502801543 05/08/2014

PATENT ASSIGNMENT COVER SHEET

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SUBMISSION TYPE:		NEW ASSIGNMENT	NEW ASSIGNMENT	
NATURE OF CONVEYANCE:		ASSIGNMENT	ASSIGNMENT	
CONVEYING PARTY D	ATA			
		Name	Execution Date	
VIKTOR N. MATVIYENK	(0		04/10/2014	
RECEIVING PARTY DA	ТА			
Name:	SYNBIAS	PHARMA LTD.		
Street Address:	230 STRE	ELKOVOY DIVIZII, 13		
City:	DONETS	≺-92		
State/Country:	UKRAINE			
Postal Code:	83092			
PROPERTY NUMBERS	Total: 3			
Property Type		Number		
Patent Number:	70	53191		
Patent Number: 7485		85707		
Patent Number:	73	88083		
CORRESPONDENCE D Fax Number: <i>Correspondence will be</i> <i>US Mail.</i> Email: Correspondent Name: Address Line 1:	e sent to tl jro LL	ne e-mail address first; if that is bins@foley.com ICAS I. SILVA 1 HUNTINGTON AVENUE	unsuccessful, it will be sent via	
Address Line 1: Address Line 2:		DLEY & LARDNER LLP		
Address Line 4:		STON, MASSACHUSETTS 021		
NAME OF SUBMITTER:		LUCAS I. SILVA	LUCAS I. SILVA	
SIGNATURE:		/Lucas I. Silva/		
DATE SIGNED:		05/08/2014		
		This document serves as an (This document serves as an Oath/Declaration (37 CFR 1.63).	
Total Attachments: 40			, , , , , , , , , , , , , , , , ,	
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CONFIRMATORY ASSIGNMENT

WHEREAS, the undersigned, Mr. Viktor N. Matviyenko (hereinafter referred to as the "ASSIGNOR"), whose first name is also sometimes spelled "Viktor" in English, is one of the inventors of the inventions claimed in in the following U.S. patents (collectively, the "PATENTS"):

- U.S. Patent 7,053,191 B2, entitled "Method of preparing 4-R-substituted 4demethoxydaunorubicin" and filed April 23, 2004 pursuant to U.S. application 10/831,448.
- (2) U.S. Patent 7,485,707 B2, entitled "Thermally stable crystalline epirubicin hydrochloride and method of making the same" and filed Jun 25, 2004 pursuant to U.S. application 10/877,221, and
- (3) US Patent 7,388,083 B2, entitled "Epimerization of 4'-C bond and modification of 14-CH3-(CO)-fragment in anthracyclin antibiotics" and filed March 4, 2006 pursuant to U.S. application 11/367,742.

WHEREAS, Synbias Pharma Ltd., a limited liability company organized and existing under the law of Ukraine and having an office at 230 Strelkovoy divizii, 13, Donetsk-92, 83092 Ukraine (hereinafter referred to as the "ASSIGNEE"), had previously obtained and acquired all rights and interest in and to the PATENTS of ASSIGNOR, and the inventions claimed in said PATENTS, pursuant to and by operation of the laws of Ukraine, including without limitation Article 9 of the Ukrainian Patent Law, as well as a written transfer agreement of June 2001 between ASSIGNEE and ASSIGNOR (the "ORIGINAL TRANSFER AGREEMENT") who was employed by ASSIGNEE at the time he made the inventions claimed in said PATENTS, a copy of which is attached hereto as <u>Exhibit A</u>;

WHEREAS, on December 28, 2011, ASSIGNEE commenced a lawsuit against Solux Corporation, a California corporation, in U.S. District Court for the Southern District of California, case no. 3:11-cv-03035-H-JMA (the "FEDERAL ACTION"), seeking *inter alia* declaratory judgment that the PATENTS are invalid, unenforceable and not infringed as set forth in ASSIGNEE's complaint, a copy of which is attached hereto as <u>Exhibit B</u>;

WHEREAS, the U.S. District Court, in an order dated August 30, 2013 (the "ORDER"), a copy of which is attached hereto as <u>Exhibit C</u>, granted summary judgment to ASSIGNEE in the FEDERAL ACTION, ruling that ASSIGNEE had acquired the rights and interest of ASSIGNOR in the PATENTS, and the inventions claimed in said PATENTS, including by operation of Article 9 of the Ukrainian Patent Law and pursuant to the ORIGINAL TRANSFER AGREEMENT, and that as a result ASSIGNEE is at least a co-owner of the PATENTS;

WHEREAS, on September 4, 2013, the U.S. District Court entered final judgment on the ORDER;

NOW, THEREFORE, ASSIGNOR AND ASSIGNEE hereby each certifies and confirms the earlier assignment and transfer and ownership unto ASSIGNEE of all rights and title to and interest of ASSIGNEE in the PATENTS, and the inventions claimed in said PATENTS; such

right, title and interest to be held and fully enjoyed by ASSIGNEE to the full end of the applicable term or terms for which such PATENTS have been granted.

ASSIGNOR AND ASSIGNEE hereby authorizes and requests that this confirmatory assignment of the rights and interest of ASSIGNOR to and in the PATENTS to ASSIGNEE for the sole use and benefit of ASSIGNEE, its successors and assigns, as confirmed by this document, be recorded in all relevant patent offices.

NAME AND SIGNATURE OF ASSIGNOR:

NAME: MR. VIKTOR N. MATVIYE	NAME: MR. VIKTOR N. MATVIYENKO	
SIGNATURE OF INVENTOR:	M. S. Martin	
DATE: 145431 10	UD/14	
NAME AND SIGNATURE OF ASSIGNEE:		
NAME: SYNBIAS PHARMA LTD.		
AUTHORIZED SIGNATURE:		
NAME AND TITLE:	edicul Rospel	
date: <u>AJSCH & W.</u> &	CIHEIAC OAPMAN	

<u>Exhibit A</u>

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CONTRACT No. _____ on the rights to a service invention

Donetsk

2001

Limited liability company Synbias Pharma Research and Development Enterprise, hereinafter referred to as the Employer, as represented by Director V.F. Donets, acting on the basis of the Charter, for the one part, and

Citizen of Ukraine,

hereinafter referred to as the **Employee**, acting on the basis of general civil capacity, for the other part, jointly hereinafter referred to as the **Parties**, have concluded this Contract on the following:

1. Based on the instructions of the Employer, the Employee shall conduct research to develop a potentially patentable product and/or method (hereinafter referred to as the Invention).

2. The Employer shall ensure that the Employee has access to its experience, production knowledge, production secrets and the equipment necessary to conduct the research.

3. The Invention under this Contract shall be a service invention.

4. If the research is successful, the Employee shall give the Employer notification in writing about the Invention created and attach a comprehensive description of the invention that is sufficient for the purposes of registration.

5. All information about the research, the results obtained from the research and the Invention shall constitute a commercial secret (knowhow).

6. All rights to the aforementioned commercial secret (knowhow) shall belong exclusively to the Employer.

7. The Employee shall not disclose the commercial secret (knowhow) and not transfer it to third parties.

8. All rights to the registration and obtaining of a patent(s) for the Invention on the territory of any state shall belong exclusively to the Employer.

