UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIOGEN IDEC INC., BIOGEN IDEC MA, INC. and GENZYME CORPORATION,

Plaintiffs,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK,

Defendant.

04 12009 MLW

CIVIL ACTION No.

MAGISTRATE JUDGE MBB

RECEIPT # 58778
AMOUNT $ 150
SUMMONS ISSUED Yes
LOCAL RULE 4.1
WAIVER FORM
MCF ISSUED
BY DPTY. CLK. FDM
DATE 9/20/04

COMPLAINT

Introduction

1. In 1983, more than twenty years ago, defendant The Trustees of Columbia University in the City of New York ("Columbia") obtained a patent on a recombinant DNA technology called "cotransformation," a process for inserting foreign DNA into a host cell to produce certain proteins. In 2002, two years after the expiration of that patent and two related patents, Columbia obtained yet another patent (the "'275 patent") on its cotransformation technology, and it maintains that the new patent will extend its patent monopoly until at least 2019.

2. When several licensees of Columbia's cotransformation patents sought recourse to the courts to challenge the validity and enforceability of the '275 patent, Columbia vexatiously manipulated the court system for the purpose of delaying judicial scrutiny of its new patent and imposing substantial burdens and costs on any licensees that challenged its patent. For example, in March 2004, after its licensees had sued for declaratory judgments that the new patent is invalid and unenforceable, Columbia sought to punish them by terminating their licenses,

ostensibly for failure to pay royalties due on the '275 patent. Columbia also sought to use the '275 patent, and to exploit the cost and uncertainty of litigation, by extracting settlements from various of its licensees. When Biogen Idec MA, Inc. and Genzyme Corporation moved to enjoin termination of their licenses, Columbia filed numerous papers opposing the motion and persuaded the Court to deny the motion, all at great cost to the plaintiffs. Less than three weeks after the Court denied their motion, Columbia reversed itself and asserted that the notices of termination were "ineffective." Columbia also filed a limited "covenant not to sue" certain parties on the '275 patent, while expressly excluding later developed products, as yet another tactic to escape judicial scrutiny of the patent. In the meantime, Columbia continued to prosecute another pending patent application in the same patent family and also filed a broadening reissue application, containing claims directed at its licensees' current commercial products. Plaintiffs bring this action for damages and declaratory relief to redress Columbia's illegitimate and costly attempts to enforce an invalid and unenforceable patent, to wrongfully terminate their licenses, and to abuse the processes of this Court in furtherance of its unlawful patent licensing strategy.

3. Columbia's first cotransformation patent issued in August 1983. In 1987 and 1993, Columbia obtained two additional patents claiming substantially the same invention. All three patents originated from a single patent application filed by Columbia on February 25, 1980, and all three patents were based upon the same experimental research described in that application. Because the United States Patent and Trademark Office ("Patent Office") determined that the second and third of Columbia's cotransformation patents claimed obvious variants of the first patent, and thus constituted impermissible "double-patenting," the Patent Office required

Columbia to disclaim any rights in those patents extending beyond the expiration date of the first issued patent. As a result, all three patents expired the same day, August 16, 2000.

4. Columbia licensed its original cotransformation patents to over thirty biotechnology companies and received hundreds of millions of dollars in royalty payments from those companies before the patents expired in 2000. In that year, Columbia mounted a widely criticized campaign to obtain special legislation from Congress extending the term of its original cotransformation patent by fifteen months, the result of which would have been an estimated $100 million windfall for Columbia in the form of additional royalty payments from its licensees. Congress soundly rejected Columbia's effort. Accordingly, all three patents expired that year, and Columbia's cotransformation inventions entered the public domain.

