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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.

1 9. Bayer Corporation is, and at all relevant times was, a corporation organized and
2 existing under the laws of the State of Indiana, with its principal place of business located in
3 Pittsburgh, Pennsylvania. Before approximately March 28, 1995, Bayer Corporation operated
4 under the name Miles Inc.

4 **ANSWER:** Admitted.

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

8 **ANSWER:** Admitted.

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

10 **ANSWER:** Admitted.

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

15 **ANSWER:** The German Bayer Entities admit (1) that Bayer AG is a German
16 corporation with its principal place of business in Leverkusen, Germany, (2) that Bayer
17 Corporation and Bayer Schering Pharma AG are wholly-owned subsidiaries of Bayer AG and
18 (3) that Bayer HealthCare LLC is a subsidiary of Bayer Corp. The German Bayer Entities deny
19 any remaining allegations not expressly admitted herein.

20 **Jurisdiction And Venue**

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

23 **ANSWER:** The German Bayer Entities admit that this action is styled on its face as a
24 diversity action under 28 U.S.C. § 1332(a), for which Onyx is claiming the matter in controversy
25 exceeds, exclusive of costs and interest, seventy-five thousand dollars (\$75,000.00). The
26 German Bayer Entities deny any remaining allegations not expressly admitted herein.

27 14. This Court has jurisdiction over the defendants because they actively do business in
28 California and have sufficient minimum contacts in California, or otherwise intentionally
availed themselves of the benefits of conducting business in California to be subject to the

1 court's jurisdiction. In particular, the Collaboration Agreement was negotiated within the
2 jurisdiction of this Court, and the parties understood that Onyx's obligations under the
3 Agreement would be performed within this Court's jurisdiction. The Collaboration Agreement
4 and the Letter Agreement (described below) expressly provide that they are governed by
5 California law.

6 **ANSWER:** The German Bayer Entities admit that the Court has specific personal
7 jurisdiction over Bayer AG and Bayer Schering Pharma AG in this matter. The German Bayer
8 Entities deny that the Court has general jurisdiction over Bayer AG and Bayer Schering Pharma
9 AG. The German Bayer Entities deny any remaining allegations not expressly admitted herein.

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

13 **ANSWER:** The German Bayer Entities admit that venue is proper in this district.

14 **Intradistrict Assignment**

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

18 **ANSWER:** The German Bayer Entities admit that the San Francisco or Oakland
19 Division is an appropriate Intradistrict Assignment for this case. The German Bayer Entities
20 deny any remaining allegations not expressly admitted herein.

21 **Common Allegations**

22 17. In the early 1990s, Bayer AG established the goal of exploiting new business
23 opportunities in the market for targeted cancer therapies. Bayer AG and its affiliates, however,
24 lacked the scientific expertise to research and develop these therapies independently. Bayer
25 AG recognized the expertise of Onyx's scientists in the Ras Pathway, and understood that
26 identifying compounds that inhibit proteins in the Ras Pathway could be the key to success in
27 targeted cancer research. Bayer AG therefore approached Onyx and sought to gain access to
28 the company's technology, know-how, and library of chemical compounds that could have
effects on the Ras Pathway.

ANSWER: The German Bayer Entities admit (1) that in the early 1990's Bayer entities
sought opportunities in the field of targeted cancer therapies, and (2) that Bayer AG and Onyx
engaged in discussions about technology relating to the Ras Pathway. The German Bayer
Entities deny that Bayer AG and its affiliates lacked the scientific expertise to research and

1 develop these therapies independently. The German Bayer Entities deny any remaining
2 allegations not expressly admitted herein.

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

10 **ANSWER:** The German Bayer Entities admit that Onyx and Bayer AG negotiated
11 various terms of the 1994 Collaboration Agreement, and ultimately Onyx and Miles (corporate
12 predecessor to Bayer Corporation) entered into the 1994 Collaboration Agreement on April 22,
13 1994, under which Miles and Onyx agreed to certain specific obligations relating to the research,
14 development, and marketing of certain specifically-defined compounds having activity inhibiting
15 Ras Function. The German Bayer Entities deny any remaining allegations not expressly
16 admitted herein.

17 19. Onyx recognized that other companies within the Bayer AG family of companies
18 might assist Bayer in performing under the Collaboration Agreement, and was concerned by
19 Bayer AG's late substitution of Bayer as the contracting party. Accordingly, "as an
20 inducement to Onyx to execute the Agreement," Bayer AG entered into an agreement (the
21 "Letter Agreement") with Bayer, contemporaneous with the signing of the Collaboration
22 Agreement, confirming that, to the extent Bayer AG or any of its "Affiliates" conducted
23 research, development, or marketing or otherwise undertook Bayer's obligations under the
24 Collaboration Agreement, the Affiliates would "do so in accordance with the provisions of the
25 Agreement." "Affiliate" was defined in the Collaboration Agreement and the Letter Agreement
26 as any entity that, directly or indirectly, is under common ownership with Bayer. The Letter
27 Agreement between Bayer and Bayer AG expressly recognized Onyx as a third-party
28 beneficiary. Onyx recently was informed by Bayer, and on that basis alleges, that the Letter
Agreement was transferred to Bayer Schering Pharma. Pursuant to such transfer, Bayer
Schering Pharma now holds (jointly with Bayer AG) Bayer AG's rights and obligations there-
under.

29 **ANSWER:** The German Bayer Entities admit that Bayer AG signed an April 22, 1994
30 letter to Miles Inc. (corporate predecessor to Bayer Corporation). The April 22, 1994 letter
31 speaks for itself and the German Bayer Entities deny Onyx's characterization of that letter. The
32 German Bayer Entities further admit (1) that the Collaboration Agreement defined "Affiliate" as
33 "any entity that directly or indirectly Owns, is Owned by, or is under common Ownership" with

1 Miles, (2) that on March 11, 2003, Bayer AG and Bayer HealthCare AG executed a “Hive-Down
2 and Transfer Agreement” between them that transferred to Bayer HealthCare AG all contracts
3 exclusively or primarily allocated to the health care business, and (3) that this transfer would
4 necessarily include the April 22, 1994 letter to the extent it is found to be a contract. On
5 December 30, 2008, Bayer HealthCare AG merged into Bayer Schering Pharma AG and, per the
6 relevant German law regulating the transformation of companies, Bayer HealthCare AG ceased
7 to exist and all assets and liabilities of Bayer HealthCare AG (including any rights and/or
8 obligations that may exist as a result of the April 22, 1994 letter) were transferred to Bayer
9 Schering Pharma AG. The German Bayer Entities deny any remaining allegations not expressly
10 admitted herein.