9. This Contract shall enter into force upon signature and remain in force until the Parties perform all their obligations thereunder.

10. This Contract is prepared in 2 (two) copies of equal legal force with one for each Party.

Employer	Employee
LLC Synbias Pharma RDE	
83114, Donetsk, pr. Panfilova, 15 account 26006980645 at DOF AKB USB MFO 334011 OKPO 23425280	
Director	
[signature]	
V.F. Donets	

ADDRESSES AND BANK DETAILS OF THE PARTIES

[Seal:] SYNBIAS PHARMA Research and Development Enterprise Ukraine, Donetsk, Limited Liability Company Code 23425280 ДОГОВОР № <u>12/06 - 2001</u> о правах на служебное изобретение

г. Донецк

«12» OG 2001 r.

Общество с ограниченной ответственностью «Научно-производственная фирма «Синбиас Фарма», именуемое в дальнейшем Работодатель, в лице Директора Донца Владимира Федоровича, действующего на основании Устава, с одной стороны, и

Физическое лицо гражданин Украины Матвиенко Виктор Николаевич, именуемый в дальнейшем Работник, действующий на основании общей гражданской дееспособности, с другой стороны, совместно именуемые Стороны, заключили настоящий Договор о нижеследующем:

- 1. Работник по заданию Работодателя проводит научные исследования, направленные на разработку потенциально патентоспособного продукта и/или способа,(далее Изобретение).
- 2. Работодатель обеспечивает Работнику доступ к своему опыту, производственным знаниям, секретам производства и оборудованию, необходимым для проведения исследований.
- 3. Изобретение по настоящему Договору является служебным.
- 4. В случае успешного проведения исследований Работник подает Работодателю в письменной форме уведомление о создании им Изобретения, к которому прилагает полное и достаточное для целей регистрации описание такого изобретения.
- 5. Вся информация о ходе исследований и полученных в результате исследований результатов, а также об Изобретении является коммерческой тайной (ноу-хау).
- 6. Все права на указанную выше коммерческую тайну (ноу-хау) принадлежат исключительно Работодателю.
- 7. Работник обязуется неразглашать коммерческую тайну (ноу-хау) и не передавать ее третьим лицам.
- 8. Все права на регистрацию и получение на территории любого государства патента (патентов) на Изобретение принадлежит исключительно Работодателю.
- 9. Настоящий Договор вступает в силу с момента его подписания и действует до полного выполнения Сторонами своих обязательств по нему.
- 10. Настоящий Договор составлен в 2 (двух) экземплярах, имеющих равную юридическую силу, по одному для каждой из Сторон.

Работодатель	Работник	
ООО НПФ «Синбиас Фарма»	Матвиенко Виктор Николаевич	
83114, г. Донецк, пр. Панфилова, 15	г. Донецьк, пр. Панфилова, д.20,кв.37,	
р/с 26006980645 в ДОФ АКБ УСБ	паспорт ВС 293262 видан Ворошиловским	
MΦO 334011	РО УМВД Украины в г.Донецке 12.07.2000	
ОКПО 23425280	ИНН 2026300416	
201700 3 000		
Директор	Власти В.Н. Матвиенко	
Exh	4	
- 2	4 - PATENT	
	REEL: 032853 FRAME: 0693	

АДРЕСА И РЕКВИЗИТЫ СТОРОН

<u>Exhibit B</u>

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1 2 3	DAVID J. AVENI CA Bar No. 251197 daveni@foley.com FOLEY & LARDNER LLP ATTORNEYS AT LAW 402 W. BROADWAY, SUITE 2100 SAN DIEGO, CA 92101-3542 TELEPHONE: 619.234.6655 FACSIMILE: 619.234.3510		
4	Of Counsel: MATTHEW B. LOWRIE, Pro Hac Vice Pending		
5	mlowrie@foley.com KEVIN M. LITTMAN, Pro Hac Vice Pending klittman@foley.com		
6	FOLEY & LÁRDNER 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		ATES DISTRICT COURT	
12	SOUTHERN D	ISTRICT OF CALIFORNIA	
13			
14	SYNBIAS PHARMA,	Case No: '11CV3035 H JMA	
15	Plaintiff,	COMPLAINT FOR DECLARATORY JUDGMENT	
16	V.		
17	SOLUX CORPORATION,		
18	DEFENDANT.		
19			
20			
21		Introduction	
22	1. This is an action for a d	eclaratory judgment of invalidity, non-infringement,	
23			
24			
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	
7906 A	COMPLAINT F	OR DECLARATORY JUDGMENT PATENT	

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.

<u>The Parties</u>

3. Synbias is a corporation duly organized and existing under the laws of
Vkraine, 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.

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The Nature of the Action

5. Under 35 U.S.C. §§ 101, et seq., and in equity, this is an action for 14 Declaratory Judgment of invalidity, non-infringement, and/or unenforceability as to three 15 patents, all of which were issued to Defendant as the named Assignee.¹ The patents at 16 issue are: (A) U.S. Patent No. 7,485,707, entitled "Thermally Stable Crystalline 17 Epirubicin Hydrochloride and Method of Making The Same" ("the '707 patent"); (B) 1819 U.S. Patent No. 7,388,083, entitled "Epimerization of 4'-C Bond and Modification of 14-20CH3-(CO)-Fragment in Anthracyclin Antibiotics" ("the '083 patent"); and (C) U.S. Patent No. 7,053,191, entitled "Method of Preparing 4-R-Substituted 4-2122Demethoxydaunorubicin" ("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 A-C, respectively. 2425

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 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.).

COMPLAINT FOR DECLARATORY JUDGMENT PATENT

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

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

8. Beginning in late 1998 or early 1999, Dmitry Itkin ("D. Itkin") agreed to 13 14 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 15 16 Synbias in the United States and elsewhere, sell Synbias's products, process payments 17 from Synbias's customers, and hold and manage money and property on Synbias's 18behalf. D. Itkin incorporated Solux in 2002 to accomplish these services for Synbias. 19 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. 20D. Itkin informed Synbias that Solux should be named as the patent applicant and 2122assignee of Synbias's inventions, and D. Itkin's brother, Aleksandr Itkin ("A. Itkin"), 23should be named as an inventor.