5. Unbeknownst to Congress and the public, however, Columbia was at the same time prosecuting still more patent applications on its cotransformation technology. Columbia filed these applications in 1995, but had delayed prosecuting them through a variety of dilatory tactics. When Columbia's lobbying effort failed, Columbia refocused its efforts on its still pending patent applications. Through this strategy, Columbia found an alternative means to extend the life of its patent monopoly, not just for the fifteen months Columbia had requested unsuccessfully from Congress, but for seventeen years. By misleading the Patent Office about the claim scope of its earlier cotransformation patents, Columbia obtained for itself on September 24, 2002 a **fourth** cotransformation patent, with a term extending all the way to 2019, based on the **same** research described in the **same** 1980 patent application that had given rise to the first three cotransformation patents. Columbia's new patent is U.S. Patent No. 6,455,275 (the "'275 patent").

6. Columbia asserts that its new '275 patent is valid, enforceable and infringed. Because the '275 patent is invalid and unenforceable, as explained below, this Court should grant declaratory and injunctive relief preventing its enforcement against plaintiffs. In addition, this Court should award damages, treble damages, and attorneys' fees as remedies for Columbia's improper actions in the Patent Office and this Court.

Parties

7. Plaintiff Biogen Idec Inc. ("Biogen Idec"), previously known as IDEC Pharmaceuticals Corporation, is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. On November 12, 2003, Bridges Merger Corporation, a wholly owned subsidiary of IDEC Pharmaceuticals Corporation, was merged with and into Biogen, Inc. with Biogen, Inc. continuing as the surviving corporation and a wholly owned subsidiary of IDEC Pharmaceuticals Corporation. At the same time IDEC Pharmaceuticals Corporation changed its name to Biogen Idec Inc. (referred to herein as "Biogen Idec") and Biogen, Inc. was renamed Biogen Idec MA, Inc. (referred to herein as "Biogen").

8. Biogen Idec developed RITUXAN® (rituximab), a leading cancer therapeutic that is approved to treat non-Hodgkin's lymphomas, and ZEVALIN® (ibritumomab tiuxetan), the first radioimmunotherapy approved for the treatment of cancer. Biogen Idec co-markets RITUXAN® with Genentech, Inc. Biogen Idec has never entered into a license agreement with Columbia with respect to Columbia's cotransformation technology.

9. Plaintiff Biogen Idec MA, Inc. ("Biogen"), previously known as Biogen Inc., is a Massachusetts corporation with its principal place of business in Cambridge, Massachusetts. Biogen has been engaged in biotechnology research for over twenty-five years. Its research led to the development of AVONEX® (Interferon beta-1a), the world's leading treatment for relapsing forms of multiple sclerosis, and AMEVIVE® (alefacept), a complex bioengineered

molecule for the treatment of certain kinds of chronic psoriasis. In 1993, Biogen entered into a license agreement ("Biogen license agreement") with Columbia to obtain rights to use the cotransformation technology that Columbia patented. Since that time, Biogen has paid more than $35 million to Columbia under the Biogen license agreement. Biogen has also entered into a variety of other agreements with Columbia, including research collaborations and license agreements.

10. Plaintiff Genzyme Corporation ("Genzyme") is a Massachusetts corporation with its principal place of business in Cambridge, Massachusetts. Genzyme was founded in 1981 and is also a pioneer in the biotechnology industry. Genzyme is dedicated to developing drugs and other products to treat patients with certain rare genetic disorders and other serious debilitating diseases. Genzyme has developed innovative treatments for lysosomal storage disorders, rare and progressive genetic conditions caused by missing enzymes. Genzyme has developed and commercialized CEREZYME® (imiglucerase), the only available enzyme replacement treatment for Type 1 Gaucher disease and THYROGEN® (thytotropin alpha) for use in thyroid cancer testing. Genzyme recently received FDA approval for FABRAZYME® (agalsidase beta) for the treatment of Fabry disease and ALDURAZYME® (laronidase) for treatment of MPS I (Mucopolysaccharidosis type-1). Genzyme is also the exclusive distributor of Biogen's AVONEX® in Japan.

11. Genzyme has entered into a variety of agreements with Columbia, including research collaborations. Columbia has also licensed certain screening technology (SAGE™, or serial analysis of gene expression) from Genzyme. In 1994, Genzyme entered into a license agreement ("Genzyme license agreement") with Columbia to obtain rights to use the cotransformation

technology that Columbia patented. Genzyme has paid almost $25 million to Columbia under the Genzyme license agreement.