11 20. The Collaboration Agreement defined two categories of compounds, referred to as
12 “Collaboration Compounds” and “Post-Collaboration Compounds,” that are the subject of joint
13 development. Collaboration Compounds generally cover compounds that, before January 31,
14 2000, were “discovered, identified or synthesized” by Onyx or Bayer and “recognized” as
15 satisfying the standard for cancer inhibiting activity set forth in Exhibit D to the Collaboration
16 Agreement. Post-Collaboration Compounds generally cover those compounds (a) whose
17 chemical genus both covers a Collaboration Compound and is claimed in an Onyx or Bayer
18 patent and (b) that were “synthesized, identified or discovered” and recognized before a later
19 cutoff date as satisfying the standard in Exhibit D.

20 **ANSWER:** The German Bayer Entities admit that the Collaboration Agreement defines
21 “Collaboration Compounds” and “Post-Collaboration Compounds” in sections 1.9 and 1.39,
22 respectively, as amended, which speak for themselves. The German Bayer Entities deny the
23 factual allegations in this paragraph to the extent they purport to summarize the definitions of
24 Collaboration Compounds and Post-Collaboration Compounds in a manner inconsistent with the
25 explicit language of sections 1.9 and 1.39 of the Collaboration Agreement. The German Bayer
26 Entities deny any remaining allegations not expressly admitted herein.

27 21. The Collaboration Agreement specifies the requirements for developing
28 Collaboration Compounds and Post-Collaboration Compounds into marketable, FDA-approved
products. The Collaboration Agreement requires the parties to work together in such
development and allows one party to pursue independent pre-clinical research of a
Collaboration Compound only if the other party is first given the opportunity for joint pre-
clinical research and declines to participate. Even then, however, the party pursuing
independent pre-clinical research must offer the other party the opportunity to collaborate in
development if the research looks promising.

1 **ANSWER:** The German Bayer Entities admit that the Collaboration Agreement's
2 various sections define the requirements and exceptions that existed during the Research Term
3 that were associated with co-development of Collaboration Compounds and Post-Collaboration
4 Compounds into FDA-approved products, as well as the requirements for either party to pursue
5 independent research and development. The German Bayer Entities deny the remaining factual
6 allegations in this paragraph to the extent they purport to summarize the detailed requirements of
7 the Collaboration Agreement's relevant sections in a manner inconsistent with the language of
8 the Collaboration Agreement. The German Bayer Entities deny any remaining allegations not
9 expressly admitted herein.

10 22. The Collaboration Agreement established a Joint Research and Development
11 Committee (JRDC), populated by representatives of Bayer and Onyx, to govern the
12 collaboration. The role of the JRDC was to manage and make decisions regarding the
13 collaboration. The JRDC, later renamed the Joint Development Committee, still exists and
14 continues to meet.

15 **ANSWER:** The German Bayer Entities admit that the Collaboration Agreement
16 established a Joint Research and Development Committee (JRDC), populated by representatives
17 of Bayer and Onyx, and that the role of the JRDC is set forth in section 3 of the Collaboration
18 Agreement. The German Bayer Entities deny that the JRDC was "later renamed the Joint
19 Development Committee." The German Bayer Entities admit that there currently is a "Joint
20 Development Committee" that was established as a subcommittee of the "Executive
21 Committee," which is the successor to the JRDC created after the end of the Research Term.
22 The German Bayer Entities deny any remaining allegations not expressly admitted herein.

23 23. So that those decisions could be well informed, the Collaboration Agreement
24 established numerous obligations for information disclosure and good faith between the
25 parties. Article 10.1 of the Collaboration Agreement, for example, requires full disclosure to
26 the other party of "the Information and all other significant information, data, and results
27 known or developed by each party as of the Effective Date and during the Research Term"
28 (defined to end on January 31, 1999) "as soon as practicable" after the information is obtained
or its significance is appreciated.

ANSWER: The German Bayer Entities admit that the Collaboration Agreement
established and defined the limits of the parties' collaboration obligations, including any
obligations for information disclosure during the "Research Term." The German Bayer Entities

1 further admit that there is a section 10.1 of the Collaboration Agreement, and it states that “Onyx
2 and Miles shall make available and disclose to each other the Information and all other
3 significant information, data, and results known or developed by each party as of the Effective
4 Date and during the Research Term, relating to the Field and the Field of Collaborative
5 Research,” “with significant discoveries or advances [in the Field and the Field of Collaborative
6 Research] being communicated as soon as practicable after such information is obtained or its
7 significance is appreciated.” The German Bayer Entities deny the factual allegations in this
8 paragraph to the extent they purport to summarize section 10.1 in a manner inconsistent with its
9 express language, and specifically deny that the Collaboration Agreement defines an express
10 contractual obligation of “good faith” between the parties. The German Bayer Entities deny any
11 remaining allegations not expressly admitted herein.

12 24. Article 10.2 of the Collaboration Agreement extends the obligation to make
13 quarterly reports to the JRDC beyond the Research Term, such that, if a party continues work
14 on Collaboration Compounds not yet in development as of the end of the Research Term, it
15 must provide sufficient disclosure to enable the other party to assess whether or not to pursue
16 joint funding of pre-clinical research and/or development.

17 **ANSWER:** The German Bayer Entities admit that section 10.2 of the Collaboration
18 Agreement states that parties shall submit quarterly reports to the JRDC beyond the Research
19 Term “regarding all work being done by such Party with respect to Collaboration Compounds
20 not yet in Development and other compounds under active investigation in the Research as of the
21 end of the Research Term, at a level of detail sufficient to enable the other Party to understand
22 the progress being made and to evaluate whether to participate in funding such preclinical work
23 under Section 9.6.” The German Bayer Entities deny any remaining allegations not expressly
24 admitted herein.

