EXHIBIT 22

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENETICS INSTITUTE, INC.,	)	
	)	
Plaintiff,	)	Civil Action No.
	)	
v.	)	92-CV-57
	)	
AMGEN INC.,	)	
	)	
Defendant.	)	

AMGEN'S OPENING BRIEF SUPPORTING ITS
RULE 12(C) MOTION TO DISMISS
PLAINTIFF'S COMPLAINT BASED ON ESTOPPEL

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I. NATURE AND STAGE OF PROCEEDINGS

This brief is filed on behalf of defendant, Amgen Inc. ("Amgen"), in support of its motion to dismiss plaintiff's complaint, which Amgen has filed pursuant to Federal Rule of Civil Procedure 12(c). More particularly, Amgen contends that plaintiff has waived its right to maintain the present action and that all claims asserted in the complaint are barred by final and conclusive determinations made in other litigation between plaintiff and Amgen.

Plaintiff, Genetics Institute, Inc. ("GI"), filed this action against Amgen on January 31, 1992. GI attempts to invoke this Court's jurisdiction pursuant to 35 U.S.C. §146.[1]

GI's complaint seeks review of the adverse decision of the Board of Patent Appeals and Interferences ("Board of Interferences") of the United States Patent and Trademark Office ("PTO") in Interference No. 102,097 ("the '097 interference") entered on December 3, 1991. (A.1) The Board of Interferences awarded priority of invention to Amgen's assignor Dr. Fu-Kuen Lin ("Dr. Lin").

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[1] §146 Civil Action in case of Interference

> Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences, may have such remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Commissioner appoints or as provided in section 141 of this title, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits, the record in the Patent and Trademark Office shall be admitted on the motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.
>
> * * *

(emphasis added).

Additionally, GI failed in its charges that Dr. Lin's claimed invention was not patentable and that Dr. Lin concealed the "best mode" of practicing the invention.

[6] This motion to dismiss is presented concurrently with Amgen's answer to GI's complaint.

II. SUMMARY OF THE ARGUMENT

This action is just the latest in a long series of biotechnology court battles between GI and Amgen over patent rights arising from Amgen's isolation and purification of the human gene encoding erythropoietin.[2] Amgen's pioneering work to isolate the human EPO gene fostered its manufacture of recombinantly produced erythropoietin ("rEPO") from transformed mammalian host cells, and provided a therapeutically useful, non-naturally occurring rEPO product, now licensed by the FDA and widely used as a therapeutically effective agent for treatment of various anemias.

The earlier court battles between Amgen and GI resulted in a determination that Dr. Lin of Amgen is the first inventor of the isolated and purified EPO gene, not GI's workers (Fritsch, et al.). Furthermore, those same prior litigations confirmed the patentability of Dr. Lin's invention, as well as the validity and enforceability of the specific patent claims granted to Dr. Lin by the PTO.

The admittedly pivotal, and statutorially prerequisite, jurisidictional issue of priority in the '096 interference, which by definition, is necessarily outcome-determinative of the '097 and '334 interferences, has been decided by the Federal Circuit in GI's appeal of that very same issue from the District Court litigation. Section 146 expressly does not contemplate the re-litigation of matters already decided by the Federal Circuit: ...unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal ... has been decided.[3]

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[2] Erythropoietin ("EPO") is a hormone which stimulates the production of red blood cells.

[3] 35 U.S.C. §146.

Once the determination of priority as to the '096 interference count was made by the Federal Circuit, GI's concession of binding impact on the remaining interferences rendered them moot in their entirety. Nevertheless, the Board independently reviewed the record in detail and decided each and every issue in Amgen's favor.

The record indisputably reveals that GI waived its right to challenge the Board of Interferences' decision awarding priority of invention to Amgen, because GI failed to appeal the decision in the related '096 interference.[4] At the final hearing before the Board of Interferences,[5] GI conceded

> ...that priority in each of the related interferences ['096, '097 and '334] turns on isolation of the EPO gene, i.e., determination of priority in Interference No. 102,096 is dispositive on the issue of priority in the present interference (see also FB-24).[6]

Accordingly, the Board of Interferences referred to the concurrent final decision in the '096 interference for disposition of "issues 1-7" in the '334 interference, including the priority of invention issue.[7] In the '096 interference, the Board of Interferences held that "Fritsch has failed to establish

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[4] The time for appeal of the '096 interference expired February 3, 1992. (35 U.S.C. §146).