10. A. Itkin contributed nothing to any of the inventions claimed in the Patentsin-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

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

8 D. Itkin falsely represented to the Synbias inventors (Matvienko, 11. 9 Matvyeyev and Zabudkin) that taking these steps of naming A. Itkin as an inventor and 10assigning the inventions to Solux would facilitate faster and more certain patenting of the inventions in the United States and in other countries because Synbias was not an 11 12American company and was not located in the United States, and because the inventors were located overseas and were not U.S. citizens. The Itkins also represented to the 13 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, and A. Itkin agreed to use the Patents-In-Suit solely as instructed by Synbias, not to use 16 17 the Patents-In-Suit to advance their own interest or to Synbias's detriment, and that they 18would 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 20assured the Synbias inventors that this was proper under United States law and procedure. 12. 21However, when the agency relationship terminated in 2010, Solux and the 22Itkins refused to return the interest and right to the Patents-In-Suit, and the Itkins have 23sought to use the Patents-In-Suit solely to advance their own interests. The Itkins began 24an 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 with allegations of infringement of these invalid and unenforceable Patents-in-Suit. 2627 13. Transo-Pharm and Chemex purchase APIs from Synbias, including

28 anthracyclines epirubicin and idarubicin. Transo-Pharm and Chemex then resell these

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

14. 4 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. Itkin stated in this email: "I want to make sure that the possible hostile transfer of the 6 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 other covered parts of the world." A true and correct copy of this email is attached as 10Exhibit D. 11

1215. 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 activities and that each of Transo-Pharm and Chemex cease and desist from all activities 1819 that are in violation of Solux's significant patent rights." A true and correct copy of this 20letter is attached as Exhibit E.

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

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117.Synbias and Transo-Pharm/Chemex are parties to a supply agreement under2which Synbias is required to supply Transo-Pharm/Chemex with APIs, including3epirubicin and idarubicin. The agreement contains a provision stating that it shall be4interpreted and enforced in accordance with the laws of Germany. Synbias and Transo-5Pharm/Chemex have also entered into an agreement under which Synbias is obligated to6indemnify 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-In16 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

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<u>Count I</u>

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.
- 28 ///

6 COMPLAINT FOR DECLARATORY JUDGMENT

PATENT

25. 1 Synbias's products and the processes used to make Synbias's products, 2including 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 have the powder X-Ray diffraction pattern presented in the table in claim 1, and in 4 5 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, 6 7 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 8 9 making epirubicin hydrochloride does not infringe claims 3-8 because Synbias's process 10does not yield the epirubicin hydrochloride of claim 1. 26. As a consequence of the foregoing, there is an actual and justiciable 11 12controversy 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. 13 14Count 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. On June 17, 2008, the '083 patent was issued. A copy of the '083 patent is 1828. attached as Exhibit B. 19 2029. The named inventors of the '083 patent are Victor Matvienko, Alexey Matvyeyev, Alexander Zabudkin, and A. Itkin. 212230. Solux purports to own the '083 patent. 23Synbias's products and the processes used to make Synbias's products, 31. 24including 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 26hydrochloride and idarubicin hydrochloride does not use step (a) of claim 1, including 27 "with AcX activated DMSO in aprotic solvent." 28/// 7 COMPLAINT FOR DECLARATORY JUDGMENT PATENT

32. Synbias also does not infringe claims 1 and 2 because, for example, they 1 2are methods for producing 4'-keto-N-Trifluoroacetyl-4-R₁ daunorubicin and N-3 Trifluoroacetyl-4'-epi-4- R₁ daunorubicin, respectively, not epirubicin hydrochloride or idarubicin hydrochloride. Synbias also does not infringe claim 3, for example, because it 4 5 is a method for producing an anthracylin having a formula represented by Formula (1), wherein $R_2 = Hal$, which is not epirubicin. For epirubicin, R_2 is hydroxl, not halogen, at 6 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 As a consequence of the foregoing, there is an actual and justiciable 33. controversy between Synbias and Solux over the non-infringement of the '083 patent, 10with respect to which Synbias is entitled to a declaratory judgment in its favor. 11 12Count III Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,053,191 13 34. 14 Synbias repeats and realleges the allegations contained in the preceding paragraphs 1-33, inclusive, as if fully set forth herein. 15 35. 16 On May 30, 2006, the '191 patent was issued. A copy of the '191 patent is 17 attached as Exhibit C. 1836. The named inventors of the '191 patent are Victor Matvienko, Alexey Matvyeyev, Alexander Zabudkin, and A. Itkin. 19 2037. Solux purports to own the '191 patent. 38. Synbias's products and the processes used to make Synbias's products, 2122including the APIs epirubicin hydrochloride and idarubicin hydrochloride, do not infringe 23 one or more claims of the '191 patent. 39. As a consequence of the foregoing, there is an actual and justiciable 2425 controversy between Synbias and Solux over the non-infringement of the '191 patent, 26with respect to which Synbias is entitled to a declaratory judgment in its favor. /// 27 28/// COMPLAINT FOR DECLARATORY JUDGMENT PATENT

1 **Count IV** 2**Declaratory Judgment of Invalidity of the '707 Patent** 3 40. Synbias repeats and realleges the allegations contained in the preceding paragraphs 1-39, inclusive, as if fully set forth herein. 4 5 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 6 7 controversy between Synbias and Solux over the invalidity of the '707 patent, with 8 respect to which Synbias is entitled to a declaratory judgment in its favor. 9 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. 1011 44. For example, all the claims are also invalid as not enabled and lack written 12description 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 13 14 for crystallizing the epirubicin hydrochloride. The missing step concerns the removal of 15 water during the crystallization process. Without disclosing this step, a person of skill in 16 the art would not have been able to make and use the claimed invention without undue 17 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 1819 another example, even were one of skill in the art able to divine a way to make the 20disclosure 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 2122claim 1. 23 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 24

- 26 claimed.
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skill in the art cannot determine what crystalline form of epirubicin hydrochloride is

46. 1 All the claims are also invalid under 35 U.S.C. § 102(f) for failure to list the 2correct 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. 47. All the claims, to the extent enabled, are also invalid under 35 U.S.C. 4 5 § 102(b) based on prior use and sales of epirubicin in the United States, including at least sales from Solux to Transo-Pharm. 6 7 **Count V** 8 **Declaratory Judgment of Invalidity of the '083 Patent** 9 48. Synbias repeats and realleges the allegations contained in the preceding paragraphs 1-47, inclusive, as if fully set forth herein. 1049. The '083 patent is invalid under the provisions of 35 U.S.C. §§ 101, et seq... 11 1250. 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 description support under 35 U.S.C. § 112 and fails to meet the utility requirement of 35 16 17 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 18as the DMSO activator, but oxalyl chloride is not "AcX" according to the definition of 19 20"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. 212252. 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 24represented by Formula (2), wherein R_1 is OMe, is N-trifluoroacetyldaunorubicin, is a 25 compound that was well known prior to March 7, 2004. Furthermore, the reaction 26conditions of Example 2 of the '083 patent were standard Swern oxidation conditions that 27have been routine since 1978. Claim 1 is a known process applied to a known material to yield an expected result. 2810

COMPLAINT FOR DECLARATORY JUDGMENT

153.As another example, claim 2 is invalid as obvious in view of prior art,2including EP Patent No. 0253654 and the fact that the reducing agent MHBL3 recited in3claim 2 was a known reducing agent.

54. As additional examples, to the extent enabled, claims 1 and 2 are invalid as 4 5 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, 6 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 No. 5,874,550 combined with U.S. Patent No. 4,345,068. 1011 55. As another example, claim 3 is invalid as anticipated and obvious in view 12of 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 sales from Solux to Transo-Pharm. 1819 Count VI **Declaratory Judgment of Invalidity of the '191 Patent** 2058. Synbias repeats and realleges the allegations contained in the preceding 2122paragraphs 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.. As a consequence of the foregoing, there is an actual and justiciable 24 60. 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.

