UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

96-1175

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiff-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellee.

Harold J. McElhinny, Morrison & Foerster LLP, of San Francisco, California, argued for plaintiff-appellant. With him on the brief were Donald S. Chisum, Alan K. Palmer, Rachel Krevans, and Debra A. Shetka. Also with him on the brief were Arthur I. Neustadt, Jean-Paul Lavalleye, Marc R. Labgold, and William J. Healey, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Arlington, Virginia. Of counsel was Gladys H. Monroy,

Morrison & Foerster LLP, of San Francisco, California.

Charles E. Lipsey, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, D.C., argued for defendant-appellee. With him on the brief were Donald R. Dunner, Howard W. Levine, and John R. Alison. Of counsel on the brief was Amy E.

Hamilton, Eli Lilly and Company, of Indianapolis, Indiana.

Appealed from: U.S. District Court for the Southern District of Indiana

Judge Dillin

United States Court of Appeals for the Federal Circuit

96-1175

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiff-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellee.

DECIDED: July 22, 1997

Before NEWMAN, LOURIE, and BRYSON, Circuit Judges.

LOURIE, Circuit Judge.

The Regents of the University of California (UC) appeal from the judgment of the District Court for the Southern District of Indiana, holding that Eli Lilly & Company (Lilly) does not infringe U.S. Patent 4,652,525 or U.S. Patent 4,431,740 in its manufacture of human insulin; that the asserted claims of the '525 patent are invalid; and that both patents are unenforceable. Regents of the Univ. of Cal. v. Eli Lilly and Co., 39 USPQ2d 1225 (S.D. Ind. 1995). We hold that the district court (1) properly exercised jurisdiction over this case for trial on the merits, (2) did not err in concluding that the asserted claims of the '525 patent are invalid for failure to provide an adequate written description of the subject matter of the asserted claims, and (3) did not clearly err in finding that Lilly did not infringe the '740 patent. We further hold that the district court (4) abused its discretion in holding that the '525 and '740 patents are unenforceable. We therefore affirm-in-part and reverse-in-part.

BACKGROUND

In 1990, UC brought this action in the Northern District of California, alleging that Lilly was infringing claims 1, 2, and 4-7 of the ‘525 patent under the doctrine of equivalents and infringing claims 2-3, 5-6, 8-10, and 13-14 of the ‘740 patent, either literally or under the doctrine of equivalents. Lilly responded that it does not infringe any of the asserted claims, that the asserted claims are invalid, and that the patents are unenforceable. Lilly did not assert any counterclaims against UC.

The patents in suit relate to recombinant DNA technology 1 and, more specifically, to recombinant plasmids and microorganisms that produce human insulin, a protein involved in the regulation of sugar metabolism. A person unable to produce insulin is afflicted with diabetes. Prior to the development of recombinant techniques for the production of human insulin, diabetic patients were treated with injections of animal insulin, which often caused allergic reactions. Human insulin produced by recombinant methods is less likely to produce such reactions. It consists of two separate amino acid chains, a 21-amino acid A chain and a 30-amino acid B chain, which are linked only by disulfide bonds. Healthy people produce insulin in vivo via the terminal enzymatic cleavage of preproinsulin (PPI) to yield proinsulin (PI), a single amino acid chain consisting of the A and B chains, linked by a sequence of additional amino acids that positions the A and B chains so that the disulfide bonds are readily formed. The PI is then further cleaved to liberate the linking sequence and yield insulin.

The '525 patent, the application for which was filed in May 1977, was based upon the determination of the PI and PPI cDNA sequences found in rats. Claim 1 of that patent reads as follows: "A recombinant plasmid replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin." (emphasis added). Claim 2 relates to a recombinant procaryotic microorganism containing vertebrate insulin-encoding cDNA. Claims 4 and 5 depend from claim 2, and are limited, respectively, to mammalian and human insulin cDNA. Claim 6 depends from claim 1 and requires that the plasmid contain "at least one genetic determinant of the plasmid col E1." Claim 7 depends from claim 2 and requires that the microorganism be of a particular strain.

The '740 patent, the application for which was filed in September 1979, was based upon the determination of

human PPI and PI cDNA sequences and the development of "tailoring" techniques for the incorporation of human PI cDNA into a recombinant plasmid. Using these techniques, a specific semi-synthetic DNA may be incorporated into a suitable transfer vector. Using one such tailoring technique, the human PI cDNA and the plasmid into which it is incorporated may be modified so that they contain complimentary oligo-dC and oligo-dG ends, which facilitate the formation of the recombinant plasmid. Independent claim 2 of the '740 patent reads: "A DNA transfer vector comprising an inserted cDNA consisting essentially of a deoxynucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxynucleotide of the sequence coding for said proinsulin." (emphasis added). Dependent claim 3 is directed, inter alia, to a recombinant microorganism containing the transfer vector of claim 2. Claim 5 reads: "A DNA transfer vector comprising a deoxynucleotide sequence coding for human proinsulin consisting essentially of a plus strand having the sequence: [nucleotides that encode human proinsulin, described in structural terms]." (emphasis added). Claim 6 depends from claim 5 in the same manner that claim 3 depends from claim 2: it is directed to a recombinant microorganism containing the transfer vector of claim 5. Claim 8 is directed to an example of a human PI-encoding recombinant plasmid described in the specification; and claims 9 and 10, to microorganisms containing that plasmid. Claims 13 and 14 are directed to a subset of the transfer vector genus of claim 5 and accordingly depend from claim 5.