[5] The final hearing encompassed the '097 interference and related interference nos. 102,096 and 102,334 ("the '096 and '334 interferences").

[6] December 3, 1991 Board of Interferences' decision in the '097 interference at p.5. (A.36) "FB-24" is a reference to page 24 of the Fritsch et al. Brief at Final Hearing filed by GI. (A.41)

[7] Board of Interferences decision in the '097 interference at pp.3-5. (A.34-36) "[I]ssues 1-7" of the '097 interference were identified as:

> 1. Whether the Lin motion for judgment (Paper No. 131) should be granted.
>
> 2. Whether Fritsch has adduced sufficient evidence to establish prior inventorship with respect to the subject matter defined by the count.

an adequate conception of the invention at issue prior to Dr. Lin's reduction to practice."[8] Therefore, based upon GI's explicit judicial concession and the outcome of the '096 interference, the Board of Interferences correctly awarded priority of invention to Dr. Lin in the '097 interference, and thereby acknowledged its duty to follow the Federal Circuit under such circumstances.

GI did not appeal the Board of Interferences' decision in the '096 interference. Consequently, the award of priority to Dr. Lin is a final and conclusive adjudication in that interference, and thus in the related '097 interference. That determination cannot now be challenged by GI through an appeal of the '097 interference decision in this §146 civil action. GI cannot backtrack on its judicial concession that the '096 priority determination is dispositive.

In addition, fundamental principles of claim preclusion estop GI from relitigating, in the guise of a § 146 civil action seeking a trial de novo, all those issues conclusively determined in prior litigation between GI and Amgen. Indeed, the Board of Interferences specifically followed and

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> 3. Whether Fritsch has adduced sufficient evidence to establish that Lin has failed to satisfy the "best mode" requirement of 35 USC 112.
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> 4. Whether Lin's involved claims are unpatentable to Lin under 35 USC 103.
>
> 5. Whether the Fritsch motion to correct inventorship (Paper No. 61), and companion motion for leave to file a corrected preliminary statement (Paper No. 58) should be granted.
>
> 6. Whether the motion by Lin under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper No. 168) should be granted.
>
> 7. Whether the motion by Fritsch under 37 CFR 1.635 and 1.656(h) to suppress evidence (Paper Nos. 163/164) should be granted.

[8] Board of Interferences' decision in the '096 interference at p.8. (A.22)

adopted "the principles and findings" of the prior litigation in disposing of all three of these interferences.

That prior litigation began in October, 1987, when Amgen filed an infringement suit against GI and Chugai Pharmaceutical Co. Ltd. ("Chugai"), GI's exclusive licensee and Japanese supplier of EPO, asserting U.S. Patent No. 4,703,008 ("the '008 patent"), which claims the same invention of Dr. Lin that is the subject of the '096 interference. The Massachusetts district court found for Dr. Lin and against Fritsch, et al. on the priority of the claimed invention of the '008 patent, i.e., the exact same priority issue in the '096 interference.

The United States Court of Appeals for the Federal Circuit ("Federal Circuit") affirmed the district court's priority holding for Dr. Lin, and the United States Supreme Court denied GI's petition for a writ of certiorari. Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), reh'g in banc denied, 1991 US App LEXIS 11131 (Fed. Cir.), cert. denied, ___ U.S. ___, 112 S.Ct. 169 (1991).

During the '096 interference, Dr. Lin filed a motion for judgment based upon the prior and conclusive Federal Circuit decision. The Board of Interferences ruled that the Federal Circuit decision is binding on the issues of priority (Issue 2), best mode (Issue 3), and obviousness (Issue 4):

> [W]e are bound by the Federal Circuit decision to the extent of the evidence considered by the court, *viz.*, to the extent the record is the same, we are compelled to reach the same conclusions.[9]

As previously noted, GI failed to appeal from the Board of Interferences' decision in the '096 interference.

