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10
11 **UNITED STATES DISTRICT COURT**
12 **SOUTHERN DISTRICT OF CALIFORNIA**

13
14 SYNBIAS PHARMA,
15
PLAINTIFF,
16
V.
17 SOLUX CORPORATION,
18
DEFENDANT.

Case No: '11CV3035 H JMA
**COMPLAINT FOR DECLARATORY
JUDGMENT**

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20
21 **Introduction**

22 1. This is an action for a declaratory judgment of invalidity, non-infringement,
23 and unenforceability by Plaintiff Synbias Pharma (“Plaintiff” or “Synbias”) of several
24 United States Patents which were issued to Defendant Solux Corporation (“Defendant” or
25 “Solux”) as the named Assignee.

26 2. Solux has threatened patent infringement action against several of
27 Synbias’s distributors, including Transo-Pharm USA LLC, whose United States
28 headquarters are located in Blue Bell, Pennsylvania, its German affiliate Transo-Pharm

1 Handels-GmbH (Transo-Pharm USA LLC and Transo-Pharm Handels-GmbH are
2 collectively referred to herein as “Transo-Pharm”), and Chemex Hamburg GmbH
3 (“Chemex”) also located in Germany, based on importation and sale of Synbias’s
4 products.

5 **The Parties**

6 3. Synbias is a corporation duly organized and existing under the laws of
7 Ukraine, with its principal place of business in the city of Donetsk, Ukraine. Synbias
8 develops and manufactures active pharmaceutical ingredients (“APIs”) for cancer therapy
9 at its facilities located in Ukraine.

10 4. Upon information and belief, Defendant Solux is a corporation duly
11 organized and existing under the laws of the state of California with its principal place of
12 business at 4455 Morena Boulevard, Suite 214, San Diego, CA 92117.

13 **The Nature of the Action**

14 5. Under 35 U.S.C. §§ 101, et seq., and in equity, this is an action for
15 Declaratory Judgment of invalidity, non-infringement, and/or unenforceability as to three
16 patents, all of which were issued to Defendant as the named Assignee.¹ The patents at
17 issue are: (A) U.S. Patent No. 7,485,707, entitled “Thermally Stable Crystalline
18 Epirubicin Hydrochloride and Method of Making The Same” (“the ‘707 patent”); (B)
19 U.S. Patent No. 7,388,083, entitled “Epimerization of 4'-C Bond and Modification of 14-
20 CH₃-(CO)-Fragment in Anthracyclin Antibiotics” (“the ‘083 patent”); and (C) U.S.
21 Patent No. 7,053,191, entitled “Method of Preparing 4-R-Substituted 4-
22 Demethoxydaunorubicin” (“the ‘191 patent”) (collectively referred to herein as the
23 “Patents-In-Suit”). True and correct copies of the Patents-In-Suit are attached as Exhibits
24 A-C, respectively.

25
26 ¹ The patents were actually fraudulently obtained by Solux and instead belong to Synbias.
27 In a separate proceeding, Synbias is seeking redress for these misdeeds by Solux. *See*
28 *Synbias Pharma v. Solux Corp., et al.*, No. 37-2011-00092961-CU-BT-CTL (Cal. Super.
Ct., County of San Diego, Central Dist.).

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Jurisdiction

6. This action arises under the laws of the United States, specifically Title 35 of the United States Code. This Court therefore has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Further, because this action presents an actual case or controversy with respect to the invalidity, non-infringement and/or unenforceability of the Patents-In-Suit, the Court may grant the declaratory relief sought pursuant to 28 U.S.C. §§ 2201 and 2202.

Actual Case or Controversy

7. Since its inception in the mid 1990s, Synbias has been developing and manufacturing anthracycline antibiotics, a class of drugs used in cancer chemotherapy. These compounds are used to treat a wide range of cancers, including leukemias, lymphomas, and breast, uterine, ovarian, and lung cancers.

8. Beginning in late 1998 or early 1999, Dmitry Itkin (“D. Itkin”) agreed to act as Synbias’s American agent. D. Itkin agreed that, among other things, he would, at Synbias’s direction and acting as Synbias’s agent, buy equipment and products for Synbias in the United States and elsewhere, sell Synbias’s products, process payments from Synbias’s customers, and hold and manage money and property on Synbias’s behalf. D. Itkin incorporated Solux in 2002 to accomplish these services for Synbias.

9. During his agency relationship with Synbias, D. Itkin, through Solux, concocted a scheme to obtain control of the patent rights to various Synbias inventions. D. Itkin informed Synbias that Solux should be named as the patent applicant and assignee of Synbias’s inventions, and D. Itkin’s brother, Aleksandr Itkin (“A. Itkin”), should be named as an inventor.

