Charles Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevalier@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Adam C. LaRock
Lauren Watt
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
alarock@sternekessler.com
lwatt@sternekessler.com

Attorneys for Plaintiffs
Catalyst Pharmaceuticals, Inc. and
SERB SA

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CATALYST PHARMACEUTICALS, INC. and SERB SA, Plaintiffs, v. TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Civil Action No. 23-cv-01109 (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Catalyst Pharmaceuticals, Inc. ("Catalyst") and SERB SA ("SERB")

(collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Teva Pharmaceuticals, Inc. ("Teva Inc."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Limited ("Teva Ltd.") (collectively, "Teva"), allege as follows:

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, arising from Teva's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218029 ("Teva's ANDA") seeking approval to engage in the commercial manufacture, use, or sale of a generic version of Catalyst's Firdapse® (amifampridine) Tablets, 10 mg drug product ("Teva's ANDA Product") prior to the expiration of one or more of United States Patent Nos. 10,626,088 ("the '088 patent), 10,793,893 ("the '893 patent"), 11,060,128 ("the '128A patent"), 11,268,128 ("the '128B patent"), 11,274,331 ("the '331 patent"), and 11,274,332 ("the '332 patent") (collectively, the "Patents-in-Suit").

THE 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 801, 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.

4. On information and belief, Defendant Teva Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, Defendant Teva Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

7. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

8. On information and belief, Teva Inc. is a wholly-owned subsidiary of Teva Ltd.

JURISDICTION AND VENUE

9. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Teva Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Inc.'s principal place of business is in Parsippany, New Jersey. On information and belief, Teva Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0450614134. On information and belief, Teva Inc. purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Teva Inc.

11. This Court has personal jurisdiction over Teva Inc. because Teva Inc. derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

12. On information and belief, Teva Inc. is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product described in Teva's ANDA. On information and belief, Teva Inc. also prepares and/or aids in the preparation and submission of ANDAs to FDA.

13. This Court has personal jurisdiction over Teva USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva USA's principal place of business is in Parsippany, New Jersey. On information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0100250184. On information and belief, Teva USA is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration Nos. 5000583 and 5003436. On information and belief, Teva USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Teva USA.

14. On information and belief, Teva USA is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Teva's ANDA. On information and belief, Teva USA also prepares and/or aids in the preparation and submission of ANDAs to FDA.

15. This Court has personal jurisdiction over Teva USA because Teva USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic

and continuous contact with the State of New Jersey. On information and belief, Teva USA regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Teva USA derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Teva USA derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

16. This Court has personal jurisdiction over Teva Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Teva USA, a company registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler, and Teva Inc., a company registered with the State of New Jersey as a business operating in New Jersey; and (2) maintained extensive and systematic contacts with the State of New Jersey, including preparation and submission of Teva's ANDA to FDA in New Jersey including through, directly or indirectly, Teva Inc., and/or the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Teva USA.

17. This Court has personal jurisdiction over Teva Ltd. because Teva Ltd. derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District. Teva Ltd.'s Securities and Exchange Commission Form 10-K filing states that it is "one of the leading generic pharmaceutical companies in the United States" and that it markets "over 550 generic prescription products in more than 1,600 dosage strengths, packaging

sizes and forms, including oral solid dosage forms, injectable products, inhaled products, transdermal patches, liquids, ointments and creams." Teva Ltd. Securities and Exchange Commission Form 10-K (for the fiscal year ended December 31, 2021) ("Teva Ltd. Form 10-K") at 3. The Teva Ltd. Form 10-K further states that its annual revenues of generic products in the United States were $3.769 billion. *Id*. at 56. It further states that, "[i]n 2021, our total prescriptions were approximately 301 million (based on trailing twelve months), representing 8.3% of total U.S. generic prescriptions . . . ." *Id*. at 60.

18. This Court has personal jurisdiction over Teva because, *inter alia*, Teva has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, by and through Teva Inc., Defendants prepared and submitted Teva's ANDA to FDA in New Jersey. Further, on information and belief, following approval of Teva's ANDA, Teva will make, use, import, sell, and/or offer for sale Teva's ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

19. On information and belief, Teva Inc., Teva USA, and Teva Ltd. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

20. On information and belief, Teva Inc. and Teva USA are United States agents acting at the direction of, and for the benefit of, Teva Ltd. regarding Teva's ANDA.

