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14 Attorneys for Defendants
BAYER CORPORATION, BAYER HEALTHCARE LLC , BAYER AG AND
15 BAYER SCHERING PHARMA AG

16 UNITED STATES DISTRICT COURT
17 NORTHERN DISTRICT OF CALIFORNIA
18 SAN FRANCISCO DIVISION

19 ONYX PHARMACEUTICALS, INC.,

20 Plaintiff,

21 v.

22 BAYER CORPORATION, et al.,

23 Defendants.
24
25

Case No. CV 09 2145 MHP

**ANSWER AND AFFIRMATIVE
DEFENSES OF BAYER AG AND
BAYER SCHERING PHARMA AG
TO ONYX PHARMACEUTICALS,
INC.'S FIRST AMENDED
COMPLAINT**

DEMAND FOR JURY TRIAL

26 Bayer AG and Bayer Schering Pharma AG (collectively, the “German Bayer Entities”)
27 respond to the First Amended Complaint of Onyx Pharmaceuticals, Inc. (“Onyx”) as follows:
28

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

4 **ANSWER:** The German Bayer Entities admit that Onyx has filed a lawsuit. The
5 German Bayer Entities deny any remaining allegations not expressly admitted herein.

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

19 **ANSWER:** The German Bayer Entities admit (1) that under a 1994 Collaboration
20 Agreement (together with its two amendments, the “Collaboration Agreement”), Bayer identified
21 and the parties developed the anti-cancer compound sorafenib, and (2) that the Collaboration
22 Agreement outlined how the parties would allocate costs as well as profits from the development
23 of compounds covered by the Collaboration Agreement. The German Bayer Entities are without
24 knowledge or information sufficient to form a belief as to the truth of the allegations relating to
25 the burden on Onyx of the development of sorafenib, and therefore denies those allegations. The
26 German Bayer Entities deny any remaining allegations not expressly admitted herein.

27 3. Ultimately, Onyx’s gamble paid off. Sorafenib (marketed as “Nexavar®”) received
28 regulatory approvals worldwide for the treatment of advanced kidney cancer and liver cancer,
and has generated sales to date of more than a billion dollars, as well as substantial profits,
which the parties have shared. From Onyx’s perspective, the Collaboration Agreement has
been an overwhelming success.

ANSWER: The German Bayer Entities admit (1) that sorafenib has received regulatory
approval in over 70 countries for treatment of kidney and liver cancer under the brand name
Nexavar®, and (2) that Nexavar® has generated total sales to date of more than a billion dollars.
The German Bayer Entities are without knowledge or information sufficient to form a belief as

1 to the truth of the allegation relating to Onyx's perspective on the success of the Collaboration
2 Agreement, and therefore deny that allegation. The German Bayer Entities deny any remaining
3 allegations not expressly admitted herein.

4 4. Bayer, as it turns out, held a different view. Now that Onyx had taught Bayer how
5 to identify effective targeted cancer therapies and introduced Bayer to a class of compounds
6 with potent anti-cancer properties, Bayer was no longer satisfied with the division of
7 sorafenib's profits. Bayer therefore devised a plan in an effort to bypass the Collaboration
8 Agreement's profit-sharing formula and appropriate for itself a substantially greater share of
9 the joint venture's blockbuster discovery. Bayer embarked on a secret program to develop a
10 compound that the parties first identified early in their collaboration. This compound, known
11 as fluoro-sorafenib, is identical to sorafenib, except for the substitution of a single fluorine
12 atom in the place of a hydrogen atom. Bayer, together with its parent company, Bayer AG,
13 and its affiliates, including Bayer HealthCare LLC ("Bayer HealthCare") and Bayer Schering
14 Pharma AG ("Bayer Schering Pharma"), then moved forward to develop the compound outside
15 the Collaboration Agreement, surreptitiously filing patent applications and initiating clinical
16 trials. When Onyx recently discovered this scheme and confronted defendants, they refused to
17 concede Onyx's rights in fluoro-sorafenib and refused to allow Onyx to join in bringing the
18 compound to market.

13 **ANSWER:** The German Bayer Entities admit that Bayer HealthCare LLC, a subsidiary
14 of Bayer Corp., is developing a new anti-cancer compound, known internally as DAST and
15 known publicly under the official International Nonproprietary Name of regorafenib, in which
16 Onyx has no rights. The German Bayer Entities deny that this development was part of a
17 "scheme" or "secret program" done in an "effort to bypass the Collaboration Agreement" or that
18 it was "surreptitiously" undertaken. The German Bayer Entities further deny that regorafenib is
19 "known as fluoro-sorafenib." The German Bayer Entities deny any remaining allegations not
20 expressly admitted herein.

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

23 **ANSWER:** The German Bayer Entities deny (1) that Onyx has rights to regorafenib,
24 (2) that any Bayer entity has caused Onyx any damage alleged in this lawsuit, and (3) that there
25 is a compound known as "fluoro-sorafenib." The German Bayer Entities are without knowledge
26 or information sufficient to form a belief as to the truth of the remaining allegations in this
27 paragraph, and therefore deny them.

28

The Parties

1
2 6. Plaintiff, Onyx Pharmaceuticals, Inc., is a small but innovative biopharmaceutical
3 company based in Emeryville, California. Onyx was founded in 1992 by a team of scientists
4 internationally recognized for their understanding of the biochemical mechanisms of cancer
5 cells. In particular, the Onyx scientists had a specialized understanding of an intracellular
6 pathway, known as the Ras Pathway, associated with the uncontrolled growth of cancer cells.
7 Onyx's highly specialized knowledge of the Ras Pathway enabled it to identify targets for
8 pharmaceutical compounds that would inhibit cancer cell proliferation and to devise laboratory
9 tests or "assays" to assess a compound's efficacy in doing so. Onyx also possessed a "library,"
10 or collection, of chemical compounds to test once the assays were developed. Onyx was thus
11 uniquely positioned with the talent and know-how to search for and identify novel drugs for
12 treating cancer. A number of large pharmaceutical companies recognized Onyx's unique
13 capabilities and sought research partnerships to tap into Onyx's expertise.

9 **ANSWER:** The German Bayer Entities admit (1) that Onyx is based in Emeryville,
10 California, (2) that Onyx had an understanding of the Ras Pathway, (3) that Onyx developed
11 "assays" to identify compounds that inhibited the Ras Pathway, and (4) that Onyx possessed a
12 small "library" of compounds available to test for inhibition of the Ras Pathway. The German
13 Bayer Entities are without knowledge or information sufficient to form a belief as to the truth of
14 the allegations relating to the founding of Onyx, and therefore deny them. The German Bayer
15 Entities deny any remaining allegations not expressly admitted herein.

16 7. Onyx's commitment to translating its knowledge of cellular processes into effective
17 cancer treatments has proved successful. Its lead cancer drug, sorafenib, is approved in over
18 70 countries for the treatment of patients with advanced kidney cancer and/or liver cancer.
19 Sorafenib also is being evaluated for treatment of patients with lung cancer, breast cancer, and
20 other cancers.

20 **ANSWER:** The German Bayer Entities admit that Bayer's compound Nexavar® has
21 been approved in over 70 countries for treatment of kidney and liver cancer, and that Bayer
22 HealthCare LLC is evaluating Nexavar® for certain types of treatment of patients with lung
23 cancer, breast cancer, and other cancers. The German Bayer Entities are without knowledge or
24 information sufficient to form a belief as to the remaining allegations in this paragraph, and
25 therefore deny them.

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

28 **ANSWER:** Admitted.

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