UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUN PHARMACEUTICAL INDUSTRIES LTD. and RANBAXY SIGNATURE, LLC,	)	
Plaintiffs,	)	CIVIL ACTION NO. 18-648 (MPT)
SAPTALIS PHARMACEUTICALS, LLC,	)	JURY TRIAL DEMANDED
Defendant.	)	

SAPTALIS PHARMACEUTICALS, LLC'S ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendant Saptalis Pharmaceuticals, LLC ("Saptalis" or "Defendant") for its answer to the Complaint filed by Sun Pharmaceutical Industries Ltd. ("Sun") and Ranbaxy Signature, LLC ("Ranbaxy") (Sun and Ranbaxy collectively "Plaintiffs") states as follows:

The Nature of the Action

1. Saptalis admits that Plaintiffs allege infringement of U.S. Patent No. 6,890,957 ("the '957 patent") under the patent laws of the United Sates for Saptalis' filing with the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application No. 211309 ("Saptalis ANDA") seeking FDA approval prior to the expiration of the '957 patent of a generic metformin hydrochloride oral solution (brand name Riomet®), but denies the remaining allegations in this paragraph.

The Parties

2. Saptalis lacks knowledge or information sufficient to admit or deny the allegations in paragraph 2 of the Complaint.

3. Saptalis lacks knowledge or information sufficient to admit or deny the allegations in paragraph 3 of the Complaint.

4. Saptalis Admits the allegations in paragraph 4 of the Complaint.

5. Saptalis admits that it participated in the research and development of the product described in the Saptalis ANDA ("Saptalis ANDA Product") and prepared and filed the Saptalis ANDA with FDA, and intends to manufacture and sell the Saptalis ANDA Product in the United States in the event FDA approves the Saptalis ANDA, but denies the remaining allegations in paragraph 5 of the Complaint.

Jurisdiction and Venue

6. Saptalis admits that this Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

7. Saptalis admits that it is a Delaware corporation, but denies the remaining allegations in paragraph 7 of the Complaint.

8. Saptalis admits that it prepared and filed the Saptalis ANDA, but denies the remaining allegations in paragraph 8 of the Complaint.

9. Saptalis denies that venue is proper in this judicial district, and, pursuant to 28 U.S.C. 1404(a), is moving to have this case transferred to the Eastern District of New York, where Plaintiffs also brought this same case.

The Patent in Suit

10. Saptalis admits that the '957 patent entitled "Liquid Formulation of Metformin"

issued on May 10, 2005, and that an alleged copy of the '957 patent is attached as Exhibit A to the Complaint, but denies the remaining allegations in paragraph 10 of the Complaint.

Riomet®

11. Saptalis admits that the '957 patent is listed in the Orange Book for the Reference Listed Drug Riomet® (NDA No. 021591), but denies the remaining allegations in paragraph 11 of the Complaint.

The Saptalis ANDA

12. Saptalis admits that the Notice Letter Concerning Saptalis ANDA No. 211309 dated March 16, 2018 ("Saptalis Notice Letter") states that Saptalis submitted ANDA No. 211309 to FDA under 21 USC 355(j) for metformin hydrochloride oral solution, but denies the remaining allegations in paragraph 12 of the Complaint.

13. Saptalis admits the allegations in paragraph 13 of the Complaint.

14. Saptalis admits that the Saptalis ANDA was submitted to FDA for approval to make and sell a generic metformin hydrochloride oral solution prior to the expiration of the '957 patent, but denies the remaining allegations in paragraph 14 of the Complaint.

15. Because the allegation in paragraph 15 of the Complaint concerns future events, Saptalis lacks knowledge or information sufficient to form a belief as to the allegation in paragraph 15 of the Complaint, and therefore denies same.

16. Saptalis denies the allegations in paragraph 16 of the Complaint, and relies on the Saptalis ANDA for the information contained therein.

Count I (Alleged Infringement of the ’957 Patent)

17. Paragraphs 1 to 16 are incorporated herein as set forth above.

18. Saptalis admits that it submitted the Saptalis ANDA to FDA seeking approval to make and sell the Saptalis ANDA Product prior to the expiration of the ’957 patent which creates a judiciable controversy, but denies the remaining allegations in paragraph 18 of the Complaint.

