

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

LIFE TECHNOLOGIES CORPORATION,

Plaintiff,

v.

OXFORD BIOMEDICAL RESEARCH, INC. and
VANDERBILT UNIVERSITY,

Defendants.

CIVIL ACTION NO. _____

DEMAND FOR JURY TRIAL

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiff Life Technologies Corporation (“Life Technologies”), formerly Invitrogen Corporation, files this Original Complaint against Defendants Oxford Biomedical Research, Inc. (“Oxford”) and Vanderbilt University (“Vanderbilt”), seeking declarations under 28 U.S.C. § 2201 regarding the scope, validity and non-infringement of U.S. Patent No. 5,886,157, (“the ’157 patent” attached as Exhibit A). In support of its claims, Life Technologies shows the Court as follows:

**I.
PARTIES**

1. Life Technologies is a Delaware corporation, with its principal place of business at 5791 Van Allen Way, Carlsbad, California 92008, and substantial research and development, manufacturing, and distribution facilities at 501 Charmany Drive, Madison, Wisconsin, 53719. In November 2008, Invitrogen Corporation changed its name to Life Technologies Corporation. Therefore, Invitrogen Corporation and Life Technologies Corporation are both referred to as “Life Technologies” throughout this Complaint.

2. Defendant Oxford is a Michigan corporation, with its principal place of business in Rochester Hills, Michigan. Oxford may be served with process through its registered agent, Denis M. Callewaert, at 4600 Gardner Rd., Metamora, Michigan 48455.

3. Defendant Vanderbilt is a private, not-for-profit corporation incorporated under the laws of Tennessee, with its principal place of business in Nashville, Tennessee. Vanderbilt may be served with process through its registered agent, Office of General Counsel, 305 Kirkland Hall, Nashville, Tennessee 37240.

II. JURISDICTION AND VENUE

4. This case involves an actual controversy arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* Accordingly, this Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338(a). Furthermore, this Court has the authority to grant the requested declaratory relief pursuant to 28 U.S.C. § 2201.

5. This Court has personal jurisdiction over Defendant Vanderbilt because it is a resident of this district.

6. This Court has personal jurisdiction over Defendant Oxford because it has purposefully availed itself of this Court's jurisdiction by establishing contacts with the State of Tennessee sufficient to warrant the exercise of jurisdiction over it pursuant to Tennessee's long arm statute, Tenn. Code Ann. § 20-2-214, and the Constitution of the United States. Such contacts include, but are not limited to, negotiating and entering into an exclusive licensing agreement (the "Vanderbilt/Oxford Agreement") pertaining to Vanderbilt's patent application that matured into the '157 patent. In the Vanderbilt/Oxford Agreement, Oxford availed itself of

the jurisdiction of this Court by agreeing to litigate any disputes arising out of the Vanderbilt/Oxford Agreement in the state and federal courts of Davidson County, Tennessee. Further, the Vanderbilt/Oxford Agreement granted Oxford a property interest in Vanderbilt's patent application and obligated Oxford to conduct business within this district on an on-going basis throughout the life of the agreement, which on information and belief is still in full force and effect. On information and belief, acting under the terms and obligations of the Vanderbilt/Oxford Agreement, Oxford has regularly supplied Dr. Guengerich's laboratory with biological materials and regularly remitted royalty payments to Vanderbilt based on the royalty payments it has received from Life Technologies and PanVera. In addition to the Vanderbilt/Oxford Agreement, on information and belief, Oxford has maintained continuous and systematic contacts by negotiating other contracts with Vanderbilt in Tennessee and Oxford has maintained continuous and systematic contacts by selling research materials into the jurisdiction.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events giving rise to these claims arose within this judicial district, and because both Oxford and Vanderbilt "reside" in this judicial district, as that term is defined under 28 U.S.C. § 1391(c).

III. FACTUAL BACKGROUND

8. Oxford is a biomedical research company in the business of producing and selling antibodies and other reagents to research laboratories. In or around 1994, Oxford, Vanderbilt, and PanVera Corporation ("PanVera")—a Madison, Wisconsin company in the business of purifying and commercializing recombinant proteins derived from genetically engineered DNA—engaged in a series of negotiations regarding the potential licensing of Vanderbilt's

cytochrome P450 recombinant protein technology including the patent application titled “Expression and Purification of Human Cytochrome P450,” developed by Dr. Peter Guengerich of Vanderbilt University. The above referenced patent application eventually matured into the ’157 patent, the patent at issue in this suit.

