UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK,	)	
Plaintiff,	)	
	)	
v.	)	**C.A. No. 93-11512-NG**
	)	
ROCHE DIAGNOSTICS GmbH, formerly known as BOEHRINGER MANNHEIM GmbH,	)	
Defendant.	)	

GERTNER, D.J.

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FINDINGS OF FACT/CONCLUSIONS OF LAW
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I. INTRODUCTION

This case involves an allegation by plaintiff Columbia University ("Columbia") of patent infringement against defendant Roche Diagnostics GmbH (formerly Boehringer Mannheim, GmbH) ("Roche"), a multinational pharmaceutical corporation having its principal place of business in Mannheim, Germany. In essence, Columbia claims that Roche induced or otherwise collaborated with Genetics Institute ("GI"), a United States company based in Cambridge, Massachusetts, to produce the drug Erythropoietin ("EPO")[1] using methods and products for which Columbia holds the patents. Columbia also alleges that Roche, without proper

[1] EPO is useful in treating end stage renal disease.

authority, imported into the United States products made by its patented processes.

The dispute revolves around U.S. Patent Nos. 4,399,216 ("the '216 patent"),[2] 4,634,665 ("the '665 patent"),[3] and 5,179,017 ("the '017 patent")[4] (collectively referred to as the "Axel patents").[5] When Columbia obtained the first of the Axel patents, it broke new ground: It identified a process to produce important proteins, including glycoproteins such as EPO, by genetic engineering. But while the Axel patents have had a significant effect on the field of biotechnology over the last twenty years, the end of the patents' protection is near; the first will expire in 2003.

The Axel patents cover processes for inserting two genes into a host cell ("cotransformation") in which one of the genes encodes a marker protein, and the other gene encodes a protein of interest.[6] The claims also cover the cell lines produced by the

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[2] The '216 patent was issued on August 16, 1983.

[3] The '665 patent was issued on January 6, 1987.

[4] The '017 patent was issued on January 12, 1993.

[5] Columbia initially brought this action against Roche for infringement of the '216 patent and the '665 patent, both entitled "Processes for Inserting DNA into Eucaryotic cells and for Producing Proteinaceous Materials." Columbia added a claim of infringement of the third patent with the same title, the '017 patent, in its Second Amended complaint.

[6] The inventors named on all three patents are Drs. Richard Axel, Saul Silverstein, and Michael Wigler (hence "the Axel patents").

process of amplification and cotransformation, variously described hereafter as the EPO generating Chinese Hamster Ovary ("CHO") host cell, the production clone, or DN2-3α3. See Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16 (D. Mass. 2000).[7] However, the claims do not cover the protein of interest itself that is produced by the cell, EPO.

On December 11, 2000, I issued a Markman decision that construed key claim language in the Axel patents. Most crucially, based upon an analysis of the intrinsic evidence, I adopted Columbia's interpretation of the phrase "dominant selectable phenotype" found in claim 54 of the '216 patent.[8] Id.

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[7] From Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996).

[8] Claim 54 of the '216 patent states:

> A process for generating a multiplicity of foreign DNA I molecules corresponding to multiple copies of a gene in a cell with a molecule which comprises transforming said eucaryotic cell with a molecule which is formed by linking one of said DNA I molecules to a DNA II molecule corresponding to an amplifiable gene for a dominant selectable phenotype not expressed by said eucaryotic cell, and culturing the transformed eucaryotic cells in the presence of successively elevated concentrations of an agent permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene, said transformation and culturing being carried out under suitable conditions.

I construed the phrase "dominant selectable phenotype" as follows: "A selectable phenotype which allows an organism or a cell of a defined genotype that acquires such phenotype, e.g. as a result of introducing a gene at a suitable copy number, to survive while other organisms or cells of the same defined genotype which have not acquired such phenotype will not survive or proliferate."

at 31. In addition, construing conflicting Federal Circuit precedent, I found that the product-by-process claims were not limited to the product prepared by the process set forth in the claims of the Axel patents. Id. at 31-32.

On April 27, 2001, I resolved motions for summary judgment. See Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 150 F. Supp. 2d 191 (D. Mass. 2001). I granted summary judgment in favor of Roche on Columbia's claims of direct infringement under 35 U.S.C. 271(a) because there was no evidence that any infringing activities by Roche had occurred in the United States. Id. at 201-204. I also found that Roche's exporting of EPO and an EPO-generating cell line did not violate 35 U.S.C. 271(f), which prevents companies from circumventing the U.S. patent laws by exporting non-infringing components to be assembled abroad into a infringing final product. Roche's actions were beyond the intended scope of liability under Section 271(f). Id. at 204-205.

However, on the question of whether Roche was liable under 35 U.S.C. § 271(b) for inducing GI to infringe the Axel patents, I found that disputed questions of material facts remained.[9]

[9] I also denied Roche's request for summary judgment on the issue of non-infringement of claims to unlinked DNA embodiments because I found, based on my interpretation of the language of the Axel Patents (embodied in my Markman findings), that subject matter that is alleged to infringe claims to linked DNA may literally infringe claims drawn to unlinked DNA. I have subsequently revised my Markman findings with respect to the terms "linked" and "unlinked."

A jury waived trial was held before me on July 10, 2001, through July 31, 2001.

II. FINDINGS OF FACT

A. The Axel Patents

The Axel patents relate to processes for inserting two genes -- a DNA I expressing a protein of interest and a DNA II expressing a protein conferring a selectable phenotype -- into a recipient cell whereby the recipient cell incorporates and expresses both of the genes and makes the proteins encoded by the genes. The process of inserting these genes into a recipient cell whereby each of the genes is expressed is referred to as "cotransformation."

In addition, because the DNA II encodes a selectable phenotype, and cells that do not express DNA II will not survive, one can select for cells that incorporate and express DNA II. Thus, the Axel patents allow for the selection of cells which have successfully incorporated the gene encoding the protein of interest (DNA I). The Axel patents also disclose that if the DNA I and DNA II are genetically linked, then amplifying (i.e.,

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See Section III(A)(1)(a), infra. This change inescapably leads to a conclusion that GI did not literally infringe any of the unlinked claims, and therefore, Roche did not induce GI to infringe any of these claims. See Section III(A)(1)(b), infra.

increasing the number of copies of the gene) DNA II will also amplify DNA I.

For a more detailed description of the Axel patents and its claims, see Trustees of Columbia University, 126 F. Supp. 2d. at 17-22.

B. The Acts At Issue

In April 1982, GI embarked upon a project to isolate the EPO gene, insert it into recipient cells, and express it in those cells. GI subsequently solicited pharmaceutical companies to help fund its research and commercialize its products worldwide. Trial Exhibits ("Trial Exs.") P138, P139. In June 1984, GI reached an agreement with Chugai Pharmaceutical Company, Ltd. ("Chugai") (the "GI-Chugai License Agreement"), in which the parties agreed to collaborate to "undertake a research and development project utilizing recombinant DNA technology for producing erythropoietin on a commercially feasible basis." Trial Ex. P142 at ¶ 2. In return for Chugai's funding of GI's research and royalty payments, GI granted a license to use GI's EPO-related patented technology and scientific knowledge to commercialize EPO in the United States, Canada, Mexico, Japan, and other Asian countries.

GI also sought a partner to develop and commercialize EPO in Europe, a territory excluded from the GI-Chugai License

Agreement. In the fall of 1984, GI began discussions with Roche to accomplish this goal as well as with at least two other large European pharmaceutical companies. Trial Transcript ("Trial Tr.") 999-1000. On January 2, 1985, GI and Roche executed a confidentiality agreement to assist their negotiations. Trial Ex. P148. By March 19, 1985, Roche's Board of Directors had "agreed in principle" to an outline of a deal between GI and Roche. Trial Ex. P24. The details of the deal had not yet been finalized; instead, the outline was merely "a good basis for [the parties'] next, more detailed discussions" that would be held later in the year. Id. at p. 3.

The parties eventually agreed to a deal on October 8, 1985, in a Development & License Agreement ("GI-Roche D&L Agreement"). Trial Ex. P29. The GI-Roche D&L Agreement stated, in part:

> [Roche] desires that GI, on behalf of and in collaboration with [Roche], [will] undertake a research and development project utilizing recombinant DNA technology for producing erythropoietin on a commercially feasible basis for use in humans. In return for certain rights under the patents and know-how developed by GI, [Roche] will financially support the research and development activities of GI and will pay GI the royalties provided for herein.

Id. at p. 1. As a part of the GI-Roche D&L License Agreement, Roche agreed to fund GI's research and development. Id. at ¶3.1. "In consideration of the research, development, and related

activities undertaken by GI with regard to the project," Roche agreed to pay GI a series of non-refundable research fees when GI reached certain development benchmarks. Id. The Agreement also authorized the exchange of confidential trade secrets and included a provision for joint ownership: "the Parties shall own jointly the entire right, title and interest in and to all patent and other rights in any product method or apparatus conceived, reduced to practice or developed jointly by GI and BM in the course of the Project." Id. at ¶¶ 2.6 & 5.3. Finally, the Agreement provided that neither party was permitted to produce "any publicity, news release or other public announcement, written or oral, relating to this Agreement, the Project or the existence of an arrangement between the parties without the prior written approval of the other Party . . . ." Id. at ¶ 10.2.

1. Manufacture of the Production Clone

Weeks before the signing of the GI-Roche D&L Agreement on October 8, 1995, GI began making the EPO production clone DN2-3α3, 10 micromolar. Trial Tr. 498-500. GI had an outstanding obligation to Chugai to produce the EPO production clone under the GI-Chugai License Agreement. On October 10, 1985, the production clone was transferred from the cell line production lab to the cell culture lab to be adapted to grow in suspension culture. Trial Ex. P171 at p. 44.