19. Saptalis denies the allegations in paragraph 19 of the Complaint.

20. Saptalis denies the allegations in paragraph 20 of the Complaint.

21. Saptalis denies the allegations in paragraph 21 of the Complaint.

22. Saptalis denies the allegations in paragraph 22 of the Complaint.

23. Saptalis admits that it was aware of the ‘957 patent prior to filing the Saptalis ANDA, but denies the remaining allegations in paragraph 23 of the Complaint.

24. Saptalis denies the allegations in paragraph 24 of the Complaint.

Alleged Exceptional Case

25. Saptalis denies the allegations in paragraph 25 of the Complaint.

Answer to Request for Injunctive Relief

26. Saptalis denies the allegations in paragraph 26 of the Complaint.

Answer to Prayer for Relief

Saptalis denies that Plaintiffs are entitled to any of the relief requested in their

Prayer for Relief.

SAPTALIS'S AFFIRMATIVE DEFENSES

Saptalis asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the plaintiff.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

1. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement)

2. The Saptalis ANDA and the making, using or selling of the Saptalis ANDA Product does not and will not infringe, either directly or indirectly, contributorily, or by inducement, any claim of the '957 patent, literally or under the doctrine of equivalence, willfully or otherwise.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

3. The '957 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(Estoppel)

4. Plaintiffs' claims and requested relief are barred by the doctrine of estoppel.

FIFTH AFFIRMATIVE DEFENSE
(No Costs)

5. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH AFFIRMATIVE DEFENSE
(Exceptional Case)

6. Saptalis' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. §285. Plaintiffs' bad faith in filing this objectively baseless suit does give rise to an exceptional case under 35 U.S.C. §285, such that Saptalis is entitled to an award of its costs and attorneys' fees incurred in defending this action.

SEVENTH AFFIRMATIVE DEFENSE
(*forum non conveniens*)

7. Venue is improper and inconvenient to Defendant in this forum, and Defendant has moved, pursuant to 28 U.S.C. 1404(a), to transfer this case to the Eastern District of New York where Plaintiffs also brought this same case against Defendant.

COUNTERCLAIMS

Saptalis hereby states for its Counterclaims against Sun and Ranbaxy the following:

1. Saptalis repeats and incorporates by reference each of the foregoing

paragraphs of Saptalis's Answer and Affirmative Defenses to the Complaint.

2. This is an action for a declaratory judgment of invalidity and non-infringement of one or more claims of United States Patent No. 6,890,957 ("the '957 patent"), for damages resulting from the filing of an objectively baseless complaint against Saptalis by Sun and Ranbaxy, and for damages resulting from the bringing of an action in violation of Section 2 of the Sherman Act by Sun and Ranbaxy.

The Parties

3. Saptalis is a corporation incorporated under the laws of Delaware, with its principal place of business at 45 Davids Dr., Hauppauge, NY 11788.

4. On information and belief, Sun is an entity organized and existing under the laws of India having a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063, India.

5. On information and belief, Ranbaxy is an entity organized and existing under the laws of Delaware, with its principal place of business at 600 College Road East, Suite 2100, Princeton NJ 08540.

Jurisdiction and Venue

6. This court has original jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a) and (b), 2201, and 2202, based on an actual controversy between Saptalis, on the one hand, and Sun and Ranbaxy, on the other hand, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and Section 4 of the Sherman Act., 15 U.S.C. § 4.

7. This court has personal jurisdiction over Sun and Ranbaxy based on, *inter alia*, the filing by Sun and Ranbaxy of this lawsuit in this jurisdiction.

8. Venue is proper in this judicial district with respect to these counterclaims based on, *inter alia*, the filing by Sun and Ranbaxy of this lawsuit in this jurisdiction.

Relevant Facts

9. The United States Patent and Trademark Office ("PTO") issued the '957 patent on May 10, 2005. Ranbaxy claims to be the sole owner of the '957 patent.

10. On information and belief, Sun is the current holder of approved New Drug Application ("NDA") No. 021591 for metformin hydrochloride oral solution 500 mg/5 mL, which is marketed as Riomet®.

11. The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

12. On information and belief, pursuant to 21 U.S.C. § 355(b)(1)(G), Sun caused the United States Food and Drug Administration ("FDA") to publish the '957 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book," in connection with NDA No. 021591.