Lilly makes human PI using a semi-synthetic DNA to yield a cleavable fusion protein that consists of a bacterial protein, a “cleavable linkage" consisting of a single methionine residue, and human PI. After the fusion protein is produced, the desired human PI is obtained by cleaving it from the remainder of the fusion protein.

In 1992, pursuant to 28 U.S.C. § 1407 (1994), the Judicial Panel on Multidistrict Litigation (JPML) consolidated this case with five other related cases for pre-trial proceedings in the District Court for the Southern District of Indiana. In re Recombinant DNA Tech. Patent and Contract Litig., No. 912 (J.P.M.L. Feb. 19, 1992). UC petitioned this court for a writ of mandamus, seeking to vacate the transfer order as barred by the Eleventh Amendment and inconsistent with various prior decisions in the consolidated cases, including two decisions of the District Court for the Northern District of California in this case. See In re Regents of the Univ. of Cal., 964 F.2d 1128, 1131-32, 22 USPQ2d 1748, 1751-52 (Fed. Cir. 1992). We denied UC's petition, holding that the transfer did not force unconsented suit upon UC and thus was permissible for purposes of pretrial discovery. Id., at 1134, 22 USPQ2d at 1754.

In 1994, responding to Lilly’s pretrial motion, the District Court for the Southern District of Indiana transferred venue to itself for trial on the merits pursuant to 28 U.S.C. § 1404(a) (1994). After conducting a bench trial, the court issued a memorandum opinion in which it ruled, inter alia, that (1) Lilly does not infringe the asserted claims of either patent, 39 USPQ2d at 1228-39, (2) the asserted claims of the ‘525 patent, those directed to mammalian, vertebrate, and human cDNA, are invalid for lack of an adequate written description, id. at 1239-41, and (3) both patents are unenforceable due to inequitable conduct on the part of UC, id. at 1247-58. UC appeals from these rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

DISCUSSION

A. Jurisdiction and Venue

As a preliminary matter, UC argues that the District Court for the Southern District of Indiana lacked

jurisdiction to hear this case on the merits and was an inappropriate venue for trial. UC first argues that the Eleventh Amendment deprives the Indiana court of jurisdiction. Specifically, UC asserts that by choosing to bring suit in the District Court for the Northern District of California, it waived its Eleventh Amendment immunity only in California federal courts. Relying on Port Authority Trans- Hudson Corp. v. Feeney, 495 U.S. 299, 307 (1990), UC argues that the Eleventh Amendment bars the transfer of this case for trial on the merits. Lilly responds that the Eleventh Amendment is inapplicable where, as here, a state asserts a claim and no counterclaim against the state is involved. We agree with Lilly that the Eleventh Amendment does not preclude trial in Indiana.

The Eleventh Amendment provides that: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. Const. amend. XI. The Supreme Court has recently confirmed that "the reference to actions 'against one of the United States' encompasses not only actions in which a State is named as a defendant, but also certain actions against state agents and state instrumentalities," such as UC. Regents of the Univ. of Cal. v. Doe, 117 S. Ct. 900, 903 (1997); see also BV Eng'g v. Univ. of Cal., 858 F.2d 1394, 1395, 8 USPQ2d 1421, 1422 (9th Cir. 1988).

The question raised by this case is whether it is one that has been brought "against" UC. In deciding this question, we are aided by the Supreme Court's guidance in its opinion in United States v. Peters, 9 U.S. (5 Cranch) 115 (1809) (Marshall, C.J.). In that case, the Court declined to apply the Eleventh Amendment to bar a suit instituted against the heirs of a deceased state treasurer. The Court stated:

The right of a state to assert, as plaintiff, any interest it may have in a subject, which forms the matter in controversy between individuals, in one of the courts of the United States, is not affected by [the Eleventh] amendment; nor can [the amendment] be so construed as to oust the court of its jurisdiction, should such claim be suggested. The amendment simply provides, that no suit shall be commenced or prosecuted against a state. The state cannot be made a defendant to a suit brought by an individual; but it remains the duty of the courts of the United States to decide all cases brought before them by citizens of one state against citizens of a different state, where a state is not necessarily a defendant.

Id. at 139. This case involves a state's assertion of a claim rather than a state being a defendant.

In the Feeney case relied on by UC, the Court applied the Eleventh Amendment because a claim for damages was asserted "against" a state instrumentality. The Feeney Court noted that "a State's Constitutional immunity encompasses not merely whether it may be sued, but where it may be sued," 495 U.S. 299, 307 (quoting Pennhurst State Sch. & Hosp. v. Halderman, 465 U.S. 89, 99 (1984)), but the Court did not construe the Eleventh Amendment to apply to suits in which a state is solely a plaintiff, as UC is here. In fact, we do not believe that the Court has ever so construed the Eleventh Amendment. This is because the Eleventh Amendment applies to suits "against" a state, not suits by a state. Thus, we need not determine whether UC waived its immunity only in California, because this case does not create an Eleventh Amendment jurisdictional issue concerning which the question of waiver even arises. This case only involves UC's patent infringement claims and Lilly's defenses; it does not involve any claim or counterclaim against UC that places UC in the position of a defendant. Accordingly, we conclude that the Eleventh Amendment does not deprive the Indiana district court of jurisdiction in this case.