10. A. Itkin contributed nothing to any of the inventions claimed in the Patents-in-Suit, however. He did not participate in the inventive process in any way, did not conceive of the inventions or any aspect of them, aid in their conception, contribute to the inventive thought, make any inventive contribution, or reduce the inventions to practice. His only role regarding the patents was merely to assist Synbias and the Synbias

1 inventors (Victor Matvienko, Alexey Matvyeyev and Alexander Zabudkin) with drafting
2 the applications for the Patents-in-Suit, communicating with patent counsel regarding the
3 Patents-in-Suit, the patent applications and the prosecution process for the Patents,
4 including forwarding requests for information and status updates regarding the
5 application process to Synbias. A. Itkin therefore knowingly filed false declarations with
6 the U.S. Patent Office in connection with each Patent-in-Suit in which he claimed under
7 oath to be a co-inventor of the inventions claimed in the patent applications.

8 11. D. Itkin falsely represented to the Synbias inventors (Matvienko,
9 Matvyeyev and Zabudkin) that taking these steps of naming A. Itkin as an inventor and
10 assigning the inventions to Solux would facilitate faster and more certain patenting of the
11 inventions in the United States and in other countries because Synbias was not an
12 American company and was not located in the United States, and because the inventors
13 were located overseas and were not U.S. citizens. The Itkins also represented to the
14 Synbias inventors that they had to execute assignments of their right to the inventions,
15 and all patent applications and patents covering the inventions, to Solux. Solux, D. Itkin,
16 and A. Itkin agreed to use the Patents-In-Suit solely as instructed by Synbias, not to use
17 the Patents-In-Suit to advance their own interest or to Synbias's detriment, and that they
18 would return the interest and right to the patents and patent applications relating to the
19 Patents-In-Suit to Synbias when the agency relationship terminated. The Itkins falsely
20 assured the Synbias inventors that this was proper under United States law and procedure.

21 12. However, when the agency relationship terminated in 2010, Solux and the
22 Itkins refused to return the interest and right to the Patents-In-Suit, and the Itkins have
23 sought to use the Patents-In-Suit solely to advance their own interests. The Itkins began
24 an intentional and purposeful campaign of interfering with Synbias's business in the
25 United States and around the world, including by threatening Synbias's business partners
26 with allegations of infringement of these invalid and unenforceable Patents-in-Suit.

27 13. Transo-Pharm and Chemex purchase APIs from Synbias, including
28 anthracyclines epirubicin and idarubicin. Transo-Pharm and Chemex then resell these

1 products, including import into and sale of the products in the United States. Synbias
2 knew Transo-Pharm and Chemex would import into and sell these products in the United
3 States.

4 14. On July 28, 2010, D. Itkin sent an email to Alexander Lipowitsch of
5 Transo-Pharm, threatening Transo-Pharm with infringement of the Patents-In-Suit. D.
6 Itkin stated in this email: “I want to make sure that the possible hostile transfer of the
7 intellectual property and further legal action by Solux Corporation will not be a shocking
8 surprise. These actions will create irreversible consequences for distribution of APIs
9 [Active Pharmaceutical Ingredients] by Transopharma and Chemex in US and EU and
10 other covered parts of the world.” A true and correct copy of this email is attached as
11 Exhibit D.

12 15. On September 17, 2010, the Vista IP Law Group, patent counsel claiming
13 to represent Solux, sent another correspondence to Transo-Pharm and Chemex
14 threatening patent infringement based on their purchase and resale of Synbias’s APIs. In
15 this September 17 letter, the Vista IP Law Group stated: “We write to you to advise you
16 of Solux’s intellectual property rights covering the APIs produced by Synbias and any
17 formulations made using the APIs, and to demand damages for all past infringing
18 activities and that each of Transo-Pharm and Chemex cease and desist from all activities
19 that are in violation of Solux’s significant patent rights.” A true and correct copy of this
20 letter is attached as Exhibit E.

21 16. On September 30, 2010, the Vista IP Law Group sent further
22 correspondence on Solux’s behalf to counsel for Transo-Pharm and Chemex. The
23 September 30 letter again alleged that Transo-Pharm and Chemex infringed the Patents-
24 In-Suit by importing and selling Synbias’s products. The letter stated, “Synbias has
25 absolutely NO rights in or to the intellectual property relating to the accused products, all
26 of which have been assigned to Solux.” A true and correct copy of this letter is attached
27 as Exhibit F.