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[9] Board of Interferences' decision in the '096 interference at pp. 4-5. (A.18-19)

The Federal Circuit not only confirmed priority of invention for Dr. Lin, its decision rejected conclusively all of GI's challenges to the validity and enforceability of the '008 patent claims directed to Dr. Lin's invention. Those claims correspond exactly to the count of the '096 interference.

As noted by the Board of Interference in its opinion, GI conceded that a priority determination in the '097 interference turns on the determination of priority in the '096 interference. GI's judicial concession coupled with the final and conclusive Federal Circuit determination of the invention priority issue dictated not only the outcome for the '096 interference, but also the same outcome in the related '097 and '334 interferences. Likewise, GI's concession combined with the Federal Circuit's conclusive decision as to the validity and the enforceability of Amgen's patent rights are dispositive of those same issues in the context of the '097 and '334 interferences.

Not only is GI estopped, therefore, from pursuing the appeal of priority from the '097 interference, GI is totally precluded from relitigating any of the claims made in its complaint before this Court. GI has twice before presented its evidence, and twice before, the courts and the Board of Interferences have held for Amgen.

Additionally, once the Board of Interferences concluded that, under the circumstances of these proceedings, the Federal Circuit's decision compelled the determination of invention priority for Dr. Lin in the '096 interference, and GI conceded that the priority determination in the '096 interference was dispositive of all priority issues in all interference proceedings, then the Federal Circuit decision effectively negated the other interferences.

The allegation of purported inequitable conduct by Amgen was neither raised by GI nor decided by the Board of Interferences in any of the three interferences. It is belatedly asserted by GI for the first time in its complaint before this Court. GI has not pleaded any facts not previously before the Board in support of such allegation. The inequitable conduct issue cannot now be raised for the first time in this §146 review proceeding. There is nothing in the PTO record for this Court

to review. No basis exists for a de novo review on a wholly new issue. Additionally, to the extent this issue was raised in the prior court litigation, it has been conclusively rejected. Finally, to the extent GI seeks to raise a different inequitable conduct issue, its failure to raise the issue below results in a waiver of its right to raise it before this Court.

III. STATEMENT OF FACTS

A. Introduction

A civil action under §146 of Title 35 in the United States Code is essentially a proceeding to review the action of the PTO Board of Interferences denying priority of invention to plaintiff. An interference is simply a proceeding in the PTO to determine who was the first inventor as between two or more inventors.[10]

The PTO interference proceedings here were conducted in the names of the inventors: Fu-Kuen Lin, the assignor of Amgen, and Edward Fritsch, Rodney M. Hewick, and Kenneth Jacobs, assignors to GI. Dr. Lin's involved application U.S. Serial No. 07/113,179, filed October 23, 1987, was accorded the benefit of prior applications:

- U.S. Serial No. 06/561,024, filed December 13, 1983, now abandoned;
- U.S. Serial No. 06/582,185, filed February 21, 1984, now abandoned;
- U.S. Serial No. 06/655,841, filed September 28, 1984; and

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[10] An interference is a proceeding instituted in the Patent and Trademark Office before the Board of Interferences to determine any question of patentability and priority of invention between two or more parties claiming the same patentable invention. An interference may be declared between two or more pending applications naming different inventors when, in the opinion of an examiner, the applications contain claims for the same patentable invention. An interference may be declared between one or more pending applications and one or more unexpired patents naming different inventors when, in the opinion of any examiner, any application and any unexpired patent contain claims for the same patentable invention. See 37 CFR §1.601(i).

- U.S. Serial No. 06/675,298, filed November 30, 1984, Patent No. 4,703,008. issued October 27, 1987.

Fritsch, et al.'s involved application U.S. Serial No. 06/693,258, filed January 22, 1985, was accorded the benefit of prior application:

- U.S. Serial No. 06/688,622, filed January 3, 1985, now abandoned.

Therefore, the senior party in the '334 interference was Dr. Lin and the junior party was Fritsch, et al.