12. Defendant Columbia is a New York non-profit corporation with a principal place of business in New York, New York. It is the owner by assignment of United States patents 4,399,216 ("'216 patent"), 4,634,665 ("'665 patent"), and 5,179,017 ("'017 patent"), which it licensed to Biogen and Genzyme under written license agreements (jointly, "License Agreements"). In addition to entering into the License Agreements with Biogen and Genzyme, under which it has accepted approximately $60 million dollars originating from Massachusetts, Columbia has also directed substantial and regular communications to plaintiffs in Massachusetts concerning the License Agreements and its patents. In 1993, Columbia brought suit to enforce the '216, '665, and '017 patents against a third party in this District. Columbia is also the owner of United States patent 6,455,275 ("'275 patent"), issued in 2002.

Jurisdiction and Venue

13. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201(a), and 2202. Also, because the amount in controversy exceeds $75,000, and the action is between citizens of different states, the Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

14. Biogen Idec herein seeks a declaratory judgment that the '275 patent is invalid and unenforceable because it has a reasonable apprehension that it will be sued by Columbia for infringement of the '275 patent. This reasonable apprehension is based at least in part upon (i) Biogen Idec's knowledge that as recently as September 1, 2004, Columbia asserted in the covenant not to sue filed in this Court that plaintiffs in the earlier action infringe the '275 patent and that the '275 patent is valid and enforceable; (ii) Columbia's repeated threats to various of its licensees that it would sue them for infringement of the '275 patent, including threats made in court papers and court proceedings; (iii) the fact that Columbia has confirmed in writing that

Biogen's affiliates are excluded from the scope of the covenant not to sue filed in court on September 1, 2004; (iv) the fact that Biogen Idec has never been a party to any license agreement with Columbia covering cotransformation technology; and (v) Biogen Idec's awareness of the facts set forth below.

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

Facts

A. Columbia's Original Cotransformation Patent Application

16. In the late 1970's, Richard Axel, Michael H. Wigler, and Saul J. Silverstein, scientists at Columbia University, carried out research on methods of inserting genes that code for certain proteins into the DNA of certain types of eukaryotic host cells. (Eukaryotic cells have a discrete nucleus, as distinguished from prokaryotic cells, which are principally bacteria and lack a structurally discrete nucleus.) Specifically, the Columbia scientists conducted experiments in cotransformation, a process of altering the genotype of a eukaryotic host or "recipient" cell by inserting into the cell both (a) a gene that codes for a desired protein and (b) a gene that codes for a "selectable marker." A selectable marker is a gene the expression of which confirms that the cell has been successfully transformed. For example, certain types of selectable markers may make a cell resistant to substances or conditions that would ordinarily kill the cell. A researcher can infer that this type of selectable marker has been incorporated into the cell's nuclear DNA if the cell survives in such hostile conditions. If the selectable marker has been incorporated into the host cell's nuclear DNA, it is likely that the cell has also incorporated the gene coding for the desired protein.

17. After conducting experiments concerning the cotransformation of certain types of mouse host cells with certain types of genes, Axel, Wigler, and Silverstein filed a patent application in February 1980. This application, serial no. 06/124,513, ("'513 application")

assigned to Columbia, issued (after amendment) as the '216 patent on August 16, 1983. The '216 patent had 73 claims, broadly covering (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, (c) processes for detecting cotransformed cells, and (d) cotransformed cells. It had a term of 17 years from the date of issuance, meaning that it would expire on August 16, 2000.

18. The research that led to the '216 patent was funded by the National Institutes of Health ("NIH"). NIH granted title to the invention to Columbia, but only upon certain conditions. Among these was the condition that any license "shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade practice."