25 25. Article 20.2 addresses patent disclosures, obligating a party to disclose to the other
26 party patentable inventions arising in the course of the collaboration. This section also requires
27 a party to furnish the other party with drafts of any patent application that discloses a
28 Collaboration Compound, allowing adequate time for review and comment before filing.

ANSWER: The German Bayer Entities admit that section 20.2 addresses “Disclosure of
Patentable Inventions,” the language of which speaks for itself. The German Bayer Entities deny
the factual allegations in this paragraph to the extent they purport to summarize section 20.2 in a

1 manner inconsistent with that section's explicit language. The German Bayer Entities deny any
2 remaining allegations not expressly admitted herein.

3 26. Article 26.2 of the Collaboration Agreement recognizes (similar to the Bayer AG
4 Letter Agreement) that Bayer may perform its obligations through Affiliates and provides that,
5 in such cases, Bayer "shall remain responsible and be guarantor" of the Affiliates' compliance
6 with the provisions of the Collaboration Agreement.

7 **ANSWER:** The German Bayer Entities admit that section 26.2 of the Collaboration
8 agreement recognizes that either party may perform some or all of its obligations through
9 Affiliates and provides that, in such cases, each party "shall remain responsible and be guarantor
10 of the performance by such Affiliates and shall cause such Affiliates to comply with the
11 provisions of this [Collaboration] Agreement in connection with such performance." The
12 German Bayer Entities deny any remaining allegations not expressly admitted herein.

13 27. Article 28.1 of the Collaboration Agreement provides that any assignment of rights
14 or obligations under the Agreement by Bayer to any Affiliate shall not relieve Bayer of its
15 responsibilities for performance of its obligations under the Agreement.

16 **ANSWER:** The German Bayer Entities admit that section 28.1 of the Collaboration
17 Agreement addresses "Assignment," and allows in subsection (a) that "[e]ither Party may assign
18 any of its rights or obligations under the Agreement in any country to any Affiliates; provided,
19 however, that such assignment shall not relieve the assigning Party of its responsibilities for
20 performance of its obligations under this Agreement." The German Bayer Entities deny any
21 remaining allegations not expressly admitted herein.

22 28. In the course of negotiations, the parties emphasized the importance of a
23 collaborative relationship built on principles of trust and good faith. To embody this model,
24 the parties included in Article 3.6 of the Collaboration Agreement an express covenant of good
25 faith:

26 In all matters related to the collaboration established by this Agreement, the
27 Parties shall be guided by standards of reasonableness in economic terms and
28 fairness to each of the Parties, striving to balance as best they can the legitimate
interests and concerns of the Parties and to realize the economic potential of the
Products. In conducting research, development, and commercialization activities
under this Agreement neither Party shall prejudice the value of a Product by
reason of such Party's activities outside of the Field.

1 **ANSWER:** The German Bayer Entities admit that the above excerpted paragraph
2 accurately quotes section 3.6 of the Collaboration Agreement. The German Bayer Entities deny
3 any remaining allegations not expressly admitted herein.

4 29. The Collaboration Agreement also sought to ensure that Onyx and Bayer shared in
5 the risks as well as the rewards of drug discovery. For example, the parties were to share
6 equally in the costs of co-developing Collaboration Compounds and Post-Collaboration
7 compounds for the marketplace, which might entail expensive and lengthy clinical trials for
8 which approval would be far from assured. If successful, however, the parties would share in
9 the rewards. For any co-developed Collaboration Compound sold in the marketplace, the
10 reward was to be an equal share of the profits. For any Post-Collaboration Compound, the
11 reward was to be a royalty paid by the seller.

12 **ANSWER:** The German Bayer Entities state that the language of the Collaboration
13 Agreement speaks for itself, and deny the allegations of this paragraph to the extent they purport
14 to summarize the detailed requirements of the Collaboration Agreement's relevant sections in a
15 manner inconsistent with the language of the Collaboration Agreement. The German Bayer
16 Entities admit that the Collaboration Agreement outlined how the parties would allocate costs as
17 well as profits from the research and development of compounds covered by the Collaboration
18 Agreement. The German Bayer Entities deny any remaining allegations not expressly admitted
19 herein.

20 30. Early in the collaboration, the parties agreed that one Ras Pathway protein, raf
21 kinase, would be a good target for investigation. Raf kinase was understood to be involved in
22 processes leading to cell division and proliferation. The parties hypothesized that raf kinase
23 inhibitors, or chemical compounds that inhibit raf kinase, would prove effective in controlling
24 cancer cell growth. Using their expert knowledge of the Ras Pathway, Onyx scientists created
25 a unique assay, exclusive to the collaboration, that could test the raf-inhibitory activity of any
26 compound.

27 **ANSWER:** The German Bayer Entities admit (1) that Bayer and Onyx identified several
28 targets for investigation, one of which was raf kinase, (2) that raf kinase was understood to be
involved in cell division and proliferation processes, (3) that Bayer and Onyx hypothesized that
compounds inhibiting raf kinase could prove effective in inhibiting cancer cell growth, and
(4) that one of the many parts of the research, testing, and development of potential targeted
cancer therapies was a cell-based assay for testing raf-inhibitory activity that Onyx provided.
The German Bayer Entities are without knowledge or information sufficient to form a belief as

1 to the truth of the allegation that Onyx “created” the assay it provided or that the assay was
2 “unique,” and therefore deny that allegation. The German Bayer Entities deny any remaining
3 allegations not expressly admitted herein.

4 31. With the assay in hand and its own library of small molecule compounds in house,
5 Onyx began searching for a Ras Pathway inhibitor. This effort succeeded, and Onyx identified
6 an inhibitor, dubbed N34213. Although N34213 was too weak an inhibitor to develop as a
7 cancer treatment, the basic chemical structure of that compound provided the key information
8 that Bayer and Onyx used to create thousands of synthetic compounds for further evaluation.
9 As the number of synthesized compounds increased over the course of the collaboration, the
10 parties decided that Bayer would conduct initial tests on the synthesized compounds, using the
11 assay created by Onyx. Onyx thus conveyed the assay protocol to Bayer, along with various
12 purified reagents necessary to carry out the assay.