The count[11] of the '097 interference states as follows:

> A process for the preparation of an in vivo biologically active glycosylated polypeptide comprising the steps of:
>
> (a) growing a mammalian host cell which is capable of effecting post-translational glycosylation of polypeptides expressed therein and which is transformed or transfected witn an isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin to allow possession of the in vivo property of causing reticulocytes and red blood cells, or the progeny thereof, under nutrient conditions suitable to allow, in sequence:
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> (i) transcription within said host cell of said DNA to mRNA in the sequence of transcription reactions directed by the nucleotide sequence of said DNA;
>
> (ii) translation within said host cell of said mRNA to a polypeptide in the sequence of translation reactions

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[11] A count defines the interfering subject matter between (1) two or more applications or (2) one or more applications and one or more patents. When there is more than one count, each count shall define a separate patentable invention. Any claim of an application or patent which corresponds to a count is a claim involved in the interference within the meaning of 35 U.S.C. Section 135(a). A claim of a patent or application which is identical to a count is said to "correspond exactly" to the count. A claim of a patent or application which is not identical to a count, but which defines the same patentable invention as the count, is said to "correspond substantially" to the count. When a count is broader in scope than all claims which correspond to the count, the count is a "phantom count." A phantom count is not patentable to any party. See 37 CFR §1.601(f).

> directed by the nucleotide sequence of said transcribed mRNA;
>
> (iii) glycosylation within said host cell of said polypeptide in a pattern directed by the amino acid sequence of said translated polypeptide and sufficiently duplicative of the pattern of glycosylation of naturally occurring human erythropoietin to allow possession by the translated glycosylated polypeptide product of the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells; and
>
> (b) isolating the glycosylated polypeptide so produced.

This count corresponds to Lin's application claims 65-69 and claims 72 and 73 of the Fritsch, et al. application. (A.34)

It should be noted that the '179 Lin application, which was involved in the '097 interference, is based on the same original application as the '008 Lin patent, which was at issue in the '096 interference.

B. The Three Related Interferences And Their Outcomes

On December 3, 1991, the Board of Interferences awarded priority of invention in the '097 interference to Dr. Lin (Amgen). (A.39)

The second and closely related '334 interference focused on the non-naturally occurring glycoprotein product of the process at issue in the '097 interference. (A.13) The glycosylated amino acid sequence of that glycoprotein product is sufficiently duplicative of naturally occurring human EPO to give it the in vivo biological property of causing bone marrow cells to increase production of reticulocyte and red blood cells.

The third and closely related '096 interference, which involved the '008 patent, dealt with a "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin" (i.e., the gene having a DNA sequence encoding human erythropoietin), used in the manufacture (i.e., the process of the '097 interference) of recombinant erythropoietin (i.e., the product of the '334 interference). (A.16)

Both in its Brief at Final Hearing and at Oral Argument, the party Fritsch, et al. (GI) conceded that priority in each of the '096, '097 and '334 interferences depended upon when the inventors isolated the EPO gene (the subject matter of the '096 interference). (A.41) Determining the priority as to the '096 interference, therefore, simultaneously determines and disposes of the priority issues in both the '097 and '334 interferences as well. In fact, the Board of Interferences determined priority of invention in that manner as reflected in its December 3, 1991 decisions. (A.36-37)

Fritsch, et al. (GI) failed to appeal from the Board's December 3, 1991 decision in the '096 interference. The statutory time for appeal from the decision has passed and the Board of Interference's determination is now absolutely final.

C. Prior Litigations
Between Amgen and GI

Amgen instituted an action against Chugai and GI in the District of Massachusetts for infringement of Amgen's '008 patent. The district court granted Chugai and GI's motions for partial summary judgment of non-infringement and on the issue of whether the '008 patent contains claims

to a "process", within the meaning of Title 35 U.S.C., for manufacturing recombinant erythropoietin. Amgen Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 9 USPQ2d 1833 (D. Mass. 1989).[12]

Amgen also instituted a complaint against Chugai with the United States International Trade Commission ("USITC"). The USITC dismissed Amgen's complaint against Chugai based on the Commission's determination that Amgen's '008 patent claims articles, i.e., host cells, but not processes. Therefore, the Commission held that it did not have subject matter jurisdiction of Amgen's complaint under 19 U.S.C. §1337(a)(1)(B)(ii). In the Matter of Certain Recombinant Erythropoietin, 10 USPQ2d 1906 (USITC 1989). The Federal Circuit on appeal vacated the USITC's 1989 decision and remanded the case with direction to dismiss Amgen's complaint on the merits. Amgen Inc. v. United States International Trade Commission, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990).