B. Columbia's "Submarine" Patent Applications

19. Shortly before the '216 patent issued in 1983, Columbia filed a continuation application, serial no. 06/522,408 ("'408 application"). A continuation application is one that relies on the same disclosure, or specification, as an earlier, or "parent" application (in this case, the '513 application that matured into the '216 patent). Because a continuation relies on the same disclosure as its parent, it is an effort to obtain additional scope for the patent monopoly based on the same work disclosed in the original specification.

20. After almost three and one-half years of prosecution, the Patent Office allowed claims in the '408 application and issued the '665 patent in January, 1987. The claims of the '665 patent closely resembled the claims of the '216 patent. Specifically, the '665 patent claims (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, and (c) cotransformed cells. Because the subject matter of the '665 patent's claims was obvious in view of the '216 patent's broad claims, the Patent Office permitted the '665 patent to issue only after Columbia filed a "terminal disclaimer," disclaiming the part of the

patent's term that would have extended past the expiration date of the '216 patent. In this way, although Columbia received additional claims from the Patent Office, it did not obtain any additional time, or "term," in which it could legally exercise its monopoly over the subject matter claimed in the '216 (or '665) patent. Columbia made no attempt to deny that the claims of the '665 patent were obvious in view of the '216 patent.

21. Columbia's effort to obtain additional patents did not end with the '665 patent. In what was to become an oft-repeated tactic, Columbia filed another continuation application, serial no. 06/915,273 ("'273 application"), on October 3, 1986, again based on the specification of the '216 patent (and thus on the same research conducted in the late 1970's), shortly before the then-pending '408 application matured into the '665 patent. In the case of the '273 application, however, Columbia abandoned it after two years of prosecution and filed another continuation, serial no. 07/346,089 ("'089 application"), on May 2, 1989. Columbia then abandoned the '089 application after three years in favor of yet another continuation, serial no. 07/716,915 ("'915 application"), filed on June 18, 1991.

22. By repeatedly filing new applications based on the original specification and research, Columbia has continued, even up to the present, to prosecute claims based on the now decades-old research of Axel, Wigler, and Silverstein. Columbia's practice of "submarine" patenting allowed it to abuse the patent system by "surfacing" with a new patent many years or even decades after filing the original application. Keeping its original specification alive by filing one continuation or divisional application after another, Columbia sought to obtain new patents to capture the latest developments in the biotechnology industry.

23. In the case of the '915 application, which Columbia filed more than a decade after the original 1980 application, Columbia used its submarine patenting strategy to seek and obtain

claims covering new advances the biotechnology industry had made during the intervening decade. For example, when Columbia filed the original '513 application in 1980, its researchers did not know that a type of Chinese hamster ovary ("CHO") cells would serve as the preferred host cell for producing desired proteins. Nonetheless, Columbia pursued claims to transformed CHO cells in the '915 application, filed June 18, 1991, and the Patent Office ultimately allowed those claims to issue as the '017 patent. Once again, however, the Patent Office allowed the claims only after Columbia filed a terminal disclaimer limiting the term of the '017 patent to the term of the original '216 patent. Columbia made no attempt to challenge the Patent Office's conclusion that the claims of the '017 patent were obvious in view of the claims already allowed in the '216 and '665 patents. In all, the '216, '665, and '017 patents contain more than 100 claims, all originating from Columbia's original patent application in 1980.

24. Columbia continued with its submarine patenting strategy. Shortly before the '017 patent issued in January 1993, it filed yet another continuation. Indeed, it ultimately filed **five** more continuations based on the original specification describing the early research of Axel and his colleagues. Instead of "surfacing" with a submarine patent, however, Columbia abandoned most of those continuations after desultory prosecution, only to file yet more continuation applications.

25. Effective June 8, 1995, Congress reformed the patent law to close many of the loopholes that had made submarine patenting possible. On June 7, 1995, the day before this change in the law went into effect, Columbia secretly filed **two** further continuation applications based on the original specification of the '513 application. Under the reform legislation, these two applications were "grandfathered" because they were filed before the change in the law went into effect. In September 2002, one of these applications, serial no. 08/484,136 ("'136

application") issued after numerous amendments as the '275 patent now in suit. Because Columbia did not file a terminal disclaimer with respect to the '275 patent, the patent will not expire until 2019.