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

U.S.C. § 101. Claim 1 provides that R may be groups other than hydrogen, but the patent
 fails to disclose how these non-hydrogen groups would exist after step 3. Consequently,
 a person of skill in the art would not have been able to make and use the claimed
 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 description support under 35 U.S.C. § 112 and fail to meet the utility requirement of 35 6 7 U.S.C. § 101 because claim 1 provides that R_2 may be hydrogen. The process will not 8 yield 4-R-substituted anthracylines 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 10where R_2 is hydrogen. Similarly, claims 12-13 are invalid as non-enabled and lack written description support under 35 U.S.C. § 112 and fail to meet the utility requirement 11 12of 35 U.S.C. § 101 because in step (1) of claim 12, the starting material may be 4demethyldaunorubicin. 4-demethyldaunorubicin is of Formula (II), with $R_1 = H$ and $R_2 =$ 13 H. Again, because the R_2 is hydrogen, this process will no yield idarubicin of Formula 14 15 **(I)**.

63. 16 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 18U.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 20disclose this. 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. 212264. Claim 1-13, to the extent enabled, are also invalid as obvious in view of prior art, including U.S. Patent No. 5,587,495, U.S. Patent No. 5,103,029, Japanese 23 24Patent 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 26prosecution 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 U.S. Patent No. 4,188,377. 2812

COMPLAINT FOR DECLARATORY JUDGMENT

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

6 66. Synbias repeats and realleges the allegations contained in the preceding
7 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 nonU.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.

1869. 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 20of the process, machine, manufacture, or composition of matter, or improvement therefore, for which he solicits a patent." The declaration must be executed and must 2122identify 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. This defect in the declaration was material because an examiner is required to reject any 24 25 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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COMPLAINT FOR DECLARATORY JUDGMENT

71. The misrepresentation was made with intent to deceive the USPTO. The 1 2facts 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 inventor, particularly because there would have been no reason to deceive the USPTO 4 5 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 6 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 respect to which Synbias is entitled to a declaratory judgment in its favor. 10**Count VIII** 11 12**Declaratory Judgment of Unenforceability of the '083 Patent** 74. Synbias repeats and realleges the allegations contained in the preceding 13 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 would more likely be granted and be granted faster than if the inventors were only non-1819 U.S. citizens. A. Itkin thus affirmatively represented to the USPTO under oath that he 20was an inventor, knowing this was false. 76. This was a material misrepresentation because a patent must list the correct 2122inventors, and thus the Examiner would have rejected all claims if he knew the inventors 23were not correctly disclosed. 77. Indeed, under 35 U.S.C. § 115, in a patent application each applicant must 24 25 "make oath [or declaration] that he believes himself to be the original and first inventor 26of the process, machine, manufacture, or composition of matter, or improvement therefore, for which he solicits a patent." The declaration must be executed and must 27 28identify each inventor by full name. A. Itkin executed such a declaration with respect to COMPLAINT FOR DECLARATORY JUDGMENT PATENT

the '083 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.

Furthermore, by submitting an unmistakably false declaration claiming to
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.

81. Additionally, the inventors of the Patents-in-Suit were aware of Ukrainian 13 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 18patent 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 20applications for the Patents-In-Suit. A. Itkin then failed to disclose the Ukrainian patent 21to the USPTO, however, despite knowing that it was highly material. In view of the high 22level 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 24the 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 been aware of the Ukrainian patent, claim 3 would have been rejected. 26

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



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1 with complex halogenides having a formula represented Page 3, lines 25-27: "Adriamycin by Formula (6), wherein R3-R8-H or a hydrocarbon hydrochloride is obtained by 2radical C1-Cat Hal --Cl, Br or I, as a halogenizing agent, treatment of daunomycin and the solvent utilized for the halogenization process hydrochloride with the complex 3 is an aprotic solvent comprising amides, simple ethers halide of formula II." and their mixtures, 4 Page 3, lines 18-23: "using, as 5 halogenating agents, the complex Formula 6 6 halides of general formula II." R⁵ R⁶ R⁷ Rat³. 7 R1, R3 N-C=0----H----O=C-N R5 R2 8 9 Formula II 1011 84. A. Itkin's failure to disclose the Ukrainian patent to the USTPO renders all 12claims of the '083 patent unenforceable due to A. Itkin's inequitable conduct. 13 85. As a consequence of the foregoing, there is an actual and justiciable 14 controversy between Synbias and Solux over the enforceability of the '083 patent, with 15 respect to which Synbias is entitled to a declaratory judgment in its favor. 16 **Count IX** 17 **Declaratory Judgment of Unenforceability of the '191 Patent** 1886. Synbias repeats and realleges the allegations contained in the preceding 19 paragraphs 1-85, inclusive, as if fully set forth herein. 2087. A. Itkin, one of the listed inventors on all three Patents-in-Suit, actually 21contributed nothing inventive to the '191 patent, and he knew this. Nonetheless, he listed 22himself as one of the inventors, because he believed that as a U.S. citizen, the application 23 would more likely be granted and be granted faster than if the inventors were only non-24U.S. citizens. A. Itkin thus affirmatively represented to the USPTO under oath that he 25 was an inventor, knowing this was false. 2688. This was a material misrepresentation because a patent must list the correct 27 inventors, and thus the Examiner would have rejected all claims if he knew the inventors 28were not correctly disclosed.

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COMPLAINT FOR DECLARATORY JUDGMENT

89. Indeed, under 35 U.S.C. § 115, in a patent application each applicant must 1 2"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 3 therefore, for which he solicits a patent." The declaration must be executed and must 4 5 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. 6 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.

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;

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COMPLAINT FOR DECLARATORY JUDGMENT

	Case 3:11-cv-03035-H-JMA Document 1 Filed 12/29/11 Page 19 of 21		
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, 2011FOLEY & LARDNER LLP DAVID J. AVENI		
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10			
11	By: <u>/s/ David J. Aveni</u>		
12	DAVID J. AVENI Attorneys for Plaintiff Synbias Pharma		
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4819-1801-7806.4	COMPLAINT FOR DECLARATORY JUDGMENT PATENT REEL: 032853 FRAME: 0713		