9. As a result of the negotiations between and among Vanderbilt, Oxford and PanVera, in 1994, Vanderbilt and Oxford executed the Vanderbilt/Oxford Agreement by which Oxford acquired an exclusive license from Vanderbilt to the patent application that matured into the ’157 patent. In 1995, 1996, 2001, and 2003, Vanderbilt and Oxford negotiated and executed four amendments to the agreement. The original agreement and the four amendments are collectively referred to as the Vanderbilt/Oxford Agreement and is attached as Exhibit B.

10. Pursuant to its right to grant sublicenses, Oxford, as exclusive licensee, granted PanVera a sublicense to the P450 protein technology in an agreement entitled “Licensing and Supply Agreement.” PanVera and Oxford twice amended the Licensing and Supply Agreement. The final version, executed in September 1996, is entitled the Licensing and Supply Agreement, Phase II (the “Phase II Agreement”), attached as Exhibit C. The Phase II Agreement superseded and terminated the prior agreements between PanVera and Oxford. The Phase II Agreement provided for a variable term, dependant upon the issuance of a patent covering “LICENSED MATERIALS,” as defined in the agreement. The term was set forth in section 5.1:

The Term of this Agreement granted hereunder shall commence upon the signing hereof and *shall continue for the life of any patent covering LICENSED MATERIAL, or, if no patent issues, for a period of ten (10) years subsequent from the date of execution unless terminated as provided herein. . . (Emphasis added).*

11. In February 2003, Life Technologies purchased certain assets of PanVera, including the Phase II Agreement. Soon after, disagreements arose between Oxford and Life Technologies with respect to several provisions of the Phase II Agreement.

12. On October 12, 2005, Oxford filed a lawsuit against Life Technologies in Michigan state court. Oxford's Complaint contained no allegations regarding the term or duration of the Phase II Agreement. Nor did it contain any allegations that Life Technologies infringes the '157 patent, or that the '157 patent (or any other patent) covered the "LICENSED MATERIALS" identified in the Phase II Agreement.

13. Life Technologies removed the case to the United States District Court for the Eastern District of Michigan on November 29, 2005 in light of the complete diversity between the parties. *See Oxford Biomedical Research, Inc. v. Life Technologies Corp.*, No. 5:05-cv-60274 (E.D. Mich., removed Nov. 29, 2005) (the "Michigan Litigation").

14. In the summer of 2007, Life Technologies and Oxford exchanged a series of letters concerning the scope and effect of the Phase II Agreement. In a letter dated July 26, 2007, counsel for Oxford posited, without explanation, that the Phase II Agreement would not terminate until the '157 patent expires.

15. On November 1, 2007, Stuart P. Hepburn, Life Technologies' Vice President of Corporate Development and Contracts, wrote to Denis Callewaert, Oxford's President, to notify him that the Phase II Agreement had expired pursuant to its terms. Mr. Hepburn specifically explained that the '157 patent is a method patent, which by its terms does not cover the LICENSED MATERIALS:

The only patent of which we are aware that issued relating in any way to the “LICENSED MATERIAL” obtained from Oxford under this Agreement is a Vanderbilt University patent (Patent No. 5,886,157) which covers a “method of purifying a recombinant cytochrome P450 protein from a host cell culture,” utilizing certain purification steps (hereinafter the “Vanderbilt Patent”). Importantly, the Vanderbilt Patent does not cover the cell culture host material itself, but covers instead only a method for purifying P450 proteins from that material. The “LICENSED MATERIAL” is defined in the Agreement to include cell culture host materials—specifically, the E coli that have been genetically engineered and which are capable of producing the Cytochrome P450 recombinant proteins, and/or the native unmodified cDNA in a commonly used expression vector for certain human Cytochrome P450s. Although a patent has issued covering a method for purifying P450 proteins from cell culture host materials, no patent has issued covering the cell culture host materials themselves. Consequently, no patent has issued covering the “LICENSED MATERIAL.”