13. By maintaining the listing of the '957 patent in the Orange Book, Sun represents that these patents "could reasonably be asserted if a person not licensed by the

owner engaged in the manufacture, use or sale of the drug." 21 U.S.C. §355(b)(l)(G).

14. Saptalis filed ANDA No. 211309 with the FDA seeking approval to market metformin hydrochloride oral solution 500 mg/5 mL, and certifying to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that the product described in ANDA No. 211309 does not infringe the claims of the '957 patent, and that the '957 patent is invalid.

15. Pursuant to 21 U.S.C. 355(j)(2)(B), Saptalis provided notice to Sun and Ranbaxy on or about March 16, 2018 of its Paragraph IV certification on the '957 patent with a detailed statement of the factual and legal bases for its Paragraph IV certification on the '957 patent (the "Notice Letter").

16. Included in the detailed statement accompanying the Notice Letter, Saptalis advised Sun and Ranbaxy, *inter alia*, that the product described in ANDA No. 211309 does not satisfy the claims of the '957 patent because each of those claims requires "a polyhydroxy alcohol present in an amount of about 15 to 55% by weight."

17. On April 4, 2018, Sun and Ranbaxy or their counsel requested certain documents from ANDA No. 211309. The requested documents were sent to Sun and Ranbaxy's counsel on or before April 19, 2018. These documents indicate that the formulation described in ANDA 211309 for which Saptalis is seeking FDA approval contains substantially less than about 15.0% of a polyhydroxy alcohol.

18. Saptalis also indicated in the Notice Letter and/or detailed statement to Sun and Ranbaxy that the doctrine of equivalents as to the polyhydroxy alcohol element in the

claims of the '957 patent is barred under the doctrine of prosecution history estoppel. Specifically, patent application No. 10/382,442, which issued as the '957 patent, was filed on March 6, 2003 with independent claim No. 1 which did not include polyhydroxy alcohol as an element, and independent claim 8 which claimed about 5% to about 55% polyhydroxy alcohol. The patent applicants, on June 18, 2003, amended claim 1 to add a polyhydroxy alcohol present in an amount of about 15% to about 55% by weight. The applicant also cancelled claim 8. The patent applicants provided no reason for making these amendments other than for reasons of patentability. Accordingly, applicants are now estopped from alleging infringement under the doctrine of equivalence with respect to the claimed element "a polyhydroxy alcohol present in an amount of about 15 to 55% by weight."

19. Despite the information in the Notice Letter, detailed statement, and documents from ANDA No. 211309 provided to Sun and Ranbaxy or their counsel, Sun and Ranbaxy filed the present Complaint against Saptalis, alleging that the Saptalis ANDA and the Saptalis ANDA Product has and will infringe the'957 patent.

20. As a result of the Complaint filed by Sun and Ranbaxy, FDA may not approve Saptalis' ANDA No. 211309 for up to 30 months from Sun and Ranbaxy's receipt of the Saptalis Notice Letter ("the 30 month stay"), pursuant to 21 U.S.C. 355(j)(5)(B)(iii). The Hatch-Waxman Act provisions giving rise to the 30 month stay are well-known in the pharmaceutical industry, and to Sun and Ranbaxy, who have litigated many such infringement lawsuits. The 30 month stay may be shortened if a U.S. district court enters judgement of non-infringement or invalidity of the '957 patent.

21. As a result of the foregoing, Sun and Ranbaxy do not have any good faith

factual basis to allege that the Saptalis ANDA and the Saptalis' ANDA Product would infringe any claim of the '957 patent, and, given the facts described herein, Sun and Ranbaxy or their counsel knew, as of the date they asserted claims of infringement of the '957 patent, that the Saptalis ANDA and the Saptalis ANDA Product could not infringe the '957 patent.

22. On information and belief, Sun and Ranbaxy filed their claims with respect to the '957 patent without regard for the merits of their infringement claims and instead did so, as described more fully herein, for the purpose of delaying FDA approval of Saptalis' ANDA Product, and to prevent competition in the relevant antitrust market, defined below, that would otherwise benefit consumers. Accordingly, Sun and Ranbaxy's infringement action against Saptalis is a sham, brought without objective basis, in bad faith, and solely for the purpose of interfering directly with Saptalis to the detriment of competition in the alleged relevant antitrust market, defined below.