Exhibit C

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	Case 3:11-cv-03035-H-BGS Document 22	3 Filed 08/30/13 Page 1 of 14	
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7			
8	UNITED STATES	DISTRICT COURT	
9	SOUTHERN DISTRI	CT OF CALIFORNIA	
10			
11	SYNBIAS PHARMA,	CASE NO. 11-CV-3035-H (JMA)	
12	Plaintiff/Counterdefendant,	ORDER DISMISSING	
13	VS.	SOLUX'S INFRINGEMENT COUNTERCLAIMS FOR	
14		LACK OF STANDING; and	
15	SOLUX CORPORATION,	ORDER DISMISSING CASE FOR LACK OF SUBJECT	
16	Defendant/Counterclaimant.	MATTER JURISDICTION	
17		[Doc. No. 40.]	
18 10	J		
19 20	On Echnyony 1 2012 Symbios Dhom	ma ("Symbias") filed a motion for summery	
20 21	On February 4, 2013, Synbias Pharma ("Synbias") filed a motion for summary indement on Solux Corporation's ("Solux") counterclaims of infringement of U.S.		
21 22	judgment on Solux Corporation's ("Solux") counterclaims of infringement of U.S. Patents 7 053 191 ("the '191 patent") 7 485 707 ("the '707 patent") and 7 388 083		
22	Patents 7,053,191 ("the '191 patent"), 7,485,707 ("the '707 patent"), and 7,388,083 ("the '083 patent") (collectively "the patents-in-suit"). (Doc. No. 103.) On July 19,		
23	2013, Solux filed an opposition. (Doc. No. 149.) On August 12, 2013, Synbias filed		
25	a reply. (Doc. Nos. 178, 183.) The Court held a hearing on August 20, 2013. Matthew		
26	Lowrie and Kevin Littman appeared for Synbias. James Sakaguchi and Neal Cohen		
27	appeared for Solux.		
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Background¹

2 This is a patent infringement action involving patents that claim inventions 3 relating to methods of producing anthracycline antibiotics-compounds that are used as first-line chemotherapy drugs for treating a range of cancers. (Doc. No. 46 ¶4.) Synbias 4 5 is a Ukranian company that manufactures and produces various active pharmaceutical ingredients, including anthracycline antibiotics. (Doc. No. 77-7 §5.) The patents-in-suit 6 7 list three Synbias employees as inventors: Victor Matvienko; Alexey Matvyeyev; and 8 Alexander Zabudkin (collectively "The Synbias Inventors"). (Doc. No. 1, Exs. A-C.) 9 The fourth listed inventor is Aleksandr Itkin ("A. Itkin"), an executive of Solux. (Id.)

10 On June 16, 2011, Synbias filed a lawsuit in California Superior Court in San Diego County against Solux and two of its executives, Dmitry Itkin ("D. Itkin") and his 11 12 brother A. Itkin, alleging causes of action, among others, of breach of contract, fraud, 13 and breach of fiduciary duty. (Doc. No. 209-30 ("State Second Amend. Compl." or "State SAC") ¶¶47-59.) A central issue in the state action is whether Solux owns the 14 15 patents-in-suit. The patents-in-suit list Solux as the owner by assignment, (Doc. No. 16 1, Exs. A-C,) but Synbias alleges that Solux fraudulently induced the Synbias inventors 17 to assign their rights to Solux. (State SAC ¶¶56-59.)

On December 29, 2011, Synbias filed a complaint in this Court seeking a
declaratory judgment of non-infringement of the patents-in-suit and a declaratory
judgment that the patents-in-suit are invalid and unenforceable. (Doc. No. 1
("Compl.").) On March 26, 2012, the Court denied Solux's motion to dismiss the
declaratory judgment claims for lack of jurisdiction. (Doc. No. 17.) Thereafter, Solux
filed an answer and asserted infringement counterclaims. (Doc. No. 19.)

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arguing that Synbias either is estopped under the doctrine of assignor estoppel or lacks

standing to assert its declaratory judgment claims that the patents-in-suit are invalid and

On November 7, 2012, Solux filed a motion for partial summary judgment,

¹For general background on the parties and the patents-in-suit, see the Court's order denying Solux's motion for partial summary judgment. (Doc. No. 99 at pp. 2-5.)

unenforceable. (Doc. No. 40.) On January 17, 2013, the Court denied Solux's motion 1 2 for partial summary judgment "without prejudice to Solux renewing its motion after the development of a more complete record." (Doc. No. 99 at p. 11.) In opposing the 3 partial summary judgment motion, Synbias asserted that it was at least a co-owner of 4 5 the patents-in-suit, and Solux's failure to join Synbias in its counterclaims deprived Solux of standing to assert its infringement counterclaims. (Doc. No. 77 at p. 16); see 6 7 Israel Bio-Engineering Project v. Amgen, Inc., 475 F.3d 1256, 1264 (Fed. Cir. 2007) 8 ("Where one co-owner possesses an undivided part of the entire patent, that joint owner must join all the other co-owners to establish standing."). The Court declined to sua 9 10 sponte grant Synbias summary judgment on Solux's infringement counterclaims, but the Court permitted Synbias to file a summary judgment motion. (Doc. No. 99.) 11 12 Additionally, the Court ordered the parties to show cause why the case should not be 13 dismissed for lack of subject matter jurisdiction given Synbias' position that it is at least a co-owner of the patents-in-suit. (Id.) 14

Synbias filed its summary judgment motion on February 4, 2013. (Doc. No.
103.) On February 15, 2013, the Court granted the parties' joint request to extend the
deadline for Solux to file its opposition to June 7, 2013, to allow Solux to conduct
discovery. (Doc. No. 110.) On May 15, 2013, the Court again extended the deadline
for Solux to file its opposition to accommodate Solux's discovery requests. (Doc. No.
118.) On July 19, 2013, Solux filed a timely opposition.²

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Discussion

22 I. Subject Matter Jurisdiction

23 "Federal courts are of courts of limited jurisdiction. They possess only that
24 power authorized by Constitution and statute." <u>Kokkonen v. Guardian Life Ins. Co. of</u>
25 <u>America</u>, 511 U.S. 375, 377 (1994). "Subject-matter jurisdiction can never be waived
26 or forfeited." <u>Gonzalez v. Thaler</u>, 132 S. Ct. 641, 648 (2012) (noting that an objection

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^{28 &}lt;sup>2</sup>The Court grants Synbias' motion to file its proposed memorandum decision under seal. (Doc. No. 219)

to a court's subject matter jurisdiction "may be resurrected at any point in the litigation, 1 2 and a valid objection may lead a court midway through briefing to dismiss a complaint in its entirety"). A dispute is presumed to lie "outside this limited jurisdiction, and the 3 burden of establishing the contrary rests upon the party asserting jurisdiction." 4 5 Kokkonen, 511 U.S. at 377 (internal citations omitted); Lanza v. Ashcroft, 389 F.3d 917, 930 (9th Cir. 2004) ("There is a general presumption against federal court review, 6 7 and the burden of establishing the contrary rests on the party asserting jurisdiction."). 8 Additionally, federal courts "have an independent obligation to determine whether subject-matter jurisdiction exists, even in the absence of a challenge from any party." 9 10 Arbaugh v. Y&H Corp., 546 U.S. 500, 514 (2006). "[W]hen a federal court concludes 11 that it lacks subject-matter jurisdiction, the court must dismiss the complaint in its 12 entirety." Id.