21. On information and belief, Teva Inc. and Teva USA are generic pharmaceutical companies that, in coordination with each other and Teva Ltd. and at the direction of Teva Ltd.,

are in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this Judicial District.

22. On information and belief, Teva Inc., Teva USA, and Teva Ltd. operate as a single integrated business.

23. On information and belief, Teva has a regular and established, physical place of business in New Jersey.

24. On information and belief, Teva Inc., intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

25. On information and belief, Teva USA, intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

26. On information and belief, Teva Ltd., intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

27. On information and belief, Teva Inc., Teva USA, and Teva Ltd. actively participated in the submission of Teva's ANDA. On information and belief, Teva Inc., Teva USA, and Teva Ltd. work in privity and/or concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including Defendants' ANDA Product, throughout the United States, including in this Judicial District, prior to the expiration of the Patents-in-Suit.

28. On information and belief, Teva has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous patent infringement actions.

29. On information and belief, Teva Inc., Teva USA, and Teva Ltd. have previously been sued in this Judicial District and have availed themselves of New Jersey courts through the assertion of counterclaims in suits brought in New Jersey and have not challenged personal jurisdiction. *See, e.g., Horizon Orphan LLC, et al. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 22-1382 (RMB)(AMD) (D.N.J.); *Evoke Pharma, Inc. v. Teva Pharmaceuticals, Inc., et al.*, Civil Action No. 22-2019 (RMB)(SAK) (D.N.J.); *Merck Sharp & Dohme B.V. and Organon USA Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-2751 (CCC)(MF) (D.N.J.); *TherapeuticsMD, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-3485 (BRM)(ESK) (D.N.J.); *Horizon Medicines LLC v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 20-8188 (SRC)(CLW) (D.N.J.); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 19-8758 (ES)(MAH) (D.N.J.); *Celgene Corporation v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 18-14366 (ES)(MAH) (D.N.J.); *Celgene Corporation v. Par Pharm., Inc., et al.*, Civil Action No. 17-3159 (ES)(MAH) (D.N.J.).

30. Teva USA and Teva Ltd. have further availed themselves of the jurisdiction of this Court by initiating litigation in this Judicial District. *See, e.g., Teva Pharmaceuticals USA, Inc. et al. v. Sandoz Inc., et al.*, Civil Action No. 17-275 (FLW)(DEA) (D.N.J.); *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 17-517 (FLW)(DEA) (D.N.J.).

31. In the alternative, this Court has personal jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or

manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

32. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

LEMS AND CATALYST'S FIRDAPSE PRODUCT

33. 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.

34. 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 subacute 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.

35. 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.

36. 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.

37. 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 Teva, 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.

38. The inventors of the '088 patent discovered methods of determining the purity of a sample of 3,4 - diaminopyridine comprising determining the presence, absence, or amount of a dimer of 3,4 - diaminopyridine or a dimer of 3,4 - diaminopyridine in the form of a salt , solvate or complex or a combination thereof. The inventors of the '893, '128A, '128B, '331, and '332 patents 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. Based on these discoveries, the inventors developed a method of treating certain diseases with amifampridine. The method accounts for the individual differences in acetylation rates among patients, and administers dosages accordingly.

PATENTS-IN-SUIT

39. Catalyst is the owner of United States Patent No. 10,626,088, which was duly and legally issued on April 21, 2020, and is titled "Determining Degradation of 3,4-Diaminopyridine."

Each and every claim of the ’088 patent is valid and enforceable. A copy of the ’088 patent is attached as Exhibit 1.

40. SERB is the owner of United States Patent No. 10,793,893, which was duly and legally issued on October 6, 2020, and is titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’893 patent is valid and enforceable. Catalyst has an exclusive license under the ’893 patent in the United States. A copy of the ’893 patent is attached as Exhibit 2.