UC next argues that, under the law of the regional circuit to which appeal from the trial court would normally

lie, the Indiana court abused its discretion by, as the court stated, transferring venue for trial on the merits from the California court to itself. See Heller Fin., Inc. v. Midwhey Powder Co., 883 F.2d 1286, 1293 (7th Cir. 1987) (applying the abuse of discretion standard of review); Lou v. Belzberg, 834 F.2d 730, 739 (9th Cir. 1987) (same). Specifically, UC argues that the Indiana court abused its discretion by, inter alia, affording too much weight to the element of judicial economy in granting Lilly's motion to transfer the case to Indiana. Lilly responds that the court acted within its discretion by retaining the case for trial and that it properly considered and weighed the relevant factors before deciding to do so.

We agree with Lilly that the court did not err on this point. A federal district court may "[f]or the convenience of parties and witnesses, in the interest of justice, . . . transfer any civil action to any other district court or division where it might have been brought." 28 U.S.C. § 1404(a) (1994). The Indiana court based its decision to retain the case for trial on the merits on its finding that, although the convenience of the parties and witnesses did not favor either the Indiana or the California court, the interests of judicial economy would be served by trial in the Indiana court. Consideration of the interest of justice, which includes judicial economy, "may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result." Coffey v. Van Dorn Iron Works, 796 F.2d 217, 220-21 (7th Cir. 1986); Allen v. Scribner, 812 F.2d 426, 436-37 (9th Cir. 1987) ("Because the transfer of this case undoubtedly would have led to delay, the district court did not abuse its discretion in denying Allen's motion notwithstanding possible inconvenience to the witnesses."); Commodity Futures Trading Comm'n v. Savage, 611 F.2d 270, 279 (9th Cir. 1979) (affirming denial of transfer motion because "[t]he district court was familiar with the case and transfer may have led to delay"). Thus, the fact that the district court ultimately afforded little or no weight to the other factors does not, standing alone, indicate that the district court abused its discretion. On the contrary, in a case such as this in which several highly technical factual issues are presented and the other relevant factors are in equipoise, the interest of judicial economy may favor transfer to a court that has become familiar with the issues. Accordingly, the court did not abuse its discretion by transferring the case after affording determinative weight to the consideration of judicial economy.

In its reply brief, UC first raises another basis for determining that Indiana was an improper venue for trial. UC argues that 28 U.S.C § 1407(a) (1994) requires that a case transferred by the JPML for consolidated pretrial proceedings be returned for trial on the merits to the court from which it was transferred. Aware that it failed to address this issue in its opening brief in this appeal, UC contends that it adequately raised this argument when it filed its petition for mandamus seeking to vacate the transfer order for consolidation of discovery in Indiana. See In re Regents, 964 F.2d 1128, 22 USPQ2d 1748. Lilly first responds that UC waived this argument by failing to raise it in its opening brief in this appeal, regardless of the argument it made in its earlier petition. Lilly also maintains that the transfer was lawful, citing In re American Continental Corp./Lincoln Savings & Loan Securities Litigation, 102 F.3d 1524 (9th Cir. 1996), cert. granted sub nom., Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 65 U.S.L.W. 3761 (U.S. May 20, 1997) (No. 96- 1482), for the proposition that § 1407(a) does not prohibit a discovery transferee court from transferring a case to itself for trial if an adequate reason for that transfer exists under 28 U.S.C. § 1404(a) (1994).

We agree with Lilly insofar as it argues that UC waived its argument regarding § 1407 by failing to raise it in its opening brief in this appeal. See Fed. R. App. P. 28(a)(6), 28(c); Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 800, 17 USPQ2d 1097, 1103 (Fed. Cir. 1990) ("[A]n issue not raised by an appellant in its opening brief . . . is waived."). UC's assertion that it adequately raised this argument when it filed its petition for mandamus is not persuasive. In denying that petition, we noted that UC expressed concern that, inter alia, "Lilly will maneuver to try the merits of the California actions in Indiana . . . thus defeating [UC's]

expectation and entitlement that the merits of the California actions will be tried in California." In re Regents, 964 F.2d at 1133, 22 USPQ2d at 1753. However, we declined to address UC's concern then because "[t]hese possibilities can not be evaluated in the abstract." Id. An assertion that the district court had actually erred was required, not the mere assertion that UC feared a potential error. We thus told UC that if it desired to contest the Indiana court's self-transfer, it would be required to raise that issue if and when the Indiana court actually transferred the case to itself. Because UC failed to do so by asserting error in a writ of mandamus or in its opening brief in this appeal, we decline to address the merits of its argument. Having determined that the Indiana court had jurisdiction and that its transfer of venue to itself under § 1404 was not, given the arguments properly before us, an abuse of that court's discretion, we address the remaining issues in UC's appeal.

B. The ‘525 Patent

1. Validity

The district court ruled that all of the claims of the '525 patent that UC asserted against Lilly, viz., claims 1, 2, and 4-7, are invalid under § 112, 1, because the specification, although it provided an adequate written description of rat cDNA, did not provide an adequate written description of the cDNA required by the asserted claims. 39 USPQ2d at 1239-41.

Whether a specification complies with the written description requirement of § 112, 1, is a question of fact, which we review for clear error on appeal from a bench trial. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985). To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

We first consider claim 5, which is specific to a microorganism containing a human insulin cDNA. UC argues that the district court clearly erred in finding that claim 5 is invalid under § 112, 1. Specifically, UC argues that a constructive or prophetic example in the '525 specification describes in sufficient detail how to prepare the claimed organism. Lilly responds that the district court properly applied the written description requirement, as this court applied it in Fiers, 984 F.2d at 1170-71, 25 USPQ2d at 1605-06, and thus did not clearly err

in finding that the cDNA encoding human insulin required by claim 5 is not adequately described in the '525 patent.