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1 17. Synbias and Transo-Pharm/Chemex are parties to a supply agreement under
2 which Synbias is required to supply Transo-Pharm/Chemex with APIs, including
3 epirubicin and idarubicin. The agreement contains a provision stating that it shall be
4 interpreted and enforced in accordance with the laws of Germany. Synbias and Transo-
5 Pharm/Chemex have also entered into an agreement under which Synbias is obligated to
6 indemnify Transo-Pharm and Chemex from infringement liability to Solux.

7 18. There is also a controversy between Synbias and Solux as to whether
8 Synbias induced infringement based on Solux's allegations that Transo-Pharm and
9 Chemex infringed the Patents-In-Suit because, among other things, the assertions made in
10 the above-referenced letters and other correspondence include an implicit assertion of
11 induced infringement by Synbias.

12 19. Synbias desires to make and sell its anthracycline antibiotics free from the
13 specter of Solux's allegations of infringement of the Patents-In-Suit.

14 20. Therefore, an actual case or controversy exists between Solux and Synbias
15 with respect to the invalidity, unenforceability and non-infringement of the Patents-In-
16 Suit. Accordingly, Synbias reasonably believes that, under all the circumstances, there is
17 a substantial controversy between Synbias and Solux of sufficient immediacy and reality
18 to warrant the issuance of a declaratory judgment.

19 **Count I**

20 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,485,707**

21 21. Synbias repeats and realleges the allegations contained in the preceding
22 paragraphs 1-20, inclusive, as if fully set forth herein.

23 22. On February 3, 2009, the '707 patent was issued. A copy of the '707 patent
24 is attached as Exhibit A.

25 23. The named inventors of the '707 patent are Victor Matvienko, Alexey
26 Matvyeyev, Alexander Zabudkin, and A. Itkin.

27 24. Solux purports to own the '707 patent.

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1 25. Synbias's products and the processes used to make Synbias's products,
2 including the APIs epirubicin hydrochloride and idarubicin hydrochloride, do not infringe
3 the claims of the '707 patent. For example, Synbias's epirubicin hydrochloride does not
4 have the powder X-Ray diffraction pattern presented in the table in claim 1, and in
5 particular Synbias's epirubicin hydrochloride lacks a peak at diffraction angle 77.815,
6 which appears in the table in claim 1 as the highest intensity peak. As another example,
7 Synbias's epirubicin hydrochloride does not infringe claim 2 because it does not have a
8 melting point of approximately 207° C. As another example, Synbias's process for
9 making epirubicin hydrochloride does not infringe claims 3-8 because Synbias's process
10 does not yield the epirubicin hydrochloride of claim 1.

11 26. As a consequence of the foregoing, there is an actual and justiciable
12 controversy between Synbias and Solux over the non-infringement of the '707 patent,
13 with respect to which Synbias is entitled to a declaratory judgment in its favor.

14 **Count II**

15 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,388,083**

16 27. Synbias repeats and realleges the allegations contained in the preceding
17 paragraphs 1-26, inclusive, as if fully set forth herein.

18 28. On June 17, 2008, the '083 patent was issued. A copy of the '083 patent is
19 attached as Exhibit B.

20 29. The named inventors of the '083 patent are Victor Matvienko, Alexey
21 Matvyeyev, Alexander Zabudkin, and A. Itkin.

22 30. Solux purports to own the '083 patent.

23 31. Synbias's products and the processes used to make Synbias's products,
24 including the APIs epirubicin hydrochloride and idarubicin hydrochloride, do not infringe
25 the claims of the '083 patent. For example, Synbias's process for making epirubicin
26 hydrochloride and idarubicin hydrochloride does not use step (a) of claim 1, including
27 "with AcX activated DMSO in aprotic solvent."
28 ///

1 32. Synbias also does not infringe claims 1 and 2 because, for example, they
2 are methods for producing 4'-keto-N-Trifluoroacetyl-4-R₁ daunorubicin and N-
3 Trifluoroacetyl-4'-epi-4-R₁ daunorubicin, respectively, not epirubicin hydrochloride or
4 idarubicin hydrochloride. Synbias also does not infringe claim 3, for example, because it
5 is a method for producing an anthracyclin having a formula represented by Formula (1),
6 wherein R₂ = Hal, which is not epirubicin. For epirubicin, R₂ is hydroxyl, not halogen, at
7 C14. Any importation of epirubicin hydrochloride or idarubicin hydrochloride into the
8 United States does not infringe method claims 1-3 under 35 U.S.C. § 271(g).

9 33. As a consequence of the foregoing, there is an actual and justiciable
10 controversy between Synbias and Solux over the non-infringement of the '083 patent,
11 with respect to which Synbias is entitled to a declaratory judgment in its favor.

12 **Count III**

13 **Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,053,191**

14 34. Synbias repeats and realleges the allegations contained in the preceding
15 paragraphs 1-33, inclusive, as if fully set forth herein.