26. Yet another application filed the same day as the '136 application, serial no. 08/477,159 ("the '159 application"), is still pending at the Patent Office. In this application, Columbia is pursuing claims specifically directed at the commercial products of certain licensees, including products first marketed after the expiration of the '216, '665, and '017 patents.

C. Columbia's '636 Patent

27. At about the same time or shortly after he completed the research on which the original '513 application was based, Axel collaborated with another researcher, James Roberts, to carry out further research on methods of cotransforming eukaryotic cells with foreign DNA encoding genes for producing desired proteins. Based on this research, which was closely related to the work that had led to the '216, '665, and '017 patents, Columbia filed a separate patent application on March 15, 1982. Columbia eventually abandoned this application, serial no. 358,206 ("'206 application"), in favor of filing a continuation. It repeated this tactic twice more, ultimately receiving U.S. patent 5,149,636 ("'636 patent") on September 22, 1992, more than a decade after it filed the initial '206 application. As discussed more fully below, Columbia never disclosed the '636 patent or its file history to the examiner in the '275 patent prosecution so that he could make a determination of its materiality to the patentability of the '275 patent.

D. Columbia's Licensing of the Axel Patents

28. Columbia granted a non-exclusive license under the '216, '665, '017, and '636 patents (and continuations thereof) to Biogen in 1993. Columbia entered into a similar non-exclusive license with Genzyme in 1994.

29. Each of the License Agreements provided for up-front royalty payments to Columbia even before plaintiffs brought any product to market. The agreements further provided for minimum annual payments regardless of sales of licensed products. Under the License Agreements, as detailed above, plaintiffs have paid approximately $60 million to Columbia. Columbia also licensed the patents to other biotechnology companies, reaping hundreds of millions of dollars in royalties.

30. Columbia's license agreements with plaintiffs and other biotechnology companies required the licensees to pay royalties not only on Columbia's issued patents such as the '216 patent, but also on patents issuing from "any and all divisions, continuations and continuations-in-part" thereof. This provision gave Columbia significant incentive to keep spawning "children" of the issued patents, including the '275 patent.

31. Section 2(b) of the License Agreements provides that "All rights granted by Columbia under this agreement are subject to any rights required to be granted to the Government of the United States of America, including without limitation any rights reserved or obligations imposed by the Government pursuant to 35 U.S.C. §200-211 [the Bayh-Dole Act], regulations thereunder and the determination letter to Columbia from the Department of Health and Human Services dated February 24, 1981, a copy of which is attached hereto...."

32. In the determination letter, the NIH granted title to the invention to Columbia, but only upon the condition that any license "shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade practice." In addition, the regulations under which the NIH granted rights to Columbia empowered the NIH to assign the rights to an invention only "for the term of the patent or such lesser period as may be deemed necessary."

E. Columbia's Failed Attempt to Persuade Congress to Extend Its Patent Monopoly

33. The '216, '665, and '017 patents expired in August, 2000. Shortly before they were due to expire, Columbia embarked on an aggressive lobbying campaign to obtain special legislation from Congress extending the term of the '216 patent. Columbia claimed, among other things, that the income stream from the patent was "absolutely critical" and the "single most important source of free and clear funding" for the university. Notwithstanding the importance of the royalty stream to Columbia, the university claimed that the biotechnology industry was not burdened by paying these royalties, which Columbia characterized as "nominal."

34. During its campaign to persuade Congress to extend the term of the '216 patent, Columbia described its patent as pioneering, and as having great breadth and scope. Columbia represented to Congress that its '216 patent "covers the process for transforming animal cells so they can produce proteins used in biological pharmaceutical products." According to Columbia, it was the '216 patent that "makes it possible to generate the cell lines that are needed to produce patented drugs," specifically identifying Biogen's AVONEX® for treatment of multiple sclerosis and Genzyme's CEREZYME® for treatment of Gaucher's disease as two such drugs. As Columbia told Congress, its patent broadly claimed both "the cotransformed cells and the process of making them."