Claim 5 is directed to a recombinant procaryotic microorganism modified so that it contains "a nucleotide sequence having the structure of the reverse transcript of an mRNA of a [human], which mRNA encodes insulin." Thus, the definition of the claimed microorganism is one that requires human insulin-encoding cDNA. The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

As indicated, Example 6 provides the amino acid sequence of the human insulin A and B chains, but that disclosure also fails to describe the cDNA. Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention. Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966. We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein. See, e.g., In re Deuel, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993). Thus, a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, 1. Because the '525 specification provides only a general method of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA. Accordingly, the district court did not err in concluding that claim 5 is invalid for failure to provide an adequate written description.

UC also argues that the district court erred in holding claims 1 and 2, which generically recite cDNA encoding vertebrate insulin, and claim 4, which is directed generically to cDNA encoding mammalian insulin, invalid. Dependent claims 6 and 7 similarly recite cDNA encoding vertebrate insulin. In support of this argument, UC cites the disclosure of a species (the rat insulin-encoding cDNA) within the scope of those generic claims. UC argues, citing In re Angstadt, 537 F.2d 498, 190 USPQ 214 (CCPA 1976) and Utter v. Hiraga, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988), that because the '525 specification meets the requirements of § 112, 1, for a species within both of these genera, the specification necessarily also describes these genera. Lilly responds that the district court did not clearly err in finding that cDNA encoding mammalian and vertebrate insulin were not adequately described in the '525 patent, because description of one species of a genus is not necessarily a description of the genus.

We agree with Lilly that the claims are invalid. Contrary to UC's argument, a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus . . . .").

The cases UC cites in support of its argument do not lead to the result it seeks. These cases do not compel the conclusion that a description of a species always constitutes a description of a genus of which it is a part. These cases only establish that every species in a genus need not be described in order that a genus meet the written description requirement. See Utter, 845 F.2d at 998-99, 6 USPQ2d at 1714 ("A specification may, within the meaning of § 112 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") (affirming board's finding that an application that "describes in detail the geometry and components that make its internal pivot embodiment work" also sufficiently describes an interference count that is "silent as to the location of the pivot"). In addition, Angstadt is an enablement case and Utter involves machinery of limited scope bearing no relation to the complex biochemical claims before us.

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as “vertebrate insulin cDNA” or “mammalian insulin cDNA,” without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial

portion of the genus. This is analogous to enablement of a genus under § 112, 1, by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); In re Robins, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification . . . mention of representative compounds may provide an implicit description upon which to base generic claim language."); Cf. Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); In re Grimme, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) ("[I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'") (citations omitted). We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, that the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Accordingly, we reject UC's argument that the district court clearly erred in finding claims 1, 2, 4, 6, and 7 invalid for failure to provide an adequate written description. Because we affirm the district court's ruling that all of the claims of the '525 patent asserted against Lilly are invalid, we need not consider whether Lilly infringed those claims. See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp., 72 F.3d 1577, 1583, 37 USPQ2d 1314, 1319 (Fed. Cir. 1996).

2. Enforceability

The district court also ruled the '525 patent unenforceable on the ground of inequitable conduct. The court based this ruling on its findings that UC had violated National Institutes of Health (NIH) guidelines in order to develop the patented invention as soon as possible and had falsified material in its patent application in an effort to disguise its violation. The court noted that at the time the application that became the '525 patent was filed, NIH had certified only three plasmids for use with mammalian DNA: pSC101, pCR1, and pMB9. 39 USPQ2d at 1249. It then found that UC researchers knowingly used the uncertified pBR322 plasmid to hasten their determination of the rat PI and PPI cDNA sequences, and misrepresented that they had used pMB9, a certified plasmid, in the actual examples of their patent application. The court also found that a reasonable patent examiner would have viewed this misrepresentation as material to patentability. Id. at 1254.

UC argues that we should reverse the district court's ruling because it is based on a misinterpretation of the applicable law on inequitable conduct. Specifically, UC argues that the district court improperly considered alleged misrepresentations made to the NIH and Congress, and failed to properly consider whether the alleged misrepresentation in the patent application regarding the use of pMB9 was material to patentability. UC also argues that the district court clearly erred in finding that UC actually used pBR322 and then misrepresented that it used pMB9. In response, Lilly argues that under General Electro Music Corp. v. Samick Music Corp., 19 F.3d 1405, 30 USPQ2d 1149 (Fed. Cir. 1994), UC's misrepresentation was sufficient to support a finding of inequitable conduct, and that such a misrepresentation need not bear directly

on patentability as long as that misrepresentation was made in an effort to obtain a patent more quickly than otherwise. Lilly also argues that the district court properly found that UC's alleged pattern of deceit before a variety of governmental bodies was sufficient to render the patent unenforceable under the broad doctrine of "unclean hands." See, e.g., Keystone Driller Co. v. General Excavator Co., 290 U.S. 240, 19 USPQ 228 (1933).

"A determination of inequitable conduct is committed to a district court's discretion. Accordingly, we review the district court's judgment for an abuse of discretion." Kolmes v. World Fibers Corp., 107 F.3d 1534, 1541, 41 USPQ2d 1829, 1834 (Fed. Cir. 1997) (citing Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988)). To overturn a discretionary ruling of a district court, "the appellant must establish that the ruling is based on clearly erroneous findings of fact or on a misapplication or misinterpretation of applicable law, or evidences a clear error of judgment on the part of the district court." Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1827 (Fed. Cir. 1995).