16 35. On May 30, 2006, the '191 patent was issued. A copy of the '191 patent is
17 attached as Exhibit C.

18 36. The named inventors of the '191 patent are Victor Matvienko, Alexey
19 Matvyeyev, Alexander Zabudkin, and A. Itkin.

20 37. Solux purports to own the '191 patent.

21 38. Synbias's products and the processes used to make Synbias's products,
22 including the APIs epirubicin hydrochloride and idarubicin hydrochloride, do not infringe
23 one or more claims of the '191 patent.

24 39. As a consequence of the foregoing, there is an actual and justiciable
25 controversy between Synbias and Solux over the non-infringement of the '191 patent,
26 with respect to which Synbias is entitled to a declaratory judgment in its favor.

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Count IV

Declaratory Judgment of Invalidity of the ‘707 Patent

40. Synbias repeats and realleges the allegations contained in the preceding paragraphs 1-39, inclusive, as if fully set forth herein.

41. The ‘707 patent is invalid under the provisions of 35 U.S.C. §§ 101, et seq.

42. As a consequence of the foregoing, there is an actual and justiciable controversy between Synbias and Solux over the invalidity of the ‘707 patent, with respect to which Synbias is entitled to a declaratory judgment in its favor.

43. For example, to the extent enabled, claims 3-8 are invalid as obvious in view of prior art, including U.S. Patent No. 6,376,469.

44. For example, all the claims are also invalid as not enabled and lack written description support under 35 U.S.C. § 112 and fail to meet the utility requirement of 35 U.S.C. § 101, at least because the specification fails to disclose at least one step necessary for crystallizing the epirubicin hydrochloride. The missing step concerns the removal of water during the crystallization process. Without disclosing this step, a person of skill in the art would not have been able to make and use the claimed invention without undue experimentation. The six Examples disclosed in the specification of the ‘707 patent are inoperable – i.e., the disclosed methods do not yield epirubicin crystals as claimed. As another example, even were one of skill in the art able to divine a way to make the disclosure in the specification work, nothing in the specification teaches how to make epirubicin hydrochloride with the X-Ray diffraction pattern presented in the table in claim 1.

45. All the claims are also invalid as indefinite under 35 U.S.C. § 112 based on incorrect X-ray data in claim 1. Because the X-ray data is incorrect, a person of ordinary skill in the art cannot determine what crystalline form of epirubicin hydrochloride is claimed.

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1 46. All the claims are also invalid under 35 U.S.C. § 102(f) for failure to list the
2 correct inventors on the '707 patent. A. Itkin was not an inventor, having made no
3 contribution to the conception or reduction to practice of any claim of the '707 patent.

4 47. All the claims, to the extent enabled, are also invalid under 35 U.S.C.
5 § 102(b) based on prior use and sales of epirubicin in the United States, including at least
6 sales from Solux to Transo-Pharm.

7 **Count V**

8 **Declaratory Judgment of Invalidity of the '083 Patent**

9 48. Synbias repeats and realleges the allegations contained in the preceding
10 paragraphs 1-47, inclusive, as if fully set forth herein.

11 49. The '083 patent is invalid under the provisions of 35 U.S.C. §§ 101, et seq..

12 50. As a consequence of the foregoing, there is an actual and justiciable
13 controversy between Synbias and Solux over the invalidity of the '083 patent, with
14 respect to which Synbias is entitled to a declaratory judgment in its favor.

15 51. For example, Claim 1 is invalid as non-enabled and lacks written
16 description support under 35 U.S.C. § 112 and fails to meet the utility requirement of 35
17 U.S.C. § 101 because there is no disclosure in the '083 patent how to use "AcX" as the
18 activator, as "AcX" is defined in the claim. Example 2 shows how to use oxalyl chloride
19 as the DMSO activator, but oxalyl chloride is not "AcX" according to the definition of
20 "AcX" in the claim. In view of the claim's definition of "AcX," therefore, a person of
21 skill in the art would also not have been able to make and use the claimed invention.

22 52. For example, to the extent enabled, claim 1 of the '083 patent is invalid as
23 obvious. The starting material N-Trifluoroacetyl daunorubicin having a formula
24 represented by Formula (2), wherein R₁ is OMe, is N-trifluoroacetyldaunorubicin, is a
25 compound that was well known prior to March 7, 2004. Furthermore, the reaction
26 conditions of Example 2 of the '083 patent were standard Swern oxidation conditions that
27 have been routine since 1978. Claim 1 is a known process applied to a known material to
28 yield an expected result.

1 53. As another example, claim 2 is invalid as obvious in view of prior art,
2 including EP Patent No. 0253654 and the fact that the reducing agent $MHBL_3$ recited in
3 claim 2 was a known reducing agent.

