**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

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| OTSUKA PHARMACEUTICAL CO., LTD. and H. LUNDBECK A/S,<br><br>Plaintiffs,<br><br>v.<br><br>ACCORD HEALTHCARE INC. and INTAS PHARMACEUTICALS LTD.,<br><br>Defendants. | Civil Action No. 1:19-cv-1072 |

## COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Intas Pharmaceuticals Ltd. ("Intas") and Accord Healthcare Inc. ("Accord") (collectively, "Defendants"), allege as follows:

## NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Defendants' filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug

Administration ("FDA") approval to engage in the commercial manufacture, use, sale, offer to sell and/or importation in the United States of generic pharmaceutical products before the expiration of the patents in suit.

## THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '362, '840, '109, '637 and '419 patents.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Intas is a corporation organized under the laws of India and its principal place of business is located at Corporate House, Near Sola Bridge, S. G. Highway, Thaltej, Ahmedabad – 380054, Gujarat, India.

6. Upon information and belief, Accord is a corporation organized under the laws of North Carolina and its principal place of business is located at 1009 Slater Road, Suite #210B, Durham, North Carolina 27703.

7. Upon information and belief, Accord is a wholly owned subsidiary of Intas.

## JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. Plaintiffs believe this case belongs in Delaware but are concurrently filing a case in this district out of an abundance of caution.

10. This Court has personal jurisdiction over Intas because, upon information and belief, Intas directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district.

11. This Court has personal jurisdiction over Accord because, upon information and belief, Accord is incorporated in North Carolina.

12. Upon information and belief, Intas and Accord hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

13. Upon information and belief, Defendants have been, and continue to be, the prime actors in the drafting, submission, approval and maintenance of ANDA No. 213788.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Accord is incorporated in the state of North Carolina.

15. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Intas is incorporated in India and may be sued in any judicial district.

## FACTUAL BACKGROUND

### The NDA

16. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets").

17. The FDA approved NDA No. 205422 on July 10, 2015.

18. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in the REXULTI® Tablets.

### The Patents In Suit

19. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '362 patent is attached as **Exhibit A**.

20. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

21. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as **Exhibit B**.

22. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, which is attached as **Exhibit C**. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of 986 days. Accordingly, the '362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

23. The '362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

24. The PTO issued the '840 patent on January 8, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '840 patent is attached as **Exhibit D**.

25. Otsuka owns the '840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

26. The '840 patent is subject to a terminal disclaimer and expires on April 12, 2026.

27. The '840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

28. The PTO issued the '109 patent on December 31, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '109 patent is attached as **Exhibit E**.

29. Otsuka owns the ’109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

30. The ’109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

31. The ’109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

32. The PTO issued the ’637 patent on December 12, 2017, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’637 patent is attached as **Exhibit F**.

33. Otsuka owns the ’637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

34. The ’637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

35. The ’637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

36. The PTO issued the ’419 patent on June 4, 2019, entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof.” A true and correct copy of the ’419 patent is attached as **Exhibit G**.

37. Otsuka owns the ’419 patent through assignment as recorded by the PTO at Reel 033930, Frame 0447.

38. The ’419 patent expires on October 12, 2032.

39. The ’419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

**The ANDA**

40. Upon information and belief, Defendants filed ANDA No. 213788 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, sale, offer to sell and/or importation in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3, and 4 mg (“Defendants’ generic products”), which are generic versions of Otsuka’s REXULTI® (brexpiprazole) Tablets.

41. Upon information and belief, ANDA No. 213788 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the commercial manufacture, use, sale, offer to sell and/or importation in the United States of Defendants’ generic products will not infringe any valid or enforceable claims of the patents in suit.

42. Otsuka received a letter sent by Defendants, dated September 5, 2019, purporting to be a “Notice of Certification” for ANDA No. 213788 (“Defendants’ Notice Letter”) pursuant to 21 U.S.C. § 355(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Defendants’ Notice Letter notified Otsuka that Defendants had filed ANDA No. 213788, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Defendants’ generic products before the expiration of the patents in suit.