13 **ANSWER:** The German Bayer Entities admit (1) that Onyx conveyed an assay protocol
14 to Bayer for testing raf-inhibitory activity, (2) that Onyx identified a raf-inhibitor molecule that
15 lacked sufficient inhibitory activity to be a potential cancer therapy, and (3) that subsequently
16 Bayer synthesized thousands of different compounds in multiple research phases. From its
17 synthesis of additional compounds, Bayer identified additional unique raf-inhibitor compounds.
18 Through further Bayer research and optimization efforts on these new and unique Bayer-
19 identified compounds, Bayer eventually discovered and synthesized the compound that became
20 Nexavar®. The German Bayer Entities deny that the “basic chemical structure of that [Onyx
21 inhibitor] compound provided the key information” for Bayer’s subsequent research efforts. The
22 German Bayer Entities deny any remaining allegations not expressly admitted herein.

23 32. Bayer synthesized and ran initial tests on compounds. They discussed some of
24 these results with Onyx, and transferred some of these compounds to Onyx for further
25 evaluation. Following discussions with Onyx, Bayer also synthesized additional compounds
26 that were structural analogs of compounds that showed promising activity.

27 **ANSWER:** The German Bayer Entities admit (1) that Bayer synthesized compounds in
28 multiple phases and ran tests on those compounds for raf-inhibitory activity, (2) that, as part of
its research plan, Bayer synthesized some structural analogs to compounds that showed
promising activity, and (3) that Bayer reported and discussed its research plans and results with
Onyx. The German Bayer Entities deny any remaining allegations not expressly admitted
herein.

1 33. This collaborative process ultimately led the parties to their pioneering cancer drug
 2 sorafenib. Sorafenib was so effective at inhibiting raf kinase, in fact, that it satisfied the
 3 specified standard for inhibitory activity set forth in Exhibit D by a factor of more than 1000.
 4 Eventually, the parties learned that sorafenib inhibited other biological targets as well,
 5 rendering it a “multi-kinase” inhibitor.

6 **ANSWER:** The German Bayer Entities admit (1) that Bayer’s research efforts led to
 7 sorafenib, (2) that sorafenib satisfies the standards in Exhibit D of the Collaboration Agreement
 8 by a factor of more than 1000, and (3) that sorafenib is a multi-kinase inhibitor. The German
 9 Bayer Entities deny Onyx’s reference to sorafenib as “their pioneering cancer drug” to the extent
 10 this implies that Onyx jointly owns sorafenib. The German Bayer Entities deny any remaining
 11 allegations not expressly admitted herein.

12 34. Sorafenib was not the only compound discovered and recognized to have inhibitory
 13 activity under the collaboration. Bayer filed a patent application on January 13, 1999 (during
 14 the Research Term) that illustrates over 100 compounds (including sorafenib) that have raf-
 15 kinase inhibitory activity satisfying the standard specified in Exhibit D.

16 **ANSWER:** The German Bayer Entities admit that Bayer filed a provisional patent
 17 application on January 13, 1999 that disclosed specific examples, including sorafenib and a
 18 variety of possible analogues. Regorafenib was not one of the example compounds disclosed in
 19 the January 13, 1999 application; and the January 13, 1999 application does not disclose
 20 regorafenib’s raf kinase inhibitory activity. The German Bayer Entities further admit that the
 21 January 13, 1999 application states that the “compounds exemplified displayed IC₅₀s of between
 22 1 nm and 10µm.” The German Bayer Entities deny any remaining allegations not expressly
 23 admitted herein.

24 35. The January 13, 1999 patent application also shows that a sorafenib molecule can
 25 be modified at one particular location with minimal effect on its raf-kinase inhibitory activity.
 26 The chemical formula for sorafenib is illustrated below in Figure 1, with an arrow pointing to
 27 the position “2” on the central ring structure of the molecule. In sorafenib, that position has a
 28 hydrogen atom attached to the ring (per standard chemical drawing practice, the hydrogen is
 not shown). The January 13, 1999 application explicitly shows two substitutions at this
 position. In one case, a chlorine atom (Cl) replaces the hydrogen. In another case, a much
 larger, methyl group (CH₃), replaces the hydrogen. In both cases, the compounds were
 confirmed to have raf kinase inhibitory activity well within the specified standard in Exhibit D
 to the Collaboration Agreement.

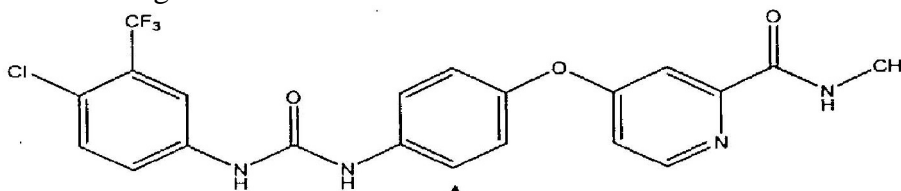


Figure 1: Sorafenib (indicating position “2”)

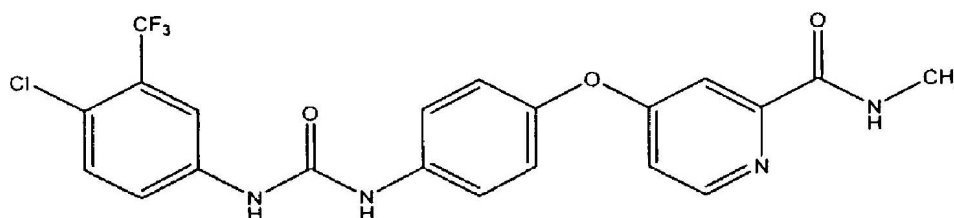
1 **ANSWER:** The German Bayer Entities admit (1) that figure 1 is the chemical formula
2 for sorafenib, (2) that the arrow in figure 1 points to a position on sorafenib where a hydrogen
3 atom is attached, and that standard chemical drawing practice omits displaying hydrogen atoms,
4 (3) that two of the compounds disclosed as specific examples in the January 13, 1999 patent
5 application are compounds that substitute a methyl group and a chlorine atom, respectively, at
6 the position indicated by the arrow in Figure 1, and (4) that the January 13, 1999 application
7 states that the “compounds exemplified displayed IC₅₀s of between 1 nm and 10µm.” The
8 German Bayer Entities deny (1) that the January 13, 1999 patent application discloses as an
9 example any compound that substitutes a fluorine atom at the position indicated by the arrow in
10 Figure 1, and (2) that the January 13, 1999 application shows that modification at the position
11 “2” indicated in Figure 1 could occur “with minimal effect on its raf-kinase inhibitory activity.”
12 The German Bayer Entities deny any remaining allegations not expressly admitted herein.