4 54. As additional examples, to the extent enabled, claims 1 and 2 are invalid as
5 anticipated or obvious in view of prior art, including Italian Patent No. 1 196 154 B, or
6 Italian Patent No. 1 196 154 B combined with Chrisman, William and Singaram,
7 Bakthan, The Effect of Different Amine Bases in the Swern Oxidization of β -Amino
8 Alcohols, Tetrahedron Letters, Vol. 38, No. 12, pp. 2053-56 (1997 Elsevier Science
9 Ltd.), or Italian Patent No. 1 196 154 B combined with EP 0 014 425 A1, or U.S. Patent
10 No. 5,874,550 combined with U.S. Patent No. 4,345,068.

11 55. As another example, claim 3 is invalid as anticipated and obvious in view
12 of prior art, including Ukrainian Patent No. 50928.

13 56. All the claims are also invalid under 35 U.S.C. § 102(f) for failure to list the
14 correct inventors on the '083 patent. A. Itkin was not an inventor, having made no
15 contribution to the conception or reduction to practice of any claim of the '083 patent.

16 57. All the claims, to the extent enabled, are also invalid under 35 U.S.C.
17 § 102(b) based on prior use and sales of epirubicin in the United States, including at least
18 sales from Solux to Transo-Pharm.

19 **Count VI**

20 **Declaratory Judgment of Invalidity of the '191 Patent**

21 58. Synbias repeats and realleges the allegations contained in the preceding
22 paragraphs 1-57, inclusive, as if fully set forth herein.

23 59. The '191 patent is invalid under the provisions of 35 U.S.C. §§ 101, et seq..

24 60. As a consequence of the foregoing, there is an actual and justiciable
25 controversy between Synbias and Solux over the invalidity of the '191 patent, with
26 respect to which Synbias is entitled to a declaratory judgment in its favor.

27 61. For example, claims 1-11 are invalid as non-enabled and lack written
28 description support under 35 U.S.C. § 112 and fail to meet the utility requirement of 35

1 U.S.C. § 101. Claim 1 provides that R may be groups other than hydrogen, but the patent
2 fails to disclose how these non-hydrogen groups would exist after step 3. Consequently,
3 a person of skill in the art would not have been able to make and use the claimed
4 invention where R is a group other than hydrogen.

5 62. For example, claims 1-11 are also invalid as non-enabled and lack written
6 description support under 35 U.S.C. § 112 and fail to meet the utility requirement of 35
7 U.S.C. § 101 because claim 1 provides that R₂ may be hydrogen. The process will not
8 yield 4-R-substituted anthracyclines of Formula (I) when R₂ is hydrogen. Consequently, a
9 person of skill in the art would not have been able to make and use the claimed invention
10 where R₂ is hydrogen. Similarly, claims 12-13 are invalid as non-enabled and lack
11 written description support under 35 U.S.C. § 112 and fail to meet the utility requirement
12 of 35 U.S.C. § 101 because in step (1) of claim 12, the starting material may be 4-
13 demethyl-daunorubicin. 4-demethyl-daunorubicin is of Formula (II), with R₁ = H and R₂ =
14 H. Again, because the R₂ is hydrogen, this process will not yield idarubicin of Formula
15 (I).

16 63. For example, claims 12-13 are also invalid as non-enabled and lack written
17 description support under 35 U.S.C. § 112 and fail to meet the utility requirement of 35
18 U.S.C. § 101 because step 3 of claim 12 is inoperable. For step 3 to work, certain
19 undisclosed compounds must participate in the reaction, but the '191 patent fails to
20 disclose this. Without disclosing this step, a person of skill in the art would not have
21 been able to make and use the claimed invention without undue experimentation.

22 64. Claim 1-13, to the extent enabled, are also invalid as obvious in view of
23 prior art, including U.S. Patent No. 5,587,495, U.S. Patent No. 5,103,029, Japanese
24 Patent No. 2002-255888, or a combination of these patents. At least one of the starting
25 materials, 4-demethyl-daunorubicin, is not novel, as conceded by the applicants during the
26 prosecution history and as disclosed, for example, in Pettit, George R., et al.,
27 Antineoplastic Agents: Structure of Carminomycin I, J. Am. Chem. Soc. (Dec. 1975) and
28 U.S. Patent No. 4,188,377.

1 65. All the claims are also invalid under 35 U.S.C. § 102(f) for failure to list the
2 correct inventors on the '191 patent. A. Itkin was not an inventor, having made no
3 contribution to the conception or reduction to practice of any claim of the '191 patent.