43. Plaintiffs commenced this action within 45 days of receiving Defendants' September 5, 2019, Notice Letter.

**COUNT I**

**(INFRINGEMENT OF THE '362 PATENT)**

44. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

45. Upon information and belief, Defendants filed ANDA No. 213788 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '362 patent.

46. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

47. Upon information and belief, in ANDA No. 213788, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

48. Defendants have actual knowledge of Otsuka's '362 patent, as evidenced by Defendants' September 5, 2019, Notice Letter.

49. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '362 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213788, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '362 patent.

50. Upon information and belief, if ANDA No. 213788 is approved, Defendants intend to and will offer to sell, sell and/or import in the United States Defendants' generic products.

51. Upon information and belief, if ANDA No. 213788 is approved, Defendants will infringe one or more claims of the '362 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213788 shall be no earlier than the expiration of the '362 patent and any additional periods of exclusivity.

52. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213788 complained of herein were done by and for the benefit of Defendants.

53. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

54. Plaintiffs do not have an adequate remedy at law.

## COUNT II

## (INFRINGEMENT OF THE '840 PATENT)

55. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

56. Upon information and belief, Defendants filed ANDA No. 213788 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '840 patent.

57. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the ’840 patent are invalid, unenforceable and/or not infringed.

58. Upon information and belief, in ANDA No. 213788, Defendants have represented to the FDA that Defendants’ generic products are pharmaceutically and therapeutically equivalent to Otsuka’s REXULTI® Tablets.

59. Defendants have actual knowledge of Otsuka’s ’840 patent, as evidenced by Defendants’ September 5, 2019, Notice Letter.

60. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the ’840 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213788, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants’ generic products before the expiration date of the ’840 patent.

61. Upon information and belief, if ANDA No. 213788 is approved, Defendants will infringe one or more claims of the ’840 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants’ generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213788 shall be no earlier than the expiration of the ’840 patent and any additional periods of exclusivity.

62. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 213788, and therefore will infringe at least one claim of the '840 patent.

63. Upon information and belief, Defendants have knowledge of the '840 patent and, by their proposed package insert for Defendants' generic products, know or should know that they will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.

64. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants' generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.

65. Upon information and belief, if ANDA No. 213788 is approved, Defendants intend to and will offer to sell, sell and/or import in the United States Defendants' generic products.

66. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213788 complained of herein were done by and for the benefit of Defendants.

67. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

68. Plaintiffs do not have an adequate remedy at law.

**COUNT III**

**(INFRINGEMENT OF THE ’109 PATENT)**

69. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

70. Upon information and belief, Defendants filed ANDA No. 213788 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants’ generic products in the United States before the expiration of the ’109 patent.

71. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the ’109 patent are invalid, unenforceable and/or not infringed.

72. Upon information and belief, in ANDA No. 213788, Defendants have represented to the FDA that Defendants’ generic products are pharmaceutically and therapeutically equivalent to Otsuka’s REXULTI® Tablets.

73. Defendants have actual knowledge of Otsuka’s ’109 patent, as evidenced by Defendants’ September 5, 2019, Notice Letter.

74. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the ’109 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213788, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants’ generic products before the expiration date of the ’109 patent.

75. Upon information and belief, if ANDA No. 213788 is approved, Defendants will infringe one or more claims of the ’109 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants’ generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213788 shall be no earlier than the expiration of the ’109 patent and any additional periods of exclusivity.

76. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants’ generic products for which approval is sought in ANDA No. 213788, and therefore will infringe at least one claim of the ’109 patent.

77. Upon information and belief, Defendants have knowledge of the ’109 patent and, by their proposed package insert for Defendants’ generic products, know or should know that they will induce direct infringement of at least one claim of the ’109 patent, either literally or under the doctrine of equivalents.

78. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants’ generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the ’109 patent.

79. Upon information and belief, if ANDA No. 213788 is approved, Defendants intend to and will offer to sell, sell and/or import in the United States Defendants' generic products.

80. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213788 complained of herein were done by and for the benefit of Defendants.

81. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

82. Plaintiffs do not have an adequate remedy at law.

**COUNT IV**

**(INFRINGEMENT OF THE '637 PATENT)**

83. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

84. Upon information and belief, Defendants filed ANDA No. 213788 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the '637 patent.

85. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '637 patent are invalid, unenforceable and/or not infringed.

86. Upon information and belief, in ANDA No. 213788, Defendants have represented to the FDA that Defendants' generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

87. Defendants have actual knowledge of Otsuka's '637 patent, as evidenced by Defendants' September 5, 2019, Notice Letter.

88. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the '637 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213788, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants' generic products before the expiration date of the '637 patent.

89. Upon information and belief, if ANDA No. 213788 is approved, Defendants will infringe one or more claims of the '637 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants' generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213788 shall be no earlier than the expiration of the '637 patent and any additional periods of exclusivity.

90. Upon information and belief, Defendants know, should know and intend that physicians will prescribe and patients will take Defendants' generic products for which approval is sought in ANDA No. 213788, and therefore will infringe at least one claim of the '637 patent.

91. Upon information and belief, Defendants have knowledge of the '637 patent and, by their proposed package insert for Defendants' generic products, know or

should know that they will induce direct infringement of at least one claim of the ’637 patent, either literally or under the doctrine of equivalents.

92. Upon information and belief, Defendants are aware and/or have knowledge that their proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Defendants’ generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the ’637 patent.

93. Upon information and belief, if ANDA No. 213788 is approved, Defendants intend to and will offer to sell, sell and/or import in the United States Defendants’ generic products.

94. Upon information and belief, Defendants’ actions relating to Defendants’ ANDA No. 213788 complained of herein were done by and for the benefit of Defendants.

95. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless this Court enjoins those activities.

96. Plaintiffs do not have an adequate remedy at law.

## COUNT V

## (INFRINGEMENT OF THE ’419 PATENT)

97. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

98. Upon information and belief, Defendants filed ANDA No. 213788 seeking approval to manufacture, use, import, offer to sell and/or sell Defendants’ generic

products in the United States before the expiration of the ’419 patent.

99. Upon information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the ’419 patent are invalid, unenforceable and/or not infringed.

100. Upon information and belief, in ANDA No. 213788, Defendants have represented to the FDA that Defendants’ generic products are pharmaceutically and therapeutically equivalent to Otsuka’s REXULTI® Tablets.

101. Defendants have actual knowledge of Otsuka’s ’419 patent, as evidenced by Defendants’ September 5, 2019, Notice Letter.

102. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed one or more claims of the ’419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213788, seeking approval to commercially manufacture, use, import, offer to sell or sell Defendants’ generic products before the expiration date of the ’419 patent.

103. Upon information and belief, if ANDA No. 213788 is approved, Defendants will infringe one or more claims of the ’419 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Defendants’ generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 213788 shall be no earlier than the expiration of the ’419 patent and any additional periods of exclusivity.

104. Upon information and belief, Defendants' actions relating to Defendants' ANDA No. 213788 complained of herein were done by and for the benefit of Defendants.

105. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless this Court enjoins those activities.

106. Plaintiffs do not have an adequate remedy at law.

## REQUEST FOR RELIEF

**WHEREFORE**, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of each of the patents in suit through Defendants' submission of ANDA No. 213788 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Defendants' generic products in the United States before the expiration of the patents in suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Defendants' making, using, offering to sell, selling or importing of Defendants' generic products before the expiration of the patents in suit will infringe, actively induce infringement and/or contribute to the infringement of the patents in suit under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Defendants' generic products shall be no earlier than the expiration date of the patents in suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale or selling Defendants' generic products within the United States, or importing Defendants' generic products into the United States, until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining or maintaining approval of the ANDA until the expiration of the patents in suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

This the 18th day of October, 2019.

/s/ Allison Mullins
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