13 36. The illustrated compounds are not the only ones discussed and described in the
14 January 13, 1999 application. In text, the patent application explains that “halogens,” a class
15 of elements to which both fluorine and chlorine belong, can be substituted for one another in
16 the compound. The patent that ultimately issued from this application as Unites States Patent
17 No. 7,351,834 claims the chemical structures of sorafenib and its halogenated brethren, and
reports the raf kinase-inhibiting properties of the entire family. Accordingly, the raf kinase-
inhibiting properties of sorafenib, chloro-sorafenib and fluoro-sorafenib were recognized well
before the cutoff date for the recognition of Collaboration Compounds, January 31, 2000.

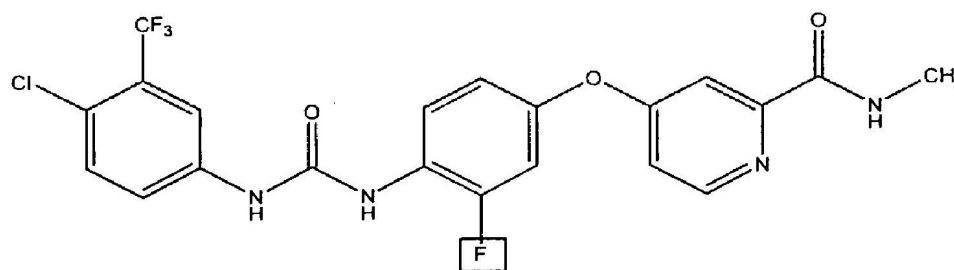
18 **ANSWER:** The German Bayer Entities admit that the January 13, 1999 patent
19 application and the issued patent U.S. Pat. No. 7,351,834 state (at column 4:21-25), “Suitable
20 halogen groups include F, Cl, Br, and/or I, from one to per-substitution (i.e. all H atoms on a
21 group replaced by a halogen atom) being possible where an alkyl group is substituted by a
22 halogen, mixed substitution of halogen atom types also being possible on a given moiety.” The
23 German Bayer Entities further admit that certain generic claims of the ‘834 patent could be read
24 to cover a variety of compound structures including the structure of sorafenib and regorafenib.
25 The German Bayer Entities deny (1) that the January 13, 1999 application “reports the raf
26 kinase-inhibiting properties of the entire family,” (2) that the regorafenib molecule was disclosed
27 in the January 13, 1999 application, (3) that regorafenib was synthesized or tested prior to
28 January 31, 2000, (4) that the raf-kinase inhibiting properties of regorafenib were “recognized”

1 before January 31, 2000, and (5) that there are any compounds known as “chloro-sorafenib” or
 2 “fluoro-sorafenib.” The German Bayer Entities deny any remaining allegations not expressly
 3 admitted herein.

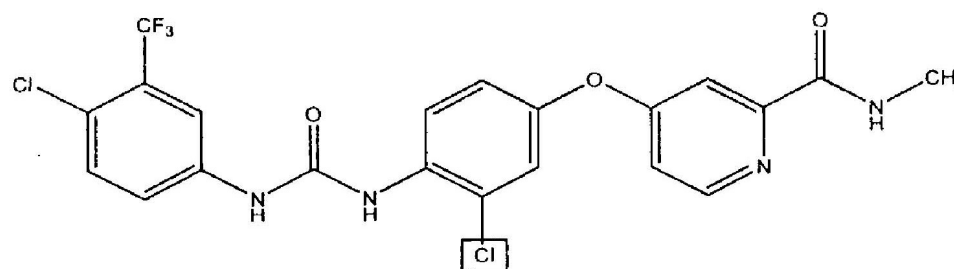
4 37. The chemical formulas for sorafenib and the fraternal twins chloro- and fluoro-
 5 sorafenib, are illustrated below in Figures 2, 3 and 4, respectively.



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10 **Figure 2: Sorafenib**



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15 **Figure 3: Fluoro-Sorafenib**



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21 **Figure 4: Chloro-Sorafenib**

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23 **ANSWER:** The German Bayer Entities deny that there are compounds known as
 24 “chloro-sorafenib” or “fluoro-sorafenib.” The German Bayer Entities admit (1) that Figure 2 is
 25 the chemical formula for sorafenib, (2) that Figure 3 is the chemical structure of regorafenib,
 26 and (3) that figure 4 is a chemical formula of a chlorine-substituted compound corresponding to
 27 example number 49 disclosed in the ‘834 patent at column 73-74. The German Bayer Entities
 28 deny any remaining allegations not expressly admitted herein.

1 38. The parties fully understood, well before the cutoff date for the recognition of
2 Collaboration Compounds, January 31, 2000, that sorafenib and its halogenated twins would
3 exhibit raf kinase-inhibitory activity well within the specified standard. This is no surprise
4 given that sorafenib and its halogenated brethren are, chemically speaking, nearly identical.

4 **ANSWER:** The German Bayer Entities admit (1) that sorafenib satisfied Exhibit D's
5 inhibitory activity standard for the primary assay prior to January 31, 2000, (2) that the chlorine-
6 substituted compound in Figure 4 was disclosed as a specific example in the January 13, 1999
7 patent application, and (3) that the January 13, 1999 application states that the "compounds
8 exemplified displayed IC₅₀s of between 1 nm and 10µm." The German Bayer Entities deny
9 (1) that regorafenib was synthesized or tested prior to January 31, 2000, (2) that the raf-kinase
10 inhibiting properties of regorafenib were "recognized" before January 31, 2000, and (3) that the
11 compounds in figures 2-4 are "chemically speaking, nearly identical." The German Bayer
12 Entities deny any remaining allegations not expressly admitted herein.