We conclude that the district court abused its discretion in holding the '525 patent to be unenforceable. An infringer asserting an inequitable conduct defense must demonstrate by clear and convincing evidence that the applicant or his attorney either failed to disclose material information or submitted false material information to the Patent and Trademark Office (PTO) and that the applicant or his attorney did so with an intent to deceive the PTO. See Kingsdown, 863 F.2d at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984).

The alleged misinformation submitted to the PTO in this case consists of statements in Examples 4 and 5 of the specification that the pMB9 plasmid was used as the cloning vector for the rat cDNA when pBR322 appears to have been used. Lilly does not argue that the pMB9 plasmid was inoperable in the stated examples, only that Examples 4 and 5 should not have been stated as actual examples (even though they presumably could have been stated as constructive, i.e., hypothetical, examples). Accordingly, Lilly must demonstrate that this distinction would have been considered material by a reasonable patent examiner. We conclude that it has not done so by clear and convincing evidence.

There is no reason to believe that a reasonable examiner would have made any different decision if UC had framed Examples 4 and 5 as constructive examples. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1578, 224 USPQ 409, 415 (Fed. Cir. 1984) ("Even if intent could be inferred, and if the examples were constructive but not disclosed to the examiner as such, [the alleged infringer] has not shown the nondisclosure to have been material, i.e., important to an examiner in allowing the patent to issue."); Manual of Patenting Examining Procedure (MPEP) § 707.07(l) (5th ed. 1993) ("The results of the tests and examples should not normally be questioned by the examiner unless there is a reasonable basis for questioning the results."); cf. Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 808-09, 15 USPQ2d 1481, 1484 (Fed. Cir. 1990) (affirming a finding of inequitable conduct based on an applicant's intentional disclosure of a "fictitious, inoperable" example and withholding of a best mode.). Moreover, the examiner would not have made any different decision if pBR322, the plasmid the district court found was actually used, was recited in the examples, because, as the record shows, the procedures described in Examples 4 and 5 for rat insulin cDNA worked to yield the intended results irrespective of whether pMB9 or pBR322 was used. The misidentification of the plasmid was therefore not material to patentability. Thus, no inequitable conduct occurred in the procurement of the patent.

In addition, contrary to the findings of the district court, a reasonable patent examiner would not have considered non-compliance with the NIH guidelines to be material to patentability. The district court based its finding of materiality on the theory that if the applicant had complied with the guidelines, the application might have been delayed and the applicants might not have been the first to apply for a patent on the claimed subject matter. However, such unfounded speculation is not clear and convincing evidence of materiality.

General Electro Music does not support Lilly's argument that UC's failure to have actually used pMB9 would have been material to patentability. In General Electro Music, we concluded that "a false statement in a petition to make special is material if, as here, it succeeds in prompting expedited consideration of the patent." 19 F.3d at 1411, 30 USPQ2d at 1154. We so concluded because, by filing a petition to make special, the applicant "requested special treatment and induced reliance on its statement that a prior art search had been conducted." Id. As explained above, UC's alleged mischaracterization of the pMB9 work as an actual example did not induce the examiner to act, or not to act, in reliance thereon. UC got no advantage in the patent examining process. Therefore, we conclude that the district court clearly erred in finding that the misidentification of the plasmid was material to patentability.

We also reject Lilly's alternative argument that the patent is unenforceable under the doctrine of "unclean hands." This court has previously refused to afford equitable relief in that guise in the absence of proof of materiality. In J.P. Stevens, 747 F.2d at 1560 n.7, 223 USPQ2d at 1093 n.7, we rejected the argument that "unclean hands" could render a patent unenforceable without proof of materiality because such a "categorization is inconsistent with this court's view that materiality is a necessary ingredient of any inequitable conduct." Accordingly, there is no legal basis for the conclusion that inequitable conduct occurred in the procurement of the patent and the district court therefore abused its discretion in its conclusion that the patent was unenforceable.

C. The '740 Patent

1. Infringement

The district court ruled that Lilly did not infringe claims 5-6 and 8-10 of the '740 patent either literally or under the doctrine of equivalents, 39 USPQ2d at 1231-38, and did not infringe claims 2-3 and 13-14 of the '740 patent under the doctrine of equivalents, id. at 1238. After evaluating the specification and the prosecution history, and receiving extrinsic evidence, the court construed these claims to be limited to genetic constructs (i.e., "plasmids" and "transfer vectors") and microorganisms from which human PI is directly expressed. Accordingly, the court found that Lilly, which does not make or use such constructs or microorganisms, but expresses a recombinant fusion protein that is later cleaved to yield human PI, did not literally infringe the asserted claims. The court further determined that Lilly did not infringe the claims under the doctrine of equivalents because claim amendments made during the prosecution of the patent application bar UC from successfully asserting that the materials Lilly uses for expressing a recombinant fusion protein are equivalent to the claims of the '740 patent.

Challenging the district court's finding of a lack of literal infringement, UC argues that the district court incorrectly interpreted the claims. Specifically, UC argues that the use of the term "comprising" in the claims indicates that a transfer vector such as that used by Lilly will infringe the claims as long as it includes the inserted cDNA encoding human PI, irrespective of the presence of other elements such as the DNA encoding the remainder of Lilly's fusion protein. Lilly responds that the district court correctly interpreted the

claims in light of the prosecution history. Lilly argues that a prior art rejection was based on the examiner's conclusion that the prior art taught how to make recombinant insulin as part of a fusion protein and that UC therefore obtained allowance of the claims by specifically disclaiming transfer vectors that encode fusion proteins.