4 **Count VII**

5 **Declaratory Judgment of Unenforceability of the '707 Patent**

6 66. Synbias repeats and realleges the allegations contained in the preceding
7 paragraphs 1-65, inclusive, as if fully set forth herein.

8 67. A. Itkin, one of the listed inventors on all three Patents-in-Suit, actually
9 contributed nothing inventive to the '707 patent, and he knew this. Nonetheless, he listed
10 himself as one of the inventors, because he believed that as a U.S. citizen, the application
11 would more likely be granted and be granted faster than if the inventors were only non-
12 U.S. citizens. A. Itkin thus affirmatively represented to the United States Patent and
13 Trademark Office ("USPTO") under oath that he was an inventor, knowing this was
14 false.

15 68. This was a material misrepresentation because a patent must list the correct
16 inventors, and thus the Examiner would have rejected all claims if he knew the inventors
17 were not correctly disclosed.

18 69. Indeed, under 35 U.S.C. § 115, in a patent application each applicant must
19 "make oath [or declaration] that he believes himself to be the original and first inventor
20 of the process, machine, manufacture, or composition of matter, or improvement
21 therefore, for which he solicits a patent." The declaration must be executed and must
22 identify each inventor by full name. A. Itkin executed such a declaration with respect to
23 the '707 patent, even though he had no involvement in the development of the invention.
24 This defect in the declaration was material because an examiner is required to reject any
25 application having a defective declaration. *See, e.g.,* M.P.E.P. § 602.03.

26 70. Furthermore, by submitting an unmistakably false declaration claiming to
27 be an inventor, A. Itkin engaged in an affirmative act of egregious misconduct.

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1 71. The misrepresentation was made with intent to deceive the USPTO. The
2 facts and circumstances indicate that this is the single most reasonable inference able to
3 be drawn. There was no other reason for A. Itkin to falsely declare himself to be an
4 inventor, particularly because there would have been no reason to deceive the USPTO
5 with this falsehood unless A. Itkin believed it would affect the issuance of a patent.

6 72. Listing A. Itkin as an inventor on the ‘707 patent renders all claims of the
7 ‘707 patent unenforceable due to A. Itkin’s inequitable conduct.

8 73. As a consequence of the foregoing, there is an actual and justiciable
9 controversy between Synbias and Solux over the enforceability of the ‘707 patent, with
10 respect to which Synbias is entitled to a declaratory judgment in its favor.

11 **Count VIII**

12 **Declaratory Judgment of Unenforceability of the ‘083 Patent**

13 74. Synbias repeats and realleges the allegations contained in the preceding
14 paragraphs 1-73, inclusive, as if fully set forth herein.

15 75. A. Itkin, one of the listed inventors on all three Patents-in-Suit, actually
16 contributed nothing inventive to the ‘083 patent, and he knew this. Nonetheless, he listed
17 himself as one of the inventors, because he believed that as a U.S. citizen, the application
18 would more likely be granted and be granted faster than if the inventors were only non-
19 U.S. citizens. A. Itkin thus affirmatively represented to the USPTO under oath that he
20 was an inventor, knowing this was false.

21 76. This was a material misrepresentation because a patent must list the correct
22 inventors, and thus the Examiner would have rejected all claims if he knew the inventors
23 were not correctly disclosed.

24 77. Indeed, under 35 U.S.C. § 115, in a patent application each applicant must
25 “make oath [or declaration] that he believes himself to be the original and first inventor
26 of the process, machine, manufacture, or composition of matter, or improvement
27 therefore, for which he solicits a patent.” The declaration must be executed and must
28 identify each inventor by full name. A. Itkin executed such a declaration with respect to

1 the '083 patent, even though he had no involvement in the development of the invention.
2 This defect in the declaration was material because an examiner is required to reject any
3 application having a defective declaration. *See, e.g.*, M.P.E.P. § 602.03.

4 78. Furthermore, by submitting an unmistakably false declaration claiming to
5 be an inventor, A. Itkin engaged in an affirmative act of egregious misconduct.

6 79. The misrepresentation was made with intent to deceive the USPTO. The
7 facts and circumstances indicate that this is the single most reasonable inference able to
8 be drawn. There was no other reason for A. Itkin to falsely declare himself to be an
9 inventor, particularly because there would have been no reason to deceive the USPTO
10 with this falsehood unless A. Itkin believed it would affect the issuance of a patent.