13 "[I]f subject-matter jurisdiction turns on contested facts, the trial judge may be authorized to review the evidence and resolve the dispute on her own." Arbaugh, 546 14 U.S. at 514; Robinson v. United States, 586 F.3d 683, 685 (9th Cir. 2009); see also 15 16 <u>Cedars-Sinai Medical Center v. Watkins</u>, 11 F.3d 1573, 1583-84 (Fed. Cir. 1993). "If, 17 however, a decision of the jurisdictional issue requires a ruling on the underlying substantive merits of the case, the decision should await a determination of the merits 18 either by the district court on a summary judgment motion or by the fact finder at the 19 20 trial." 5B C. Wright & A. Miller, Federal Practice and Procedure § 1350 (3d ed. 2004); 21 Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004).

To assert its infringement counterclaims, Solux must plead and prove sole patent
ownership. <u>Hall v. Bed Bath & Beyond, Inc.</u>, 705 F.3d 1357, 1362 (Fed. Cir. 2013)
(noting that to plead a patent infringement claim, a patentee must "(1) allege ownership
of the patent, (2) name each defendant, (3) cite the patent that is allegedly infringed, (4)
state the means by which the defendant allegedly infringes, and (5) point to the sections
of the patent law invoked."); <u>Phonometrics, Inc. v. Hospitality Franchise Systems, Inc.</u>,
203 F.3d 790, 794 (2000). If Solux is not the sole owner, the Court must dismiss the

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counterclaims for lack of standing. <u>Israel Bio-Engineering</u>, 475 F.3d at 1264. With
 these principles in mind, the Court turns to the summary judgment motion.

3

II. Summary Judgment

4 "Under Rule 56(c), summary judgment is proper 'if the pleadings, depositions, 5 answers to interrogatories, and admissions on file, together with the affidavits, if any, 6 show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Celotex Corp. v. Catrett, 477 U.S. 317, 322 7 (1986) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986)). As to 8 9 materiality, "[o]nly disputes over facts that might affect the outcome of the suit under 10 the governing law will properly preclude the entry of summary judgment." Anderson, 477 U.S. at 248. At the summary judgment stage, the judge's function is not to weigh 11 12 the evidence and determine the truth of the matter but to determine whether there is a 13 genuine issue for trial. Id. at 249. In making a determination on summary judgment, the evidence of the nonmovant is to be believed, and all reasonable inferences are to be 14 drawn in his favor. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1348 (Fed. Cir. 15 2001); Rockwell Int'l Corp. v. United States, 147 F.3d 1358, 1362 (Fed. Cir. 1998). 16 17 The court resolves pure questions of law on a summary judgment motion, however. 18 See, e.g., Medina v. Cram, 252 F.3d 1124, 1127 (10th Cir. 2001); Faust v. U.S., 101 19 F.3d 675, 678-79 (Fed. Cir. 1996).

20 A party seeking summary judgment bears the initial burden of establishing the 21 absence of a genuine issue of material fact. Celotex, 477 U.S. at 323. The moving 22 party can satisfy this burden in two ways: (1) by presenting evidence that negates an 23 essential element of the nonmoving party's case; or (2) by demonstrating that the 24 nonmoving party failed to establish an essential element of the nonmoving party's case 25 on which the nonmoving party bears the burden of proving at trial. Id. at 322-23. "Disputes over irrelevant or unnecessary facts will not preclude a grant of summary 26 judgment." T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n, 809 F.2d 626, 630 27 (9th Cir. 1987). Once the moving party establishes the absence of genuine issues of 28

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material fact, the burden shifts to the nonmoving party to set forth facts showing that
a genuine issue of disputed fact remains. <u>Celotex</u>, 477 U.S. at 322. "The 'opponent
must do more than simply show that there is some metaphysical doubt as to the material
fact." <u>Kennedy v. Allied Mut. Ins. Co.</u>, 952 F.2d 262, 265-66 (9th Cir. 1991) (citing
<u>Matsushita Elec. Indus. Co. v. Zenith Radio Corp.</u>, 475 U.S. 574, 586 (1986)).

6

A.

Patent Ownership

7 Patent ownership "is a question of who owns legal title to the subject matter claimed in a patent." Beech Aircraft Corp. v. EDO Corp., 990 F.2d 1237, 1248 (Fed. 8 9 Cir. 1993). "State statutory and common law have long been recognized as governing 10 the ownership of patent property." DDB Techs., L.L.C. v. MLB Advanced Media, L.P., 517 F.3d 1284, 1296 (Fed. Cir. 2008); see also Jim Arnold Corp. v. Hydrotech Sys., 11 12 Inc., 109 F.3d 1567, 1572 (Fed. Cir. 1997) ("[T]he question of who owns the patent 13 right and on what terms typically is a question exclusively for state courts."). Similarly, the law of a foreign jurisdiction may determine ownership of the subject matter claimed 14 in a U.S. patent. See Akazawa v. Link New Tech. Int'l, Inc., 520 F.3d 1354, 1357 (Fed. 15 16 Cir. 2008) (applying Japanese law to determine intestate ownership of a patent because 17 the inventor was a Japanese resident at the time of his death); Int'l Nutrition Co. v. 18 Horphag Research Ltd., 257 F.3d 1324, 1329 (Fed. Cir. 2001) (concluding that the 19 district court did not abuse its discretion in granting comity to a French court's 20 determination that an assignment of a U.S. patent was invalid under French law). While 21 state or foreign law generally governs the issue of patent ownership, "the question of 22 whether a patent assignment clause creates an automatic assignment or merely an 23 obligation to assign is intimately bound up with the question of standing in patent cases,' and therefore [courts] have treated it as a matter of federal law."" Sky Techs. 24 25 LLC v. SAP AG, 576 F.3d 1374, 1379 (Fed. Cir. 2009) ((quoting DDB Techs., 517 F.3d at 1290)). 26

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1. Assignment from the Inventors

2 Solux is listed as the owner by assignment of the patents-in-suit. (Doc. No. 1, 3 Exs. A-C.) As a matter of U.S. patent law, it is permissible for inventors to assign their 4 patent rights in inventions to third parties. See, e.g., Board of Trustees of Leland Stanford Junior University v. Roche Molecular Sys., Inc., 583 F.3d 832, 842 (2009). 5 Yet, an assignment may be invalid under the law of the particular jurisdiction governing 6 7 patent ownership. See Horphag Research, 257 F.3d at 1327, 1329-31 (enforcing a 8 French court judgment invalidating an assignment of patent rights because unilateral 9 assignment of jointly held patent rights was contrary to French law); Jim Arnold Corp. 10 v. Hydrotech Systems, Inc., 108 F.3d 1567, 1577 (Fed. Cir. 1997) (noting that an assignment of patent rights may be null and void "under a provision of applicable state 11 12 law").