The DN2-3α3, 10 micromolar production clone was the source for both a master cell bank ("MCB") and master working cell bank ("MWCB"). After the production clone was adapted to grow in suspension, a small quantity of those cells produced from the production clone were grown in a large vat in October 1985. Then, GI created the MCB by taking small amounts of the cells from the vat and freezing and storing these cells in individual vials. Trial Tr. 723-724. The MCB was "laid down," meaning the cells were frozen and put in vials, on December 4, 1985. Trial Tr. 452-453.

Out of the two to three hundred vials of the MCB, one was thawed and in two weeks, grew into a larger quantity of cells. These cells, referred to as the MWCB, were then again divided into small portions, put into individual vials, and frozen on December 18, 1985. Trial Tr. 764-765.

The production of the DN2-3α3, 10 micromolar production clone, the MCB, and the MWCB was all done exclusively by GI. Trial Tr. 510. Roche had no involvement with the specifics of GI's production of these items. No detailed technical information concerning the production of the clone, the MCB, or the MWCB was passed from GI to Roche until November 1985, or after the signing of the GI-Roche D&L Agreement. Trial Tr. 437.

The cells of the MWCB were used to make bulk EPO, which GI later shipped to Roche in Europe. To make bulk EPO, GI would thaw one of the vials of the MWCB and grow the cells under certain culture conditions in a large tank with a stirring rod. Trial Tr. 723-727. Nutrients and media were fed into the tank by GI, and the cells, floating in suspension, were in the solution. Id. During the entire growth process, EPO was expressed first inside the cells and subsequently secreted outside of the cells into the medium in the tank. Id. Then, on a routine basis, GI removed a portion of the media containing the EPO into a new tank, where GI separated the cells away from the solution. Id. Finally, the solution went through a series of purification steps until only the pure EPO molecule remained.

On February 24, 1986, GI shipped vials of the MCB and the MWCB of the DN2-3α3, 10 micromolar EPO production clone to Chugai in Japan pursuant to the GI-Chugai License Agreement. Trial Ex. P152; Trial Tr. 506-507. On March 4, 1986, GI sent 15 vials of the MCB and 15 vials of the DN2-3α3, 10 micromolar EPO production clone to Roche in Germany. Trial Ex. P112 at B100793. In July 1986, GI sent its first shipment of good manufacturing practice ("GMP") bulk EPO to Roche in Germany.[10] Trial Ex. P114.

[10] Good manufacturing practices or "GMP" are essentially a set of guidelines established by the Food and Drug Administration and other regulatory authorities that ensure that the product is of a sufficiently high quality for human use.

From July 1986 until 1991, when GI was enjoined from making EPO in Amgen v. Chugai Pharmaceutical Co., Ltd., 13 U.S.P.Q. 2d 1737 (D. Mass. 1989), aff'd in part, 927 F.2d 1200 (Fed. Cir. 1991), GI produced bulk EPO which it shipped to Roche in Germany.[11] After GI provided the bulk EPO to Roche in Europe, Roche was responsible for finishing the clinical development of the drug in Europe and for commercializing EPO in Europe.

2. Shipment Of "Bailed" EPO Production Cells

In September 1987, GI shipped certain "bailed" cells to Roche in Germany. Trial Exs. P180 & P181. These cells consisted of twelve vials of MCB, six vials of MWCB, four vials of EPO producing cells in a serum-free medium, and twelve vials of other EPO producing clones. Id. Although Roche agreed to keep these cells for GI as "'insurance' in the event of unfavorable legal/patent developments in the U.S.," the parties agreed that the cells would remain GI's exclusive property. Trial Ex. P181. In early 1989, Roche returned 6 vials to GI by shipping them to GI in the United States at GI's request.

3. Shipment Of Albumin-Free EPO

In March 1989, using bulk EPO which GI had created from the DN2-3α3, 10 micromolar production clone and had shipped to Roche

[11] In October 1987, Amgen, Inc. sued GI (along with Chugai) and alleged that GI's process for producing EPO infringed its patent on cloning the EPO gene. Pursuant to this action, in 1991, GI was enjoined from making EPO.

earlier, Roche formulated some albumin-free EPO for use by GI in a clinical trial involving Jehovah's Witnesses in the United States. Trial Ex. P293; Trial Tr. 446-450. For religious reasons, the Jehovah's Witnesses did not wish to use ordinary EPO, which contained human or animal derived blood products. GI administered this albumin-free EPO to Jehovah's Witness patients as a "compassionate treatment" in the United States, and Roche received no revenue from GI as a result of the shipment. Id.

4. Freezing Of the EPO Production Clone

Since the 1991 Amgen Injunction enjoining GI from making, using, or selling EPO, GI has kept its EPO production clone frozen in a state of suspended animation using liquid nitrogen. It was GI's decision to keep these cells frozen. Trial Tr. 482.

III. LEGAL ANALYSIS

A. Infringement

Columbia argues that Roche is liable for patent infringement under two theories. First, Columbia claims that Roche violated 35 U.S.C. 271(b) ("Section 271(b)") by inducing GI to infringe the Axel patents. Also, Columbia argues that Roche directly infringed the Axel patents under 35 U.S.C. 271(g) ("Section 271(g)") by improperly importing into the United States a product made by a process patented in the United States.

Under either theory, Roche's liability depends on GI's. It is liable only if GI's underlying actions directly infringed the Axel patents. Under Section 271(b), if there is no direct infringement by GI, Roche cannot be liable for inducing infringement. See Fina Research, S.A. v. Baroid Limited, 141 F.3d 1479, 1484 (Fed. Cir. 1998) (holding that "direct infringement is a prerequisite to inducing infringement"). Under Section 271(g), Roche can only be held responsible if it imported a product made by a patented process into the United States. See 35 U.S.C. 271(g). If the product shipped by Roche into the United States was made by a process that did not directly infringe upon Columbia's patents, then Roche cannot have violated Section 271(g).

I will first address whether GI directly infringed the Axel patents with its actions before considering whether Roche induced this infringement under Section 271(b) or imported a product made by Columbia's patented process under Section 271(g).

1. Did GI Directly Infringe The Axel Patents?

a. Revision of Markman Findings With Respect To The Terms "Linked" and "Unlinked"

Before I reach the question of whether GI directly infringed any of Columbia's patents, I must revise my earlier Markman definitions of the terms "linked" and "unlinked" as used in the Axel patents. (I note at the outset, that the issue of the precise meaning of "linked" and "unlinked" was not briefed as carefully as other issues at the Markman stage). I have reviewed intrinsic evidence of the claims themselves, the patent specification, and the prosecution history. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (identifying the intrinsic evidence as "the most significant source of legally operative meaning of the disputed claim language.") After first reviewing the intrinsic evidence and determining that this evidence was not unambiguous, I looked to the extrinsic evidence as well.

In my Markman findings, I defined "linked" as "[p]hysically and chemically joining DNA I and DNA II into the same piece of contiguous DNA prior to their insertion into the eucaryotic cell Mammalian Cell." Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 126 F. Supp. 2d 16, 33 (D. Mass. 2000). In contrast, I defined "unlinked" as "[n]ot physically or chemically linked on the same piece of contiguous DNA." Id. at 34.

Virtually every scientist -- including Dr. Weinberg, produced by Columbia -- who testified in this case suggested that the Court's definition did not comport with the accepted scientific definitions of these terms. Trial Tr. 423; 923-924. Columbia correctly notes that I must construe these terms according to the standard of what these words would have meant to a person having ordinary skill in the art at the time of the application for the patent. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1556 (Fed. Cir. 1983). However, Columbia presents no compelling intrinsic or extrinsic evidence to support its interpretation that the terms "linked" and "unlinked" refer only to whether the two DNA strands were linked in nature and not simply if they were linked at the moment of their insertion into a eucaryotic cell.

As a result, I amend my Markman findings as follows: The distinction made in the patents as between linked and unlinked DNA refers to the status of the DNA I and DNA II cells at the moment of their insertion into a eukaryotic cell.[12]

[12] I formally construe the disputed claim language as follows:

"Linked" -- "Physically and chemically joining DNA I and DNA II into the same piece of contiguous DNA at the moment of their insertion into the eucaryotic cell."

"Unlinked" -- "Not physically or chemically linked on the same piece of contiguous DNA at the moment of insertion into the eucaryotic cell."

b. Did GI Directly Infringe Any Of The Unlinked Claims?

(1) Literal Infringement

Generally, a claim is literally infringed only if each properly construed claim element reads on the accused product or process. See Cortland Line Co. v. Orvis Co., 203 F.3d 1351, 1358 (Fed. Cir. 2000); Atlantic Thermoplastics Co., Inc. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992). Changing my earlier Markman definitions of "linked" and "unlinked" to recognize that these terms refer to whether the DNA I and DNA II were linked at the moment of their insertion into the eucaryotic cell directly affects the literal infringement analysis with respect to the unlinked cotransformation claims. The allegedly infringing acts committed by GI involve the use of only two DNAs -- a DNA I encoding EPO and a DNA II encoding Dihydrofolate Reductase ("DHFR") -- which were joined by cotransformation prior to their insertion into the eucaryotic cell. Thus, GI could not have literally infringed any of the unlinked claims of the Axel patents. In other words, because GI's processes involved only linked cotransformation, GI could not have literally infringed any of the unlinked cotransformation claims of the Axel patents.

This conclusion revises my earlier finding on summary judgment concerning non-infringement of claims involving unlinked

DNA. See Trustees of Columbia University in the City of New York v. Roche Diagnostics GmbH, 150 F. Supp. 2d 191, 209-210 (D. Mass. 2001).[13] The DN2-3α3, 10 micromolar production clone made by GI was made using only linked DNA. The DNA I encoding the EPO gene and the DNA II encoding the DHFR gene were physically linked on the same plasmid prior to insertion into the eucaryotic cell. As such, GI could not have literally infringed any of Columbia's claims involving unlinked cotransformation. Therefore, the only claims at issue with regard to literal infringement are claim 54 of the '216 patent and its dependant claims.

