

II. JURISDICTION

3. This Court has exclusive jurisdiction pursuant to 28 U.S.C. § 1338(a), as Repros' right to relief depends on the resolution of a substantive question of federal patent law. Repros seeks a declaratory judgment of ownership and inventorship pursuant to 35 U.S.C.A. § 256 regarding the following issued United States Patents: 7,173,064 (the "064 patent"), (see Exhibit 1), 7,368,480 (the "480 patent"), (see Exhibit 2), 7,737,185 (the "185 patent"), (see Exhibit 3), and 7,759,360 (the "360 patent"), (see Exhibit 4). The Repros Patents were issued by the United States Patent and Trademark Office ("USPTO") and Repros is the Assignee of the full rights, title and interest of each of the Repros Patents. As the assignee to the full interest of the Repros Patents, Repros has standing to bring this suit.

4. This Court is empowered to issue the declarations sought in the action pursuant to 28 U.S.C. § 2201.

5. The Court has specific personal jurisdiction over Fisch as this dispute arises from a meeting that he initiated with plaintiff, who Fisch knew is a Texas-based company. Fisch purposefully availed himself of the privileges and benefits of doing business in Texas by seeking to potentially collaborate and do business with a Texas-based company. Related to those contacts, Fisch requested that plaintiff enter into a Confidentiality Agreement (the "Agreement") with him and executed that Agreement, which calls for the application of Texas law.

6. The Court also has general jurisdiction over Fisch because he regularly and routinely directs economic activities toward and in the State of Texas. Fisch is a public figure who, upon information and belief, provides commentary and advice with the expectation that it will be heard and received in Texas and, in turn, inure to Fisch's financial benefit. Furthermore, upon information and belief, Fisch engages in business ventures and activities that target those

persons and entities in Texas. For example, Fisch has actively worked with a prior subsidiary of Repros to market and distribute medical goods in Texas.

III. VENUE

7. Venue is proper in this district and division under 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims in this action occurred in this district and division and all alleged acts of inventorship occurred, or are believed to have occurred in this district.

IV. FACTUAL BACKGROUND

8. Repros is a development-stage biopharmaceutical company focused on the development of small molecule drugs for major unmet needs in male and female health.

9. Repros is the owner and assignee of the full rights, title, and interest of each of the Repros Patents.

10. Dr. Harry Fisch is a urologist and national media personality.

11. By letter and draft complaint sent to Repros President and CEO Joseph S. Podolski and Repros on July 19, 2013, Fisch wrongfully alleges he is a co-inventor on the '360, '064, and '185 patents and threatens to file suit if no response is received by August 5, 2013. True and correct copies of the July 19, 2013 letter and draft complaint are attached hereto as Exhibits 5 and 6.

12. One of the drugs in Repros' pipeline is Androxal®, an isolated trans-isomer of clomiphene citrate currently in successful late-stage (Phase III) FDA clinical trials for treatment of male secondary hypogonadism. Secondary hypogonadism is a term which defines a state of low testosterone, the underlying cause of which is a failure of the hypothalamus or pituitary gland to signal the testicles to produce testosterone. Importantly, secondary hypogonadism is not

a disorder related to androgen deficiency, but rather describes the condition of low testosterone per se.

13. The '360 patent, covering the use of the isolated clomiphene trans-isomer for treatment of male secondary hypogonadism, was applied for by inventor and Repros President and CEO Joseph S. Podolski starting in 2001 with the filing of a provisional patent application. The '360 patent, which claims priority to the 2001 filing, issued in 2010.

14. In or about the late 1990's, a former division of Repros, Fertility Technologies Inc., sold and distributed sperm quality kits on Fisch's behalf. Fertility Technologies was sold in 1999, which ended the parties' commercial relationship at the time.