23. Saptalis reasonably expected its ANDA to be approved in less than 30 months, but that approval will now be delayed by this sham litigation improperly filed by Sun and Ranbaxy. The conduct of Sun and Ranbaxy described herein – which allowed them to illegally monopolize or attempt to monopolize the relevant market by preventing and delaying Saptalis from proceeding with plans to sell a generic product, is causing damage to Saptalis, including future lost sales, future lost profits, expenses of re-directed resources, and the cost of defending this baseless lawsuit, and will continue to cause harm to both Saptalis and consumers who do not have the benefit of competition between products in the relevant antitrust market unless the Court grants the relief sought herein.

Liquid Formulated Metformin is a Relevant Product Market

24. For purposes of the antitrust counterclaim herein, the relevant product market is a liquid formulation of metformin in the form of orally administered medication that serves a relevant market of patients who are unable or find it difficult to swallow metformin pills or tablets. The branded drug Riomet® is included and is the only product within this relevant market. As is described more fully below, a liquid formulation of metformin is touted by Sun and Ranbaxy as a separate and distinct product. Sun and Ranbaxy's marketing materials and the '957 patent tout their unique ability to fulfill medical needs of prescribing physicians and patients. Thus, based on these representations alone, there does not appear to be any reasonably interchangeable or medically acceptable substitutes for a liquid formulation of metformin available with respect to diabetic patients who cannot, or who find it difficult to, swallow tablets. See attached Exhibit A of internet marketing materials for Riomet from Plaintiffs' website.

25. The '957 patent proclaims that "Unfortunately, as sold, the [metformin hydrochloride] tablet is very large, making it difficult to swallow. Moreover, due to its size, this drug cannot be used by children or adults who are not able to swallow tablets. However, the present inventors realize that a liquid formulation would be useful for children and adults who cannot swallow large size tablets or orally intake chewable tablets. To date, no one has heretofore made a liquid formulation of metformin hydrochloride salt which has masked the unpleasant taste thereof. Moreover, to date, no one has made a liquid formulation of metformin or salt thereof."

26. In addition, Sun and Ranbaxy's marketing materials provide that many

patients have trouble swallowing metformin tablets. According to Sun and Ranbaxy, these patients include young children, certain elderly individuals, and other patients with dysphagia, a medical condition characterized by difficulty or the impossibility of safely swallowing. Patients with many different conditions are prone to dysphagia, including patients who suffer from Alzheimer's Disease, amyotrophic lateral sclerosis (ALS), Parkinson's disease, dementia, or stroke. The American Speech-Language-Hearing Association estimates that dysphagia impacts more than 15 million Americans.

27. Sun and Ranbaxy's marketing materials recognize this relevant product market. The Riomet® website indicates Riomet® for use in specific populations that are known to have trouble swallowing metformin tablets and capsules; namely pediatric, geriatric, and other patients that have trouble swallowing pills.

28. Sun and Ranbaxy's marketing materials also recognize their monopoly of this market. The Riomet® website states "RIOMET (metformin hydrochloride oral solution) is the first and only liquid metformin." Sun and Ranbaxy also boldly display the catchphrase, "The Only Liquid choice" at the top of the Riomet® website, using stylistic characters that resemble the registered trademark and trade dress of the website, bringing particular attention to the term "only." (See attached Exhibit A.) There are no generic versions of this product currently on the market. On information and belief, the Sun and Ranbaxy share of the relevant market for liquid formulations of metformin is 100 percent. Accordingly, on information and belief, Sun and Ranbaxy have monopoly power in the relevant market.

29. Because Sun and Ranbaxy enjoy a monopoly as the sole provider of a liquid

metformin formulation, the price of Riomet® is, on information and belief, much higher than the price of metformin HCl in the tablet form. Whereas Sun's National Sale Price for a bottle of Riomet® containing about 100 doses of 500 mg (per 5 mL) of metformin HCl is over $500, Sun's National Sale Price for a bottle containing 100 tablets of 500 mg metformin HCl is under $2. Thus, despite the availability of metformin in other forms, Sun and Ranbaxy have been able to raise and maintain the price of Riomet® well-above (more than 250 times) the price of metformin in tablet form. This suggests that these other forms of metformin are not reasonably interchangeable substitutes for a liquid metformin formulation, and for these reasons they are not a part of the relevant product market in this case.