(2) Doctrine Of Equivalents

Although GI did not literally infringe the unlinked cotransformation claims, the doctrine of equivalents could apply to GI's processes with respect to these claims. The doctrine of equivalents allows a court to find infringement when an accused product or process is the substantial equivalent of a patented invention or process. See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17 (1997). The essential inquiry is whether the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. Id. at 40.

[13] While amplification processes remain a principal difference between the linked and unlinked claims of the Axel patents, see Trustees of Columbia University in the City of New York, 150 F. Supp. 2d at 209-210, the linkage of the two DNAs at the moment of insertion is also crucial.

Specifically, Roche focuses on the prosecution history of the '216 patent. Roche argues that Columbia's statements before the PTO during the prosecution of the '216 patent relinquished any claim that linked cotransformation infringes by equivalents the unlinked cotransformation claims of the Axel patents.

Before I address Roche's claims, however, I must address the question of which party bears the burden of proof in this instance. Where the patentee is seeking to broaden the scope of the literal terms of his patent through the doctrine of equivalents, he or she bears the burden of showing that amendments made to his claim during the prosecution history did not relinquish the particular equivalent he identifies as infringing, at least where he made the amendment for a substantial reason relating to patentability. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 122 S. Ct. 1831, 1841-42 (2002); Gentile v. Franklin Sports, Inc., 211 F. Supp. 2d 334, 336-338 (D. Mass. 2002). The patentee bears a similar burden with regard to arguments or statements made to the Patent and Trademark Office ("PTO") for a substantial reason relating to patentability. Id.; Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc., 170 F.3d 1373, 1376-77 (Fed. Cir. 1999); Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc). However, for such an estoppel to apply,

the statements made by Columbia to the PTO must clearly have surrendered the subject matter in question. Pharmacia & Upjohn Co., 170 F.3d at 1376-77.

Having these standards in mind, I find as follows: During the prosecution of Columbia's '216 patent, the PTO Examiner rejected claims covering unlinked cotransformation and transformed cells obtained by unlinked cotransformation on the ground that these claims would have been obvious to a person having ordinary skill in the art in light of the teachings of Kretschmer, et al. and Mantei, et al. Columbia attempted to distinguish their claims involving unlinked cotransformation from the teachings of the Mantei, et al. article by arguing that "the Mantei, et al. article involves linked DNA which is distinguishable from Applicant's unlinked DNA." Trial Ex. P288 at 216-154. Later in the same document submitted to the PTO to overcome the Examiners' objections with respect to the Mantei, et al. article, Columbia "reiterate[d] their position that use of linked DNA is patentably distinguishable from their claimed invention." Id. at 216-155.

Despite Columbia's protestations to the contrary, its representations to the PTO that its claims involving unlinked cotransformation were "patentably distinguishable" from the use of linked DNA in the prior art is a sufficiently clear surrender

of the subject matter necessary to trigger estoppel here. Having clearly distinguished between the use of linked and unlinked DNA before the PTO in order to overcome an objection by the Patent Examiner (indisputably a substantial reason relating to patentability), Columbia cannot now claim that the two are substantially equivalent.

Because GI did not directly infringe any of the unlinked cotransformation claims of the Axel patents, either literally or through the doctrine of equivalents, Roche is not liable for inducing GI to infringe any of the unlinked claims. Thus, Roche did not infringe claims 1, 2, 9, 10, 11, 14, 15, 18-22, 24-28, 30-32, 39, 41, 42, 44-51, and 53 of the '216 patent or claims 1, 3-5, 7, 10-18, and 21-23 of the '665 patent under Section 271(b) or Section 271(g).

c. Did GI Directly Infringe Any of the Linked Claims (Claims 54-73 Of The '216 Patent)?

Roche interprets the language of claims 54-73 of the '216 patent to require cotransformation using a "DNA II molecule corresponding to an amplifiable gene for a dominant selectable phenotype." Roche asserts that "in claim 54, it is the selection step that requires the use of an amplifiable gene encoding a 'dominant' selectable phenotype. It is not the amplification step." Roche Post-Trial Memorandum at 19. In other words, Roche

suggests that, according to the Axel patents, amplification must be part of the process by which the dominant phenotype is selected.

In contrast, Roche argues that GI's processes do not infringe because in GI's approach, only a single copy of the DHFR gene was used in each cell to confer selectability. The DNA I (EPO) was ligated to DNA II (DHFR) and inserted into a DHFR deficient cell. GI, it suggests, performed amplification only after this selection stage. Thus, the amplification of the DHFR gene did not effect the selection of the DHFR gene. Because GI utilized a process in which selection of cotransformants was based on a single copy of DHFR, and not the amplification process, GI did not infringe claim 54 of the '216 patent.[14]

Roche's arguments are based upon an incorrect premise -- that this Court interpreted the claims to require that it was the amplification process that enabled the DNA II gene to become dominant. The language of claim 54 does not require that the amplification step cause dominance; instead, to be covered by claim 54, the DNA II must only correspond to an amplifiable gene

[14] Roche also argues that GI's process was fundamentally different than the process described in claim 54 because the DHFR marker gene used by GI could not be used as a dominant selectable marker. It was too weak to dominate over the host DHFR gene. As such, the process did not involve the use of a "DNA II molecule corresponding to an amplifiable gene for a dominant selectable phenotype."

However, nothing in claim 54 suggests that "dominance" should be interpreted so narrowly.

for a dominant selectable phenotype. It is undisputed that the DHFR gene is an amplifiable gene and that it is covered by the language of the Axel patents as an "amplifiable gene for a dominant selectable phenotype."[15]

As a result, GI's process of creating its EPO production clone by inserting the linked EPO gene and DHFR gene into the cell and then amplifying the copies of the genes by exposing them to successively elevated concentrations of methotrexate infringed claim 54 of the '216 patent. The bulk EPO made by GI to ship to Roche in Europe between 1986 and 1991 infringed claim 54 of the '216 patent and its dependent process claims (claims 55, 62, 64-65, and 69-71 of the '216 patent) as well as the product-by process claims (claims 72 and 73). Trial Tr. 424-25, 563-64, 720, 838-852, 969-970. If Roche induced GI to make this bulk EPO with the requisite specific intent (see Section III(A)(2)(b), infra), Roche will be liable for inducing this infringement under Section 271(b) unless it prevails on one of its affirmative defenses.

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[15] Roche also repeats its argument from the Markman proceedings that the phrase "DNA II molecule corresponding to an amplifiable gene for a dominant selectable phenotype" should be construed as "a gene which is amplifiable and expresses a protein that confers on a eucaryotic wild type cell the ability to survive in culture medium lethal to the eucaryotic wild type cell." In my Markman opinion, I rejected this proposed construction, finding that it was "unsupported by the intrinsic evidence, including the prosecution history." Trustees of Columbia Univ., 126 F. Supp. 2d at 31. I find no reason to change my earlier construction or to accept Roche's conclusions here.

In addition, both the "bailed" MWCB cells and the albumin-free EPO that Roche returned to GI in the United States in 1989 were likewise made with a process that directly infringed claims 54-55, 62, 64-65, and 69-71 of the '216 patent. As a result, if Roche "import[ed]" these products to GI in the United States without Columbia's authority, it will be liable for infringement under Section 271(g) if it does not prevail on one of its affirmative defenses.

2. Did Roche Induce GI to Commit Any of the Allegedly Infringing Acts?

Under the statute, anyone who induces another to infringe a patent is also liable as an infringer. See 35 U.S.C. § 271(b) ("Section 271(b)") (providing that "[w]hoever actively induces infringement of a patent shall be liable as an infringer.") To prove that a defendant has induced infringement, a plaintiff must demonstrate "that the alleged infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." Manville Sales Corp. v. Paramount Systems, Inc., 917 F.2d 544, 553 (Fed. Cir. 1990). In addition, the plaintiff must demonstrate that the alleged infringer knowingly induced infringement with "a specific intent to encourage another's infringement and not merely that the

defendant had knowledge of the acts alleged to constitute infringement." Id.

In effect, this statute is analogous to a criminal statute imposing liability for one who acts as an accessory before the fact. Sims v. Western Steel Co., 551 F.2d 811, 817 (10th Cir. 1977) ("This subsection contemplates that the inducer shall have been an active participant in the line of conduct of which the actual infringer was guilty. Thus he should be in the nature of an accessory before the fact.")[16] While the plaintiff need not prove that the defendant exercised control over the third party infringer's actions to support a finding of inducement liability, VLT Corp. v. Unitrode Corp., 130 F. Supp. 2d 178, 200-201 (D. Mass. 2001), he must demonstrate by either direct or circumstantial evidence that the defendant knowingly aided and abetted another's direct infringement. Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988), cert. denied, 484 U.S. 968 (1988).

a. Did Roche Induce GI To Make The EPO Production Clone, MCB, Or MWCB?

Columbia alleges that Roche induced GI to infringe the Axel patents by inducing GI to create the DN2-3α3, 10 micromolar EPO

[16] During the jury waived trial, I analogized the differences between an accessory before the fact and one who receives stolen property. Section 271(b) only targets an active participant (effectively, the accessory) and not the passive recipient (i.e. the "fence").

production clone, MCB, and MWCB. However, regardless of whether GI directly infringed the Axel patents with its making of these cells, Roche is not liable for any infringement by GI because it did not induce GI to create these cells.