A determination of infringement requires a two-step analysis. “First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process.” Carroll Touch, Inc. v. Electro Mechanical Sys., Inc., 15 F.3d 1573, 1576, 27 USPQ2d 1836, 1839 (Fed. Cir. 1993). The first step, claim construction, is a question of law which we review de novo; the proper construction of the claims is based upon the claim language, the specification, the prosecution history, and if necessary to aid the court’s understanding of the patent, extrinsic evidence. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-81, 34 USPQ2d 1321, 1329-31 (Fed. Cir. 1995) (in banc), aff’d, 116 S. Ct. 1384, 38 USPQ2d 1461 (1996). The second step, determining whether a particular device infringes a properly construed claim, is a question of fact which we review for clear error on appeal from a bench trial. See Fed. R. Civ. P. 52(a); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). In order to prove infringement, a patentee must show that "the accused device includes every limitation of the [asserted] claim or an equivalent of each limitation." Dolly, Inc. v. Spalding & Evenflo Cos., 16 F.3d 394, 397, 29 USPQ2d 1767, 1769 (Fed. Cir. 1994).

We agree with Lilly that UC surrendered coverage of DNA that encodes a fusion protein. The district court correctly interpreted the asserted claims to be limited to genetic constructs and microorganisms that do not include DNA coding for a fusion protein. UC argues that the direct expression of human PI and the expression of human PI via a fusion protein are both described in the patent as part of the invention of the '740 patent, but that fact doesn’t change the prosecution history which indicates that UC surrendered coverage of the latter in order to overcome prior art.

This surrender is best exemplified by the prosecution history relating to the claims that ultimately issued as claims 2 and 5. These claims as originally filed were directed, with varying degrees of specificity, to a DNA transfer vector comprising a DNA sequence coding for human PI. The word "comprising," as UC argues and as is well-established, permits inclusion of other moieties. However, during the prosecution of the patent, the examiner rejected these claims as unpatentable based on, inter alia, Ullrich et al., 196 Science 1313 (June 17, 1977) and Villa-Komaroff et al., 75 PNAS 3727 (August 1978). The district court, essentially repeating the statements made by the patent examiner during the prosecution of the patent, found that these references taught, respectively, the need "to combine the genetic information for the eukaryotic insulin gene with prokaryotic regulatory sequences, to obtain expression of insulin in bacteria," and "a general method for the expression and secretion of any eukaryotic protein [such as human PI] provided another protein . . . will serve as a carrier [as part of a fusion protein], by virtue of its leader sequence." 39 USPQ2d at 1232. The examiner thus rejected the claims because he believed that the prior art taught the use of recombinant eukaryotic/procaryotic fusion proteins for the production of a eukaryotic protein, including insulin, in a recombinant bacterium.

In an effort to overcome the rejection based on these references, UC first amended claim 2 to read, in pertinent part: "A DNA transfer vector comprising an inserted cDNA having a [DNA] sequence coding for human [PI] . . . ." The word "having" still permitted inclusion of other moieties. When again confronted by a rejection based upon the same references and a later requirement that the word "having" be changed to "consisting essentially of," a narrower term, UC ultimately complied by amending claim 2 to its present form,

viz., "A DNA transfer vector comprising an inserted cDNA consisting essentially of a [DNA] sequence coding for human [PI]." Similarly, UC amended claim 5 to its present form, which reads, in pertinent part: "A DNA transfer vector comprising a [DNA] sequence coding for human [PI] consisting essentially of a plus strand having the sequence . . . ." (emphasis added). The examiner allowed these claims, noting that the required "consisting essentially of" language "excludes from the cDNA the presence of sequences other than [those coding for PI]." We agree with the district court that UC thus narrowed its claims in response to a prior art rejection to exclude the materials producing a fusion protein, as Lilly now does. UC urges us to read the examiner's statement on allowance of the claims narrowly as pertaining only to claim 2 and to exclude only DNA other than naturally-occurring human cDNA. However, that statement is not so limited; it expressly applies to claim 5 and, moreover, reflects the examiner's consistent requirement, acquiesced in by UC, that the DNA inserted in the claimed vectors code only for PI, not for a PI-containing fusion protein.

We have considered all of the other arguments made by UC, including its assertion that the examiner's rejections were based on a distinction between tailored and non-tailored cDNA, but find them to be unpersuasive. In light of the prosecution history, we agree with the district court that claims 5 and 6, which contain the language added during prosecution, cannot be construed to literally cover Lilly's expression of human PI via a fusion protein. Furthermore, UC has stated in its appeal brief that, for purposes of the analysis of literal infringement, the scope of claims 8-10 is no broader than that of claims 5 and 6, and that it does not appeal the court's finding with respect to claims 8-10. Accordingly, we affirm the district court's construction of claims 5-6 and 8-10; its factual finding that Lilly does not literally infringe claims 5-6 is not clearly erroneous and is therefore also affirmed.

Regarding the district court's application of the doctrine of equivalents, UC argues that the district court improperly interpreted the prosecution history to indicate that UC had disclaimed vectors encoding fusion proteins instead of to indicate, as properly interpreted, that the claims were limited to "tailored" cDNA inserts. However, as indicated above, we find no error in the district court's interpretation of the claims and the prosecution history and hence its conclusion that Lilly does not infringe the asserted claims under the doctrine of equivalents.