The district court infringement action proceeded toward trial in Massachusetts. Shortly before trial, Ortho Pharmaceutical Corporation attempted to intervene in the case. Magistrate Saris recommended that Ortho not be permitted to intervene. Amgen Inc. v. Chugai Pharmaceutical Co., 11 USPQ2d 1466 (D. Mass. 1989).

Thereafter, Amgen, Chugai and GI tried the patent infringement case to Magistrate Saris. The district court ruled that claims 2, 4 and 6 of Amgen's '008 patent on its genetically engineered host cells containing a gene having a DNA sequence encoding human erythropoietin are valid, enforceable and infringed by GI. Amgen Inc. v. Chugai Pharmaceutical Co., 13 USPQ2d 1737 (D. Mass. 1989).

On appeal, the Federal Circuit affirmed the district court's decision that Amgen's host cell claims in the '008 patent are valid, enforceable, and infringed by GI. Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ 2d 1016 (Fed. Cir. 1991). The Federal Circuit

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[12] Chugai and GI counterclaimed therein for infringement of GI's '195 patent. The court granted Chugai and GI's motion for partial summary judgment that claims 1, 3, 4 and 6 of the '195 patent were infringed by Amgen.

confirmed not only Amgen's priority position adversely to GI, but also rejected GI's attacks on the validity and enforceability of Amgen's patent rights to the very same invention that is the subject of the count in the '096 interference. Id.

Thus, in Amgen's prior infringement suit against GI and Chugai, the trial court found expressly that Dr. Lin is entitled to priority of invention as against Fritsch, et al. on the subject matter of isolating the EPO gene (i.e., the very same priority issue confronted in the '096 interference).[13] Moreover, the Federal Circuit affirmed the trial court's ruling and the United States Supreme Court has denied GI's petition for a writ of certiorari.[14]

The Board of Interferences, thereafter, expressly relied upon the Federal Circuit's decision and held under the circumstances of this case that it was bound by it in determining priority of invention for the '096 interference. (A.18-22)

IV. ARGUMENT

A. GI Waived Its Right To Appeal The Award of Priority to Amgen

Title 35 of the United States Code at Section 135 requires that the Board of Interferences "shall determine questions of priority of the inventions and may determine questions of patentability. . . ." Section 146 of Title 35 provides for review of the Board of Interferences' decision through a civil action brought by "[a]ny party to an interference dissatisfied with the decision of the Board."

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[13] Amgen Inc. v. Chugai Pharmaceutical Co., 13 USPQ2d 1737 (D. Mass. 1989).

[14] Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), reh'g in banc denied, 1991 US App LEXIS 11131 (Fed. Cir.), cert. denied, ___ U.S. ___, 112 S.Ct. 169 (1991).

A section 146 civil action is primarily an appellate proceeding conducted by a district court to review a determination of priority of invention made by the PTO Board of Interferences.

The subject matter of the first interference, the '096 interference, was the same as that involved in the litigation finally decided by the Federal Circuit in March, 1991, *viz.*, an isolated and purified DNA sequence encoding human EPO. As to this interference, the Board of Interferences held that under the circumstances it was bound by the Federal Circuit's decision ruling that Amgen's Dr. Lin was the first inventor. (A.18-22) Accordingly, it held that Dr. Lin was entitled to the award of priority on the subject matter of the isolated and purified human EPO gene and that he was entitled to his patent claiming that invention. (A.30-31) GI has not asked and now cannot ask this Court or the Federal Circuit to review the Board's '096 interference holding that GI "has failed to establish an adequate conception of the invention at issue prior to Dr. Lin's reduction to practice." (A.22)

The subject matter of the second interference ('097) involved processes for making rEPO product in the transformed mammalian host cell. By use of recombinant techniques, the human EPO gene is incorporated into the genetic machinery of the host cell and causes the cell to produce an rEPO product that is a replacement for the naturally occuring erythropoietin which functions in the human body to stimulate the production of red blood cells.