GI had begun its research into developing a commercially feasible EPO production clone even before its first contact with Roche in 1984 and continued this work throughout 1985. Weeks before it signed the GI-Roche D&L Agreement on October 8, 1985, GI had begun work on the DN2-3α3, 10 micromolar EPO production clone. GI had an outstanding obligation to Chugai to produce this EPO production clone in order to meet its duties under the GI-Chugai License Agreement to Chugai. Although the clone was not transferred from the cell line production lab to the cell culture lab to be adapted to grow in suspension culture until October 10, 1985, GI created the EPO production clone prior to its being adapted to suspension culture. Thus, I am satisfied that the production clone was virtually finished prior to the signing of the GI-Roche D&L Agreement on October 8, 1985. While GI attempts to point to a March 1985 "agreement in principle" between the parties as evidence that Roche's inducement began before the parties signed the GI-Roche D&L Agreement, any agreement between the parties at that point was too tentative to hold Roche liable for GI's actions as an accessory before the

fact with the specific intent to induce GI to infringe the Axel patents.

Similarly, I find that Roche did not induce GI to infringe the Axel patents by creating the MCB or MWCB. The cells of the MCB were not "laid down," that is, frozen and put into individual vials, until December 4, 1985; the MWCB was not laid down until December 18, 1985. However, once again, GI had completed over ninety percent of the work to produce the MCB and MWCB prior to the dates that they were laid down. Under these circumstances, I cannot find that Roche induced GI to infringe the Axel patents by creating these cells.

b. Did Roche Induce GI To Make Bulk EPO?

My conclusions are different with respect to the question of whether Roche induced GI to make the bulk EPO that GI shipped to it between 1986 and 1991.[17] Roche makes three arguments:

First, Roche argues that GI would have made the bulk EPO to supply a European company to finish the clinical development of the drug and market the drug in Europe, even without Roche's involvement. Accordingly, Roche cannot be held responsible for inducing GI to make the bulk EPO. To be sure, GI did negotiate

[17] Roche conceded at trial that GI's use of the cell line, the production clone, to make bulk EPO would infringe Columbia's claims if the making of the cell line itself infringed those claims. Trial Tr. 785.

with at least two other European companies in addition to Roche. However, there is no conclusive evidence that GI would have produced the bulk EPO that it produced without Roche's involvement in the project.

In a related argument, Roche argues that it did not induce GI into making bulk EPO because GI was already committed to produce bulk EPO for Chugai as a result of its contract with Chugai before Roche and GI signed the GI-Roche D&L License Agreement. In February 1986, GI did ship vials of the MCB and the MWCB of the DN2-3α3, 10 micromolar EPO production clone to Chugai in Japan pursuant to the GI-Chugai License Agreement. However, under the GI-Chugai License Agreement, GI did not retain any rights to manufacture bulk EPO. Instead, under the agreement, GI was to supply Chugai with the cell lines and a sample of expressed and purified EPO, and Chugai would manufacture the bulk EPO product in Japan for itself. In contrast, under the GI-Roche D&L Agreement, GI retained rights to manufacture bulk EPO for Roche with Roche's support.

Next, Roche argues that it did not induce GI's production of bulk EPO because it did not control the details of GI's processes to produce the bulk EPO. Without this hands-on control over GI's infringing actions, it could not have possessed the specific intent necessary to induce infringement under the Manville Sales

test. Instead, relying on Keplinger v. De Young, 23 U.S. 358, 365-366 (1825), Roche styles itself as a mere purchaser of goods who is not liable for purchasing a product that a third party happened to make with an infringing process, utilizing the "receiver of stolen property" analogy.

However, while control over a third party infringer's actions is relevant evidence as whether a defendant has induced that third party to directly infringe, control is not a necessary condition for a finding of inducement liability. In VLT Corp. v. Unitrode Corp., 130 F. Supp. 2d 178, 200-201 (D. Mass. 2001), the court examined the relevant Federal Circuit precedent of Hewlett-Packard Co. v. Bausch & Lomb, Inc., 909 F.2d 1464 (Fed. Cir. 1990) and Water Technologies Corp. to reject this argument that an inducing defendant must have some control over the design, manufacture, or marketing of an infringing device to be held liable under Section 271(b).

Admittedly, Roche did not exert control over the specifics of how GI would manufacture the bulk EPO that GI would provide to it under their agreement. GI produced the EPO according to GMP standards, a set of guidelines established by the FDA and other regulatory agencies that drug manufacturers need to follow if the drug is going to be used by humans. While Roche had an independent responsibility for ensuring that GI used GMP

practices in manufacturing the bulk EPO, it did not tell GI how to meet those requirements or supervise GI's production in any detailed way.

As explained above, however, whether Roche immediately supervised the production of the bulk EPO is not dispositive. As long as Roche encouraged GI to take actions that it knew or should have known would infringe the Axel patents with the requisite specific intent, Roche is liable under Section 271(b). The key question is not whether Roche controlled GI's actions, but whether Roche encouraged those actions with the requisite prior knowledge and specific intent to infringe. I conclude that it did.

Finally, Roche argues that it did not induce GI into making the bulk EPO because it never encouraged GI to make the bulk EPO in the first place. It argues that Roche wanted to make the bulk EPO itself in Germany and only consented to GI making the bulk EPO for it as a concession to GI under the GI-Roche D&L License Agreement. Under the GI-Roche D&L License Agreement, GI had the exclusive right to manufacture a minimum of 100% of Roche's bulk EPO for the first three years of the contract, 85% for year four, 65% for year five, and 50% for the remainder of the contract. Trial Ex. P29 at B100111. However, although Roche's first option

may have been to manufacture the bulk EPO itself in Germany, the bargain it entered into said otherwise.

The details of the relationship between GI and Roche as defined by the GI-Roche D&L License Agreement demonstrate that Roche was intimately involved with inducing GI to make bulk EPO. Roche was more than a mere purchaser of goods who arrived on the scene after GI finished creating the bulk EPO. As a part of the GI-Roche D&L License Agreement, Roche agreed to fund GI's research and development. Trial Ex. P29 at ¶ 3.1. "In consideration of the research, development, and related activities undertaken by GI with regard to the project," Roche agreed to pay GI a series of non-refundable research fees when GI reached certain development benchmarks. Id. The Agreement also authorized the exchange of confidential trade secrets and included a provision for joint ownership: "the Parties shall own jointly the entire right, title and interest in and to all patent and other rights in any product method or apparatus conceived, reduced to practice or developed jointly by GI and BM in the course of the Project." See id. at ¶¶ 2.6 & 5.3. As this Court previously explained:

> . . . BMG's D & L Agreement was not merely a contract to purchase goods in Massachusetts for delivery outside of Massachusetts. Rather it created, by its own wording, a "collaboration" between the two companies.

> Although it appears that only GI personnel actually performed experimental or production work in Massachusetts, BMG's connection with that work was more intimate than that of a mere customer. BMG was the principal underwriter of the research in question. If the research produced valuable technology, BMG was to have an exclusive license to use the technology outside the United States. Moreover, BMG retained, under the D & L agreement, the right to prosecute foreign patent applications on any technology developed by GI which GI failed to prosecute itself.

Trustees of Columbia University, 35 U.S.P.Q.2d at 1368.

In this case, GI had not fully developed the bulk EPO before Roche and GI agreed to collaborate. In addition, unlike the creation of the DN2-3α3, 10 micromolar EPO production clone, the MCB, or the MWCB, GI had not virtually completed its production of the bulk EPO before beginning its relationship with Roche. To the contrary, GI did not send its first shipment of GMP bulk EPO to Roche in Germany until July 1986, nine months after the parties entered into their Agreement in October 1985. Prior to Roche's involvement, GI had not completed its production of the bulk EPO that it sent to Roche, and Roche's research funding, royalty payments, and support clearly encouraged GI to utilize the EPO production clone, MCB, and MWCB to do so.

With respect to the creation of the bulk EPO, Roche acted as an accessory before the fact with full knowledge that GI would

utilize the EPO production clone, MCB, and MWCB to manufacture the bulk EPO. Therefore, because Columbia has shown that GI directly infringed the Axel patents by creating these cell lines,[18] and because Roche possessed the specific intent necessary to be held culpable for inducing this infringement by encouraging GI's production of bulk EPO, Roche induced GI to make bulk EPO in violation of Section 271(b). In doing so, it induced GI to infringe the linked claims (claims 54-73) of the '216 patent (see Section III(A)(1)(b), supra).

c. Did Roche Induce GI to Freeze and Store the Epo Production Clone after GI Was Enjoined from Producing EPO?

Columbia also alleges that Roche induced GI to store and maintain its EPO production clone in a frozen state of suspended animation since GI was enjoined from producing EPO in 1991. However, even if this act by GI did directly infringe the Axel patents -- and it is not at all clear that it did -- Columbia has presented no evidence to support its claim that Roche induced this allegedly infringing act, and therefore, Roche cannot be held liable for GI's actions in this instance.

3. Did Roche Directly Infringe The Axel Patents Under 35 U.S.C. § 271(g)?

[18] Whether GI's actions in creating these cell lines directly infringed the Axel patents is discussed in Section III(A)(1)(b)-(c), supra.