When a claim has been narrowed by amendment for a "substantial reason related to patentability," such as to avoid a prior art rejection, the patentee may not assert that the surrendered subject matter is within the range of equivalents. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S.Ct. 1040, 1049-51, 41 USPQ2d 1865, 1871-73 (1997); Insituform Techs., Inc. v. Cat Contracting, Inc., 99 F.3d 1098, 1107, 40 USPQ2d 1602, 1609 (Fed. Cir. 1996), cert. denied, 117 S. Ct. 1555 (1997); ("Prosecution history estoppel bars the patentee from recapturing subject matter that was surrendered by the patentee during prosecution in order to promote allowance of the claims."). "The application of prosecution history estoppel is a question of law subject to de novo review." Id.; see also Warner-Jenkinson, 117 S.Ct. at 1049-51, 41 USPQ2d at 1871-73.

As the district court properly concluded, the above-described prosecution history estops UC's '740 patent from dominating Lilly's expression of its fusion protein. As a matter of law, the material used by Lilly for expressing its fusion protein is not equivalent to that of the above-analyzed claims, or to the materials of the other asserted claims, i.e., claims 2-3 and 13-14, for such an application of the doctrine of equivalents would allow UC to recapture subject matter it surrendered during the prosecution of the '740 patent. Accordingly, UC cannot meet its burden of establishing infringement under the doctrine of equivalents. The district court did not clearly err in determining that Lilly did not infringe the '740 patent, either literally or under the doctrine

of equivalents.

2. Enforceability

The district court ruled that the '740 patent was unenforceable for inequitable conduct. 39 USPQ2d at 1255-58. The court based this ruling in part on its finding that UC failed to disclose to the PTO a highly-material reference, European Patent Application No. 1929 (EPA-1929), entitled "Plasmid for Transforming Bacterial Host to Render It Capable of Polypeptide Expression" in which the expression of human somatostatin and insulin are used as examples. The court also based its ruling on its finding that UC was made aware of the materiality of EPA-1929 when it was cited as prior art by the European Patent Office (EPO) during the prosecution of the European counterpart of the application that led to the '740 patent. The court found that under these facts, it would "draw an inference of intent to mislead," id. at 1257, and accordingly, found that UC had engaged in inequitable conduct.

UC argues that it did not have a duty to disclose EPA-1929 to the PTO because it was merely cumulative of the references it had submitted to the PTO. Specifically, UC argues that EPA-1929 was cumulative of the two references on which EPA-1929 was based, which were already before the examiner when UC became aware of EPA-1929: Goeddel et al., 76 PNAS 3727 (1979) and Itakura et al., 198 Science 1056 (1977). UC also argues that the district court misapplied the law on inequitable conduct by inferring an intent to deceive when the uncited reference was merely cumulative. Lilly responds that EPA-1929 was not cumulative because, unlike the reference before the examiner, it described a specific, enabling technique for making "tailored" DNA that would encode for a fusion protein including human PI. Lilly argues that UC's assertions of subjective good faith amount to no more than a mere denial of bad faith and accordingly that the district court properly disregarded those assertions. We agree with UC that the district court clearly erred in finding that EPA- 1929 was not cumulative and, accordingly, in inferring an intent to deceive.

As stated above, we review a district court's ruling that a patent is unenforceable for inequitable conduct under an abuse of discretion standard. Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988). An infringer asserting an inequitable conduct defense must prove by clear and convincing evidence that the applicant or his attorney failed to disclose material information or submitted false material information to the PTO, with an intent to deceive the PTO. See id. at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984). However, even where an applicant fails to disclose an otherwise material prior art reference, that failure will not support a finding of inequitable conduct if the reference is "simply cumulative to other references," i.e., if the reference teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO. Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582, 18 USPQ2d 1001, 1014 (Fed. Cir. 1991).

The district court correctly found that UC knew of the materiality of EPA-1929 because the EPO considered EPA-1929 to be material to the examination of the European counterpart of the '740 patent. However, if EPA-1929 was merely cumulative of other references already before the examiner, UC's failure to cite it will not support a finding of inequitable conduct because one is justified in not submitting cumulative prior art. The record indicates that EPA-1929 was cumulative. The examiner had already noted the relevance of both the Itakura article, entitled "Expression in Escherichia coli of Chemically Synthesized Gene for the Hormone Somatostatin," and the Goeddel article, entitled "Expression in Escherichia coli of Chemically Synthesized

Genes for Human Insulin." As is suggested by their respective titles and their dates of publication and submission, the work described in the two articles is essentially the same as that described in EPA-1929. In fact, the record indicates that the European patent examiner cited EPA-1929 against the European counterpart of the '740 patent, but cited the Goeddel article merely to demonstrate the state of the art and did not cite the Itakura article at all.

Lilly argues that these articles are distinguishable from EPA-1929 based on the fact that EPA- 1929 also includes a claim (claim 6) directed, in part, to a plasmid encoding human proinsulin. But the inclusion of a claim is not controlling in a determination whether EPA-1929 is cumulative. What is relevant is whether EPA-1929 discloses subject matter relevant to the examination of the ‘740 patent application that is not taught by the Goeddel and Itakura articles. Plainly it does not. The Goeddel article and EPA-1929 describe in similar detail the same experiments which led to the production of a recombinant human insulin/b-galactosidase fusion protein. That Genentech attempted to claim a plasmid encoding human proinsulin in EPA-1929 does not add to its disclosure compared with the Goeddel article. We therefore conclude that the district court clearly erred in finding that EPA-1929 was not cumulative.