30. Upon information and belief, the consumers of this medication would benefit if Saptalis and/or other suppliers entered with generic versions of Riomet®.

31. The relevant geographic market for liquid formulations of metformin is the United States. Federal law and FDA regulations create significant barriers to entry for foreign drugs into the United States. As a result, U.S. consumers cannot turn to drugs imported by entities unapproved by the FDA. Saptalis' ANDA seeks approval to sell a generic, or therapeutically equivalent, liquid formulation of metformin in the United States as a competitor to Sun and Ranbaxy's Riomet® product.

32. Sun and Ranbaxy thus have monopoly power over prices in the relevant market. Their monopoly power is further evidenced by their efforts to exclude or delay entrance by others such as by seeking to enforce the '957 patent against Saptalis and subjecting Saptalis' non-infringing product to a mandatory 30-month stay. Upon review of

Saptalis' ANDA, Sun and Ranbaxy knew that Saptalis' liquid formulation of metformin could not infringe their '957 patent. Sun and Ranbaxy's sole motive in bringing this patent infringement suit is to unjustifiably continue to maintain their prices above a competitive level to the detriment of both generic competitors and consumers.

Exceptional Case

33. This case is an exceptional one, and Saptalis is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

FIRST COUNT
(Declaratory Judgment of Non-Infringement of U.S. Pat. No. 6,890,957)

34. Saptalis repeats and incorporates by reference each of the foregoing paragraphs of Saptalis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

35. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court, exists between Saptalis on the one hand and Sun and Ranbaxy on the other concerning the non-infringement of the claims of the '957 patent.

36. Sun and Ranbaxy assert that the Saptalis ANDA Product will infringe the '957 patent.

37. The Saptalis ANDA Product will not infringe any claim of the '957 patent.

38. Saptalis is entitled to a declaratory judgment that the claims of the '957 patent would not be infringed by the Saptalis ANDA Product.

SECOND COUNT
(Declaratory Judgment of Invalidity of U.S. Pat. No. 6,890,957)

39. Saptalis repeats and incorporates by reference each of the foregoing paragraphs of Saptalis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

40. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Saptalis on the one hand and Sun and Ranbaxy on the other concerning the invalidity of the claims of the '957 patent.

41. The claims of the '957 patent are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.,* including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112 and 120.

42. Saptalis is entitled to a declaratory judgment that the claims of the '957 patent are invalid and not infringed.

THIRD COUNT
(Monopolization and Attempted Monopolization in Violation of 15 U.S.C. § 2)

43. Saptalis repeats and incorporates by reference each of the foregoing paragraphs of Saptalis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

44. Despite the information in the Notice Letter, detailed statement, and documents from ANDA No. 211309 provided to Sun and Ranbaxy or their counsel, Sun and Ranbaxy filed the present Complaint against Saptalis, alleging that the Saptalis ANDA

and the Saptalis ANDA Product will infringe the'957 patent. Sun and Ranbaxy filed this meritless suit to leverage the judicial system and relevant laws to delay Saptalis' ability to make a competing liquid metformin formulation, for the sole reason of maintaining their monopoly and significant financial incentives.

45. Accordingly, Sun and Ranbaxy's infringement action against Saptalis is both objectively baseless and subjectively intended to harm competition, because they knew, as of the date of filing its claims of infringement of the '957 patent against Saptalis, that the Saptalis ANDA and the Saptalis ANDA Product did not and will not infringe the '957 patent.

46. For antitrust purposes, the relevant product market is the market for metformin in the form of an orally administered liquid formulation. Products within this market are recognized by Sun and Ranbaxy as a separate and distinct product market for those patients that have trouble swallowing pills. The relevant geographic market for the product market is the United States for the reasons explained herein.

47. On information and belief, Sun and Ranbaxy have improperly maintained their existing monopoly power in the relevant product and geographic markets through the willful, anticompetitive and exclusionary acts described herein rather than as a consequence of a superior product, business acumen or historic accident. These acts have enabled them to illegally control prices and exclude competition from the relevant product and geographic markets to the detriment of generic competition, including Defendant, and consumers.