15. As detailed further below, in May of 2000, Fisch applied for a patent on a different invention based on clomiphene citrate, a mixture of clomiphene isomers comprising between 30% and 50% of the cis-isomer. It was not until much later—in 2007, after the application for the '360 patent had published—that Fisch sought to patent the use of the isolated clomiphene trans-isomer. Fisch's attempt, which was made by amendment to the claims of his European patent application on June 12, 2007, was rejected by the European Patent Office as being unsupported by his application.¹

16. Notably, the invention described in Fisch's patent application, which ultimately issued as U.S. Patent No. 6,391,920 (the "'920 patent"), is directed to the use of clomiphene or clomiphene citrate, defined by the '920 patent as a mixture of clomiphene cis- and trans-isomers, for treating disorders related to androgen deficiency (or male menopause), not to treating male secondary hypogonadism. In fact, Fisch admitted during a reexamination of the '920 patent that his invention does not extend to the treatment of male secondary hypogonadism.

¹ See European Patent Office May 5, 2010 communication at sheet 1, section 1.3, a true and correct copy is attached as Exhibit 7.

A. Repros and Fisch Enter Into Confidentiality Agreement, but Their Relationship Ends There

17. In 2001, Fisch contacted Podolski, in Podolski's capacity as President and CEO of Repros.

18. In order to further the discussions that Fisch contemplated concerning a provisional patent application he filed on or about May 26, 2000, Fisch and Repros executed the Confidentiality Agreement on or about March 27, 2001. That Agreement is governed by Texas law.

19. After executing the Agreement, the parties met in March of 2001, in New York. During that meeting, the parties discussed various aspects of Fisch's provisional patent application, but there was no discussion about individual clomiphene citrate isomers, much less whether any individual isomer could be used to treat any medical condition.

20. After the meeting, the parties decided not to enter into any business relationship with one another.

B. The Parties Separately Patent Entirely Different Inventions

21. Subsequent to the meeting in March of 2001, both Podolski and Fisch obtained patents on their respective inventions. The claims of these patents are directed to distinct subject matter and represent different inventions.

22. On or about May 15, 2001, Fisch filed International Application No. PCT/US01/159900 claiming priority from his U.S. provisional patent application. While the application addressed clomiphene citrate in some respects, it did not address the use of the individual isomers at all.

23. On or about July 9, 2001, Podolski filed a provisional application, No. 60/304,314, which claimed the use of the single clomiphene trans-isomer.

24. On or about October 26, 2001, Fisch amended his application, to include claims directed to compositions comprising clomiphene isomers.

25. Fisch's application, including the above-described amendments, was not published—and therefore not public—until on or about December 6, 2001. It was published as WIPO Publication No. WO 2001/091744 and ultimately issued as the '920 patent.

26. Fisch's patent has had a rocky past. Not all of the claims have survived further scrutiny by the Patent and Trademark Office ("PTO") and others have been extensively modified.

27. For those claims that have survived, they did so, in part, on the basis that Fisch expressly stated that his invention did not cover the treatment of androgen deficiency per se (i.e. hypogonadism) but rather was limited to treating disorders associated with androgen deficiency.

28. Based on Fisch's own representations to the PTO, he has expressly disclaimed that his invention encompasses the treatment of male secondary hypogonadism because secondary hypogonadism is simply another name for androgen deficiency and is not a disorder related to androgen deficiency.

29. Unlike Fisch, Podolski did not amend his claims prior to prosecution of the application that issued as the '360 patent. Podolski's patent application was published on or about January 23, 2003, as WIPO Publication No. WO 2003/005954. Unlike any of Fisch's iterations of his application, the '360 patent application consistently described and claimed an invention comprising the use of the single trans-isomer of clomiphene citrate for the treatment of low testosterone per se. Similarly, the '064 patent, the '480 patent and the '185 patent applications, each of which was filed subsequent to, and claims priority from, the '360 patent application, consistently described and claimed an invention comprising the use of the single

trans-isomer of clomiphene citrate for the treatment of various disorders related to low testosterone.

30. Recognizing the importance of Podolski's invention, shortly after publication of the '360 patent application, Fisch offered to purchase Podolski's patent for approximately \$200,000. Repros refused.

31. In 2007, over four years after publication of the '360 patent, Fisch attempted to obtain patent protection for the use of single clomiphene isomers—in Europe. The European authority rejected Fisch's attempt as beyond the scope of his patent application. Briefly stated, the European authority asserted that Fisch's patent application describes clomiphene only in the context of mixtures of clomiphene isomers and that neither the single isomers individually nor their use are described.

