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ONYX PHARMACEUTICALS, INC.

11  
12 UNITED STATES DISTRICT COURT  
13 NORTHERN DISTRICT OF CALIFORNIA  
14 SAN FRANCISCO DIVISION

16 ONYX PHARMACEUTICALS, INC.,

17 Plaintiff,

18 v.

19 BAYER CORPORATION, BAYER AG,  
BAYER HEALTHCARE LLC, AND  
20 BAYER SCHERING PHARMA AG,

21 Defendants.

Case No. C09-02145 MHP

**FIRST AMENDED COMPLAINT FOR:**

- (1) BREACH OF CONTRACT;**
- (2) BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING;**
- (3) BREACH OF FIDUCIARY DUTY; AND**
- (4) DECLARATORY RELIEF**

**DEMAND FOR JURY TRIAL**

22  
23  
24 **INTRODUCTION**

25 Onyx Pharmaceuticals, Inc. (“Onyx”) alleges as follows:

26 1. Onyx files this lawsuit to stop Bayer Corporation (“Bayer”) from seizing for itself  
27 what the parties agreed to share – the proceeds from a potentially lifesaving and lucrative cancer  
28 drug discovered through the parties’ longstanding scientific collaboration.

1           2.       That collaboration, first formalized in a 1994 Collaboration Agreement, merged  
2 Onyx's expertise regarding a biochemical process associated with the growth of cancer cells (and  
3 potential therapies for preventing growth of those cells) with Bayer's experience with small  
4 molecule pharmaceutical compounds. Following years of investigation and analysis, the parties  
5 identified a compound, known as sorafenib, as a promising candidate, and agreed to move  
6 forward with development activities, including clinical trials. Under the Collaboration  
7 Agreement, the parties equally shared the costs of development. For Bayer, the American arm of  
8 a multinational pharmaceutical giant, the costs were modest. But for Onyx, a start-up company  
9 with few assets beyond the human capital of its scientists, the investment in sorafenib literally  
10 was a "bet the company" proposition. To finance its share of the cost, Onyx was forced to  
11 sacrifice all activities not essential to the development of sorafenib: the company shut down all  
12 of its discovery efforts on other compounds, laid off its entire drug discovery team, and  
13 terminated an unrelated clinical program.

14           3.       Ultimately, Onyx's gamble paid off. Sorafenib (marketed as "Nexavar<sup>®</sup>")  
15 received regulatory approvals worldwide for the treatment of advanced kidney cancer and liver  
16 cancer, and has generated sales to date of more than a billion dollars, as well as substantial  
17 profits, which the parties have shared. From Onyx's perspective, the Collaboration Agreement  
18 has been an overwhelming success.

19           4.       Bayer, as it turns out, held a different view. Now that Onyx had taught Bayer how  
20 to identify effective targeted cancer therapies and introduced Bayer to a class of compounds with  
21 potent anti-cancer properties, Bayer was no longer satisfied with the division of sorafenib's  
22 profits. Bayer therefore devised a plan in an effort to bypass the Collaboration Agreement's  
23 profit-sharing formula and appropriate for itself a substantially greater share of the joint venture's  
24 blockbuster discovery. Bayer embarked on a secret program to develop a compound that the  
25 parties first identified early in their collaboration. This compound, known as fluoro-sorafenib, is  
26 identical to sorafenib, except for the substitution of a single fluorine atom in the place of a  
27 hydrogen atom. Bayer, together with its parent company, Bayer AG, and its affiliates, including  
28 Bayer HealthCare LLC ("Bayer HealthCare") and Bayer Schering Pharma AG ("Bayer Schering

1 Pharma”), then moved forward to develop the compound outside the Collaboration Agreement,  
2 surreptitiously filing patent applications and initiating clinical trials. When Onyx recently  
3 discovered this scheme and confronted defendants, they refused to concede Onyx’s rights in  
4 fluoro-sorafenib and refused to allow Onyx to join in bringing the compound to market.

5 5. Onyx brings this suit to establish its rights to fluoro-sorafenib and to recover the  
6 damages caused by defendants’ actions.

#### 7 THE PARTIES

8 6. Plaintiff, Onyx Pharmaceuticals, Inc., is a small but innovative biopharmaceutical  
9 company based in Emeryville, California. Onyx was founded in 1992 by a team of scientists  
10 internationally recognized for their understanding of the biochemical mechanisms of cancer cells.  
11 In particular, the Onyx scientists had a specialized understanding of an intracellular pathway,  
12 known as the Ras Pathway, associated with the uncontrolled growth of cancer cells. Onyx’s  
13 highly specialized knowledge of the Ras Pathway enabled it to identify targets for pharmaceutical  
14 compounds that would inhibit cancer cell proliferation and to devise laboratory tests or “assays”  
15 to assess a compound’s efficacy in doing so. Onyx also possessed a “library,” or collection, of  
16 chemical compounds to test once the assays were developed. Onyx was thus uniquely positioned  
17 with the talent and know-how to search for and identify novel drugs for treating cancer.  
18 A number of large pharmaceutical companies recognized Onyx’s unique capabilities and sought  
19 research partnerships to tap into Onyx’s expertise.