Mr. Hepburn’s letter goes on to explain that, at any rate, Life Technologies has never practiced the method specified in the ’157 patent to purify the P450 proteins from the cell culture host. Accordingly, Mr. Hepburn explained that the Phase II Agreement originally would have expired by its terms on September 11, 2006—10 years after its execution date. As further explained in Mr. Hepburn’s letter, Life Technologies offered in early 2007 to extend the term of the Phase II Agreement for an additional one year by presenting its annual royalty check. Oxford accepted this offer by depositing the check. Therefore, the Phase II Agreement expired on September 11, 2007.

16. Oxford did not refute, respond to, or otherwise challenge the facts set forth in Mr. Hepburn’s letter.

17. On May 28, 2008, Oxford filed its Opposition to Life Technologies’ Motion for Partial Summary Judgment, where, for the first time, it attempted to inject into the Michigan Litigation its factually and legally baseless theory that the ’157 patent covered the LICENSED MATERIALS. Here, and not in any other official pleadings, Oxford asserted (without support)

that because the '157 patent covered the LICENSED MATERIALS, the Phase II Agreement would not terminate until the '157 patent expires in 2016.

18. Indeed, before May 28, 2008, Oxford had not alleged or even suggested in the Michigan Litigation that the '157 patent covered the LICENSED MATERIALS, nor could they, because Vanderbilt, an essential party to any litigation addressing such claims, is not a party to that Michigan Litigation. As such, no *Markman* hearing has been requested, scheduled, or argued, Oxford has not identified any method practiced by Life Technologies that it believes infringes the claims of the '157 patent, and Oxford has presented no technical experts to opine on claim construction or infringement issues. Trial in the Michigan Litigation is set for March of this year.

19. On June 17, 2008 and July 30, 2008, Oxford served Life Technologies with successive reports from its damages expert in the Michigan Litigation, Glenn C. Sheets. In the expert reports, Mr. Sheets alleges a total of \$173 million in damages resulting from Life Technologies' alleged breach of the Phase II Agreement. A significant portion of the \$173 million calculation is attributable to anticipated future damages based on the faulty assumptions that (1) '157 patent is valid (which it is not), and (2) that the term of the Phase II Agreement extends to 2016—an extra 10 years—because, as properly construed, the claims of the '157 patent “cover LICENSED MATERIALS” (which they do not).

20. On July 30, 2008, Oxford also submitted to Life Technologies a purported expert report, from its President Denis Callewaert, ostensibly setting out the damages Oxford has sustained as the result of Life Technologies' alleged failure to pay royalties on products Oxford asserts were purified using the method patented in the '157 patent. Thus, in this report Oxford

accuses Life Technologies of infringing the '157 patent to produce a host of products. The accused products include Purified Recombinant P450s and Reductases (with SKU labels of P2194, P2294, P2774, P2788, P2355 and P2308); Kits containing Purified Recombinant P450s (with SKU labels of P2304, P2305, P2306, P2362, P2787, and P2775); Baculosomes with Recombinant P450s (with SKU labels of P2377, P2512, P2792, P 2984, P2283, and P3021); and Kits containing Baculosomes with Recombinant P450s (with SKU labels of P2856, P2857, P2858, P2862, P2863, P2968, P2969, P2971, and P2972).

21. Neither Mr. Sheet's expert reports nor any of Oxford's filings or submissions in the Michigan Litigation contain factual or legal support for the proposition that the claims of the '157 patent cover the LICENSED MATERIALS, or that Life Technologies practices or infringes the claims of the '157 patent.

22. By incorporating these assumptions regarding the '157 patent's scope into the formulation of its damage model for breach of contract, Oxford is proceeding as if these matters have been litigated in its favor. That is, Oxford is attempting to avoid its burden of proving (1) that the claims of the '157 patent, as properly construed, cover the LICENSED MATERIALS, and (2) that the processes Life Technologies uses to purify P450 proteins are claimed by the '157 patent. This course of action by Oxford denies Life Technologies the opportunity to challenge the validity of the patent or to raise other defenses to the claims Oxford is making.