13 39. Ultimately, the parties chose to develop sorafenib and began clinical trials in late
14 2000. In accordance with the Collaboration Agreement, the parties co-funded the clinical
15 trials, and Onyx made substantial payments to Bayer, which otherwise funded and managed
16 the trials. The trials ultimately proved successful, leading to FDA approval in 2005 and 2007
17 for the marketing of sorafenib for treating patients with kidney and liver cancer, respectively.

16 **ANSWER:** The German Bayer Entities admit (1) that the parties ultimately decided to
17 focus development efforts on sorafenib and (2) that the parties co-funded the clinical trials of
18 sorafenib. The German Bayer Entities deny that Bayer "otherwise funded and managed the
19 trials." The German Bayer Entities further admit that Bayer managed trials relating to kidney
20 and liver cancer, which ultimately resulted in FDA approval, but states that Onyx managed
21 clinical trials relating to melanoma, which failed to secure FDA approval. The German Bayer
22 Entities deny any remaining allegations not expressly admitted herein.

23 40. Meanwhile, as the jointly-funded clinical trials progressed and Bayer began to
24 realize that sorafenib was destined for success, defendants secretly launched a plan to displace
25 it. In or around 2003, Bayer, along with other subsidiaries of Bayer AG, surreptitiously began
26 filing patent applications directed to fluoro-sorafenib. Fluoro-sorafenib was not a compound
27 that Bayer had recently discovered or, indeed, that involved any new discovery effort by Bayer
28 or its Affiliates following the end of the Research Term in early 1999. On the contrary, Onyx
and Bayer had explicitly identified fluoro-sorafenib in 1998. Nonetheless, neither Bayer nor
its Affiliates disclosed the patent filings for fluoro-sorafenib to Onyx, which remained unaware
of these actions. Then, in or around 2005, Bayer and its Affiliates announced clinical trials on
a cancer drug they referred to as DAST. But the announcement omitted the chemical formula

1 for DAST, leaving Onyx unaware that DAST was a code name for fluoro-sorafenib. Nor did
2 defendants ever notify the Joint Development Committee that they were beginning clinical
3 trials on a compound that arose from the collaboration. Defendants have given Onyx no
4 chance to review and comment on the clinical trial submissions, much less to participate in the
5 trials.

6 **ANSWER:** The German Bayer Entities deny that there is a compound known as “fluoro-
7 sorafenib.” The German Bayer Entities deny that Bayer “secretly launched a plan to displace”
8 sorafenib. The German Bayer Entities admit (1) that Bayer filed patent applications relating to
9 regorafenib beginning in the summer of 2003, (2) that Bayer did not disclose such patent
10 applications to Onyx, as it was not required to do so, (3) that Bayer announced its regorafenib
11 clinical trials in or around 2005, and, per standard procedure, did not at that time disclose the
12 chemical formula of regorafenib in these announcements, and (4) that Bayer did not, nor was it
13 required to, notify the JRDC of its clinical trials on regorafenib, nor ask Onyx or the JRDC to
14 comment on, or participate in, the clinical trials on regorafenib. The German Bayer Entities deny
15 any remaining allegations not expressly admitted herein.

16 41. In or around April 2007, Bayer Affiliates made a presentation to Onyx of various
17 cancer compounds they were investigating. But despite the fact that clinical trials for fluoro-
18 sorafenib had been initiated in 2005 and were ongoing, the executives and employees attending
19 the April 2007 meeting failed to disclose to Onyx that Bayer Affiliates were developing fluoro-
20 sorafenib.

21 **ANSWER:** The German Bayer Entities deny that there is a compound known as “fluoro-
22 sorafenib.” The German Bayer Entities admit (1) that beginning in around April 2007, Bayer
23 HealthCare, LLC began discussions with Onyx about potential business arrangements relating to
24 various new, Bayer-developed compounds, including regorafenib and (2) that Bayer HealthCare,
25 LLC did not, at that time, specifically disclose the chemical structure of any of its newly
26 developed products, including regorafenib. The German Bayer Entities deny any remaining
27 allegations not expressly admitted herein.

28 42. Bayer Affiliates then began publishing their research and discovery efforts with
DAST. In June 2007, Bayer HealthCare AG and Bayer Schering Pharma announced DAST as
being one of their development candidates for cancer therapy (again without revealing that it
was fluoro-sorafenib).

1 **ANSWER:** The German Bayer Entities deny that there is a compound known as “fluoro-
2 sorafenib.” The German Bayer Entities admit that Bayer HealthCare, LLC or one of its
3 predecessors began publishing articles relating to regorafenib, and that in and around
4 approximately June 2007 it announced regorafenib as a development candidate for targeted
5 cancer therapy. The German Bayer Entities deny any remaining allegations not expressly
6 admitted herein.

7 43. In early 2009, as the details of the DAST clinical trials became better known, Onyx
8 asked Bayer Affiliates to reveal the chemical structure of DAST. Initially, they denied that
9 DAST was a Collaboration Compound, but refused to reveal more. Finally, on March 31,
10 2009, an executive of Bayer HealthCare Pharmaceuticals, Inc. (an Affiliate of Bayer),
11 admitted that the chemical structure of DAST was, indeed, fluoro-sorafenib. According to the
12 executive, because Bayer had postponed testing of fluoro-sorafenib until after January 31,
13 2002, Bayer had not “recognized” that the compound satisfied the specified standard for ras
14 inhibitory activity by that date. Accordingly, the executive declared, Bayer and its Affiliates
15 are entitled to develop and market fluoro-sorafenib “unrestrained” by Onyx.

16 **ANSWER:** The German Bayer Entities deny that there is a compound known as “fluoro-
17 sorafenib.” The German Bayer Entities admit that on March 20, 2009, Onyx wrote a letter to
18 Bayer HealthCare LLC asking it to confirm that regorafenib had the chemical formula listed
19 above in figure 3 and demanding that Bayer acknowledge regorafenib as a “Collaboration
20 Compound” or “Post-Collaboration Compound” under the Collaboration Agreement. The
21 German Bayer Entities further admit that Bayer HealthCare, LLC confirmed the chemical
22 structure of regorafenib, informed Onyx that regorafenib is not a “Collaboration Compound” or
23 “Post-Collaboration Compound,” and informed Onyx that Onyx has no rights in regorafenib
24 under the Collaboration Agreement. The German Bayer Entities deny any remaining allegations
25 not expressly admitted herein.