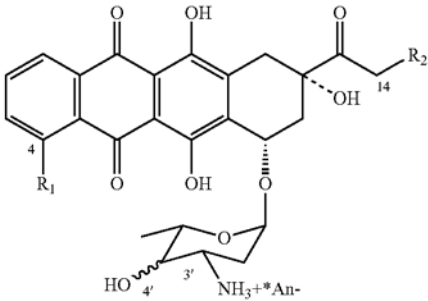
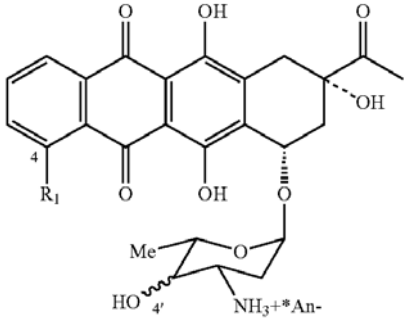
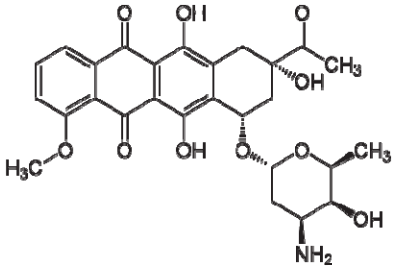
11 80. Listing A. Itkin as an inventor on the '083 patent renders all claims of the
12 '083 patent unenforceable due to A. Itkin's inequitable conduct.

13 81. Additionally, the inventors of the Patents-in-Suit were aware of Ukrainian
14 Patent No. 50928 ("the Ukrainian patent"), which discloses every step of claim 3 of the
15 '083 patent. The Ukrainian patent is a Synbias patent with two common inventors,
16 Victor Matvienko and Alexander Zabudkin. The Synbias inventors of the Patents-In-Suit
17 (Victor Matvienko, Alexey Matvyeyev and Alexander Zabudkin) disclosed the Ukrainian
18 patent to A. Itkin, who generally acted as Synbias's agent and the intermediary between
19 the Synbias inventors and patent counsel with respect to preparing and prosecuting the
20 applications for the Patents-In-Suit. A. Itkin then failed to disclose the Ukrainian patent
21 to the USPTO, however, despite knowing that it was highly material. In view of the high
22 level of materiality of the Ukrainian patent, the fact that it was a Synbias patent with two
23 common inventors, and the Synbias inventors' disclosure of this patent to A. Itkin with
24 the expectation that he would then disclose it to patent counsel and the USPTO, A. Itkin
25 withheld the Ukrainian patent with the intent to deceive the USPTO. If the Examiner had
26 been aware of the Ukrainian patent, claim 3 would have been rejected.

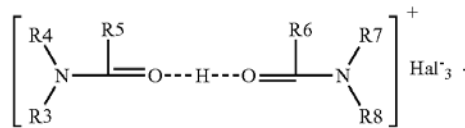
27 82. During prosecution, after a rejection of claims by the Examiner, the
28 applicants described as "novel" the halogenizing agent in the claimed process, as set forth

1 in a response dated December 3, 2007. However, the Ukrainian patent discloses this
 2 halogenizing agent. For at least this reason, the Ukrainian patent was not cumulative of
 3 prior art that was submitted to the USPTO.

4 83. The following claim chart demonstrates how each element of claim 3 of the
 5 '083 patent is met by the Ukrainian patent:

'083 Patent	UA 50928 A (citations to English translation)
<p>6 3. A method of producing an anthracyclin having a 7 formula represented by Formula (1), wherein $R_2 = \text{Hal}$, com- 8 prising:</p> <p>9</p> <p>10 </p> <p>11 Formula 1</p>	<p>12 Abstract: "formation of the 14 13 halogen-derivative of 14 daunomycin." 15 Page 3, lines 28-29: "There is 16 formation of a 14-halogen- 17 derivative of daunomycin, which is 18 subjected to hydrolysis."</p>
<p>19 (a) reacting an anthracyclin having a formula represented 20 by Formula (5), wherein R_1 is defined as H, OH, OMe; 21 $4' - \text{OH}$ is ax[ial] or eq[atorial]; An^- is an anion of a 22 strong acid</p> <p>23 </p> <p>24 Formula 5</p>	<p>25 Page 3, lines 25-27: "Adriamycin 26 hydrochloride is obtained by 27 treatment of daunomycin 28 hydrochloride with the complex halide of formula II." Daunomycin hydrochloride (shown below without the anion) is identical to Formula (5):</p> <p></p>

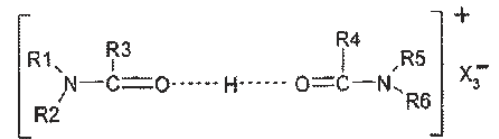
with complex halogenides having a formula represented by Formula (6), wherein R₃-R₈=H or a hydrocarbon radical C₁-C₄, Hal =Cl, Br or I, as a halogenizing agent, and the solvent utilized for the halogenization process is an aprotic solvent comprising amides, simple ethers and their mixtures,



Formula 6

Page 3, lines 25-27: “Adriamycin hydrochloride is obtained by treatment of daunomycin hydrochloride with the complex halide of formula II.”