C. Unable To Innovate, Fisch Seeks To Harm Repros's Business

32. Fisch has undertaken a strategy to undermine Repros' business and interfere with its economic relationships and has done so in an effort to enrich himself by claiming to own Repros' invention and claiming to be an inventor of the subject matter claimed in the Repros Patents. He does not now, nor has he ever, owned any Repros invention. Nor did he contribute in any way to the conception or reduction to practice of the subject matter claimed in any of the Repros Patents.

33. On or about August 12, 2012, Fisch spoke to Repros' investors and the media and represented that Repros would not be able to market or sell Androxal freely because, in Fisch's view, Fisch owns the invention. That statement or any similar statement is simply false.

34. Fisch's comments led, in part, to an August 27, 2012 article in the Financial Times. That article stated in part that "Repros . . . will need to resolve potential patent conflicts

around Androxal . . . before it can secure a partner The company will likely have to negotiate a deal with the original patent owner[.]”

35. The August 27 article is incorrect because it wrongly infers that Repros does not already own the invention and that Podolski is not the original patent owner.

36. Because his initial comments did not have the desired effect—ostensibly, to extract substantial money from Repros—Fisch resumed his efforts against Repros.

37. Fisch has continuously and consistently shared his false narrative with potential investors, investment banks, and the media.

38. On or about May 2, 2013, BioPharm Insight published another article based on Fisch’s false narrative. Again, the article incorrectly stated that Androxal faced a “legal barrier” and this time alleged that it “may have been generated outside of a confidentiality agreement, a source has claimed.” The information contained in the article is extensive regarding the March 2001 meeting, and that information could have only come from Fisch—whether directly or indirectly.

39. It was a violation of the Agreement to disclose the existence or subject matter of any negotiations or business relationship that were contemplated by the parties.

40. BioPharm published a second article on or about May 8, 2013, reiterating many of the same incorrect claims. However, the second article raised the specter of a patent infringement suit between Fisch and Repros. The article again referenced an unknown source, which is either Fisch or someone whom Fisch is using to peddle these inaccurate stories.

41. More recently, Fisch’s false disclosures generated a May 9, 2013 article in The Street. Like the previous articles, the May 9 article contains numerous inaccuracies—inaccuracies that Fisch is peddling in an effort to profit off of Repros’ invention. This time,

however, Fisch went on the record directly. Among other things, Fisch falsely stated that Podolski “stole my idea.”

42. There is no apparent end to Fisch’s calculated scheme to harm Repros’ reputation, economic standing, and business prospects. Indeed, Fisch is intent to use his media savvy to harm Repros as widely and permanently as possible with investors, business partners, and the public.

43. The full economic fallout of Fisch’s ongoing activities are not known.

44. Based on Fisch’s allegations and his explicit threat to sue, Repros has a reasonable apprehension that Fisch will file suit regarding inventorship of the Repros patents. Notably, the draft complaint lists this forum as the proper forum.

V. COUNT I: DECLARATORY JUDGMENT OF OWNERSHIP AND INVENTORSHIP OF THE ’360 PATENT

45. Repros repeats and realleges the foregoing allegations as if fully set forth herein.

46. Repros is the owner and assignee of the full rights, title, and interest of the ’360 patent.

47. The ’360 patent lists the true and correct inventor of its subject matter, Joseph S. Podolski.

48. The application for the ’360 patent was originally filed on or about July 9, 2002, as international Patent Application No. PCT/US02/21524, which claims the benefit of U.S. Provisional Patent Application No. 60/304,313, filed on July 9, 2001.

49. The application for the ’360 patent was originally published on or about January 23, 2003, as WIPO Publication No. WO 2003/005954 and again published on or about December 2, 2004, as U.S. Patent Application Pub. No. 2004/0241224.

50. The ’360 patent granted on July 20, 2010, and includes 7 claims.

51. Fisch did not contribute to the conception of the subject matter of any claim of the '360 patent and is therefore not an inventor as set forth by the patent laws of the United States. *See* 35 U.S.C. § 101 and 102(f) (pre-AIA). *See also* MPEP 2137.01.