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i. Initial Ownership

Synbias argues that its employees, the Synbias inventors, were not collectively 14 the sole owners of the inventions claimed in the patents-in-suit at the time they 15 16 purportedly assigned their rights to Synbias. The Court agrees. The parties do not 17 dispute that the patented subject matter was created by the Synbias inventors, while they 18 were employees of Synbias, and while working in Synbias' facilities in the Ukraine. Solux's expert agrees with Synbais that Ukraine law governs initial ownership of the 19 20 inventions. (Doc. No. 148 ("Paliashvili Decl.") ¶6 ("[T]he intellectual property rights 21 to the inventions described and claimed in the [patents-in-suit] . . . are governed by Ukraine law.").) As such, the Court applies Ukraine law to determine initial ownership 22 of the patents-in-suit.³ Akazawa v. Link New Tech. Int'l, Inc., 520 F.3d at 1357. 23 24 Inventions that arise of out an employment relationship between an inventor

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 ³ Rule 44.1 of the Federal Rules of Civil Procedure provides that in determining foreign law a "court may consider any relevant material or source, including testimony, whether or not submitted by a party or admissible under the Federal Rules of Evidence. The court's determination must be treated as a ruling on a question of law."

employee and his employer are "service inventions" under Ukranian law.⁴ (Doc. No. 1 2 62 ("Butler Decl.") ¶¶5-6.) Article 429 of the Ukranian Civil Code governs initial 3 ownership of the intellectual property rights of a service invention. (Id. ¶17.) Under Article 429, initial ownership of a service invention is determined by the employment 4 5 contract, and in the absence of such a contract, the employer and the inventor jointly hold the intellectual property rights. (Id. ¶18.) Synbias submitted copies of 6 7 employment agreements between Synbias and the inventors which provide that Synbias 8 is the initial owner of the inventions, and the inventors state in their declarations and in their depositions that they signed the agreements in 2001, prior to the purported 9 assignments to Solux. (Doc. No. 70 ("Zabudkin Decl.") ¶¶8-9, Exs. 1-3; Doc. No. 170-102, Ex. G.) Solux argues that these agreements are without effect because they were 11 12 recently created by Synbias for purposes of this litigation. Solux provides minimal 13 support for this assertion. In any event, the parties' factual dispute is not material under Ukranian law, since even if Synbias failed to execute proper employment agreements 14 with the inventors, Synbias was initially at least a co-owner of the patented subject 15 16 matter under Article 429. (Butler Decl. ¶18.)

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ii.

Assignment under Article 9

18 The parties dispute whether ownership later passed from Synbias to the inventors under Article 9 of the Ukranian Patent Law. Article 9(2) requires employee inventors 19 20 to provide written notification to their employer "disclosing the essence of the invention 21 (or utility model) sufficiently clearly and fully." (Butler Decl. ¶11.) Once the employee 22 inventor provides written notice, the employer must decide to file for a patent, transfer 23 patent rights to another, or preserve the invention as confidential. (Id. ("Article 9(3)").) 24 If the employer fails to choose any of these three options within four months of 25 receiving written notice, patent rights in the invention automatically pass to the 26 employee owners. (Id.)

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⁴Solux's expert agrees that "the contributions of the Synbias Inventors to the Inventions were 'service inventions." (Paliashvili Decl. ¶8.)

Synbias argues that ownership of the patents-in-suit did not pass to the inventors
 because it never received written notification. (Doc. No. 70 ("Zabudkin Decl.") ¶14.)
 Zabudkin and Matvienko both state in their declarations that they did not provide
 Synbias with written notice as required under Article 9.⁵ (Doc. No. 68 ("Matvienko
 Decl.") ¶14; Zabudkin Decl. ¶14.)

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Solux does not argue that the inventors provided written notice to other 6 7 executives or directors of Synbias. Rather, Solux argues that Alexandr Zabudkin, as 8 Sybnias's executive director, was high enough within Synbias such that his knowledge 9 constituted proper notice on behalf of Synbias. The Court disagrees. The Supreme 10 Court of Ukraine recently held that an inventor cannot properly notify himself given the obvious conflict of interest. (Butler Decl. ¶24, Ex. 29 ("Rivneazot Decision").) Solux's 11 12 expert notes that the Rivneazot decision dealt with proper notice under an employment 13 contract, not proper notice under Article 9. (Paliashvili Decl. ¶46.) Yet, Synbias submitted employment agreements in which the Synbias inventors agreed to provide 14 15 written notice to Synbias of their inventions so that Synbias could take appropriate 16 action. (See Zabudkin Decl. Ex. 3 (Appendix No. 2 to Company Order No. 10, signed 17 by Zabudkin) ("If the research is successful, the Employee [Zabudkin] shall give the 18 Employer [Synbias] notification in writing about the Invention created and attach a 19 comprehensive description of the invention that is sufficient for the purposes of 20 registration.") Under the agreements, notice to an inventor would plainly be 21 insufficient. (Butler Decl. ¶24.)

Additionally, the Court is not persuaded that the conflict-of-interest analysis employed by the Ukranian Supreme Court only applies in the context of notice under an employment agreement. Article 9 provides that ownership of patent rights in a service invention automatically passes from an employer to the inventor if the employer fails to take certain actions. (Butler Decl. ¶11.) If notice to an inventor were sufficient,

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⁵The third inventor, Matvyeyev, passed away in 2012. (Doc. No. 170 at p. 21.)

the inventor could simply wait out the clock until he possessed full ownership based on 1 2 his own inaction. The conflict-of-interest is immediately apparent from the face of 3 Article 9. Thus, written notice to the inventors fails either under the employment agreements or under Article 9. The record does not reveal any writing purporting to 4 5 assign Synbias' ownership rights to the inventors, and under either U.S. or Ukranian law, assignments of patent interests must be in writing. Sky Techs., 576 F.3d at1379; 6 7 (Butler Decl. ¶59.) Accordingly, Synbias remained at least a co-owner of the patents-8 in-suit.

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2. Ownership under the EXP Contract

10Solux argues that, even if Synbias partially owned patent rights in the claimed inventions, Synbias assigned its rights to Solux pursuant to a development contract. (D. 11 12 Itkin Decl., Ex. 1 ("the EXP Contract").) The Court disagrees. The EXP contract only assigned "know-how," not patent rights.⁶ (Id.) Under the EXP contract, Solux agreed 13 to pay Synbias \$150,000 to develop new manufacturing methods for doxorubicin 14 hydrochloride, epirubicin hydrochloride, and idarubicin hydrochloride-chemical 15 compounds described in the patents-in-suit.⁷ (Id.) Article 7.2 grants Solux "property 16 17 right[s] to Manufacturing Method of chemical substances developed under the present 18 contract." (Id.) Yet, Article 7.1 defines the "Manufacturing Method of chemical substances [as] intellectual product - 'know-how.'" (Id.) Additionally, Article 7.3 19 20 provides Solux with "the right to make any actions following [sic] from rights of 21 possession, using and the order [sic] Manufacturing Method of chemical substances

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- ⁶Because Article 11.3 provides that the arbitration of disputes is governed by the law of the Ukraine, the Court applies Ukranian law in interpreting the EXP Contract.
 See Hilgraeve Corp. v. Symantec Corp., 265 F.3d 1336, 1340, 1344-45 (Fed. Cir. 2001) (applying Ontario law in interpreting an agreement transferring "know-how" and technical expertise). Under Ukranian law, the contract language governs the relationship of the parties, and extrinsic evidence is inadmissible to contradict unambiguous contract terms. (3d Littman Decl., Ex. 44 ("Paliashvili Deposition").)
- ⁷The parties submitted different versions of the EXP contract, each claiming that their version is the effective agreement. This dispute is not material as the text of Article 7 (limiting the property transferred to "know-how") and Article 9 (requiring confidentiality) is identical in either party's version.