Columbia alleges that Roche directly infringed its patents by importing products made using the Axel patents into the United States. See 35 U.S.C. 271(g) ("Section 271(g)") (providing that "[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer. . . .") Columbia argues that Roche violated Section 271(g) when it shipped albumin-free EPO to GI in the United States in March 1989 and when it returned GI's "bailed" vials of the MWCB, also in early 1989. Columbia argues that GI made both the albumin-free EPO and the "bailed" vials of the MWCB by utilizing and directly infringing its patented processes. Columbia further alleges that Roche imported these products into the United States without authority from Columbia in violation of Section 271(g).

a. Importing Albumin-Free EPO

Roche makes two arguments to refute Columbia's claim of liability under Section 271(g) with respect to its shipping albumin-free EPO to GI in the United States. First, it argues that because GI (and not Roche) manufactured the albumin-free EPO, it cannot be held liable under Section 271(g). Unfortunately for Roche, it is irrelevant under Section 271(g) who manufactured the goods so long as the goods were manufactured

using a patented process. Instead, under the statute, liability attaches to one who, without authority, imports a product made by a patented process into the United States. The defendant need not have performed the patented process itself. See Pfizer Inc. v. Aceto Corp., 853 F. Supp. 104, 106 (S.D.N.Y. 1994) (Lasker, J.) (corporation that imported, but did not manufacture, product made by patented process was nevertheless liable under Section 271(g)).[19]

Roche next argues that it is not liable under Section 271(g) because it was not the "importer" of the albumin-free EPO. Instead, it claims that GI imported the goods itself into the United States in order to administer it to the Jehovah's witness patients. This argument clearly fails. The evidence demonstrates that Roche shipped the albumin-free EPO to GI in the United States. Under the statute, the term "import" has its "plain ordinary meaning of bringing goods into the United States." Bristol-Myers Co. v. Erbamont Inc., 723 F. Supp. 1038, 1044 (D. Del. 1989). Because the albumin-free EPO was made using

[19] The legislative history also makes clear that "the offending act is the importation of a product made through the use of a protected process patent or its subsequent sale in the United States." H.R. Rep. No. 60, 100th Cong., 1st Sess. 6 (1987) (emphasis added).

a patented process,[20] Roche is liable under Section 271(g) for shipping these goods to GI in the United States.

To the extent that Roche is arguing that it cannot be held liable under the statute because it merely shipped the albumin-free EPO to GI in the United States, and neither Roche nor GI sold the product, this argument founders on the plain language of the statute. Under Section 271(g), liability attaches to one who "imports into . . . or . . . sells . . . within the United States a product which is made by a process patented in the United States." (Emphasis added). While selling the product within the United States is an alternative ground for violating the statute, merely importing the offending product into the United States is a sufficient basis to impose liability. Thus, because these cells were made using a process patented by Columbia,[21] Roche is liable under Section 271(g) for shipping these goods to GI in the United States.

b. Importing GI's "Bailed" Cells

In early March 1989, Roche returned a number of so-called "bailed" vials of MWCB to GI in the United States at GI's

[20] Whether GI created the product by utilizing a process patented by the Axel patents was discussed in Section III(A)(1)(b)-(c), supra.

[21] Whether GI created these MWCB cells by utilizing a process patented by the Axel patents was discussed in Section III(A)(1)(b)-(c), supra.

request. To defend against Columbia's claim of liability, in addition to the same failed arguments that it raised in the albumin-free EPO context, Roche argues that it cannot be held liable under Section 271(g) because it never owned these "bailed" cells, which at all times remained the property of GI. It claims that it could not have "imported" these cells under Section 271(g), if it never owned the cells.

This argument again finds no support in the plain language of the statute or in the common meaning of the word "import," and not surprisingly, Roche cannot cite a single authority that supports its interpretation. Whether or not Roche owned the cells is irrelevant. It is undisputed that Roche shipped the cells into the United States, and thus imported them under the statute. See Bristol-Myers Co., 723 F. Supp. at 1044 (finding that "Congress did not intend the term 'importation' to turn upon extremely intricate concepts of title and sales contracts.") As a result, because these cells were made using a process patented by Columbia,[22] Roche is liable under Section 271(g) for shipping these goods to GI in the United States.

[22] Whether GI created these MWCB cells by utilizing a process patented by the Axel patents was discussed in Section III(A)(1)(b)-(c), supra. I concluded that Roche did not induce the creation these cells in Section III(A)(2)(a), supra. However, Roche's importing these cells back into the United States creates an independent basis for liability, as described in Section III(A)(3).

B. Roche's Defenses

Roche asserts numerous affirmative defenses to liability under Sections 271(b) or 271(g). It raises the defenses of obviousness, inequitable conduct, unclean hands and patent misuse, possession of an implied license, and laches. I will address each of these in turn.

1. Are Claims 54-73 Of The '216 Patent Invalid Because Of Obviousness?

Roche argues that claims 54-73 of the '216 are invalid due to obviousness. In doing so, it argues that these claims, which involve linked cotransformation followed by subsequent amplification, would have been obvious to a person having ordinary skill in the art at the time the invention was made. However, Roche explicitly concedes that "it is not asserting that the claims of unlinked cotransformation are obvious." Roche's Post-Trial Memorandum at p. 20 (emphasis added).

Because a patent is presumed to be valid once it is issued by the PTO, Roche bears the burden of proving its defense of the invention's invalidity by clear and convincing evidence. 35 U.S.C. § 282; Greenwood v. Hattori Seiko Co., Ltd., 900 F.2d 238, 241 (Fed. Cir. 1990). Under 35 U.S.C. §103(a), a patent may not be obtained if its "subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art . . . ." In order to determine whether a patent would have been obvious at the time the invention was made to a person having ordinary skill in the art, the Supreme Court has instructed courts to examine the following four factors: (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art, and (4) objective evidence of non-obviousness, such as commercial success, long-felt but unsolved need, or the failure of others. Graham v. John Deere & Co., 383 U.S. 17-18 (1966); Greenwood, 900 F.2d at 241. I must also consider the obviousness of the claimed invention as a whole. Even if elements of the claimed invention viewed in isolation would be obvious, "[w]hat must be found to be obvious to defeat the patent is the claimed combination." Gillette Co. v. S.C. Johnson & Son, Inc., 919 F.2d 720, 724 (Fed. Cir. 1990).

The objective secondary factors, for the most part, weigh heavily in Columbia's favor. Most significantly, the overwhelming commercial acquiescence by the pharmaceutical industry to the legitimacy of the Axel patents supports a finding of non-obviousness. See Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1575 (Fed. Cir. 1992); Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1270-71 (Fed. Cir. 1991) (holding that the

significance of a new invention "is often better measured in the marketplace than in the courtroom.") Twenty-eight major pharmaceutical companies have paid for a license to the Axel patents, generating over hundreds of millions of dollars in royalties for Columbia based upon billions of dollars in drug sales by these companies. That these companies were willing to part with such extraordinary sums is strong independent evidence that the Axel patents were not obvious.

Roche points to the prior art publications, specifically those of Nunberg, et al. (Trial Ex. D206) and Schimke, et al. (Trial Ex. D474) to argue that the claims of the Axel patents describing linked cotransformation followed by subsequent amplification would have been obvious.[23] While it does not claim that the linked cotransformation claims were obvious in light of either publication by itself, it suggests that it would have been obvious to a person having ordinary skill in the art to combine their teachings and conceive of the invention embodied in the Axel patents. To support this conclusion, Roche offers the expert opinion of its witness, Dr. Kaufman, who testified that the prior art had established that "when genes get amplified,

[23] In addition, Roche points to Mantei, et al. Trial Ex. D108, which was cited to the PTO during the prosecution of the patents. The citation was withdrawn after the inventors filed a declaration under Rule 131, 37 C.F.R. § 1.131, noting that their invention was conceived and reduced to practice before Mantei's publication. Roche challenges this representation. See infra, III.B.

they amplify a large piece of DNA. They amplify sequences that are adjacent to the gene. So, it becomes obvious that if the genes were linked, that they would amplify together." Trial Tr. 1299:24-1300:2.

Roche bolsters Dr. Kaufman's opinion by arguing that during the prosecution of the '665 patent, the PTO Examiner rejected claims based on linked cotransformation offered by Columbia because these claims were obvious in light of prior art publications by Willicke, et al. in view of publications by Nunberg, et al. The PTO did not reject the linked claims during the prosecution of the '216 patent, the only patent at issue here, Roche claims, because the Examiner was not aware of the Nunberg, et al. article at that time.

What Roche has not done is to offer any credible evidence concerning what the level of ordinary skill in the art was at the time of the invention. Graham, 383 U.S. at 17; see also Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir.1991) ("the level of ordinary skill in the art is a factual question that must be resolved and considered.") Dr. Kaufman offered his opinion that linked cotransformation would have been obvious to him at the time of the invention, but there is no evidence that

the skill level of Dr. Kaufman was the same as that of a person having ordinary skill in the art.[24]

Given its burden of proof, Roche's invalidity defense to claims 54-73 of the '216 patent fails.

2. Are Claims 54-73 of the '216 Patent Barred By Inequitable Conduct By Columbia?

Patent applicants have a duty to prosecute their patent applications in the PTO with good faith, candor, and honesty. Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). Roche argues that inequitable conduct by Columbia's attorney John White during the prosecution of the Axel patents bars any recovery by Columbia for infringement. To prevail on this defense, Roche must prove by clear and convincing evidence that Columbia made affirmative misrepresentations of fact, submitted materially false evidence, or failed to disclose material information to the PTO and did so with an intention to deceive the PTO. Molins, 48 F.3d at 1178-81; Baxter Intern., Inc. v. McGaw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1573-74 (Fed. Cir. 1991).

[24] Dr. Kaufman also acknowledged that he had not read the Court's Markman findings and thus could not relate his conclusions to the claims as construed.

Roche is not claiming that the inventors themselves lied to the PTO. Instead, it argues that Columbia attorney John White intentionally misrepresented statements contained in the declarations filed by the inventors pursuant to 37 C.F.R. § 1.131 ("Rule 131 declarations").[25]

Attorney White argued to the PTO that the Rule 131 declarations established that the inventors "actually reduced to practice claimed embodiments of their invention prior to the effective date of the Mantei et al. article (September 6, 1979) or the Lai et al. article (January 1980)." Trial Ex. P288 at 216-249 - 216-250 (emphasis added). Roche claims that White's representation that the Rule 131 declarations established that the invention was reduced to practice prior to the effective date of the Mantei et al. article was deliberately misleading because the declarations did not state that the subject matter of the linked claims were reduced to practice prior to the Mantei et al. article. In fact, while the inventors did declare that the

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[25] 37 C.F.R. § 1.131(a) states:

> When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim . . . may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based.

