IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

CATALYST PHARMACEUTICALS, Inc., and SERB SA, Plaintiffs, v. PANTHERX SPECIALTY LLC, and PANTHER SPECIALTY HOLDING, CO., Defendants.	Case No. 2:20-cv-1574 **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Catalyst Pharmaceuticals, Inc. ("Catalyst") and SERB SA ("SERB", and collectively "Plaintiffs"), for their Complaint against Defendant Pantherx Specialty LLC and Panther Specialty Holding, Co., hereby allege as follows:

NATURE OF THIS ACTION

1. This is a civil action for infringement of U.S. Patent No. 10,793,893 ("the '893 patent"). This action arises under the Patent Laws of the United States, 35 U.S.C. §100, *et seq.*

PARTIES

2. Plaintiff Catalyst is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 355 Alhambra Circle, Suite 1250, Coral Gables, Florida 33134. Catalyst is a commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating, chronic neuromuscular and neurological diseases.

3. Plaintiff SERB is a corporation organized and existing under the laws of Belgium with its principal place of business at 480 Avenue Louise, Brussels, 1050, Belgium. SERB is the owner by assignment of the ’893 patent.

4. SERB has standing to sue because it is the owner by assignment of the ’893 patent.

5. Catalyst is the exclusive licensee of the ’893 patent and holds substantial rights in the ’893 patent, including (1) the exclusive right to commercialize the ’893 patent in the United States, (2) the right to enforce the ’893 patent against infringement by third-parties, (3) the right to sublicense the ’893 patent, and (4) the right to control prosecution of the ’893 patent and all related patent applications.

6. Catalyst has standing to sue because it holds the right by license to enforce the ’893 patent.

7. On information and belief, Pantherx Specialty LLC is a limited liability company incorporated in the state of Pennsylvania having a place of business at 24 Summit Park Drive Pittsburgh, Pennsylvania, 15275.

8. On information and belief, Panther Specialty Holding, LLC is a limited liability company incorporated in the state of Pennsylvania having a place of business at 24 Summit Park Drive Pittsburgh, Pennsylvania, 15275.

9. On information and belief, Pantherx Specialty LLC and Panther Specialty Holding, LLC (collectively “Pantherx”) are affiliates who together and in concert, do business under the fictitious names PANTHERx Rare and PANTHERx Rare LLC.

JURISDICTION AND VENUE

10. This Court has subject-matter jurisdiction over Catalyst’s patent infringement claims under 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Pantherx Specialty LLC and Panther Specialty Holding, LLC at least because each resides in the State of Pennsylvania, is registered as a limited liability corporation in the state of Pennsylvania, and has a principal place of business in Pittsburgh, Pennsylvania.

12. On information and belief, Pantherx regularly and continuously transacts business within the Western District of Pennsylvania ("District"), including selling pharmaceutical products in Pittsburgh, Pennsylvania. On information and belief, Pantherx distributes, offers for sale, and sells Ruzurgi® throughout the United States, including this District. On information and belief, Pantherx purposefully has conducted and continues to conduct business, directly or through its agents and affiliates, in this District, and this District is a likely destination of Ruzurgi®.

13. On information and belief, Pantherx derives substantial revenue from selling pharmaceutical products throughout the United States, including this District, including from the sale of Ruzurgi®. On information and belief, Pantherx derives substantial revenue from the sale of those products in this District and has availed itself of the privilege of conducting business in this District.

14. On information and belief, Pantherx intends to engage in a future course of conduct that includes continuing acts of patent infringement in the Commonwealth of Pennsylvania. These acts will lead to foreseeable harm and injury to Plaintiffs in this District and throughout the United States. For example, Pantherx will continue to market, offer for sale, sell, and distribute pharmaceutical products, including Ruzurgi®, throughout the United States, including in Pennsylvania, prior to the expiration of the patent-in-suit.

15. Venue is proper in this District under 28 U.S.C. §§ 1400(b) at least because Pantherx Specialty LLC and Panther Specialty Holding, LLC each reside in this District and also each has a regular and established place of business in this District and because, on information and belief, they have induced acts of patent infringement in this District by marketing, distributing, and shipping into this District, or by using, distributing, offering to sell, or selling, or by causing others to use, offer to sell, or sell in this District.