35. In its submissions to Congress, Columbia requested urgent action on its patent term extension request, representing that "Columbia's cotransformation patent expires on August 16, 2000." Columbia did not tell Congress that Columbia was simultaneously prosecuting secret patent applications that sought the issuance of new patents, with new 17-year terms, claiming the same cotransformation technology. And, just as Columbia did not tell Congress that it was

seeking further patent term by pursuing additional continuation applications, Columbia did not tell the Patent Office what it told Congress, namely, that it believed the '216 patent to have extremely broad claim scope, covering both cotransformed cells and the process of making them.

36. Columbia's request for extension of the term of the '216 patent met with widespread public outcry, and Congress rejected it, recognizing that Columbia had already reaped rich rewards from its seventeen-year patent monopoly. Congress decided that biotechnology companies should not be burdened by paying additional royalties for the period after the expiration of the '216 patent under their licenses with Columbia. Thus, the inventions claimed in the '216, '665, and '017 patents passed into the public domain in August 2000. This meant that plaintiffs, and other biotechnology companies, were free to develop and sell recombinant biological products without the economic burden of paying further royalties to Columbia. Referring to Congress's rejection of Columbia's proposed special legislation, Columbia's spokesperson said, "I do not believe there's a next step in this patent extension story ... it's an issue that's by us. ... Either you get the patent extended or it expires, and there's just no way to go back after it expires, so we're not going to be making any attempt."

F. The Surfacing of the '275 Submarine Patent

37. In fact, however, Columbia had an alternative plan already in place to extend the patent monopoly on its cotransformation technology. As previously set forth, Columbia had in 1995, unbeknownst to its licensees, Congress, or the public, filed two additional patent applications relying on the same patent disclosure and specification that its researchers had made some fifteen years earlier and that had been the basis for the '216, '665, and '017 patents.

38. Since these continuation applications were the last Columbia could file under the pre-reform patent prosecution rules, Columbia could not simply abandon them and further drag out the patent prosecution process as it had done so many times before. If it had filed new

continuation applications after June 7, 1995, any patent to issue from those applications would have expired, under the new rules, in February 2000. Instead, Columbia employed dilatory tactics to keep its June 7, 1995 continuation applications pending, including filing for extensions and filing notices of appeal to gain additional time. These tactics delayed the issuance of additional patents and thereby extended the term of those patents as far as possible into the future.

39. Using these tactics, Columbia strung out the prosecution of the continuation applications to such an extent that one application is still pending eight years after filing and the other did not mature into a patent until more than seven years after its filing date. That patent, the '275 patent, issued on September 24, 2002, almost twenty-three years after the filing of the original specification and more than two years after the expiration of its three earlier cotransformation patents. It was the product of **eight** continuing or divisional applications, of which five were abandoned. During prosecution of the '275 patent, which did not even **begin** until fifteen years after Columbia filed the original application, Columbia sought extensions of time amounting to some twenty-two months, filed two notices of appeal that it did not pursue, and added many new claims at a late stage in the prosecution.

40. Columbia's dilatory prosecution of the '275 patent and its predecessor applications was not Columbia's only abuse of the patent process. Columbia also resorted to misleading the patent examiner to obtain the patent, as set forth below.

41. Like the '017 patent, the '275 patent purports to claim developments in biotechnology that the Columbia researchers either had not achieved or had been unaware of at the time they filed the '513 application in 1980. Like the '017 patent, the '275 patent claims transformed CHO cells, a cell type that the inventors had never, as of the filing date, used successfully as a vehicle

for the production of medically valuable proteins. It also claims methods of producing and recovering protein materials that the inventors had not successfully practiced as of the time they filed the original '513 application. It also claims a "DNA construct," a term that does not appear in the original specification and came into use in the biotechnology industry only later.