48. On information and belief, in bringing and/or maintaining their allegations

of infringement against Saptalis, Sun and Ranbaxy were subjectively motivated by an intent to interfere directly with Saptalis' business relationships through the use of litigation, by precluding, delaying and/or multiplying the costs of Saptalis' entry into the relevant market rather than being motivated by the merit or outcome of the litigation.

49. On information and belief, Sun and Ranbaxy engaged in the anticompetitive and exclusionary acts against Saptalis described herein, with the specific intent to obtain and/or maintain their dominant market position and monopoly power in the relevant product and geographic markets.

50. On information and belief, Sun and Ranbaxy engaged in the anticompetitive and exclusionary acts described herein, including bringing this infringement action when they knew that Saptalis did not infringe the '957 patent, in furtherance of their specific intent to restrict entry into the relevant market and improperly obtain and perpetuate their monopoly.

51. The unlawful activities alleged above constitute the willful acquisition or maintenance of Sun and Ranbaxy's monopoly power in the relevant product and geographic markets in violation of the prohibition on actual monopolization under Section 2 of the Sherman Act, 15 U.S.C. § 2.

52. As a direct and proximate result of Sun and Ranbaxy's anticompetitive conduct and improperly motivated pursuit of baseless litigation against Saptalis with respect to the '957 patent, Saptalis is being forced to expend significant and unjustified costs – including but not limited to the costs of its legal defense – by virtue of Sun and Ranbaxy's anti-competitive conduct. Put simply, this is a sham litigation which Saptalis

has no choice but to defend and to suffer the consequences of the 30-month stay excluding Saptalis' generic liquid metformin formulation from the market.

53. Sun and Ranbaxy's anticompetitive conduct and objectively baseless litigation will also cause Saptalis damages including lost sales, lost profits, and the expense of re-directed resources. Sun and Ranbaxy's monopolistic behavior will also delay and deprive Saptalis of its right to compete in the relevant market with its non-infringing product.

54. Due to Sun and Ranbaxy's unlawful actions, Saptalis has been, and will continue to be, injured.

JURY DEMAND

55. Saptalis demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Saptalis prays that judgement be entered in its favor and the Court:

A. Dismiss Plaintiffs' Complaint with prejudice;

B. Declare that the Saptalis ANDA Product will not infringe any claim of the '957 patent;

C. Declare that the '957 patent claims are invalid;

D. Adjudge and declare that Sun and Ranbaxy have violated Section 2 of the Sherman Antitrust Act (15 U.S.C. § 2) and awarding to Saptalis damages

(including provable harm, lost profits, costs and reasonable attorneys' fees) and that such damages be trebled, and permanently enjoining Sun and Ranbaxy, its officers, agents, directors, servants, employees, subsidiaries, and assigns, and all those acting under the authority of or in privity with any of them, from asserting or otherwise seeking to enforce the '957 patent against Saptalis.

E. Declare that this case is exceptional;

F. Award Saptalis any and all damages, including lost profits;

G. Award Saptalis damages and its costs, expenses and reasonable attorneys' fees incurred in this action; and,

H. Grant such further relief as the Court may deem just and proper.

Dated: May 22, 2018

/s/ Kenneth L. Dorsney

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EXHIBIT A

Riomet®
(metformin HCl oral solution)
THE only LIQUID CHOICE

About Diabetes | About Riomet | RIOMET $AVINGS | Diabetes Links | Healthcare Professionals | Contact Information

- What is RIOMET?
- How can you benefit from RIOMET?
- How does RIOMET work?

What is RIOMET?[1]

RIOMET (metformin hydrochloride oral solution) is the first and only liquid metformin. In adjunct with diet and exercise, RIOMET is an effective oral drug that helps in improving blood sugar levels of Type 2 diabetes patients.

PLEASE SCROLL TO SEE ALL IMPORTANT INFORMATION BELOW

Collapse

IMPORTANT INFORMATION FOR RIOMET®

INDICATIONS AND USAGE

RIOMET is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus.

DOSAGE AND ADMINISTRATION

- Individualize the dose based on effectiveness and tolerability, while not exceeding the maximum recommended daily dose of 2550 mg (25.5 mL) for adults and 2000 mg (20 mL) for pediatric patients (10 to 16 years of age).
- Start RIOMET at a low dose, with gradual dose escalation.
- Adult Dosage: The usual starting dose of RIOMET is 500 mg (5 mL) twice a day or 850 mg (8.5mL) once a day, given with meals.
- Pediatrics Dosage: The usual starting dose of RIOMET is 500 mg (5 mL) twice a day, given with meals.