('know-how')." (Id.) Like in U.S. law, "know-how" is a property interest distinct from 1 2 patent rights under Ukranian law. (Paliashvili Decl. ¶18 ("Article 1 of the Law of Ukraine No. 1560-XII 'On Investment Activity' . . . states know-how is 'technical, 3 technological, and other knowledge, but not patented."") Further, the EXP contract 4 5 would be internally inconsistent if it transferred patent rights as Article 9 prohibits both Solux and Synbias from disclosing the manufacturing methods developed under the 6 7 contract to third parties. (D. Itkin Decl., Ex. 1.) Subject to certain exceptions not 8 applicable here, U.S. patent applications are generally published by the PTO. See 35 9 U.S.C. § 122. Accordingly, the EXP contract did not effect a transfer of patent rights 10 from Synbias to Solux.

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3. Judicial Estoppel

In the state litigation, Solux filed a notice of removal. Synbias filed a motion to
remand arguing that it lacked standing to assert its sole federal claim of correction of
inventorship under 35 U.S.C. § 256 because it lacked legal ownership of the patents-insuit. (Case No. 11-cv-1625, Doc. No. 6.) Solux now argues that Synbias is estopped
in this case from asserting that it is at least a co-owner based on arguments in the prior
case before another judge of this Court.

18 "Judicial estoppel is an equitable doctrine that prevents a litigant from 'perverting' the judicial process by, after urging and prevailing on a particular position 19 20 in one litigation, urging a contrary position in a subsequent proceeding-or at a later 21 phase of the same proceeding–against one who relied on the earlier position." Sandisk 22 Corp. v. Memorex Prods., 415 F.3d 1278, 1290 (Fed. Cir. 2005); see Hamilton v. State 23 Farm Fire & Cas. Co., 270 F.3d 778, 782 (9th Cir. 2001). The Supreme Court has 24 identified three factors to guide the court's decision to apply judicial estoppel: (1) the 25 party's later position must be clearly inconsistent with the earlier position; (2) the party must have succeeded in persuading a court to adopt the earlier position in the earlier 26 27 proceeding, such that it would create the perception that either the first or second court 28 was misled; and (3) the courts consider whether the party seeking to assert an

inconsistent position would derive an unfair advantage or impose an unfair detriment 1 2 on the opposing party if not estopped. <u>New Hampshire v. Maine</u>, 532 U.S. 742, 750-51 3 (2001). In addition, the Ninth Circuit "has restricted the application of judicial estoppel to cases where the court relied on, or 'accepted,' the party's previous inconsistent 4 5 position." Hamilton, 270 F.3d at 783. But, the Supreme Court has noted that these factors "do not establish inflexible prerequisites or an exhaustive formula for 6 7 determining the applicability of judicial estoppel. Additional considerations may inform the doctrine's application in specific factual contexts." New Hampshire, 532 8 9 U.S. at 751. "It is within the trial court's discretion to invoke judicial estoppel and preclude an argument." Sandisk, 415 F.3d at 1290; see also New Hampshire, 532 U.S. 10at 750 ("[J]udicial estoppel 'is an equitable doctrine invoked by a court at its 11 12 discretion."").

13 Here, Synbias is not estopped from asserting an ownership interest. In its motion to remand, Synbias claimed that it was a beneficial owner. (Doc. No. 6-1 at p. 7 14 (Synbias "claims beneficial ownership of [the patents-in-suit].") Additionally, Synbias' 15 16 position-that Solux is not a sole owner-is not inconsistent with its prior position of 17 beneficial ownership. Further, the Court granted Solux over five months to conduct 18 discovery to oppose Synbias' motion, and the Court requested briefing on the 19 jurisdictional issue. Moreover, estoppel is an equitable doctrine. As such, the Court 20 concludes that application of estoppel in this context is inappropriate since it would 21 confer patent jurisdiction in federal court where it does not exist. Israel Bio-22 Engineering, 475 F.3d at 1264; see also Kokkonen, 511 U.S. at 377 ("Federal courts are 23 of courts of limited jurisdiction. They possess only that power authorized by Constitution and statute.") As such, the Court exercises its discretion and determines 24 25 that application of judicial estoppel is not warranted.

In sum, Synbias was at least a co-owner of the inventions under Ukranian law
and its ownership interests did not pass to the inventors prior to the purported
assignments. Additionally, Solux did not obtain an assignment from Synbias under the

EXP contract. As such, the Court dismisses Solux's counterclaims for lack of standing.
 Israel Bio-Engineering, 475 F.3d at 1264.

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III. Declaratory Judgment Claims

4 Dismissal of Solux's counterclaims leaves Synbias' declaratory claims as the only 5 remaining claims in this litigation. Federal courts have subject matter jurisdiction over claims for declaratory relief as long as "the dispute [is] definite and concrete, touching 6 7 the legal relations of parties have adverse legal interests." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (quotations omitted). "An 'adverse legal 8 9 interest' requires a dispute as to a legal right-for example, an underlying legal cause of 10 action that the declaratory defendant could have brought or threatened to bring." Arris Grp., 639 F.3d at 1374; see also Microchip Tech. Inc. v. Chamberlain Grp., Inc., 441 11 F.3d 936, 943 (Fed. Cir. 2006) ("Without an underlying legal cause of action, any 12 13 adverse economic interest that the declaratory plaintiff may have against the declaratory defendant is not a legally cognizable interest sufficient to confer declaratory judgment 14 jurisdiction."). Here, the legal cause of action underlying Synbias' declaratory claims 15 16 was Solux's claim for patent infringement. (Doc. No. 19.) As Solux lacks standing to 17 assert infringement, there is no underlying legal cause of action that Solux could have brought or threatened to bring. Arris Grp., 639 F.3d at 1374. As such, this Court lacks 18 subject matter jurisdiction over Synbias' declaratory claims because the parties no 19 20 longer have adverse legal interests. Accordingly, the Court dismisses Synbias' 21 complaint in its entirety. Arbaugh v. Y&H Corp., 546 U.S. at 514.

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Conclusion

For the foregoing reasons, the Court dismisses Solux's counterclaims for lack of standing, Israel Bio-Engineering, 475 F.3d at 1264, and dismisses Synbias' complaint for lack of subject matter jurisdiction. Arbaugh v. Y&H Corp., 546 U.S. at 514. As such, the parties may proceed with their state court action to resolve their business disputes, involving allegations of breach of contract, breach of fiduciary duty, and fraud. (State SAC ¶¶47-59; D. Itkin Decl. ¶7 (contending that Solux and Synbias entered into a joint venture); 11-cv-1625, Doc. No. 6-1 at p. 2 (claiming that Solux was Synbias' agent).) **IT IS SO ORDERED.** Dated: August 30, 2013 UNITED STATES DISTRICT COURT - 14 -PATENT REEL: 032853 FRAME: 0728

RECORDED: 05/08/2014