**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF FLORIDA**

**CASE NO. 12-61917-CIV-DIMITROULEAS/SNOW**

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| IVAX LLC,<br><br>Plaintiff,<br><br>v.<br><br>CELGENE CORPORATION,<br><br>Defendant. | ) | **JURY TRIAL DEMANDED** |

**AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

For its Amended Complaint against Defendant Celgene Corporation ("Celgene" or "Defendant"), Plaintiff IVAX LLC ("IVAX") alleges as to its own acts, and on information and belief as to the acts of others, as follows:

## NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and seeking damages and injunctive relief under 35 U.S.C. §§ 271, 281, 283–285.

## THE PARTIES

2. Plaintiff IVAX LLC (f/k/a/ Ivax Corporation) is a Florida limited liability company with a principal place of business at 3400 Universal Boulevard, Weston, Florida 33331.

3. On information and belief, Defendant Celgene Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

## 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).

## THE PATENT-IN-SUIT

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. 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.

9. The '481 Patent claims priority to provisional patent application No. 60/880,182, filed on January 11, 2007, provisional patent application No. 60/880,810, filed on January 16, 2007, provisional patent application No. 60/933,474, filed on June 5, 2007, and provisional patent application No. 60/998,338, filed on October 9, 2007.

10. Sixteen of the twenty claims of the '481 Patent require an azacitidine composition containing a certain range of non-volatile solvents. (Ex. A, claims 1-16 at col. 23:27-24:64.) Claim 1, for example, recites "5-Azacytidine containing about 10ppm [parts per million] to about 2000 ppm of non-volatile solvents." (*Id.*, col. 23:27-29.) The '481 Patent defines "non-volatile solvents" as "organic solvents having a boiling point of at least 140$^{o}$ C. Examples of such solvents include but [are] not limited to DMSO [dimethyl sulfoxide], formamide, DMF, DMA, NMP, and others." (*Id.*, col. 8:1-4.)

11. The specification of the '481 Patent provides several examples showing the improvement that IVAX made in reducing non-volatile solvent levels in azacitidine products. (*Id.*, col. 19:21-23:25.) Comparative Example 14 of the '481 Patent discloses the crystallization of azacitidine according to a process disclosed in U.S. Patent No. 6,887,855 ("the '855 Patent"), which is assigned to Pharmion Corp. and Ash Stevens, Inc. – predecessors-in-interest to Defendant Celgene in the development of the azacitidine product marketed by Celgene as Vidaza®. (*Id.*, col. 21:61-22:10.) On information and belief, the process disclosed in the '855 Patent was used to manufacture the product marketed as Vidaza® prior to the filing of the patent application that resulted in the '481 Patent. Comparative Example 14 of the '481 Patent shows that the azacitidine composition formed according to the process disclosed in the '855 Patent resulted in a level of the non-volatile solvent DMSO of 5,570ppm. (*Id.*, col. 21:61-22:10.) This is outside the non-volatile solvent range ultimately claimed by IVAX in the '481 Patent.

## THE ACCUSED VIDAZA® (AZACITIDINE) PRODUCT

12. On information and belief, Pharmion Corporation ("Pharmion") began selling an azacitidine product under the brand name Vidaza® in 2004 pursuant to approved New Drug Application ("NDA") No. 50-794. On information and belief, the Vidaza® product sold in 2004 was manufactured by Ben Venue Laboratories, Inc. ("Ben Venue") in Bedford, Ohio. A copy of the May 18, 2004 Label for Vidaza® reflects this information and is attached hereto as Exhibit B.

13. In a March 16, 2006 SEC 10-K filing, Pharmion admitted that improvements were being made to Vidaza's® formulation: "Finally, we are also working to improve the Vidaza's formulation. These efforts are focused on improving administration and manufacturing efficiencies, and, as a result of these activities, potentially enhancing our intellectual property." A copy of the March 16, 2006 SEC 10-K filing is attached hereto as Exhibit C.

14. On information and belief, a labeling change on August 20, 2008 indicates that Celgene, which had acquired Pharmion, began selling a product under the brand name Vidaza® that was manufactured by either Ben Venue or by Baxter Oncology GmbH ("Baxter") at its facility in Halle/Westfalen, Germany. A copy of the August 28, 2008 Label is attached hereto as Exhibit D.

15. On information and belief, a labeling "Manufacturing Change or Addition" on December 19, 2012 indicates that Celgene currently sells a product under the brand name Vidaza® that is manufactured by either Baxter or BSP Pharmaceuticals S.r.l. in Latina Scalo, Italy or Ben Venue. A copy of the December 19, 2012 Label is attached hereto as Exhibit E.