VI. COUNT II: DECLARATORY JUDGMENT OF OWNERSHIP AND INVENTORSHIP OF THE '185 PATENT

52. Repros repeats and realleges the foregoing allegations as if fully set forth herein.

53. Repros is the owner and assignee of the full rights, title, and interest of the '185 patent.

54. The '185 patent lists the true and correct co-inventors of its subject matter, Joseph S. Podolski and Ronald Wiehle.

55. The application for the '185 patent (U.S. Patent Application No. 11/750,190) was filed on May 17, 2007 as a continuation-in-part of U.S. Patent Application No. 10/427,768, filed on April 30, 2003, now U.S. Patent No. 7,368,480, which is a continuation-in-part of international Patent Application No. PCT/US02/021524, filed on July 9, 2002, which claims the benefit of U.S. Provisional Patent Application No. 60/304,313, filed on July 9, 2001.

56. U.S. Patent Application No. 11/750,190 was published on or about October 25, 2007, as U.S. Patent Application Pub. No. 2007/0249726.

57. The '185 patent granted on June 15, 2010, and includes 7 claims.

58. Fisch did not contribute to the conception of the subject matter of any claim of the '185 patent and is therefore not an inventor as set forth by the patent laws of the United States. *See* 35 U.S.C. § 101 and 102(f) (pre-AIA). *See also* MPEP 2137.01.

VII. COUNT III: DECLARATORY JUDGMENT OF OWNERSHIP AND INVENTORSHIP OF THE '480 PATENT

59. Repros repeats and realleges the foregoing allegations as if fully set forth herein.

60. Repros is the owner and assignee of the full rights, title, and interest of the '480 patent.

61. The '480 patent lists the true and correct co-inventors of its subject matter, Joseph S. Podolski and Ronald Wiehle.

62. The application for the '480 patent (U.S. Patent Application No. 10/427,768) was filed on April 30, 2003 as a continuation-in-part of International Patent Application No. PCT/US02/21524, filed on July 9, 2002, which claims the benefit of U.S. Provisional Patent Application No. 60/304,313, filed on July 9, 2001.

63. U.S. Patent Application No. 10/427,768 was published on or about May 20, 2004, as U.S. Patent Application Publication No. 2004/0097597.

64. The '480 patent granted on May 6, 2008 and includes 7 claims.

65. Fisch did not contribute to the conception of the subject matter of any claim of the '480 patent and is therefore not an inventor as set forth by the patent laws of the United States. *See* 35 U.S.C. § 101 and 102(f) (pre-AIA). *See* also MPEP 2137.01.

VIII. COUNT IV: DECLARATORY JUDGEMENT OF OWNERSHIP AND INVENTORSHIP OF THE '064 PATENT

66. Repros repeats and realleges the foregoing allegations as if fully set forth herein.

67. Repros is the owner and assignee of the full rights, title, and interest of the '064 patent.

68. The '064 patent lists the true and correct co-inventors of its subject matter, Joseph S. Podolski and Ronald Wiehle.

69. The application for the '064 patent (U.S. Patent Application No. 10/712,546) was filed on November 12, 2003, as a continuation-in-part of U.S. Patent Application No. 10/427,768, filed on April 30, 2003, now U.S. Patent No. 7,368,480, which is a continuation-in-

part of international Patent Application No. 2002/021524, filed on July 9, 2002, which claims the benefit of U.S. Provisional Patent Application No. 60/304,313, filed on July 9, 2001.

70. U.S. Patent Application No. 10/712,546 was originally published on or about September 2, 2004, as U.S. Patent Application Pub. No. 2004/0171697.

71. The '064 patent granted on February 6, 2007, and includes 7 claims.

72. Fisch did not contribute to the conception of the subject matter of any claim of the '064 patent and is therefore not an inventor as set forth by the patent laws of the United States. *See* 35 U.S.C. § 101 and 102(f) (pre-AIA). *See* also MPEP 2137.01.

IX. JURY DEMAND

73. Repros hereby demands a jury trial on all issues, claims, actions, and defenses in this case.

X. PRAYER

Wherefore, Repros respectfully requests the following relief:

a. A declaration that Fisch is not an inventor under the laws of the United States on the Repros Patents and has no ownership interest in the Repros Patents;

b. Reasonable attorney's fees under 35 U.S.C. § 285; and

c. All other and further relief to which Repros may be entitled and to which this Court deems just and proper.

Dated: August 2, 2013

Respectfully submitted,

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