Because we conclude that the district court's finding of materiality was clearly erroneous, we also necessarily conclude that the district court clearly erred in inferring deceptive intent from the mere fact that UC did not cite EPA-1929. UC's failure to disclose the EPA-1929 reference, given its cumulative nature, is not clear and convincing evidence of inequitable conduct. Because the district court's conclusion that the '740 patent is unenforceable for inequitable conduct is based on clearly erroneous findings of materiality and intent, that conclusion is reversed.

CONCLUSION

The district court properly exercised jurisdiction over this case and did not abuse its discretion in transferring the case to itself for a trial on the merits. It did not clearly err in finding that the '525 patent does not provide an adequate written description of the subject matter of the asserted claims and thus properly held that those claims are invalid, nor did it clearly err in finding that Lilly did not infringe the asserted claims of the '740 patent. The court abused its discretion in holding that the '525 and '740 patents are unenforceable. Accordingly, the decision of the district court is

AFFIRMED-IN-PART and REVERSED-IN-PART.

COSTS

Costs to Lilly.

Footnotes

1 For a detailed discussion of recombinant DNA technology, see Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207-08 n.4, 18 USPQ2d 1016, 1022 n.4 (Fed. Cir. 1991) and In re O'Farrell, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988) and references therein.

2 For a detailed discussion of fusion proteins, see Schendel v. Curtis, 83 F.3d 1399, 1400 & n.3, 38 USPQ2d 1743, 1744 & n.3 (Fed. Cir. 1996).

3 UC also argues that the Indiana court abused its discretion by erroneously determining that UC could have brought this suit in Indiana without the state of California's consent, by overruling inconsistent decisions of the California district court, and by failing to give special weight to UC's choice of forum. We have considered these arguments and do not find them to be persuasive.

4 We note that in claims 4, 5, and 12-14 of the '740 patent, genera of DNA sequences encoding human PI or PPI are described by reference to the structure of the claimed DNA sequences rather than by reference to their function.

5 Several other publications of record before the PTO were found by the district court to teach the use of fusion proteins in the production of human PI. See 39 USPQ2d at 1231 n.12. For the sake of brevity, we do not discuss them here.

6 UC also appears to argue that the district court clearly erred in finding that these references taught the production of human PI via a fusion protein. This argument misses the point of the analysis of prosecution history. As the Supreme Court recently noted, the question of the correctness of the examiner's rejection is "properly addressed on direct appeal from the denial of the patent, and will not be revisited in an infringement action." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S.Ct. 1040, 1051 n.7, 41 USPQ2d 1865, 1872-73 n.7 (1997). In construing the claims in view of prosecution history or in deciding whether to estop a patentee from asserting a certain range of equivalents, a court may only explore "the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." Id. Thus, the district court properly accepted the examiner's arguments for the purpose of construing the claims in view of the prosecution history.

7 UC's later-filed amendment pursuant to 37 C.F.R. § 1.312 (1983) ("Amendments after allowance"), in which it argued that the claims as allowed would not necessarily encompass the "trivial" oligo-dC and oligo-dG ends actually used to construct the plasmid of the '740 patent, also supports this broader reading of the examiner's statement.

8 This application was filed by Genentech, Inc. and named Drs. Itakura and Riggs as inventors.

9 Drs. Itakura and Riggs, inventors of the EPA-1929 subject matter, are noted as authors on both of these articles.

For a detailed discussion of fusion proteins, see Schendel v. Curtis, 83 F.3d 1399, 1400 & n.3, 38 USPQ2d 1743, 1744 & n.3 (Fed. Cir. 1996). UC also argues that the Indiana court abused its discretion by erroneously determining that UC could have brought this suit in Indiana without the state of California's consent, by overruling inconsistent decisions of the California district court, and by failing to give special weight to UC's choice of forum. We have considered these arguments and do not find them to be persuasive. We note that in claims 4, 5, and 12-14 of the '740 patent, genera of DNA sequences encoding human PI or PPI are described by reference to the structure of the claimed DNA sequences rather than by reference to their function. Several other publications of record before the PTO were found by the district court to teach the use of fusion proteins in the production of human PI. See 39 USPQ2d at 1231 n.12. For the sake of brevity, we do not discuss them here. UC also appears to argue that the district court clearly erred in finding that these references taught the production of human PI via a fusion protein. This argument misses the point of the analysis of prosecution history. As the Supreme Court recently noted, the question of the correctness of the examiner's rejection is "properly addressed on direct appeal from the denial of the patent, and will not be

revisited in an infringement action." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S.Ct. 1040, 1051 n.7, 41 USPQ2d 1865, 1872-73 n.7 (1997). In construing the claims in view of prosecution history or in deciding whether to estop a patentee from asserting a certain range of equivalents, a court may only explore "the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." Id. Thus, the district court properly accepted the examiner's arguments for the purpose of construing the claims in view of the prosecution history. UC's later-filed amendment pursuant to 37 C.F.R. § 1.312 (1983) ("Amendments after allowance"), in which it argued that the claims as allowed would not necessarily encompass the "trivial" oligo-dC and oligo-dG ends actually used to construct the plasmid of the '740 patent, also supports this broader reading of the examiner's statement. This application was filed by Genentech, Inc. and named Drs. Itakura and Riggs as inventors. Drs. Itakura and Riggs, inventors of the EPA-1929 subject matter, are noted as authors on both of these articles.