37 C.F.R. § 1.131(a).

invention as a whole was reduced to practice prior to Mantei, they did not specifically state that the claims involving linked amplification followed by subsequent amplification (which later became claims 54-73 of the '216 patent) were reduced to practice prior to Mantei et al. Compare Trial Ex. P288 at 216-166 - 216-169, Trial Tr. 1579-1580 with Wigler Depo. at 94:16- 98:3, 171:1-173:7; Silverstein Depo. at 96, 98-100, 103. Roche argues that both the PTO and Mr. White believed that linked cotransformation was patentably distinct from unlinked cotransformation, so when White said that "the invention" was reduced to practice prior to Mantei et al., he made a material omission because the inventors had not reduced to practice the process described in claim 54-73 of the '216 patent relating to linked cotransformation prior to Mantei et al.

Roche's argument falls for several reasons. First, it is not at all clear that White made any material misrepresentations or omissions. By stating that the declarations established that the inventors of the Axel patents had reduced the invention to practice prior to the effective date of Mantei et al., he was accurately reporting what the inventors had stated in their declarations. Furthermore, Rule 131 requires that the applicant make an oath "to facts showing a completion 'of the invention.' That requirement does not mean [the] affiant must show a

reduction to practice of every embodiment of the invention." In re Hostettler, 356 F.2d 562, 565-66 (C.C.P.A. 1966). Finally, even if Columbia had been required to show a reduction to practice of the specific claims at issue, Roche had produced no evidence to support a finding of a specific intent to deceive the PTO by White. White clearly believed that evidence of a reduction to practice of the invention as a whole was sufficient to meet the PTO's concerns, and there is no evidence that he intentionally deceived the PTO.

As a result, Roche's inequitable conduct defense fails.

3. Does Columbia Have Unclean Hands, or Did it Misuse its Patents with Anti-competitive Effect?

Roche next argues that the Axel patents are unenforceable due to Columbia's unclean hands and patent misuse. It claims that Columbia's license of the Axel patents to Johnson & Johnson ("J&J") violated restrictions placed upon the patents by the National Institute of Health ("NIH") and unlawfully restricted competition in the EPO market for J&J's benefit.

A defense of unclean hands arises from the equitable maxim, "he who comes into equity must come with clean hands." It prevents one who is "tainted with inequitableness or bad faith relative to matter in which he seeks relief" from obtaining

relief from a court of equity. Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806, 816 (1945).

A party asserting the affirmative defense of patent misuse must prove that the patent owner has "impermissibly broadened the scope of the patent grant with anticompetitive effect." C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998), cert. denied, 526 U.S. 1130 (1999). The patent misuse defense is available even if the infringer has not suffered personally from the misuse of the patent. Morton Salt Co. v. G.S. Suppinger Co., 314 U.S. 488, 494 (1942).

Certain actions constitute per se patent misuse, including (1) requiring the purchase of unpatented goods for use with patented apparatus or processes ("tying"); (2) prohibiting production or sale of competing goods; and (3) conditioning the grant of a license under one patent upon acceptance of another and different license. See Donald S. Chisum, 6 Chisum on Patents, § 19.04[3] at 19-451 (2002). "Anticompetitive effects that are not per se violations of law are reviewed in accordance with the rule of reason. Patent owners should not be in a worse position by virtue of the patent right to exclude, than owners of other property used in trade." Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 708 (Fed. Cir. 1992). Under the rule of reason, I must "decide whether the questioned practice imposes an

unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." Virginia Panel Corp. v. MAC Panel Co., 133 F.3d 860, 869 (Fed. Cir. 1997).

In 1980, Columbia filed a "Petition for Determination" with NIH to request approval of the assignment of the invention to Columbia and of its plan to license the invention to third parties for development. NIH had funded the research that produced the patents, and seeking that approval was a requirement if Columbia wanted to commercialize an invention made with federal funds. Sgarlat Depo. 34:15-20. NIH responded by letter in February 1981 (the "NIH Determination letter") and denied Columbia's request to grant it an exclusive license. The letter allowed Columbia to license the invention non-exclusively, subject to conditions, including 1) every license "shall include adequate safeguards against unreasonable royalties and excessive trade practices," and 2) Columbia must not grant any exclusive license for a period longer than five years without the approval of NIH. Trial Ex. D315.

In 1989, Columbia granted a license to J&J which granted J&J "exclusive" rights to use the Axel patents in the making, using,

and selling of EPO. Trial Ex. P257 at 2-3. However, that license recognized that twelve other companies had been previously licensed to use the Axel patents in the making, selling, and using of EPO and that they would continue to be able to do so. It also contained a provision where J&J was required to issue a sublicense to four other companies (including GI and Roche) upon their request, provided that these companies would agree not to assert a patent infringement claim against J&J based on J&J's making, selling, or using EPO. Id. Columbia also reserved all rights required to be granted to the U.S. Government. Id.

Roche argues first that Columbia is guilty of unclean hands because the 1989 license to J&J violated the terms of the NIH Determination letter. Roche claims that Columbia violated the NIH Conditions by (1) not submitting the 1989 "exclusive" license to J&J to NIH for approval; (2) granting J&J exclusivity over using the Axel patents for making, using, and selling EPO for over eleven years even though the Determination Letter limited the duration of any exclusive license to five years; and (3) making abandoning a right to sue J&J for patent infringement a condition of J&J's granting of a sublicense to four companies (including Roche and GI) because this condition was an "excessive

trade practice" in violation of the NIH Determination letter's ban of such practices.

However, the license that Columbia granted to J&J in 1989, although labelled an "exclusive" license, was not truly exclusive. It explicitly provided that twelve companies that had previously granted a license to make, use, or sell EPO under the Axel patents could continue to do so. It also included a provision which required J&J to sublicense four additional companies (including Roche and GI), provided that these companies agreed to drop any infringement claim against J&J based upon J&J's manufacture, use, or sale of EPO. Therefore, the license was not truly exclusive, and the fact that Columbia did not send this license with J&J to the NIH for approval does not make it guilty of unclean hands.

Roche further claims that independent of whether Columbia violated the terms of the NIH Determination letter, Columbia is guilty of patent misuse because its 1989 license to J&J wrongfully restricted competition in the EPO market for J&J's benefit. Roche argues that the clause in the 1989 license stating that J&J only needed to issue a sublicense to Roche and GI if they dropped any EPO patent infringement suit against J&J was a "suicide clause" because if Roche had agreed to this provision, it would have been effectively forced out of the EPO

market. Trial Tr. 1111-12. Roche says that this is per se patent infringement because it is analogous to a non-competition clause in the sale of EPO. They also argue that even if per se patent misuse does not apply, under the rule of reason, Columbia attempted to impermissibly broaden the scope of the Axel patents with anti-competitive effect.

The argument that Columbia engaged in predatory licensing practices does not pass muster. Roche was offered an opportunity to purchase a license to the Axel patents in 1984, without any restrictions about relinquishing its infringement claims against J&J. It refused to take such a license. Furthermore, Roche has failed to prove that an anti-competitive effect in the United States resulted from Columbia's licensing practices. Columbia correctly notes that Columbia licensed the Axel patents to dozens of companies. Its license to J&J even provided that J&J would sublicense the patents to Roche and GI if these companies agreed to drop certain patent infringement claims against J&J. Although Roche understandably might not have wished to give up an infringement claim against J&J in order to receive a sublicense to produce EPO under the Axel patents, it has failed to show an

anti-competitive effect on the market as a whole or even to provide any evidence defining any relevant market.[26]

As a result, Roche's defenses of unclean hands and patent misuse fail.

4. Did Columbia Grant An Implied License To GI And Roche?

Roche next argues that its conduct did not infringe the Axel patents because Columbia granted an implied license to use these patents to both GI and Roche. There is a two-pronged test for determining whether an implied license has been granted: "First, the equipment involved must have no noninfringing uses . . . . Second, the circumstances of the sale must plainly indicate that the grant of a license should be inferred." Met-Coil Systems Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 686 (Fed. Cir. 1986). The alleged infringer bears the burden of showing the establishment of an implied license. Id.; Bandag, Inc. v. Al Bosher's Tire Stores, Inc., 750 F.2d 903, 924 (Fed. Cir. 1984).

Roche's argument centers around a license granted by Lawrence and Gail Urlaub Chasin, professors at Columbia, to GI in 1984 (the "GI-Chasin license") to "make and use the Chinese

[26] Columbia points out that Roche stood in a different position vis a vis other Columbia licensees. It was a competitor who had asserted GI patents against J&J in Germany. Moreover, while the clause at issue restricted patent suits against J&J, it did not restrict patent suits against Amgen, the owner of J&J's patents.

hamster dihydrofolate reductase-deficient mutant cell lines" that they had isolated. Trial Ex. D227. The license stated that the authorization of Columbia had been obtained to grant the license to GI and that "[n]o right of . . . Columbia University . . . will be violated by the exercise of rights hereunder." Id. Roche also points to a substantially similar November 14, 1986, license from the Chasins to permit Roche to utilize the Chasins' cell lines to argue that Roche was granted an implied license as well.

Roche argues that the Chasin licenses created an implied license under the Axel patents because the DHFR-deficient CHO cell line that GI and Roche were licensed to use had no reasonable licensed use that did not infringe the Axel patents, and the circumstances surrounding the Chasin-GI license indicate that an implied license should be inferred.

What Roche fails to recognize is that the evidence suggested that the DHFR-deficient CHO cell line did have other reasonable uses that would not infringe the Axel patents. For instance, the DHFR-deficient CHO cell line could be used for general scientific research and study of the DHFR gene. Trial Tr. 576, 1336.