The subject matter of the third interference ('334) was the recombinantly produced rEPO product itself, a non-naturally occurring product of mammalian host cells having an average carbohydrate composition differing from that of naturally occurring EPO made in human cells.[15]

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[15] The EPO molecule can be thought of as being made up of a protein backbone chain of many amino acid residues to which is attached highly branched carbohydrate groups composed of various sugar components having various structural configurations. The protein backbone of rEPO and naturally-occurring EPO is the same, but the carbohydrate make up is different because the mammalian host cells used to make rEPO cannot duplicate the human cell's mechanism for carbohydrate addition.

GI conceded that priority of invention as to all three related interferences ('096, '097 and '334) would be determined by finding who was the first inventor of the subject matter in the '096 interference. (A.14, A.41) The Board of Interferences held that Dr. Lin was the first to isolate the EPO gene and thus awarded priority of invention to him in the '096 interference. (A.22, A.30-31) Consequently, Dr. Lin was awarded priority in the '097 and '334 interferences consistent with GI's concession and the outcome of the '096 interference. (A.5, A.36-37) In order to give sanctity to the Board's final judgment, GI should not be allowed to ignore its concession and the outcome of the '096 interference and have yet another "bite at the apple." As noted by the Federal Circuit, "the Rules were not designed to engender such perverse results." Woods v. Tsuchiya, 754 F. 2d 1571, 1582, 225 USPQ 11, 18 (Fed. Cir.), cert. denied, 474 U.S. 825, 106 S.Ct. 81 (1985).

GI did not appeal the basic award of priority made in the '096 interference by the Board of Interferences. Thus, that decision constitutes an incontestable and final adjudication of the rights between Amgen and GI as to the issue of priority in the '096 interference, and thereby necessarily so too in the related '097 interference. GI has judicially conceded the issue it now attempts to appeal and thereby waived its right to contest the directly derivative awards of priority in the '097 and '334 interferences.

In the '096 interference, GI conceded that Dr. Lin was the first to successfully reduce the invention to practice, but argued that GI scientists were the first to conceive of the invention and that they were diligent in reducing it to practice. (A.20) It was on that basis alone that GI argued for an award of priority to Fritsch, et al.

The Board of Interferences, however, disagreed with GI, as had the Federal Circuit in its earlier decision. The Federal Circuit, along with the Board of Interferences, held that Fritsch, et al. had "failed to establish an adequate conception of the invention at issue prior to Dr. Lin's reduction to practice." (A.22) In essence, the Board of Interferences adopted the Federal Circuit's ruling that

neither party had an adequate conception of EPO's DNA sequence or how to attain it until a reduction to practice had been achieved by isolating and purifying the EPO gene. (A.21-22) Since Amgen's Dr. Lin was admittedly the first to reduce to practice, a holding that he was the first to conceive and reduce to practice followed inevitably. Accordingly, the Board of Interferences awarded invention priority to Dr. Lin in the '096 interference, just as the Federal Circuit had upheld that same finding made by the Massachusetts District Court after a full trial on the merits. (A.22)

The outcome determinative factor in the remaining two interferences ('097 and '334) was GI's judicial admission that the proper award of priority in all interferences rested on the award of priority in the '096 interference. (A.14, A.41) Since the outcome of that interference resulted in a judgment of priority in favor of Amgen's Dr. Lin, and since that judgment is now final and unappealable, GI has judicially conceded that it is not entitled to an award of priority in the '097 interference at issue in this action.

GI has waived any right to contest the issue of priority in this Court or any other. Therefore, GI's complaint cannot state a claim under §146 for which relief could be granted.

B. Fundamental Claim Preclusion Principles Bar GI From Relitigating Issues That Have Been Completely Adjudicated In Other Proceedings

To conserve judicial resources and foster the worthwhile goal of finality, our courts historically have looked first to their own power to decide matters before taking cognizance of such matters. As the Federal Circuit recently stated in Foster v. Hallco Manufacturing Co., 947 F.2d 469, 475-476 20 USPQ2d 1241, 1246 (Fed. Cir. 1991), "[t]he principles of law denominated 'res judicata' embody the public policy of putting an end to litigation", citing Southern Pacific Railroad Co. v. United States, 168 U.S. 1 (1897) and 18 C. Wright, A. Miller, and E. Cooper, Federal Practice and Procedure, §4403 at p.15 (1981).