41. SERB is the owner of United States Patent No. 11,060,128, which was duly and legally issued on July 13, 2021, and is titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’128A patent is valid and enforceable. Catalyst has an exclusive license under the ’128A patent in the United States. A copy of the ’128A patent is attached as Exhibit 3.

42. SERB is the owner of United States Patent No. 11,268,128, which was duly and legally issued on March 8, 2022, and is titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’128B patent is valid and enforceable. Catalyst has an exclusive license under the ’128B patent in the United States. A copy of the ’128B patent is attached as Exhibit 4.

43. SERB is the owner of United States Patent No. 11,274,331, which was duly and legally issued on March 15, 2022, and is titled “Methods of Administering 3,4-Diaminopyridine.” Each and every claim of the ’331 patent is valid and enforceable. Catalyst has an exclusive license under the ’331 patent in the United States. A copy of the ’331 patent is attached as Exhibit 5.

44. SERB is the owner of United States Patent No. 11,274,332, which was duly and legally issued on March 15, 2022, and is titled “Methods of Administering 3,4-Diaminopyridine.”

Each and every claim of the ’332 patent is valid and enforceable. Catalyst has an exclusive license under the ’332 patent in the United States. A copy of the ’332 patent is attached as Exhibit 6.

ACTS GIVING RISE TO THIS ACTION

45. Catalyst is the holder of NDA No. 208078, by which FDA granted approval for 10 mg amifampridine tablets. Catalyst markets these tablets in the United States under the tradename Firdapse.

46. Firdapse and the use of Firdapse in accordance with its label are covered by one or more claims of the Patents-in-Suit.

47. FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) lists the Patents-in-Suit in connection with Firdapse.

48. By letter dated January 17, 2023 (the “Notice Letter”), Teva notified Catalyst and SERB that it had submitted to FDA Teva’s ANDA, seeking approval for the commercial manufacture, use, and sale of Teva ANDA Product in the United States prior to the expiration of the Patents-in-Suit.

49. In the Notice Letter, Teva notified Catalyst and SERB that, as a part of Teva’s ANDA, it had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit, asserting that those patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Teva’s ANDA Product in the United States.

50. By filing Teva’s ANDA, Teva has necessarily represented to FDA that, upon approval, Teva’s ANDA Product will have the same active ingredient, method of administration, dosage form, and strength as Firdapse, and will be bioequivalent to Firdapse.

51. The Notice Letter contained an offer of confidential access, the terms of which the parties have begun negotiating in good faith in an effort to reach a mutually acceptable agreement,

and under which Teva's ANDA would be provided to Plaintiffs. The parties have been unable to reach agreement.

52. The Complaint has been filed before the expiration of forty-five days from the date Catalyst and SERB received the Notice Letter.

COUNT I: INFRINGEMENT OF THE '088 PATENT

53. Plaintiffs reallege paragraphs 1-52 as if fully set forth herein.

54. Teva's submission of Teva's ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Product in or into the United States, prior to the expiration of the '088 patent, constitutes direct and indirect infringement of the '088 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

55. On information and belief, Teva's ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Teva or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '088 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Teva's ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '088 patent.

56. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would constitute

direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the ’088 patent, either literally or under the doctrine of equivalents. On information and belief, Teva intends that Teva’s ANDA Product be used by patients and medical professionals. Also, on information and belief, Teva knows that Teva’s ANDA Product is especially made or adapted for use in infringing the ’088 patent, and that Teva’s ANDA Product is not suitable for substantial non-infringing use.

57. Plaintiffs will be irreparably harmed if Teva is permitted to make, use, sell, offer to sell, and/or import Teva’s ANDA Product in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Teva’s ANDA be a date that is not earlier than the expiration date of the ’088 patent, or any later expiration of exclusivity for the ’088 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

58. Teva has had knowledge of the ’088 patent since at least the date Teva submitted Teva’s ANDA and was aware that submission of Teva’s ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

59. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE ’893 PATENT

60. Plaintiffs reallege paragraphs 1-59 as if fully set forth herein.

61. Teva’s submission of Teva’s ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva’s ANDA Product in or into the United States, prior to the expiration of the ’893 patent, constitutes infringement of the

’893 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

62. On information and belief, Teva’s manufacturing, use, offer for sale, sale, and/or importation of Teva’s ANDA Product, once Teva’s ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’893 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

63. On information and belief, Teva’s ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Teva or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’893 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Teva’s ANDA Product will occur with Teva’s specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs’ rights under the ’893 patent.