Page 3, lines 18-23: “using, as halogenating agents, the complex halides of general formula II.”



Formula II

84. A. Itkin’s failure to disclose the Ukrainian patent to the USTPO renders all claims of the ‘083 patent unenforceable due to A. Itkin’s inequitable conduct.

85. As a consequence of the foregoing, there is an actual and justiciable controversy between Synbias and Solux over the enforceability of the ‘083 patent, with respect to which Synbias is entitled to a declaratory judgment in its favor.

Count IX

Declaratory Judgment of Unenforceability of the ‘191 Patent

86. Synbias repeats and realleges the allegations contained in the preceding paragraphs 1-85, inclusive, as if fully set forth herein.

87. A. Itkin, one of the listed inventors on all three Patents-in-Suit, actually contributed nothing inventive to the ‘191 patent, and he knew this. Nonetheless, he listed himself as one of the inventors, because he believed that as a U.S. citizen, the application would more likely be granted and be granted faster than if the inventors were only non-U.S. citizens. A. Itkin thus affirmatively represented to the USPTO under oath that he was an inventor, knowing this was false.

88. This was a material misrepresentation because a patent must list the correct inventors, and thus the Examiner would have rejected all claims if he knew the inventors were not correctly disclosed.

1 89. Indeed, under 35 U.S.C. § 115, in a patent application each applicant must
2 “make oath [or declaration] that he believes himself to be the original and first inventor
3 of the process, machine, manufacture, or composition of matter, or improvement
4 therefore, for which he solicits a patent.” The declaration must be executed and must
5 identify each inventor by full name. A. Itkin executed such a declaration with respect to
6 the ‘191 patent, even though he had no involvement in the development of the invention.
7 This defect in the declaration was material because an examiner is required to reject any
8 application having a defective declaration. *See, e.g.*, M.P.E.P. § 602.03.

9 90. Furthermore, by submitting an unmistakably false declaration claiming to
10 be an inventor, A. Itkin engaged in an affirmative act of egregious misconduct.

11 91. The misrepresentation was made with intent to deceive the USPTO. The
12 facts and circumstances indicate that it is the single most reasonable inference able to be
13 drawn. There was no other reason for A. Itkin to falsely declare himself to be an
14 inventor, particularly because there would have been no reason to deceive the USPTO
15 with this falsehood unless A. Itkin believed it would affect the issuance of a patent.

16 92. Listing A. Itkin as inventor on the ‘191 patent renders all claims of the ‘191
17 patent unenforceable due to A. Itkin’s inequitable conduct.

18 93. As a consequence of the foregoing, there is an actual and justiciable
19 controversy between Synbias and Solux over the enforceability of the ‘191 patent, with
20 respect to which Synbias is entitled to a declaratory judgment in its favor.

21 **Prayer for Relief**

22 WHEREFORE, Synbias respectfully requests the following relief:

- 23 a. The entry of judgment declaring that each of the Patents-In-Suit is invalid;
24 b. The entry of judgment declaring that Synbias has not infringed any of the
25 Patents-in-Suit;
26 c. The entry of judgment declaring that each of the Patents-In-Suit are
27 unenforceable;

28 ///

1 d. The entry of judgment declaring this to be an exceptional case pursuant to 35
2 U.S.C. § 285 and awarding Synbias its reasonable attorneys' fees expended in bringing
3 and maintaining this action;

4 e. An award of Synbias's costs, disbursements, and other expenses; and

5 f. An award of such other costs and further relief as the Court deems just and
6 proper.

7
8 Dated: December 28, 2011

FOLEY & LARDNER LLP
DAVID J. AVENI

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11 By: /s/ David J. Aveni
12 DAVID J. AVENI
13 Attorneys for Plaintiff Synbias Pharma
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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Synbias Pharma

(b) County of Residence of First Listed Plaintiff N/A (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) David J. Aveni, SBN 251197 Foley & Lardner LLP 402 W. Broadway, Ste. 2100 San Diego, CA 92101 619-234-6655

DEFENDANTS

Solux Corporation

County of Residence of First Listed Defendant San Diego (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

'11CV3035 H JMA

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Table with columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal categories like Insurance, Personal Injury, Real Property, etc.

V. ORIGIN

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from another district (specify), 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. §§ 2201 and 2202. Brief description of cause: Declaratory judgment of invalidity, non-infringement, and unenforceability of several US patents.

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23. DEMAND \$Declaratory Relief. CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.**

Example:

U.S. Civil Statute: 47 USC 553

Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.