LEMS AND CATALYST'S FIRDAPSE® PRODUCT

16. Lambert-Eaton Myasthenic Syndrome ("LEMS") is a rare and debilitating neuromuscular disorder involving impairment of neuromuscular transmission and serious muscle weakness. Clinically, LEMS is characterized by proximal muscle weakness and fatigability, hyporeflexia, or areflexia, and symptoms of autonomic dysfunction such as impotence, dry mouth, and constipation. Other symptoms may include paresthesias, diplopia, and orthostatic hypotension.

17. The neuromuscular symptoms in patients with LEMS typically develop after 40 years of age with a peak incidence between 50 and 70 years of age. Although the exact prevalence of LEMS in the general population is unknown, it has been estimated to affect approximately 1 in 100,000 people. The diagnosis of LEMS can be challenging since the clinical presentation of sub-acute progressive fatigue and weakness is unspecific. As a result, diagnosis of LEMS is often delayed for months to decades, and is often misdiagnosed for other diseases such as myasthenia gravis, which is characterized by weakness and rapid fatigue of muscles.

18. Amifampridine, also known as 3,4-diaminopyridine or 3,4-DAP, is a nonspecific voltage-dependent potassium channel blocker. Amifampridine blocks the presynaptic voltage-gated potassium channels resulting in a prolonged action potential and increased influx of calcium, which facilitates the release of acetylcholine from the motor nerve terminal and improves neuromuscular transmission.

19. Catalyst holds New Drug Application ("NDA") No. 208078 for the use of amifampridine tablets, which it sells under the trade name Firdapse®. Catalyst's Firdapse® product received FDA approval on November 28, 2018, and was the first product that FDA approved for the treatment of LEMS based on clinical data demonstrating safety and efficacy. Prior to its approval, Firdapse® received breakthrough therapy designation and orphan drug designation from the FDA.

20. Prior to FDA approval of Firdapse®, amifampridine was available in the United States only as an investigational drug product in clinical studies or under the FDA's Expanded Access program, which provides a pathway for a patient to gain treatment to an investigational medical product outside of clinical trials when no comparable or satisfactory alternative therapies are available. No pharmaceutical company, including Pantherx, could lawfully market amifampridine for any indication prior to the approval of Firdapse® as nobody prior to Catalyst had conducted and submitted the pre-clinical and clinical work necessary to obtain FDA approval.

THE '893 PATENT

21. The inventors of the '893 patent discovered that amifampridine undergoes 3-*N*-acetylation to form a single major circulating inactive metabolite that subsequently undergoes renal elimination. The inventors also discovered that the acetylation rate of amifampridine varied significantly depending on certain genetic polymorphisms. The inventors further discovered that amifampridine could be more safely and efficaciously administered by taking into account the individual differences in acetylation rates among patients treated with amifampridine-sensitive diseases.

22. On October 6, 2020, the United States Patent and Trademark Office duly and legally issued the ’893 patent, titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’893 patent is valid and enforceable. A true and correct copy of the ’893 patent is attached as Exhibit 1.

23. Claim 1 of the ’893 patent recites:

> A method of treating a human patient diagnosed with a 3,4-diaminopyridine (3,4-DAP) sensitive disease in need of treatment thereof comprising administering a dose of about 2.5 mg to about 30 mg of 3,4-DAP or a pharmaceutically acceptable salt thereof to a human patient who is a slow acetylator having an N-acetyl transferase 2 (NAT2) gene comprising: a C282T mutation on both alleles of the NAT2 gene; a T341C mutation on both alleles of the NAT2 gene; or a C282T mutation on one allele of the NAT2 gene and a T341C mutation on the other allele of the NAT2 gene or genotype.

(Exhibit 1, at 85.)

THE RUZURGI® PRODUCT

24. On information and belief, the amifampridine distributed by Pantherx is manufactured by Jacobus Pharmaceuticals, Inc. (“Jacobus”) pursuant to New Drug Application No. 209321.

25. On May 6, 2019, FDA approved NDA 209321 for the treatment of LEMS in pediatric patients who were between 6 and 17 years of age.

26. On information and belief, Exhibit 2 is a true and correct copy of the current FDA-approved Prescribing Information for Ruzurgi® (“Ruzurgi® Prescribing Information”).

27. The Ruzurgi® Prescribing Information contains extensive information that promotes using NAT2 status to administer amifampridine to patients.

28. The “Dosage and Administration” section of the Ruzurgi® Prescribing Information promises, encourages, and directs health care providers: “The recommended starting

dosage of RUZURGI in pediatric patients weighing 45 kg or more who are known N-acetyltransferase 2 (NAT2) poor metabolizers is 15 mg daily taken orally in divided doses. The recommended starting dosage in pediatric patients weighing less than 45 kg who are known NAT2 poor metabolizers is 7.5 mg daily taken orally in divided doses." (Ex. 2, at 3.)