23. In October 2008, Life Technologies filed a motion in the Michigan Litigation seeking, among other things, to amend its answer to include requests for a declaration regarding the proper construction, and therefore scope, of the '157 patent claims, and a declaration that the '157 patent is invalid and expired. On October 31, the Michigan court denied that motion,

issuing an opinion reflecting its position that the case before it is limited to issues of contract interpretation. As such, the Michigan court declined to adjudicate the issues that are the subject of this Complaint.

24. Also in October 2008, Life Technologies filed a declaratory judgment complaint in the United States District Court for the Western District of Wisconsin asking the court, *inter alia*, to declare that the '157 patent is invalid and that Life Technologies does not use the method patented in the '157 patent in the purification in any P450 products. *See Life Technologies Corp. v. Oxford Biomedical Research, Inc. and Vanderbilt University*, No. 3:08-cv-00599-slc (W.D. Wis.). On December 30, 2008, the Wisconsin court dismissed Vanderbilt for lack of personal jurisdiction. Because Vanderbilt is an essential party to any suit seeking adjudication of the scope and/or validity of the '157 patent, Life Technologies now seeks relief from this Court.

IV. PRESENCE OF A CASE OR CONTROVERSY

25. As discussed above, Oxford has sued Life Technologies in Michigan claiming various breaches of the Phase II Agreement. In calculating the damages purportedly due it as the result of those alleged breaches (Life Technologies denies the breaches, and therefore denies that it owes *any* damages to Oxford), Oxford has assumed that fundamental issues of patent law have been adjudicated in its favor. Namely, Oxford has assumed (1) that the claims of the '157 patent cover the LICENSED MATERIALS, and/or (2) that Life Technologies practices the method claimed by Vanderbilt's '157 patent in producing certain products that it sells.

26. Oxford's wholly improper tactics attempt to deny Life Technologies the right to assert affirmative defenses governed by fundamental questions of patent law, including those of non-infringement and invalidity. Oxford's actions create an actual and substantive controversy

between Life Technologies and the real parties in interest to the '157 patent, namely Vanderbilt as the assignee and Oxford as the exclusive licensee. Vanderbilt retained all enforcement rights under the Vanderbilt/Oxford Agreement; as a result, it is an essential party to any suit challenging its scope or validity. Oxford has attempted to inject into a breach of contract claim in Michigan the scope of Vanderbilt's '157 patent. Specifically, Oxford's assertions (1) that Life Technologies owes royalties for allegedly using the claimed method of the '157 patent (and thereby allegedly infringing the '157 patent) and (2) that the '157 patent covers the LICENSED MATERIALS and thereby extends the term of the Phase II Agreement, raise a real and concrete threat of harm to Life Technologies –over 100 million dollars in supposed damages. These allegations raise an actual controversy over the scope and validity of the claims of the '157 patent between Life Technologies and Oxford, and between Life Technologies and Vanderbilt, the assignee of the '157 patent as an essential party to any suit challenging its scope or validity. Life Technologies asked the Michigan court to address the patent issues raised by Oxford, but the court refused leaving Life Technologies no choice but to file a declaratory judgment action. Meanwhile, Life Technologies and Vanderbilt have been in negotiations regarding a potential stipulation that the patent is invalid in light of certain prior art, which Life Technologies has provided to Vanderbilt. Vanderbilt has, to date, refused to enter such a stipulation and continues to assert the validity of the '157 patent despite the evidence to the contrary. Accordingly, this controversy is definite and concrete and admits of adjudication through a decree of conclusive character, namely a decree construing the claims of the '157 patent and therefore the scope of the '157 patent, a decree regarding whether the purification protocols Life Technologies has used and currently use to purify its P450 products infringe the '157 patent, and a decree regarding whether the patent claims are invalid.

V.

COUNT I—DECLARATORY RELIEF REGARDING INVALIDITY

27. This case involves an actual controversy between Life Technologies on the one hand, and Oxford and Vanderbilt on the other, regarding the validity of the '157 patent.

28. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, Life Technologies requests a declaration that claims 1 through 9 of the '157 patent are invalid and unenforceable because they fail to satisfy the conditions for patentability specified in 35 U.S.C. § 101 *et seq.*, including without limitation, sections 101, 102, 103, and/or 112. More specifically, Life Technologies requests a declaration that the claims are invalid under 35 U.S.C. §§ 102(a), 102(b) and/or 103 over the prior art, including but not limited to the following references: Alterman and Dowgii, "A Simple and Rapid Method for the Purification of Cytochrome P-450 (Form LM4)," *Biomedical Chromatography* 4(5):221-222 (1990); Johnson et al., "Multiple Forms of Cytochrome P-450: Catalytic Differences Exhibited by Two Homogeneous Forms of Rabbit Cytochrome P-450," *Molecular Pharmacology* 15:708-718 (1979); Waxman and Walsh, "Cytochrome P-450 Isozyme 1 from Phenobarbital-Induced Rat Liver: Purification, Characterization, and Interactions with Metyrapone and Cytochrome *b*₅," *Biochemistry* 22:4846-4855 (1983); McManus et al., "Metabolism of 2-Acetylaminofluorene and Benzo(*a*)pyrene and Activation of Food-derived Heterocyclic Amine Mutagens by Human Cytochromes P-450," *Cancer Research* 50:3367-76 (1990); Ichikawa and Yamano, "Reconversion of Detergent- and Sulfhydryl Reagent-Produced P-420 to P-450 by Polyols and Glutathione," *Biochimica Et Biophysica Acta* 131:490-97 (1967); and Larson et al., "Alcohol-inducible Cytochrome P-450IIE1 Lacking the Hydrophobic NH₂-terminal Segment Retains Catalytic Activity and Is Membrane-bound When Expressed in *Escherichia coli*," *The Journal of Biological Chemistry*

266(12):7321-24 (1991). The above cited references teach (either expressly or inherently), or render obvious, each and every element of claims 1-9 of the '157 patent.

29. Life Technologies expressly reserves the right to identify and rely upon additional pieces of prior art of which it becomes aware as the case progresses, and which invalidate the claims of the '157 patent under 35 U.S.C. §§ 102 and/or 103. Life Technologies further reserves the right to assert additional bases of invalidity of which it becomes aware as the case progresses under 35 U.S.C. § 101 *et. seq.*, including but not limited to additional bases for invalidity under 35 U.S.C. § 112, first and second paragraph.

VI.
COUNT II—DECLARATORY RELIEF REGARDING NON-INFRINGEMENT

30. This case involves an actual controversy between Life Technologies on the one hand, and Oxford and Vanderbilt on the other, regarding Life Technologies' non-infringement of the '157 patent.

31. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et. seq.*, Life Technologies requests a declaration that, in the process of producing its P450 products Life Technologies has not and does not practice, infringe, induce the infringement, or contribute to the infringement of any valid and enforceable claim, if any, of the '157 patent, either literally or under the doctrine of equivalents. Specifically, Life Technologies requests a declaration that its activities with respect to at least the following Life Technologies P450 products do not infringe: Purified Recombinant P450s and Reductases (with SKU labels of P2194, P2223, P2294, P2774, P2788, P2355 and P2308); Kits containing Purified Recombinant P450s (with SKU labels of P2304, P2305, P2306, P2362, P2787, and P2775); Baculosomes with Recombinant P450s (with SKU labels of P2377, P2512, P2792, P2984, P2283, and P3021); and Kits containing

Baculosomes with Recombinant P450s (with SKU labels of P2856, P2857, P2858, P2862, P2863, P2968, P2969, P2971, P2972, and P3021).

**VII.
DEMAND FOR JURY TRIAL**

32. Pursuant to Federal Rule of Civil Procedure 38, Life Technologies Corporation demands a jury trial on all issues triable by a jury.

**VIII.
PRAYER FOR RELIEF**

33. Wherefore, Life Technologies respectfully requests that this Court enter judgment in Life Technologies' favor against Oxford and Vanderbilt and issue an order:

- a. Declaring that claims 1 through 9 of the '157 patent are invalid;
- b. Declaring that Life Technologies and PanVera have not practiced since the termination of the Phase II Agreement, and do not currently practice, infringe, induce the infringement, or contribute to the infringement of any valid claim, if any, of the '157 patent, either literally or under the doctrine of equivalents; and
- c. Awarding Life Technologies its costs and any other such relief as is just and proper.

Date: January 9, 2009

Respectfully submitted,



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