26 44. On April 15, 2009, Onyx proposed a meeting of executives to negotiate in good
27 faith toward a resolution of the parties’ dispute regarding whether fluoro-sorafenib is covered
28 under the Agreement. The executives met, but the parties were unable to resolve the dispute.

1 **ANSWER:** The German Bayer Entities deny that there is a compound known as “fluoro-
2 sorafenib.” The German Bayer Entities admit (1) that on April 15, 2009, Onyx sent Bayer
3 HealthCare, LLC a letter as formal notice that Onyx was invoking the dispute resolution
4 provisions under the Collaboration Agreement relating to Onyx’s position on regorafenib, and

1 (2) that Bayer HealthCare, LLC and Onyx executives met, but were unable to resolve the
 2 situation. The German Bayer Entities deny any remaining allegations not expressly admitted
 3 herein.

4 45. In May 2009, Bayer HealthCare Pharmaceuticals, Inc., which is responsible for a
 5 clinical trial of fluoro-sorafenib in the U.S., reported on the results of a phase II trial in kidney
 6 cancer and announced its intention to move forward with a phase III trial. Onyx is informed
 7 and believes that if fluoro-sorafenib secures FDA approval, Bayer and its Affiliates intend to
 8 market Onyx and Bayer's joint discovery—fluoro-sorafenib—as a direct competitor to the
 9 parties' joint product, sorafenib, thereby reaping all of the benefits of the parties' collaboration
 10 without sharing the rewards.

11 **ANSWER:** The German Bayer Entities deny that there is a compound known as “fluoro-
 12 sorafenib.” The German Bayer Entities admit that Bayer HealthCare Pharmaceuticals Inc.
 13 supported a phase II trial for regorafenib in kidney cancer, the results of which were reported in
 14 May 2009 at an industry conference. The German Bayer Entities deny any remaining allegations
 15 not expressly admitted herein.

16 46. Onyx is informed and believes, and based thereon alleges, that its damages exceed
 17 the amount of seventy-five thousand dollars (\$75,000), exclusive of costs and interest.

18 **ANSWER:** Denied.

19 **First Claim For Relief**
 20 **(Breach Of Contract)**

21 47. Onyx re-alleges and incorporates by reference paragraphs 1-46, inclusive, as though
 22 fully set forth herein.

23 **ANSWER:** The German Bayer Entities refer to and incorporates herein by reference
 24 their answers to all the foregoing allegations of paragraphs 1-46 inclusive as if fully set forth
 25 herein.

26 48. Onyx performed all of the terms and conditions of the parties' Collaboration
 27 Agreement, as amended.

28 **ANSWER:** The German Bayer Entities are without knowledge or information sufficient
 to form a belief as to the truth of the allegations in this paragraph and therefore deny that
 allegation.

49. Defendants breached the Collaboration Agreement by, among other things:

- 1 (a) failing to disclose their research and development plans for fluoro-sorafenib;
- 2 (b) failing to treat fluoro-sorafenib as a Collaboration Compound; and
- 3 (c) undermining the value of sorafenib through their development of fluoro-sorafenib.

4 **ANSWER:** Denied.

5 50. Defendants further breached their obligations under the Collaboration Agreement
6 and the Letter Agreement to cause their Affiliates to comply with the provisions of the
7 Collaboration Agreement.

8 **ANSWER:** Denied.

9 51. Alternatively, in the event a compound must be tested to be recognized under the
10 Collaboration Agreement as a Collaboration Compound, defendants breached the
11 Collaboration Agreement if (as Bayer claims) they deferred testing of fluoro-sorafenib until
12 after January 31, 2000.

13 **ANSWER:** Denied.

14 52. As a proximate result of defendants' breach of the Collaboration Agreement and the
15 Letter Agreement, Onyx has sustained, continues to sustain, and will sustain damages,
16 including, but not limited to lost sales, damage to goodwill, and the inability to profit from
17 sales of fluoro-sorafenib. In addition, defendants were, are, and will be unjustly enriched
18 through their appropriation for themselves of the entire value of fluoro-sorafenib.

19 **ANSWER:** Denied.

20 **Second Claim For Relief**
21 **(Breach Of Implied Covenant Of Good Faith And Fair Dealing)**

22 53. Onyx re-alleges and incorporates by reference paragraphs 1-46, inclusive, as though
23 fully set forth herein.

24 **ANSWER:** The German Bayer Entities refer to and incorporates herein by reference
25 their answers to all the foregoing allegations of paragraphs 1-52 inclusive as if fully set forth
26 herein.

27 54. A covenant to deal fairly and act in good faith is implied in the Onyx/Bayer
28 Collaboration Agreement and later amendments.

ANSWER: Denied.

55. Defendants breached these covenants by, among other things:

- 27 (a) failing to disclose their research and development plans for fluoro-sorafenib;
- 28 (b) failing to treat fluoro-sorafenib as a Collaboration Compound; and

1 (c) undermining the value of sorafenib through their development of
2 fluoro-sorafenib.

3 **ANSWER:** Denied.

4 56. Defendants further breached these covenants by failing to satisfy their obligations
5 under the Collaboration Agreement and the Letter Agreement to cause their Affiliates to
6 comply with the provisions of the Collaboration Agreement.

6 **ANSWER:** Denied.

7 57. Alternatively, in the event a compound must be tested to be recognized under the
8 Collaboration Agreement as a Collaboration Compound, Bayer breached these covenants if (as
9 Bayer claims) it deferred testing until after January 31, 2000.

9 **ANSWER:** Denied.

10 58. As a proximate result of defendants' breach of the Collaboration Agreement and the
11 Letter Agreement, Onyx has sustained, continues to sustain, and will sustain damages,
12 including, but not limited to lost sales, damage to goodwill, and the inability to profit from
13 sales of fluoro-sorafenib. In addition, defendants were, are, and will be unjustly enriched
14 through their appropriation for themselves of the entire value of fluoro-sorafenib.