Roche argues that the fact that the cell line might have a reasonable non-infringing use as a tool for general scientific

research does not count for the purposes of the implied license analysis because general scientific research is not a commercial use of the cell line. Chasin testified that he generally did not require a license if someone wanted to use the cell line for non-commercial purposes. Chasin Depo. 15:12-21, 46:10-13. However, the fact that Dr. Chasin did not enforce his patent rights against those who might use his patented cell line without a license for general scientific research purposes does not change the fact that using the cell line for scientific research was a reasonable non-infringing use of the cell line. There is nothing in the case law that requires the reasonable non-infringing use to be of a commercial nature.

More importantly, the circumstances as a whole do not indicate that an implied license should be inferred. Columbia never gave any indication to Roche or GI that they had permission to use the Axel patents without an express license. In fact, although Columbia offered an express license to Roche in 1984 before GI received a license from Chasin, Roche refused that offer. Trial Ex. P273. In order to prove the granting of an implied license, Roche must prove a sale "by one with the authority of the patent owner." Donald S. Chisum, 5 Chisum On Patents 16.03[2][c] at 16-157 (2002). Even if Chasin represented that he had Columbia's authority to grant a license for

Columbia's Axel patents, he did not actually have the authority to do so. Even a minimum amount of due diligence by GI or Roche would have confirmed this fact. Chasin signed his license on his own behalf and not as an authorized representative of Columbia. Trial Ex. D227. Therefore, any assumption by Roche or GI that they had a license to use the Axel patents after receiving a license to utilize the Chasin's cell line was unreasonable.

GI's own actions also support the conclusion that GI did not receive an implied license to use the Axel patents from the GI-Chasin license. If GI had firmly believed that it possessed an implied license to use the Axel patents, it would not have purchased a license from Columbia to use the Axel patents to create products other than EPO and subsequently have paid millions of dollars to Columbia under the terms of the license. Trial Ex. P168; Trial Tr. 631.

Because the Chasin cell line had reasonable non-infringing uses and the surrounding circumstances do not indicate that an implied license should be granted, Roche's implied license defense fails.

5. Are Columbia's Infringement Claims Barred By Laches?

In order to assert the defense of laches, Roche must prove by a preponderance of the evidence: "(1) plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against defendant, and (2) the delay operated to the prejudice or injury of the defendant." A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1032 (Fed. Cir. 1992). Laches is presumed where the plaintiff delays filing suit for more than six years after the date the patentee knew or should have known of the infringer's activity. Id. at 1028. The patentee may then rebut this presumption by showing that the delay, in fact, was reasonable or that the defendant suffered no prejudice by the delay. The patentee also may be charged with constructive knowledge of the activity (even without actual knowledge) if the infringer's undiscovered activities are "sufficiently prevalent in the inventor's field of endeavor." Wanlass v. General Electric Co., 148 F.3d 1334, 1339 (Fed. Cir. 1998).

Roche argues that a series of events should have put Columbia on notice of its claims against Roche. Columbia filed its Complaint in the current action on July 12, 1993, almost ten years after the '216 patent was issued on August 16, 1983. Trial Ex. P1. Columbia sent a license solicitation to Roche in 1984,

which Roche refused. Trial Ex. P273. The GI-Roche D&L Agreement to produce EPO for commercial purposes was signed on October 8, 1985. However, there is no evidence in the record that GI or Roche made the fact of this agreement public. In fact, the agreement provided that neither party was permitted to produce "any publicity, news release or other public announcement, written or oral, relating to this Agreement, the Project or the existence of an arrangement between the parties without the prior written approval of the other Party . . . ." Trial Ex. P29 at ¶ 10.2.

In June 1986, GI's CHO-cell expression system that Columbia claims directly infringes the Axel patents was made public in GI's PCT patent application entitled "Method for the Production of Erythropoietin." Trial Ex. P169; Trial Tr. 536-541. However, Roche and its involvement are not mentioned anywhere in the patent application. According to the testimony of Eisen (former vice president and patent counsel for GI), it was "generally known" by 1986-87 that GI had a license with Roche for the EPO technology. Trial Tr. 705:12-18. However, Dr. Kaufman of GI stated that when he found out sometime in 1986 that Roche was working with his cells, he was quite surprised. Trial Tr. 1307.

In 1989, Dr. Silverstein of Columbia knew about GI's manufacture of bulk EPO but was not aware of any relationship

between Roche and GI. On February 2, 1989, a preliminary injunction hearing in the case of Amgen, Inc. v. Chugai Pharmaceutical Co. was held where GI's development of the EPO-production clone and manufacture of bulk EPO was addressed. However, it is unclear whether Roche's involvement was addressed at that hearing. On December 14, 1989, Columbia and J&J signed an agreement that Columbia had in its possession "substantial evidence of infringement" by GI. Trial Ex. P257. However, once again, this letter did not mention Roche. On November 20, 1990, Columbia filed suit against GI claiming that GI violated the Axel patents by making and selling EPO. Columbia decided to dismiss its lawsuit "without prejudice" against GI in June 1991. Trial Ex. D333.

By May 20, 1992, however, it is clear that Columbia had knowledge of Roche's activity with respect to EPO. On that date, Columbia sent a letter to Roche asking Roche to "take a sublicense with respect to your sales of EPO in Europe." Trial Ex. P90.

Roche argues that Columbia should have known about GI's production of EPO and its association with Roche back in 1986-1987 and that as a result, a presumption of laches should apply. This date is more than six years before Columbia filed its current lawsuit in 1993. However, the question of knowledge

properly relates to when Columbia was aware of Roche's involvement, not just GI's. One could not expect Columbia to sue Roche until it had reason to know that Roche had infringed Columbia's patents itself or had induced GI to infringe.

Although Eisen did testify that it was "generally known" that Roche had taken a license from GI with regard to its EPO production in 1986-87, the testimony of Dr. Kaufman and Dr. Silverstein, as well as the secrecy surrounding the Development and Licensing Agreement between Roche and GI, convinces me that Columbia was not aware, and should not have been aware, of Roche's activities at that time. The evidence establishing that Columbia knew about GI's relationship with Roche is quite thin before 1992.

Even if Columbia should have been aware of Roche's activities by 1989, a four year delay in filing suit would not be unreasonable under these circumstances. By November 1990, Columbia had filed suit against GI for patent infringement, and the Federal Circuit has held that existence of other litigation involving the same patent can excuse delays in filing suit. Auckerman, 960 F.2d at 1033; Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA, 944 F.2d 870, 876-77 (Fed. Cir. 1991). In this case, a delay by Columbia in filing suit against Roche until its litigation with GI had finished would be reasonable.

Nor has Roche shown material prejudice as a result of delay by Columbia. According to the Federal Circuit, "[e]conomic prejudice may arise where a defendant and possibly others will suffer the loss of monetary investments or incur damages which likely would have been prevented by earlier suit." Auckerman, 960 F.2d at 1033. Roche argues that it was prejudiced because between 1989 and 1991, it "continued to receive GI's shipments of bulk EPO without reason to believe that Columbia would attempt to enforce the U.S. Axel patents against such EPO." Roche's Post-Trial Memorandum at 37. However, to determine if the defendant has been prejudiced, "courts must look for a change in the economic position of the alleged infringer during the period of delay." Auckerman, 960 F.2d at 1033 (emphasis added). Having merely continued to receive the shipments of bulk EPO and not having changed its position, Roche cannot claim to have been prejudiced by Columbia's delay.

Because Columbia did not unreasonably delay in bringing its suit against Roche, and Roche was not materially prejudiced by any delay that did occur, Roche's defense of laches fails.

C. Damages

Because I have concluded that Roche has violated Section 271(b) and Section 271(g), and Columbia has prevailed on all of

Roche's affirmative defense, Columbia is entitled to damages as a result of Roche's infringement.

1. Was Roche's Infringement Willful?

Columbia argues that it is entitled to triple damages under 35 U.S.C. § 284 because Roche's infringement of the Axel patents was willful. Columbia must prove the willfulness of Roche's patent infringement by clear and convincing evidence. Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1221 (Fed. Cir. 1995). There is no per se rule for determining willful infringement. The totality of the circumstances must be considered. Graco, Inc. v. Binks Mfg. Co., 60 F.3d 785, 792 (Fed. Cir. 1995).

A potential infringer having actual notice of another's patent rights has an affirmative duty of due care which normally will entail the obtaining of competent legal advice before engaging in potentially infringing activity. Spindelfabrik Suessen-Schurr, Stahlecker & Grill GmbH v. Schubert & Salzer Maschinenfabrik Aktiengesellschaft, 829 F.2d 1075, 1084 (Fed. Cir. 1987). Although the absence of an opinion of counsel is pertinent evidence in determining good faith, it is not dispositive. Rite-Hite Corp. v. Kelley Co., 819 F.2d 1120, 1125 (Fed. Cir. 1987); American Original Corp. v. Jenkins Food Corp., 774 F.2d 459, 465 (Fed. Cir. 1985). The primary focus of the

willfulness determination is the defendant's intent and reasonable beliefs. Ortho Pharmaceutical Corp. v. Smith, 959 F.2d 936, 944 (Fed. Cir. 1992); Stickle v. Heublein, Inc., 716 F.2d 1550, 1565 (Fed. Cir. 1983).

Columbia makes two arguments: First, it argues the infringement was willful because Roche never sought the advice of U.S. patent counsel concerning the making, using, and selling of GI's cell lines and EPO even though it knew about the Axel patents and had declined an opportunity to license the Patents in 1984. Instead, Roche relied solely on the opinion of its German in-house patent counsel, Dr. Fouquet, who believed it was not necessary to obtain an opinion from U.S. counsel. Trial Tr. 1142-1143.