64. On information and belief, Teva’s manufacturing, use, offer for sale, sale, and/or importation of Teva’s ANDA Product, once Teva’s ANDA is approved by FDA, would contribute to infringement of one or more claims of the ’893 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Teva knows that Teva’s ANDA Product is especially made or adapted for use in infringing the ’893 patent, and that Teva’s ANDA Product is not suitable for substantial non-infringing use.

65. Plaintiffs will be irreparably harmed if Teva is permitted to make, use, sell, offer to sell, and/or import Teva's ANDA Product in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Teva's ANDA be a date that is not earlier than the expiration date of the '893 patent, or any later expiration of exclusivity for the '893 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

66. Teva has had knowledge of the '893 patent since at least the date Teva submitted Teva's ANDA and was aware that submission of Teva's ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

67. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE '128A PATENT

68. Plaintiffs reallege paragraphs 1-67 as if fully set forth herein.

69. Teva's submission of Teva's ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Product in or into the United States, prior to the expiration of the '128A patent, constitutes infringement of the '128A patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

70. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '128A patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

71. On information and belief, Teva's ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Teva or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '128A patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Teva's ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '128A patent.

72. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would contribute to infringement of one or more claims of the '128A patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '128A patent, and that Teva's ANDA Product is not suitable for substantial non-infringing use.

73. Plaintiffs will be irreparably harmed if Teva is permitted to make, use, sell, offer to sell, and/or import Teva's ANDA Product in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Teva's ANDA be a date that is not earlier than the expiration date of the '128A patent, or any later expiration of exclusivity for the

’128A patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

74. Teva has had knowledge of the ’128A patent since at least the date Teva submitted Teva’s ANDA and was aware that submission of Teva’s ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

75. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE ’128B PATENT

76. Plaintiffs reallege paragraphs 1-75 as if fully set forth herein.

77. Teva’s submission of Teva’s ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva’s ANDA Product in or into the United States, prior to the expiration of the ’128B patent, constitutes infringement of the ’128B patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

78. On information and belief, Teva’s manufacturing, use, offer for sale, sale, and/or importation of Teva’s ANDA Product, once Teva’s ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’128B patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

79. On information and belief, Teva’s ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Teva or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the ’128B patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On

information and belief, the administration of Teva's ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '128B patent.

80. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would contribute to infringement of one or more claims of the '128B patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '128B patent, and that Teva's ANDA Product is not suitable for substantial non-infringing use.

81. Plaintiffs will be irreparably harmed if Teva is permitted to make, use, sell, offer to sell, and/or import Teva's ANDA Product in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Teva's ANDA be a date that is not earlier than the expiration date of the '128B patent, or any later expiration of exclusivity for the '128B patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

82. Teva has had knowledge of the '128B patent since at least the date Teva submitted Teva's ANDA and was aware that submission of Teva's ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

83. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT V: INFRINGEMENT OF THE '331 PATENT

84. Plaintiffs reallege paragraphs 1-83 as if fully set forth herein.

85. Teva's submission of Teva's ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva's ANDA Product in or into the United States, prior to the expiration of the '331 patent, constitutes infringement of the '331 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

86. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '331 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

87. On information and belief, Teva's ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Teva or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one claim of the '331 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Teva's ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '331 patent.

88. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would contribute

to infringement of one or more claims of the ’331 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Teva knows that Teva’s ANDA Product is especially made or adapted for use in infringing the ’331 patent, and that Teva’s ANDA Product is not suitable for substantial non-infringing use.

