

1 DAVID J. AVENI CA Bar No. 251197

daveni@foley.com

2 **FOLEY & LARDNER LLP**

ATTORNEYS AT LAW

402 W. BROADWAY, SUITE 2100

3 SAN DIEGO, CA 92101-3542

TELEPHONE: 619.234.6655

FACSIMILE: 619.234.3510

4 Of Counsel:

MATTHEW B. LOWRIE, Pro Hac Vice Pending

mlowrie@foley.com

5 KEVIN M. LITTMAN, Pro Hac Vice Pending

klittman@foley.com

6 **FOLEY & LARDNER LLP**

ATTORNEYS AT LAW

7 111 HUNTINGTON AVE.

BOSTON, MA 02199-7610

TELEPHONE: 617.342.4000

8 FACSIMILE: 617.342.4001

9 Attorneys for Plaintiff Synbias Pharma

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**

19
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

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

The Parties

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

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

The Nature of the Action

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

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

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

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

Count II

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

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

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

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

30. Solux purports to own the '083 patent.

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

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

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

Count III

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

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

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

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

37. Solux purports to own the '191 patent.

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

39. As a consequence of the foregoing, there is an actual and justiciable controversy between Synbias and Solux over the non-infringement of the '191 patent, 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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47. All the claims, to the extent enabled, are also invalid under 35 U.S.C. § 102(b) based on prior use and sales of epirubicin in the United States, including at least sales from Solux to Transo-Pharm.

Count V

Count V

Declaratory Judgment of Invalidity of the '083 Patent

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

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

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

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

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

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

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

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

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

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

Count VI

Declaratory Judgment of Invalidity of the '191 Patent

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

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

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

61. For example, claims 1-11 are invalid as non-enabled and lack written 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 R_2 may be hydrogen. The process will not
8 yield 4-R-substituted anthracyclines of Formula (I) when R_2 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 R_2 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 demethyldaunorubicin. 4-demethyldaunorubicin is of Formula (II), with $R_1 = H$ and $R_2 =$
14 H. Again, because the R_2 is hydrogen, this process will no 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-demethyldaunorubicin, 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.

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

Count VII

Declaratory Judgment of Unenforceability of the '707 Patent

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

67. A. Itkin, one of the listed inventors on all three Patents-in-Suit, actually contributed nothing inventive to the '707 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 United States Patent and Trademark Office ("USPTO") under oath that he was an inventor, knowing this was false.

68. 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.

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

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

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

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

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

Count VIII

Declaratory Judgment of Unenforceability of the '083 Patent

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

75. A. Itkin, one of the listed inventors on all three Patents-in-Suit, actually contributed nothing inventive to the '083 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.

76. 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.

77. Indeed, under 35 U.S.C. § 115, in a patent application each applicant must "make oath [or declaration] that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement therefore, for which he solicits a patent." The declaration must be executed and must 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.

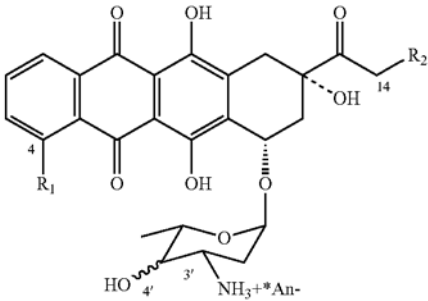
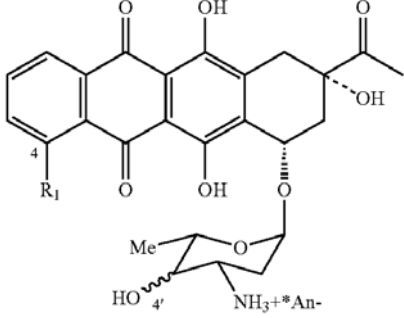
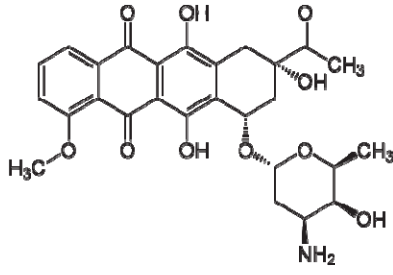
11 80. Listing A. Itkin as an inventor on the '083 patent renders all claims of the
12 '083 patent unenforceable due to A. Itkin's inequitable conduct.

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.

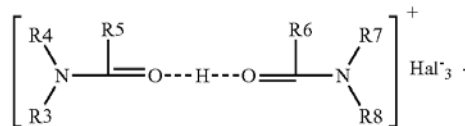
27 82. During prosecution, after a rejection of claims by the Examiner, the
28 applicants described as "novel" the halogenizing agent in the claimed process, as set forth

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

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

'083 Patent	UA 50928 A (citations to English translation)
<p>3. A method of producing an anthracyclin having a formula represented by Formula (1), wherein $R_2 = \text{Hal}$, comprising:</p> <p style="text-align: right;">Formula 1</p> 	<p>Abstract: "formation of the 14 halogen-derivative of daunomycin."</p> <p>Page 3, lines 28-29: "There is formation of a 14-halogen-derivative of daunomycin, which is subjected to hydrolysis."</p>
<p>(a) reacting an anthracyclin having a formula represented by Formula (5), wherein R_1 is defined as H, OH, OMe; $4'\text{—OH}$ is ax[ial] or eq[atorial]; An^- is an anion of a strong acid</p> <p style="text-align: right;">Formula 5</p> 	<p>Page 3, lines 25-27: "Adriamycin hydrochloride is obtained by treatment of daunomycin hydrochloride with the complex halide of formula II."</p> <p>Daunomycin hydrochloride (shown below without the anion) is identical to Formula (5):</p> 

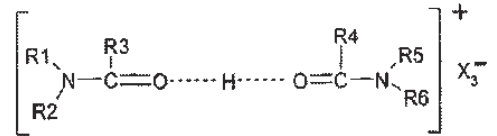
with complex halogenides having a formula represented by Formula (6), wherein R_3 - R_8 =H or a hydrocarbon radical C_1 - C_4 , Hal =Cl, Br or I, as a halogenizing agent, and the solvent utilized for the halogenization process is an aprotic solvent comprising amides, simple ethers and their mixtures,



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.

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

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

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

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

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

Prayer for Relief

WHEREFORE, Synbias respectfully requests the following relief:

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

///

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

Symbias 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
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES

(For Diversity Cases Only)

(Place an "X" in One Box for Plaintiff)

and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT

(Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Med. Malpractice PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus - Alien Detainee (Prisoner Petition) <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 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.