IMPORTANT SAFETY INFORMATION FOR RIOMET **Rx only**

WARNING: LACTIC ACIDOSIS

See full prescribing information for complete boxed warning

- Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as sepsis, dehydration, excess alcohol intake, hepatic impairment, renal

Riomet
(metformin HCl oral solution)
THE only LIQUID CHOICE

About Diabetes | About Riomet | RIOMET $AVINGS | Diabetes Links | Healthcare Professionals | Contact Information

- What is RIOMET?
- How can you benefit from RIOMET?
- How does RIOMET work?
- Is RIOMET right for you?

How can you benefit from RIOMET?

If you have dysphagia (difficulty swallowing)with metformin tablets then you may benefit from RIOMET.

RIOMET is:

- ***Convenient*** for Type 2 diabetes patients who struggle to ingest large tablets (i.e., children over ten years, the elderly, and institutionalized patients)
- The ***only liquid metformin*** available
- **Easy to measure** for ***accurate dosing***
- ***Suitable for a wide-range of patient-types***
- **For *initiating and maintaining*** therapy

RIOMET is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus.[1]

RIOMET may be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adult patients.[1]

PLEASE SCROLL TO SEE ALL IMPORTANT INFORMATION BELOW

Expand

IMPORTANT INFORMATION FOR RIOMET®

Riomet
(metformin HCl oral solution)
THE only LIQUID CHOICE

About Diabetes | About Riomet | RIOMET $AVINGS | Diabetes Links | Healthcare Professionals | Contact Information

- What is RIOMET?
- How can you benefit from RIOMET?
- How does RIOMET work?
- Is RIOMET right for you?

Is RIOMET right for you?[1]

RIOMET is a liquid option for indicated patients diagnosed with Type 2 diabetes (above the age of 10[1]). RIOMET should be considered for all Type 2 diabetes patients (above the age of 10) that are newly diagnosed and that currently struggle with the tablet formulation of metformin.

RIOMET may be the right choice for a wide range of patients who prefer and/or need liquid formulations. For example:

- Monotherapy for pediatric patients (10 years of age and older)
  - Who *will not swallow* tablets
  - Prefer to take *all medications* in liquid form
- Older adult patients
  - Who have *difficulty swallowing* tablets
  - Who *cannot swallow* tablets due to an illness
  - Who *take multiple tablets* at one time
  - Who *resort to crushing* tablets
- Younger adult patients
  - Who do not like to swallow tablets
  - Who cannot swallow tablets

This model is for illustrative purposes only and does not endorse this product.

PLEASE SCROLL TO SEE ALL IMPORTANT INFORMATION BELOW

Expand

IMPORTANT INFORMATION FOR RIOMET®

Riomet
(metformin HCl oral solution)
THE only LIQUID CHOICE

About Diabetes | About Riomet | RIOMET $AVINGS | Diabetes Links | Healthcare Professionals | Contact Information

- What is RIOMET?
- How can you benefit from RIOMET?
- How does RIOMET work?
- Is RIOMET right for you?

How does RIOMET work?[1]

This unique liquid formulation of metformin, RIOMET, employs the same mechanism as the tablet form to improve glucose tolerance in patients with Type 2 diabetes.

RIOMET (Metformin) is an anti-hyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Its pharmacologic mechanisms of action are different from other classes of oral anti-hyperglycemic agents. RIOMET (Metformin) decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization.

Unlike sulfonylureas, RIOMET (metformin) does not produce hypoglycemia in either patients with type 2 diabetes or normal subjects (except in special circumstances, see PRECAUTIONS in Prescribing Information) and does not cause hyperinsulinemia.

With RIOMET (metformin) therapy, insulin secretion remains unchanged while fasting insulin levels and daylong plasma insulin response may actually decrease.

Notes:

* Hypoglycemia, also called low blood sugar, occurs when your blood glucose (blood sugar) level drops too low to provide enough energy for your body's activities

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IMPORTANT INFORMATION FOR RIOMET®