Also, Columbia claims that a Roche employee's destruction of correspondence between GI and Roche relating to GI's manufacture of EPO after the lawsuit commenced was an effort to hide information which supports an inference against Roche on the question of willfulness. Trial Ex. D510. These documents, as well as thirty boxes of files relating to "dead" projects, according to the record, were discarded during a routine office move in February of 1995.

As such, Columbia has failed to carry its burden of proving Roche's willfulness by clear and convincing evidence. Roche's in-house counsel, Dr. Fouquet, determined that Roche did not need a license because Roche had no U.S. activities and believed that it had an implied license. Trial Tr. 1143:8-1146:13. Dr. Fouquet was the head of Roche's patent infringement division and had an understanding of U.S. patent law when he gave this opinion. While his opinion was incorrect, it was not an unreasonable interpretation of the facts as they applied to Roche.

In addition, the destruction of documents that Columbia trumpets cannot support a finding of willfulness. There is no evidence that these documents were destroyed in bad faith, and it does not in any way justify a finding of willful infringement by Roche.

2. Columbia's Damages

Because Columbia has proven that Roche infringed the Axel patents, it is entitled to damages under 35 U.S.C. § 284. 35 U.S.C. § 284 states:

> Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer,

> together with interest and costs as fixed by the court.

Columbia argues that the "entire market value rule" entitles it to damages in the amount of "the entire market value of the benefit enjoyed by Roche." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1544-46 (Fed. Cir. 1995). The "entire market rule" typically allows the recovery of damages based on the entire value of an apparatus with several features, even though only one feature is patented. Paper Converting Machine Co. v. Magna-Graphics Corp., 745 F.2d 11, 22 (Fed. Cir. 1984). Columbia's argument is that Roche's inducing GI to provide it with the MCB, MWCB, and bulk EPO, made it possible for Roche to produce EPO in Europe, so Columbia ought to be able to recover any profits that Roche received from its sale of EPO in Europe. At the very least, Columbia argues that it is entitled to a reasonable royalty rate of 6% of net sales of EPO by Roche in Europe.

However, Columbia has incorrectly determined the relevant market for determining its damages. United States patent law permits no recovery for extraterritorial acts. See Johns Hopkins University v. CellPro, Inc., 152 F.3d 1342, 1367 (Fed. Cir. 1998) (If defendant's "infringement has damaged [plaintiff's] ability to service foreign markets, [plaintiff] must rely on foreign patent protection."); Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 527-531 (1972) ("The statute [35 U.S.C. § 271] makes it

clear that it is not an infringement to make or use a patented product outside of the United States . . . . Our patent system makes no claim to extraterritorial effect.") Even though this Court has concluded that Roche is responsible for inducing GI to produce and sell bulk EPO, it is not responsible for subsequent acts that it may have taken outside of the U.S. border with respect to the bulk EPO thus obtained. Damages for foreign acts should be sought in foreign courts. John Hopkins University, 152 F.3d at 1367. Roche's liability is necessarily limited to damages which occurred in the United States, and does not extend to any subsequent use of the bulk EPO by Roche in Europe or sales of EPO developed from the bulk EPO.

However, while Columbia is entitled to a reasonable royalty rate from Roche's inducing GI to create bulk EPO to sell to Roche in Europe, the actual profits that Columbia lost due to Roche's infringement cannot be determined. Columbia does not, and has never attempted to, manufacture EPO. As such, Columbia's damages should be based on the construct of a reasonable royalty under the case law. Trell v. Marlee Electronics Corp., 912 F.2d 1443, 1445 (Fed. Cir. 1990).

This reasonable royalty may be based upon an established royalty, as Roche urges. Id. Columbia negotiated licenses to use the Axel patents with thirty-three companies. The

overwhelming majority of the licenses established a 3.0% royalty rate for bulk products. In 1989, Columbia did grant a license to J&J giving it "exclusive" rights to use the Axel patents in the making, using, and selling of EPO, which had a provision providing that J&J was authorized to sublicense to Roche the use of the Axel patents in the production of EPO for a royalty rate of 6.0%. However, the more established, and more reasonable, rate in light of all of Columbia's other licenses, is the 3.0% royalty rate for the sale of bulk products.

a. Columbia's Damages For Roche's Inducing GI to Produce Bulk EPO

Columbia is entitled to a reasonable royalty rate of 3.0% of the price of the bulk EPO sold by GI to Roche. However, the parties dispute whether Roche bought 133.69 grams of bulk EPO from GI or 241.237 grams. Columbia created a chart summarizing invoices of shipments from GI to Roche which stated that GI sold 241.237 grams of Bulk EPO to Roche at a cost of $39,758,300. Trial Ex. P267. However, Dr. Fouquet of Roche testified, without record support, that he thought that Roche received just over 130 grams of EPO from GI, but that an estimate of 162 grams seemed more plausible than 240 grams. Trial Tr. 1198-1200. Also, GI created its own chart summarizing its billing status with Roche in 1991, months after an injunction against GI was entered in the

Amgen case. This chart shows that GI shipped 133.69 grams of EPO to Roche at a cost of $26,737,540. Trial Ex. P76.

I find that a preponderance of the evidence suggests that GI shipped 241.237 grams of bulk EPO to Roche. Trial Ex. P267 summarized the invoices of shipments of bulk EPO from GI to Roche. Significantly, Roche did not object to whether Trial Ex. P267 summarized these invoices accurately. Instead, it argued that the invoices summarized by the chart did not accurately reflect the amount of bulk EPO shipped. However, although I gave Roche the opportunity at trial to provide evidence that the shipments described by the invoices were not received or accepted (see Trial Tr. 1194-1197), it failed to do so. As a result, I find that the invoices summarized by Trial Ex. P267 prove that GI shipped 241.237 grams of bulk EPO to Roche.

GI shipped this bulk EPO to Roche in Europe for a total sales price of $39,758,300. Taking a reasonable royalty rate of 3.0%, I find that Columbia is entitled to $1,192,749 in damages as a result of these sales.

b. Columbia's Damages For Roche's Shipping Albumin-Free EPO To GI

Roche is directly liable under 35 U.S.C. 271(g) for infringing the Axel patents by shipping albumin-free EPO to GI.

Neither Roche nor GI profited from this infringement. GI administered this albumin-free EPO to Jehovah's Witness patients as a "compassionate" treatment, and Roche received no revenue from GI as a result of the shipment. Trial Tr. 447-450. As a result, I find that this infringement entitles Columbia to only one dollar of nominal damages.

c. Columbia's Damages For Roche's Return Of Bailed Cells Of GI's EPO Production Clone

Roche is directly liable under 35 U.S.C. 271(g) for infringing the Axel patents by returning the bailed cells of the EPO production clone in 1989. However, Columbia has failed to prove that GI ever used these cells to make bulk EPO, and the cells have remained frozen since the Amgen injunction in 1991.[27] As a result, I find that Columbia is entitled to only one dollar of nominal damages as a result of this infringement.

IV. CONCLUSION

Because Columbia has proven that Roche has violated both 35 U.S.C. § 271(b) and 35 U.S.C. § 271(g), with respect to claim 54 and its dependent claims of the '216 patent, **JUDGMENT is hereby**

[27] Dr. Fritsch of GI's testimony was that he was uncertain whether these cells were ever used to make EPO. Trial Tr. 462-463.

ORDERED to issue in favor of Columbia in the amount of One Million, One Hundred Ninety-Two Thousand, Seven Hundred Fifty-One And 00/100 ($1,192,751.00) Dollars.

SO ORDERED.

Dated: September 30, 2002

NANCY GERTNER, U.S.D.J.

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Attorneys

John A. Bauer
Fulbright & Jaworski
666 Fifth Avenue
New York, NY 10103
212-318-3000
Assigned: 10/30/2001
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing
Gmbh Boehringer Mannheim
(Defendant)

Sarah C. Columbia
Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109-2804
617-248-5053
617-248-4000 (fax)
scolumbia@choate.com
Assigned: 05/05/1994
TERMINATED: 05/25/2000
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing

Columbia University, The Trustees,
(Plaintiff)

Peter F. Felfe
Fulbright & Jaworski
666 Fifth Avenue
New York, NY 10103
212-318-3000
Assigned: 12/02/1993
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing
Gmbh Boehringer Mannheim
(Defendant)

Rodney E. Gould
Rubin, Hay & Gould
205 Newbury Street
Framingham, MA 01701
508-875-5222
Assigned: 10/13/1999
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing
Columbia University, The Trustees,
(Plaintiff)

Thomas F. Maffei
Griesinger, Tighe & Maffei, LLP
176 Federal Street
Boston, MA 02110
617-542-9906
617-542-0900 (fax)
tmaffei@gtmllp.com
Assigned: 07/12/1993
TERMINATED: 10/13/1999
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing

Columbia University, The Trustees,
(Plaintiff)

Cornelius J. Moynihan, Jr.
Nixon Peabody, LLP
101 Federal Street
Boston, MA 02210
617-345-1000
Assigned: 05/07/2001
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing
Gmbh Boehringer Mannheim
(Defendant)

Nicholas G. Papastavros
Nixon Peabody, LLP
101 Federal Street
Boston, MA 02210
617-345-1000
Assigned: 12/26/1996
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing
Gmbh Boehringer Mannheim
(Defendant)

Donna A. Tobin
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036
212-278-0400
Assigned: 02/22/1995
TERMINATED: 03/01/2001
LEAD ATTORNEY
ATTORNEY TO BE NOTICED
representing
Columbia University, The Trustees,
(Plaintiff)

Norman H. Zivin
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036
212-278-0400
Assigned: 03/01/2001
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

representing

Columbia University, The Trustees,
(Plaintiff)