



**JURISDICTION AND VENUE**

4. This Court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Celgene because Celgene continuously, systematically and purposefully conducts business within this District, including but not limited to the business of developing, manufacturing and selling various pharmaceutical products, many of which are marketed, distributed and sold in Florida.

6. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b) and (c).

**FACTUAL BACKGROUND**

7. Azacitidine is a chemotherapeutic drug known as a nucleoside metabolic inhibitor. It is useful in the treatment of myelodysplastic syndrome (“MDS”). Azacitidine is indicated by the FDA for the treatment of patients with the following French-American-British MDS subtypes: Refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia.

8. Upon information and belief, Celgene holds approved New Drug Application (“NDA”) No. 50-794 for azacitidine, which Celgene commercially markets in the United States under the brand name VIDAZA®.

9. Upon information and belief, Celgene engages in the manufacture, importation, use, sale, and/or offer for sale of azacitidine as lyophilized powder in 100 mg single-use vial dosages in the United States.

**THE PATENT-IN-SUIT**

10. U.S. Patent No. 7,759,481 (“the ‘481 Patent”), entitled “Solid State Forms of 5-Azacytidine and Processes for Preparation Thereof,” was duly and legally issued by the United States Patent and Trademark Office on July 20, 2010. A copy of the ‘481 Patent is attached hereto as Exhibit A. IVAX has been assigned right, title and interest to enforce the ‘481 Patent in the United States.

**DEFENDANT’S INFRINGEMENT OF THE PATENT-IN-SUIT**

11. Upon information and belief, Celgene infringes one or more claims of the ‘481 Patent by its manufacture, importation, use, sale and/or offer for sale of azacitidine that infringes the ‘481 Patent and/or which is made in part by use of a process that infringes the ‘481 Patent.

12. As a direct and proximate cause of the infringement by Celgene and unless Celgene is enjoined by the Court from manufacturing, importing, using, selling, or offering to sell within the United States products that infringe IVAX’s patent and/or that are made using IVAX’s patented processes, IVAX is being and will continue to be substantially and irreparably harmed in its business and property rights.

13. Additionally, IVAX is suffering injury for which it is entitled to monetary relief as a result of Celgene’s infringement.

14. As a result of Celgene’s infringement of the ‘481 Patent, an immediate and justiciable controversy exists between Celgene and IVAX regarding the infringement of the ‘481 Patent.

**COUNT I**  
**(Celgene's Infringement of the '481 Patent)**

15. IVAX incorporates by reference the allegations contained in Paragraphs 1–14 of the Complaint as if fully set forth herein.

16. By its manufacture, importation, use, sale and/or offer for sale of azacitidine, Celgene has infringed and is infringing, either literally or under the doctrine of equivalents, one or more claims of the '481 Patent under 35 U.S.C. § 271(a).

17. On information and belief, Celgene actively and intentionally induces infringement of one or more claims of the '481 Patent under 35 U.S.C. § 271(b). Specifically, Celgene was aware of the '481 Patent at least as early as August 2011, when IVAX brought the '481 Patent to Celgene's attention. Both before and after Celgene became aware of the '481 Patent, Celgene has induced third parties such as Ben Venue Laboratories, Inc., Baxter Oncology GmbH or BSP Pharmaceuticals S.r.l. to manufacture azacitidine or products containing azacitidine that infringe one or more claims of the '481 Patent. Celgene does so with the knowledge that such induced acts constitute patent infringement, and Celgene has the specific intent to induce such infringement.

18. On information and belief, Celgene also contributorily infringes one or more claims of the '481 Patent under 35 U.S.C. § 271(c). Specifically, on information and belief, Celgene participates in or controls the manufacture and importation of products containing azacitidine that infringe one or more claims of the '481 Patent. Celgene knows that the azacitidine used in these products is especially made or especially adapted for a use that infringes one or more claims of the '481 Patent, is a material part of the invention of the '481 Patent, and has no substantial non-infringing use.

19. On information and belief, Celgene's infringement of the claims of the '481 Patent has been and continues to be willful.

**PRAYER FOR RELIEF**

**WHEREFORE**, IVAX respectfully requests that this Court enter a Judgment and Order:

- (a) Finding that the '481 Patent is valid and enforceable;
- (b) Finding that Celgene infringes, either literally or under the doctrine of equivalents, at least one valid and enforceable claim of the '481 Patent, or contributes to or induces such infringement, under 35 U.S.C. § 271;
- (c) Awarding IVAX damages adequate to compensate for Celgene's infringement, but in no event less than a reasonable royalty;
- (d) Finding that Celgene's infringement is willful and IVAX is entitled to treble damages under 35 U.S.C. § 284;
- (e) Permanently enjoining Celgene, its officers, agents, servants, and employees and those persons in active concert or participation with any of them from manufacturing, importing, using, selling or offering to sell within the United States products that infringe the '481 Patent or products made by a process that infringes the '481 Patent;
- (f) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding IVAX its attorneys' fees, costs, and expenses, based in part on, but not limited to, Celgene's willful infringement; and
- (g) Granting IVAX such other and further relief as this Court deems just, proper, and equitable.

**DEMAND FOR JURY TRIAL**

IVAX respectfully demands a jury trial on all issues so triable.

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