The Restatement (Second) of Judgments (1982), in an introductory note to Section 13, provides the following basic statement:

> The principal concepts developed in this Chapter are: merger - the extinguishment of a claim in a judgment for plaintiff (§18); bar - the extinguishment of a claim in a judgment for defendant (§19); and issue preclusion - the effect of the determination of an issue in another action between the parties on the same claim (direct estoppel) or a different claim (collateral estoppel) (§27). The term "res judicata" is here used in a broad sense as including all three of these concepts. When it is stated that "the rules of res judicata are applicable," it is meant that the rules as to the effect of a judgment as a merger or a bar as a collateral or direct estoppel are applicable.

See, Young Engineers, Inc. v. United States International Trade Commission, 721 F.2d 1305, 1314, 219 USPQ 1142, 1150 (Fed. Cir. 1983).

The principles of issue preclusion apply to this proceeding. Section 27 of the Restatement provides the general rule of issue preclusion:

> When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.

Restatement (Second) of Judgments §27; Foster, 947 F.2d at 480, 20 USPQ2d at 1249. GI and Amgen actually litigated the issues of invention priority, patentability, and enforceability in the prior district court infringement lawsuit. The trial court determined that Dr. Lin was the first inventor and entitled to priority in isolating the EPO gene and confirmed that Amgen's corresponding '008 patent claims are valid and enforceable. Those determinations were essential to the district court's judgment. The Federal Circuit reviewed the district court's decision and affirmed. Following the United States Supreme Court's denial of GI's petition for a writ of certiorari, the Federal Circuit's decision, and that of the trial court, became final and incontestable.

In the subsequent interferences, and the '096 interference, the Board of Interferences held that the Federal Circuit's decision upholding priority of invention to Dr. Lin was conclusive in the proceeding before it. GI improperly and inappropriately seeks to relitigate priority of invention through this §146 collateral attack despite GI's judicial concession that priority of invention in the '096 interference was dispositive of the priority issue in all the companion interferences.

GI's judicial concession coupled with the final and conclusive Federal Circuit determination of the invention priority issue dictated not only the same outcome for the '096 interference, but also the same outcome in the related '097 and '334 interferences. Likewise, GI's concession combined with the Federal Circuit's conclusive decision as to the validity and the enforceability of Amgen's patent rights are dispositive of those same issues in the context of the '097 and '334 interferences.

Not only is GI estopped, therefore, from pursuing the appeal of priority from the '097 interference, GI is totally precluded from relitigating any of the claims made in its complaint before this Court. GI having conceded that the outcome of the '096 interference was outcome-determinative of the '097 and '334 interferences, and in view of the fact that the '096 priority issue was decided by the Federal Circuit, there is no other issue for this Court to decide. Accordingly, Amgen is entitled to a judgment and GI's complaint should be dismissed with prejudice.

C. The Court Should Not Consider Issues Of Alleged Inequitable Conduct That GI Failed To Raise In The PTO

Since a §146 action is essentially an appellate proceeding to review the action of the Board, the authorities make it clear that the inequitable conduct issues now pleaded by GI for the first time in this appeal are not properly before this Court. GI has no right or basis at this late date to present allegations of inequitable conduct as reflected in paragraph 11 of its Complaint. See, DSL Dynamic Sciences Limited v. Union Switch & Signal, Inc., 928 F.2d 1122, 1124 (Fed. Cir. 1991).

The speculative, nonspecific allegations on "information and belief" in GI's complaint on their face fail to meet any criteria for review under Section 146, a statute that contemplates record review. See, Brunswick Corporation v. Riegel Textile Corporation, 627 F.Supp. 147 (N.D. Il 1985), GI also fails to meet the specificity requirements for pleading inequitable conduct as required by Rule 9, Fed.R.Civ.P.

V. CONCLUSION

For the foregoing reasons, Amgen requests that the Complaint in Civil Action 92-CV-57 be dismissed in its entirety.

BAYARD, HANDELMAN & MURDOCH, P.A.

Dated: February 21, 1992

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Amgen's Opening Brief Supporting its Rule 12(c) Motion to Dismiss Plaintiff's Complaint Based on Estoppel was delivered by hand on local counsel as follows:

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