29. The "Use in Specific Populations" section of the Ruzurgi® Prescribing Information further promotes: "Exposure of RUZURGI is increased in patients who are N-acetyltransferase 2 (NAT2) poor metabolizers … Therefore, initiate RUZURGI in patients who are known NAT2 poor metabolizers at the lowest recommended starting dosage and monitor for adverse reactions … Consider dosage modification of RUZURGI for patients who are known NAT2 poor metabolizers as needed based on clinical effect and tolerability." (Ex. 2, at 7.)

30. The "Pharmacogenomics" section of the Ruzurgi® Prescribing Information further promotes: "Genetic variants in the N-acetyltransferase gene 2 (NAT2) affect the rate and extent of RUZURGI metabolism. In normal healthy volunteers, poor metabolizers, also referred to as "slow acetylators" (i.e., carriers of two reduced function alleles) had higher average plasma amifampridine concentrations than intermediate metabolizers, also referred to as "intermediate acetylators" (i.e., carriers of one reduced and one normal function alleles), and normal metabolizers, also referred to as "fast/rapid acetylators" (i.e., carriers of two normal function alleles)." (Ex. 2, at 11.) It further states that, within the general population, the "NAT2 poor metabolizer phenotype prevalence is 40-60% in the White and African American populations, and in 10-30% in Asian ethnic populations." (*Id.*)

31. On information and belief, physicians prescribing Ruzurgi® have administered, and will continue to administer, the drug to patients with LEMS who are slow acetylators of amifampridine, including patients having an NAT2 gene with a C282T mutation on both alleles,

a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele.

32. On information and belief, Pantherx knows that healthcare providers have and will continue to administer Ruzurgi® to patients with LEMS who are slow acetylators of amifampridine, including patients having an NAT2 gene with a C282T mutation on both alleles, a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele, in accordance with the dosing guidance contained on the Ruzurgi® Prescribing Information.

33. On information and belief, Pantherx intends for Ruzurgi® to be administered to patients with LEMS who are slow acetylators of amifampridine, including patients having an NAT2 gene with a C282T mutation on both alleles, a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele, in accordance with the Prescribing Information for Ruzurgi®.

34. On information and belief, Pantherx operates a website with the address www.pantherxrare.com/rare-disorders/lambert-eaton-myasthenic-syndrome-lems/ ("the Pantherx LEMS website") that includes links to www.ruzurgi.com ("the Ruzurgi® website"). The Ruzurgi® website promotes and encourages the administration of Ruzurgi® to patients with LEMS who are slow acetylators of amifampridine.

35. On information and belief, Pantherx markets the amifampridine product that is the subject of NDA No. 209321 under the brand name Ruzurgi®. The average retail price of Ruzurgi® is approximately $175,000 per patient per year before any applicable discounts.

COUNT I: INFRINGEMENT OF '893 PATENT

36. Plaintiffs incorporate by reference paragraphs 1-35 as if fully set forth herein.

37. On information and belief, Pantherx has been and is now actively inducing infringement of at least claim 1 of the ’893 patent in violation of 35 U.S.C. §271(b) by marketing, promoting, offering for sale, and selling Ruzurgi® for use by patients with LEMS who are slow acetylators of amifampridine.

38. Prior to the filing of this Complaint, Catalyst notified Pantherx by letter sent both electronically and by overnight delivery of the existence of the ’893 patent and of the infringing uses of Ruzurgi®. As a result, Pantherx had actual knowledge of the existence of the ’893 patent and of its infringing activities by at least its receipt of Catalyst’s notice before filing this Complaint.

39. On information and belief, Pantherx has knowledge of the ’893 patent and of the infringing use of Ruzurgi® at least as of the filing and/or service of this Complaint.

40. On information and belief, Pantherx intends for healthcare providers to administer Ruzurgi® to patients in accordance with the Ruzurgi® Prescribing Information, including the safety information and other conditions of use provided on the Ruzurgi® Prescribing Information, and intends for patients to take Ruzurgi® in accordance with instructions from their healthcare providers and the Ruzurgi® Prescribing Information.

41. The Ruzurgi® Prescribing Information directs, encourages, and promotes the treatment of an amifampridine-sensitive disease, LEMS, by administering a dose between about 2.5 mg to about 30 mg of amifampridine to patients who are slow acetylators of amifampridine, having an NAT2 gene with a C282T mutation on both alleles, a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele.