42. Unlike the '017 patent, however, the '275 patent issued **without any terminal disclaimer**. Thus, although the discoveries on which it is based had to have been made before the original February 1980 filing date, the '275 patent, were it valid, would remain in effect until **September 2019**. In effect, the combined terms of the new patent and the '216 patent run for thirty-six years, from 1983 to 2019 (with a two-year gap between the expiry of the '216 patent and the issuance of the '275 patent). This combined term is far in excess of the limited monopoly contemplated by the Patent Act and the NIH determination letter, and would significantly burden the efforts of plaintiffs and other biotechnology companies to develop new innovative recombinant therapeutic and diagnostic products.

43. Had Columbia filed the terminal disclaimer that should properly have accompanied the '275 patent, that patent would have expired along with the three earlier patents on August 2000 – before it issued.

G. Columbia's Demands Under the License Agreements

44. Shortly after the '275 patent issued, Columbia announced to Biogen, Genzyme, and other licensees that, contrary to their expectations that royalty payments under the license agreements had come to an end, the issuance of the '275 patent had triggered the obligation to pay royalties under their license agreements once again. For example, by letter to Biogen dated October 3, 2002, Columbia advised Biogen of the issuance of the '275 patent and noted that "Columbia does not agree" that Biogen's last payment was "its last royalty owed." Thus, although plaintiffs believed that their royalty obligations to Columbia had expired with the

expiration of the '216, '665, and '017 patents, Columbia demanded royalty payments for another seventeen years, the term of the '275 patent.

H. Litigation Relating To The '275 Patent

45. On July 15, 2003, Biogen, Genzyme and Abbott Bioresearch Center, Inc., filed suit against Columbia in the District of Massachusetts alleging the invalidity and unenforceability of the '275 patent. Genentech, Inc., another licensee, had sued Columbia in the Northern District of California in April 2003 to challenge the '275 patent. Thereafter, several additional cases were filed alleging that the '275 patent was invalid and enforceable. On October 31, 2003, Columbia sued its licensees Johnson & Johnson and Ares Trading S.A. for a declaration that the '275 patent is valid and enforceable, and for breach of contract, alleging that these companies owed royalties on the '275 patent.

46. When the companies that filed suit against Columbia attempted to move their cases forward, Columbia stalled. Columbia refused to permit discovery and sought to stay various cases while it filed motions under 28 U.S.C. § 1404 to transfer venue of each of the cases to the Northern District of California. In its motion papers, Columbia contended that the alternative of multidistrict consolidation would be inappropriate. Later, with several such motions briefed and pending, Columbia reversed course, abandoned its venue motions, and moved for multidistrict transfer of all pending cases to the Northern District of California under 28 U.S.C. § 1407.

47. On April 8, 2004, the Judicial Panel on Mulidistrict Litigation ("JPML") issued a Transfer Order, granting Columbia's request to consolidate the several cases for pretrial proceedings but denying its request to transfer the actions (the "MDL cases") to the Northern District of California. Instead, the JPML ordered transfer of the MDL cases to the District of Massachusetts, assigning them to the Honorable Mark L. Wolf (the "MDL court"). Since that date, the litigation has proceeded in the District of Massachusetts. The original plaintiffs in the

Multidistrict Litigation were Biogen Idec MA, Inc. (formerly Biogen Inc.); Genzyme Corporation; Abbott Bioresearch Center, Inc.; Baxter Healthcare Corporation; Serono, Inc.; Ares Trading, S.A.; Wyeth; Genetics Institute, Inc.; Amgen, Inc.; Genentech, Inc.; Immunex Corporation; and Johnson & Johnson ("MDL plaintiffs").

I. Reexamination and Reissue Proceedings

48. On February 25, 2004, a third party, the Public Patent Foundation, filed a Request for Ex Parte Reexamination of the '275 patent on the grounds of double patenting. Columbia took no action upon learning of the reexamination request. It did not file its own reexamination request, it did not file a reissue application, and it did not retract its demands to the MDL plaintiffs for payment of royalties under the '275 patent.

49. The Patent Office granted Public Patent Foundation's Request for Reexamination on May 6, 2004. Columbia took no action at the time in response to this development. Instead, on May 27, 2004, this Court issued an Order that, among other things, directed the parties to address the implications of the Patent Office's decision to reexamine the '275 patent.