89. Plaintiffs will be irreparably harmed if Teva is permitted to make, use, sell, offer to sell, and/or import Teva’s ANDA Product in or into the United States, and is not enjoined from doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Teva’s ANDA be a date that is not earlier than the expiration date of the ’331 patent, or any later expiration of exclusivity for the ’331 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

90. Teva has had knowledge of the ’331 patent since at least the date Teva submitted Teva’s ANDA and was aware that submission of Teva’s ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

91. This case is “exceptional,” and Plaintiffs are entitled to an award of reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT VI: INFRINGEMENT OF THE ’332 PATENT

92. Plaintiffs reallege paragraphs 1-91 as if fully set forth herein.

93. Teva’s submission of Teva’s ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Teva’s ANDA Product in or into the United States, prior to the expiration of the ’332 patent, constitutes infringement of the ’332 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

94. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '332 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

95. On information and belief, Teva's ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Teva or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '332 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of Teva's ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Plaintiffs' rights under the '332 patent.

96. On information and belief, Teva's manufacturing, use, offer for sale, sale, and/or importation of Teva's ANDA Product, once Teva's ANDA is approved by FDA, would contribute to infringement of one or more claims of the '332 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents. On information and belief, Teva knows that Teva's ANDA Product is especially made or adapted for use in infringing the '332 patent, and that Teva's ANDA Product is not suitable for substantial non-infringing use.

97. Plaintiffs will be irreparably harmed if Teva is permitted to make, use, sell, offer to sell, and/or import Teva's ANDA Product in or into the United States, and is not enjoined from

doing so. Plaintiffs are entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of Teva's ANDA be a date that is not earlier than the expiration date of the '332 patent, or any later expiration of exclusivity for the '332 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

98. Teva has had knowledge of the '332 patent since at least the date Teva submitted Teva's ANDA and was aware that submission of Teva's ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

99. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '088 patent through Teva's submission of ANDA No. 218029 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '088 patent;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '088 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '088 patent;

(c) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '893 patent through Teva's submission of ANDA No. 218029 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '893 patent;

(d) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '893 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '893 patent;

(e) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '128A patent through Teva's submission of ANDA No. 218029 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '128A patent;

(f) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '128A patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '128A patent;

(g) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '128B patent through Teva's submission of ANDA No. 218029 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '128B patent;

(h) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '128B patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '128B patent;

(i) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '331 patent through Teva's submission of ANDA No. 218029 to FDA seeking

approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '331 patent;

(j) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '331 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '331 patent;

(k) A judgment under 35 U.S.C. § 271(e)(2)(A) that Teva has infringed at least one claim of the '332 patent through Teva's submission of ANDA No. 218029 to FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import within or into the United States Teva's ANDA Product before the expiration of the '332 patent;

(l) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Teva's commercial manufacture, use, offer for sale, sale, and/or importation within or into the United States of Teva's ANDA Product before the expiration of the '332 patent will infringe, actively induce infringement, and/or contribute to the infringement of at least one claim of the '332 patent;

(m) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Teva's ANDA, shall not be earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(n) The entry of a permanent and/or preliminary injunction enjoining Teva, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from making, having made, using, offering to sell, selling, marketing, distributing, and importing in or into the United States Teva's ANDA Product, or any product that infringes the Patents-in-Suit, or inducing or contributing to the infringement of the Patents-in-Suit until after the latest expiration

date of the Patents-in-Suit, including any extension and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(o) The entry of a permanent and/or preliminary injunction enjoining Teva, and its affiliates and subsidiaries, and each of their officers, agents, servants, and employees, from seeking, obtaining, or maintaining approval of Teva's ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

(p) Damages or other monetary relief to Plaintiffs if Teva engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of Teva's ANDA Product prior to the expiration of the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(q) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorney's fees incurred in this action; and

(r) Such further relief as this Court deems proper and just.

Dated: March 1, 2023

By: /s/ Charles H. Chevalier

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevalier@gibbonslaw.com

Attorneys for Plaintiffs Catalyst Pharmaceuticals, Inc. and SERB SA

Of Counsel:

Dennies Varughese, Pharm. D.
Adam C. LaRock
Lauren Watt
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
alarock@sternekessler.com
lwatt@sternekessler.com