14 **ANSWER:** Denied.

15 **Third Claim For Relief**
16 **(Breach of Fiduciary Duty)**

16 59. Onyx re-alleges and incorporates by reference paragraphs 1-46, inclusive, as though
17 fully set forth herein.

18 **ANSWER:** The German Bayer Entities refer to and incorporates herein by reference
19 their answers to all the foregoing allegations of paragraphs 1-58 inclusive as if fully set forth
20 herein.

21 60. The Collaboration Agreement created a legal joint venture. As collaborators and
22 joint venturers, defendants owed Onyx the highest degree of fiduciary duty, including but not
23 limited to the duty of loyalty and honesty.

23 **ANSWER:** Denied.

24 61. Defendants breached their fiduciary duty to Onyx by, among other things:

- 25 (a) failing to disclose their research and development plans for fluoro-
26 sorafenib;
27 (b) failing to treat fluoro-sorafenib as a Collaboration Compound; and
28 (c) undermining the value of sorafenib through their development of fluoro-
sorafenib.

28 **ANSWER:** Denied.

1 62. Alternatively, in the event a compound must be tested to be recognized under the
2 Collaboration Agreement as a Collaboration Compound, Bayer Corporation breached its
fiduciary duty if (as Bayer claims) it deferred testing until after January 31, 2000.

3 **ANSWER:** Denied.

4 63. As a proximate result of defendants' breach of the Collaboration Agreement and the
5 Letter Agreement, Onyx has sustained, continues to sustain, and will sustain damages,
6 including, but not limited to lost sales, damage to goodwill, and the inability to profit from
7 sales of fluoro-sorafenib. In addition, defendants were, are, and will be unjustly enriched
through their appropriation for themselves of the entire value of fluoro-sorafenib.

8 **ANSWER:** Denied.

9 64. Defendants' conduct in breaching their fiduciary duties was malicious, oppressive,
fraudulent, and otherwise entitles Onyx to an award of exemplary and punitive damages.

10 **ANSWER:** Denied.

11 **Fourth Claim For Relief**
12 **(Declaratory Relief)**

13 65. Onyx re-alleges and incorporates by reference paragraphs 1-46, inclusive, as though
14 fully set forth herein.

15 **ANSWER:** The German Bayer Entities refer to and incorporates herein by reference
16 their answers to all the foregoing allegations of paragraphs 1-64 inclusive as if fully set forth
17 herein.

18 66. Onyx desires a declaration regarding its rights to fluoro-sorafenib.

19 **ANSWER:** The German Bayer Entities deny that there is a compound known as "fluoro-
20 sorafenib." The German Bayer Entities are without knowledge or information sufficient to form
21 a belief as to the truth of the remaining allegations in this paragraph and therefore deny that
22 allegation.

23 67. An actual controversy exists between Onyx and the defendants relating to their
24 respective rights to fluoro-sorafenib. In particular, there is a dispute regarding whether fluoro-
25 sorafenib is a Collaboration Compound. Defendants contend that it is not, and that they
26 therefore may independently develop fluoro-sorafenib and eventually sell it without sharing
profits with Onyx. Onyx contends that fluoro-sorafenib is a Collaboration Compound,
entitling Onyx to participate equally in co-development and to share equally in the profits from
any future sales.

27 **ANSWER:** The German Bayer Entities deny that there is a compound known as "fluoro-
28 sorafenib." The German Bayer Entities admit that this First Amended Complaint describes an

1 actual controversy between Onyx and Bayer with respect to regorafenib in the manner alleged in
2 this paragraph. The German Bayer Entities deny any remaining allegations not expressly
3 admitted herein.

4 68. In order to resolve this dispute, Onyx requests that the Court declare the rights and
5 obligations of Onyx and Bayer regarding fluoro-sorafenib. Specifically, Onyx requests a
6 declaration that fluoro-sorafenib is a Collaboration Compound, that Onyx is entitled to
7 participate equally in co-development, and that Onyx should receive a 50% share in the profits
8 (as defined in the Collaboration Agreement) from any future sales of fluoro-sorafenib.

9 **ANSWER:** Denied.

10 **RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF**

11 The German Bayer Entities deny that Onyx is entitled to the judgment it seeks in
12 paragraphs 1-9 of its Prayer For Relief. Onyx's First Amended Complaint should be dismissed,
13 and its prayer for relief should be denied in its entirety, with prejudice.

14 **AFFIRMATIVE DEFENSES**

15 Further answering the First Amended Complaint and as additional defenses thereto, the
16 German Bayer Entities assert the following affirmative defenses, without assuming any burden
17 of proof it would not otherwise bear under applicable law.

18 **FAILURE TO STATE A CLAIM**

19 1. The First Amended Complaint fails to state a claim upon which relief can be
20 granted.

21 **STATUTE OF LIMITATIONS**

22 2. Onyx's claims are barred in whole or in part by relevant statutes of limitations.

23 **ESTOPPEL, WAIVER, AND/OR LACHES**

24 3. Onyx's claims are barred in whole or in part by the doctrines of Estoppel, Waiver,
25 and/or Laches.

26 **AGREEMENT, RATIFICATION, AND ACQUIESCENCE**

27 4. Onyx's claims are barred in whole or in part by its agreement to, ratification of,
28 and/or acquiescence to, the acts and omissions about which it now complains.

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FAILURE OF CONDITIONS PRECEDENT

5. Onyx’s claims are barred in whole or in part by the failure of conditions precedent to Bayer’s performance.

UNCLEAN HANDS

6. Onyx’s claims are barred in whole or in part by the doctrine of unclean hands.

RESERVATION OF RIGHTS

7. The German Bayer Entities reserve the right to assert any and all additional affirmative defenses that may be determined during the course of discovery.

JURY DEMAND

The German Bayer Entities respectfully request that a jury try the issues in this matter.

Dated: August 12, 2009

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically. As such, this document was served on all counsel who are deemed to have consented to electronic service. Pursuant to Fed. R. Civ. P. 5(d) all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this 12th day of August, 2009.

BY: /s/ LAWRENCE R. KATZIN

LAWRENCE R. KATZIN