20 7. Onyx’s commitment to translating its knowledge of cellular processes into  
21 effective cancer treatments has proved successful. Its lead cancer drug, sorafenib, is approved in  
22 over 70 countries for the treatment of patients with advanced kidney cancer and/or liver cancer.  
23 Sorafenib also is being evaluated for treatment of patients with lung cancer, breast cancer, and  
24 other cancers.

25 8. Onyx is a corporation organized and existing under the laws of the State of  
26 Delaware, with its principal place of business located in Emeryville, California.

27 9. Bayer Corporation is, and at all relevant times was, a corporation organized and  
28 existing under the laws of the State of Indiana, with its principal place of business located in

1 Pittsburgh, Pennsylvania. Before approximately March 28, 1995, Bayer Corporation operated  
2 under the name Miles Inc.

3 **10.** Onyx is informed and believes, and on that basis alleges, that Bayer HealthCare is  
4 a limited liability company whose sole owner and member is Bayer Corporation. Onyx is further  
5 informed and believes, and on that basis alleges, that in 2007, the right, title, and interest in and to  
6 the Collaboration Agreement were assigned to Bayer HealthCare LLC.

7 **11.** Bayer Schering Pharma is a corporation organized and existing under the laws of  
8 Germany, with its principal place of business located in Berlin, Germany.

9 **12.** Bayer Corporation, Bayer HealthCare and Bayer Schering Pharma are part of  
10 Bayer AG, a German holding company with over 100,000 employees, operations in nearly every  
11 country in the world, and sales in 2008 exceeding 32 billion Euros. Bayer AG is a corporation  
12 organized and existing under the laws of Germany, with its principal place of business located in  
13 Leverkusen, Germany.

14 **JURISDICTION AND VENUE**

15 **13.** This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(a), in that this is  
16 a civil action between citizens of different states in which the matter in controversy exceeds,  
17 exclusive of costs and interest, seventy-five thousand dollars (\$75,000.00).

18 **14.** This Court has jurisdiction over the defendants because they actively do business  
19 in California and have sufficient minimum contacts in California, or otherwise intentionally  
20 availed themselves of the benefits of conducting business in California to be subject to the court's  
21 jurisdiction. In particular, the Collaboration Agreement was negotiated within the jurisdiction of  
22 this Court, and the parties understood that Onyx's obligations under the Agreement would be  
23 performed within this Court's jurisdiction. The Collaboration Agreement and the Letter  
24 Agreement (described below) expressly provide that they are governed by California law.

25 **15.** Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) and (c).  
26 A substantial part of the events underlying this action occurred within this district. This Court  
27 also has personal jurisdiction over defendants and, accordingly venue is proper.  
28

**INTRADISTRICT ASSIGNMENT**

1  
2       **16.** The appropriate Intradistrict Assignment for this case is the San Francisco  
3 Division or the Oakland Division, pursuant to Civ. L.R. 3-2(c) and (d). A substantial part of the  
4 events underlying this action occurred within Alameda County and Contra Costa County.

**COMMON ALLEGATIONS****The Collaboration Agreement**

6  
7       **17.** In the early 1990s, Bayer AG established the goal of exploiting new business  
8 opportunities in the market for targeted cancer therapies. Bayer AG and its affiliates, however,  
9 lacked the scientific expertise to research and develop these therapies independently. Bayer AG  
10 recognized the expertise of Onyx's scientists in the Ras Pathway, and understood that identifying  
11 compounds that inhibit proteins in the Ras Pathway could be the key to success in targeted cancer  
12 research. Bayer AG therefore approached Onyx and sought to gain access to the company's  
13 technology, know-how, and library of chemical compounds that could have effects on the Ras  
14 Pathway.

15       **18.** Bayer AG and Onyx engaged in extensive negotiations over the terms of the  
16 proposed collaboration to develop cancer drugs. Late in the negotiations, Bayer AG informed  
17 Onyx that Bayer (then known as Miles Inc.), not Bayer AG, would be the party that would sign a  
18 contract with Onyx. Shortly thereafter, on April 22, 1994, Onyx and Bayer entered into a  
19 Collaboration Agreement. Under the Collaboration Agreement and its 1996 and 1999  
20 amendments, the parties committed to work together to discover, develop and market chemical  
21 compounds having activity against proteins in the Ras Pathway.

22       **19.** Onyx recognized that other companies within the Bayer AG family of companies  
23 might assist Bayer in performing under the Collaboration Agreement, and was concerned by  
24 Bayer AG's late substitution of Bayer as the contracting party. Accordingly, "as an inducement  
25 to Onyx to execute the Agreement," Bayer AG entered into an agreement (the "Letter  
26 Agreement") with Bayer, contemporaneous with the signing of the Collaboration Agreement,  
27 confirming that, to the extent Bayer AG or any of its "Affiliates" conducted research,  
28 development, or marketing or otherwise undertook Bayer's obligations under the Collaboration

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