

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TENNESSEE**

ST. JUDE CHILDREN'S
RESEARCH HOSPITAL, INC.

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS CORP.,

Defendant.

Civil Case No. _____

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, St. Jude Children's Research Hospital, Inc., files this Complaint and demand for jury trial seeking relief for patent infringement by the Defendant. Plaintiff states and alleges the following:

THE PARTIES

1. Plaintiff St. Jude Children's Research Hospital, Inc. ("St. Jude") is a non-profit medical corporation organized and existing under the laws of Tennessee, with its principal place of business at 262 Danny Thomas Place, Memphis, Tennessee 38105. St. Jude is a pediatric cancer research center. Its mission is to find cures for children with cancer and other catastrophic diseases through research and treatment.

2. On information and belief, Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Novartis because it regularly conducts business in the State of Tennessee and has substantial and continuous contacts within this judicial district; because it has purposefully availed itself to the privileges of conducting business in this judicial district; and/or because it has committed acts of patent infringement in this judicial district.

5. More particularly, Novartis has conducted various activities in its efforts to research, develop, and evaluate small molecule tyrosine kinase inhibitors, including, but not limited to, LDK378. Since at least April 2, 2013, Novartis has been conducting a study in Memphis, Tennessee involving LDK378. The activities relating to the research, development, and evaluation of LDK378 form the basis of this action.

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

COUNT I
(Patent Infringement)

7. St. Jude restates and realleges the preceding paragraphs of this Complaint.

8. On June 25, 1996, United States Patent No. 5,529,925 (“the ’925 patent”) entitled “Nucleic Acid Sequences and Fusion Proteins Present in Human T(2;5) Lymphoma” was duly and legally issued by the United States Patent and Trademark Office. St. Jude owns the ’925 patent by assignment. A true and correct copy of the ’925 patent is attached as Exhibit A.

9. On June 23, 1998, United States Patent No. 5,770,421 (“the ’421 patent”) entitled “Human ALK Protein Tyrosine Kinase” was duly and legally issued by the United States Patent and Trademark Office. St. Jude owns the ’421 patent by assignment. A true and correct copy of the ’421 patent is attached as Exhibit B.

10. On February 24, 2004, United States Patent No. 6,696,548 (“the ’548 patent”) entitled “Antibodies for Recognition of ALK Protein Tyrosine/Kinase Receptor” was duly and legally issued by the United States Patent and Trademark Office. St. Jude owns the ’548 patent by assignment. A true and correct copy of the ’548 patent is attached as Exhibit C.

11. Novartis has conducted various activities to research, develop, and evaluate small molecule tyrosine kinase inhibitors, including, but not limited to, LDK378. Upon information and belief, as part of those activities, Novartis has made or used ALK nucleic acids, proteins, polypeptides, and/or antibodies in a manner that infringes the ’925, ’421, and ’548 patents.

12. After an investigation of publicly-available information, St. Jude suspected that Novartis may have infringed the ’925, ’421, and ’548 patents. On September 17, 2012, St. Jude sent a letter to Scott Brown Esq., Vice President and General Counsel for Novartis. That letter notified Novartis of the ’925, ’421, and ’548 patents and identified certain activities conducted by Novartis that would require a license to those patents.

13. On September 24, 2012, Novartis responded to the September 17, 2012 letter by stating that Novartis was reviewing the letter and the St. Jude patents.

14. After hearing nothing further from Novartis, St. Jude sent correspondence to Novartis on November 30, 2012 inquiring about the status of the review apparently undertaken by Novartis and when the review would be complete.

15. On January 12, 2013, after receiving no further response from Novartis, St. Jude contacted Novartis and requested a telephone conference to discuss the issues raised in St. Jude's previous correspondence.

16. On January 16, 2013, Novartis responded by characterizing St. Jude's correspondence as a "solicitation" and stating that Novartis was "currently not interested."

17. On January 30, 2013, St. Jude responded to Novartis' January 16, 2013 correspondence by identifying numerous activities conducted by Novartis that would require a license to the St. Jude patents. The January 30 letter also requested that Novartis provide a detailed explanation as to why those activities would not require a license. St. Jude further requested that Novartis provide a response by February 15, 2013. No response was ever received by St. Jude.

18. On March 27, 2013, St. Jude sent another letter to Novartis regarding the previous letters and communications. The letter, once again, asked for an explanation as to why a license was not required and requested a response by April 10, 2013. No response to the March 27 letter was ever received by St. Jude.

19. Because Novartis has refused to respond to St. Jude's inquiries, St. Jude has not been able to analyze the extent of Novartis' infringement beyond the information that is publically available. Therefore, St. Jude also pleads in the alternative that Novartis has made and used, and is currently making and using ALK nucleic acids, proteins, polypeptides, and/or antibodies that practice one or more claims of the '925, '421, and '548 patents under the precedent established in *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000).

20. On information and belief, Novartis has been and is infringing the '925, '421, and '548 patents with knowledge of the patents, and thus, Novartis' infringement is willful.

21. On information and belief, Novartis will continue to infringe the '925, '421, and '548 patents unless and until it is enjoined by this Court.

22. Novartis has caused and will continue to cause St. Jude irreparable injury and damage by infringing the '925, '421, and '548 patents. St. Jude will suffer further irreparable injury, for which it has no adequate remedy at law, unless and until Novartis is enjoined from infringing the '925, '421, and '548 patents.

PRAYER FOR RELIEF

WHEREFORE, St. Jude respectfully requests that this Court:

- (1) Enter judgment that Novartis has infringed the '925, '421, and '548 patents;
- (2) Enter an order permanently enjoining Novartis and its officers, agents, employees, attorneys, and all persons in active concert or participation with it, from infringing the '925, '421, and '548 patents;
- (3) Award St. Jude damages in an amount sufficient to compensate it for Novartis's infringement of the '925, '421, and '548 patents, together with pre-judgment and post-judgment interest and costs under 35 U.S.C. § 284;
- (4) Award St. Jude an accounting for Novartis's acts of infringement not presented at trial and an award by the Court of additional damage for any such acts of infringement;
- (5) Treble the damages awarded to St. Jude under 35 U.S.C. § 284 by reason of Novartis's willful infringement of the '925, '421, and '548 patents;
- (6) Declare this case to be "exceptional" under 35 U.S.C. § 285 and award St. Jude its attorney fees, expenses, and costs incurred in this action; and

(7) Award St. Jude such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

St. Jude demands a jury trial on all issues so triable.

Dated: October 11, 2013

Respectfully Submitted,

By: *s/ Amy M. Pepke*

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