50. On June 10, 2004, over a month after the Patent Office's grant of reexamination, Columbia moved for a stay of the MDL proceedings. Columbia based this motion on the reexamination proceeding and its intent to file a reissue application with the Patent Office. Columbia filed its reissue application on June 18, 2004. Its application seeks to broaden the scope of the claims in the '275 patent.

51. Columbia could have filed a reexamination request or a reissue application under 35 U.S.C. § 251 at any time after the '275 patent issued in September 2002, but did not do so until June 2004, almost four months after the filing of the request for reexamination and a mere three months before the expiration of the two-year window for seeking a broadening reissue.

52. In its reissue application, Columbia seeks to expand the scope of the '275 patent by adding no fewer than seventeen new, broader claims and by amending its existing claims to enlarge their breadth as well. In other words, after waiting to file the reissue application until **nearly two years after issuance** of the '275 patent and **more than twenty-four years** after filing the original patent application, Columbia is using the reissue application on the '275 patent to begin prosecuting new, broader claims. Moreover, now that Columbia has filed for a broadening reissue, it can seek additional broadening claims even after the two-year deadline for broadening reissue applications, and it can appeal from any new claims rejected by the examiner, dragging out the prosecution still further. Columbia tries to justify the reopening of prosecution, some twenty-four years after filing its original application and after having obtained dozens of claims in three earlier issued patents, on the ground that it "failed to obtain the full scope of protection" for its 1980 invention.

53. Columbia's reissue application is the next chapter in its attempt to string out its patent prosecution. In the ex parte Patent Office reissue and reexamination proceedings, Columbia has substantial control over the length of the process. Columbia has already begun to exploit the numerous opportunities for delay provided by the rules for reexamination and reissue.

54. For example, at a June 22, 2004 hearing, in seeking to persuade the Court that reissue and reexamination would provide an efficient resolution of plaintiffs' claims, Columbia told the Court that "it's very common to ask for reissue, and that's why there's a procedure to merge the two proceedings when someone asks for a reexamination. But it both happened together on the same track by the same examiner so nothing gets slowed down. That's what we want to happen. We want to get this done quickly in the Patent Office too." Tr. at 90-91.

55. On July 7, 2004, however, just over two weeks later, and without informing the Court, Columbia filed a request to stay the reexamination of the '275 patent until completion of the reissue proceedings which it did not initiate until almost two years after the '275 patent issued. In its request to stay the reexamination, Columbia stated that "a merger of the two proceedings is not the preferred approach because in the above-identified reexamination, Patentees will not be permitted to obtain the broadened claims which Patentees are seeking, and are permitted to obtain, in their reissue application." Columbia also maintained that merger would be inappropriate because the obviousness-type double patenting issues that the Public Patent Foundation proposed for consideration on reexamination will be resolved in the reissue proceedings that Columbia initiated. If Columbia's request to stay the reexamination is allowed, the reexamination will not even begin until after the conclusion of the reissue proceedings.

56. In other words, Columbia not only plans to take the maximum time to replay and fine-tune its previous seven-year prosecution of the '275 patent, it proposes that when the reissue concludes, the patent will then, and only then, enter the reexamination proceeding instituted by the Public Patent Foundation.

J. License Termination and Motion for Preliminary Injunction

57. On March 9, 2004, after the request for reexamination was filed, Columbia again asserted the '275 patent against Biogen and Genzyme and others. In particular, Columbia sent letters to Biogen and Genzyme asserting that they were in breach of their license agreements and stating its intention to terminate the licenses for non-payment of royalties under the '275 patent.

58. On April 7, 2004, Biogen and Genzyme moved for a preliminary injunction to enjoin the termination of their licenses. In their motion papers, they demonstrated a high likelihood of success on the merits, showing that the '275 patent is invalid for double-patenting and unenforceable by reason of prosecution laches. In opposing the motion, Columbia said not one