical and manufacturing development for other formulations and indications for Periostat, it cannot be certain to maintain this profitability in the future, if at all. Research and development costs alone during the six months ended June 30, 2004 amounted to \$3.8 million, and are projected to reach \$8.5 by the end of the financial year.

22. In connection with the settlement with Mutual, CollaGenex entered into a License and Supply Agreement, pursuant to which Mutual received a license to sell a branded version of

Periostat. Under this agreement, CollaGenex is the sole supplier of the product to Mutual, subject to certain conditions, at prices below CollaGenex's average manufacturer's price, through May 15, 2007, or the earlier termination of the agreement. Among other things, if a generic version of Periostat is shipped by a third party-generic and remains available for sale, Mutual would be granted a license entitling it to independently manufacture and freely sell its own branded version of Periostat. CollaGenex would not receive any revenues from these sales, leading to a significant decline in sales and material and irreparable harm to CollaGenex.

24. If IVAX obtains approval to market a generic version of Periostat, Mutual will also be entitled to market its own generic version. Both will be able to free ride on CollaGenex's substantial investment in innovation long before CollaGenex has had an opportunity to recoup its investment in Periostat. The effects on CollaGenex are those described in the Gallagher Declaration at paragraphs 49-61. Approval of a generic version of Periostat by IVAX, or any other generic company, still threatens the viability of CollaGenex.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 13th September 2004

Colin Stewart
COLIN W. STEWART