16. On information and belief, despite being identified on the December 19, 2012 Label, Ben Venue has not manufactured a Vidaza® product for Celgene since at least November 2011 when Ben Venue voluntarily suspended manufacture and distribution of products.

**THE DISCUSSIONS BETWEEN THE PARTIES PRIOR TO SUIT**

17. Subsequent to the issuance of the '481 Patent, IVAX conducted new testing on the current Vidaza® product marketed by Celgene. The results of this new testing indicated that the level of DMSO in the current Vidaza® product is within the "about 10ppm to about 2000 ppm" range claimed in claim 1 of the '481 Patent. The new testing, along with the test results shown in Comparative Example 14 of the '481 Patent, led IVAX to conclude, on information and belief, that the process used by Celgene to manufacture Vidaza® has changed over time, and Celgene is now infringing the '481 Patent.

18. Celgene was on notice before the beginning of this action that IVAX believes the process used to manufacture Vidaza® has changed over time. IVAX first contacted Celgene regarding the '481 Patent in August 2011. The parties subsequently met face-to-face on three occasions between August 2011 and July 2012 to discuss IVAX's belief that Vidaza® infringes the '481 Patent and that any Vidaza® sold by Pharmion that may be prior art to the '481 patent contained levels of non-volatile solvents above the claimed ranges and thus outside the scope of the '481 patent. Numerous letters were also written between the parties regarding these issues during that time.

19. As part of those meetings, IVAX provided test results to Celgene supporting IVAX's belief that Vidaza® changed over time. The test results given to Celgene included the data reflected in Comparative Example 14 of the '481 Patent, which shows that the azacitidine manufactured according to the process disclosed prior to the '481 Patent did not fall within the scope of the '481 Patent's claims. The test results given to Celgene also included the data indicating that the current Vidaza® product is infringing at least claim 1 of the '481 Patent.

20. Celgene asserted that the '481 Patent is invalid because Vidaza® was on sale in 2004, prior to the priority date of the '481 Patent, and the process used to manufacture Vidaza® has not changed over time. Celgene further claimed that the testing shown in Comparative Example 14 of the '481 Patent should not be relied upon by IVAX because the process for manufacturing Vidaza® has additional steps that are not reflected in Celgene's '855 Patent.

21. IVAX repeatedly requested to see complete, unredacted information under appropriate confidentiality restrictions to evaluate Celgene's claims because the evidence available to IVAX shows that Vidaza® has changed over time. Celgene refused to provide complete information. For instance, Celgene showed IVAX a few pages of redacted Celgene manufacturing documents during a meeting prior to this suit, but Celgene prevented IVAX from seeing certain parameters of the manufacturing process. IVAX asked to see the redacted information, which is uniquely within Celgene's possession, but Celgene did not respond to that request. Further, after the filing of the original Complaint in this suit, Celgene provided IVAX with incomplete information about testing of purported prior art samples of Vidaza® that also are uniquely in Celgene's possession. Celgene alleges that those test results support its invalidity claim. IVAX asked for complete information on Celgene's testing so IVAX could see the whole picture regarding Celgene's claim. Celgene again refused.

22. Celgene has the burden of proof to show that the claims of the '481 are invalid by clear and convincing evidence.

23. The information provided to IVAX by Celgene regarding Celgene's invalidity contentions falls far short of this standard, and is so incomplete that IVAX cannot rely upon it.

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

24. IVAX thus continues to believe that it has reliable test results showing that Vidaza® has changed over time such that Celgene's importation, use, sale and/or offer for sale of azacitidine after the issuance of the '481 patent infringes at least claim 1 of the '481 Patent.

25. 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.

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

27. 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)**

28. IVAX incorporates by reference the allegations contained in Paragraphs 1–27 of the Amended Complaint as if fully set forth herein.

29. 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).

30. 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.

31. 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.

32. 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.

Dated: March 13, 2013

Respectfully submitted,

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## CERTIFICATE OF SERVICE

I hereby certify that on **March 13, 2013**, I electronically filed the foregoing document with the Clerk of Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record identified on the attached Service List in the manner specified, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

s/ Robin L. Scott

**SERVICE LIST**

IVAX LLC v. Celene Corporation
Case No. 0:12-cv-61917 - Dimitrouleas/Snow
United States District Court, Southern District of Florida
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