42. On information and belief, healthcare providers have administered and will continue to administer Ruzurgi® to patients who are slow acetylators of amifampridine, having

an NAT2 gene with a C282T mutation on both alleles, a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele.

43. On information and belief, healthcare providers will directly infringe the method of at least claim 1 of the ’893 patent when administering Ruzurgi® to patients who are slow acetylators, including patients who are slow acetylators of amifampridine, having an NAT2 gene with a C282T mutation on both alleles, a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele.

44. On information and belief, patients who are slow acetylators, including patients who are slow acetylators of amifampridine, having an NAT2 gene with a C282T mutation on both alleles, a T341C mutation on both alleles, or a C282T mutation on one allele and a T341C mutation on the other allele, will directly infringe the method of at least claim 1 of the ’893 patent when taking Ruzurgi® in accordance with their healthcare providers’ instructions and the Ruzurgi® Prescribing Information.

45. On information and belief, Pantherx actively induces infringement of at least claim 1 of the ’893 patent because it knows and intends for healthcare providers and patients to infringe the method of at least claim 1 when following the instructions on the Ruzurgi® Prescribing Information.

46. On information and belief, Pantherx’s continuing infringement of the ’893 patent occurs with full knowledge of the ’893 patent and without a reasonable basis for believing that it does not infringe the ’893 patent.

47. As a direct and proximate result of Pantherx’s infringement of the ’893 patent, Plaintiffs have suffered and will continue to suffer monetary damages, including lost profits.

48. Plaintiffs are entitled to recover from Pantherx the damages sustained by Plaintiffs as a result of Pantherx's wrongful acts in an amount to be determined at trial.

49. Pantherx's acts of infringement of the '893 patent will continue unless enjoined by the Court.

50. Unless Pantherx's infringing activities are enjoined by the Court, Plaintiffs have been and will continue to be substantially and irreparably harmed for which there is no adequate remedy at law. Accordingly, Plaintiffs are entitled to preliminary and/or permanent injunction against further infringement.

51. On information and belief, Pantherx's infringement of the '893 patent has been and continues to be willful. Pantherx's conduct with respect to the '893 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. §285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

A. Declare that Pantherx has induced infringement of the '893 patent;

B. Preliminarily and permanently enjoin Pantherx and their officers, employees, and all persons acting in concert or in privity with them, from infringing the '893 patent until the expiration of the '893 patent (including any exclusivities or extensions to which Plaintiffs are or become entitled), and for all further and proper injunctive relief pursuant to 35 U.S.C. § 283;

C. Award to Plaintiffs such past damages in the form of lost profits or a reasonable royalty that is adequate to fully compensate Plaintiffs for Pantherx's infringement of the '893 patent;

D. Declare that Pantherx's infringement has been willful, wanton, and deliberate and that the damages against it be increased up to treble on this basis or for any other basis in accordance with the law;

E. Declare this case is "exceptional" and an award to Plaintiffs of their costs and reasonable attorneys' fees, as provided by 35 U.S.C. §285; and

F. Grant Plaintiffs such further and other relief as the Court may deem proper and just.

DEMAND FOR JURY TRIAL

Plaintiffs demand a jury trial on all issues so triable.

Dated: October 16, 2020

Respectfully submitted,

/s/ Erica Pietranton

Alan G. Towner
Erica Pietranton
LEECH TISHMAN FUSCALDO & LAMPL, LLC
525 William Penn Place, 28th Floor
Pittsburgh, PA 15219
(412)-694-7281
(412)-227-5551
atowner@leechtishman.com
epietranton@leechtishman.com

Of Counsel:
Dennies Varughese
Paul A. Ainsworth (*pro hac vice forthcoming*)
Gaby Longsworth (*pro hac vice forthcoming*)
Adam LaRock (*pro hac vice forthcoming*)

Sterne, Kessler, Goldstein & Fox P.L.L.C
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600
(202) 371-2540 (fax)
dvarughese@sternekessler.com
painsworth@sternekessler.com
glongsworth@sternekessler.com
alarock@sternekessler.com

COUNSEL FOR PLAINTIFFS CATALYST PHARMACEUTICALS, INC. and SERB S.A.

TABLE OF EXHIBITS

EXHIBIT 1	U.S. Patent No. 10,793,893
EXHIBIT 2	Ruzurgi® Prescribing Information (April 2020 revision)