Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA
One Riverfront Plaza
1037 Raymond Blvd, Suite 600
Newark, NJ 07102
(973) 757-1101
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Attorneys for Plaintiffs Patheon Softgels Inc. and Bionpharma Inc.

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

PATHEON SOFTGELS INC. and BIONPHARMA INC. **Plaintiffs,** **v.** **APOTEX INC. and APOTEX CORP.** **Defendants.**	**Consolidated Civ. No. 3:17-cv-13819 (MAS-LHG)** *(Filed Electronically)*
PATHEON SOFTGELS INC., BIONPHARMA INC., and BIONPHARMA HEALTHCARE LLC **Plaintiffs,** **v.** **OHM LABORATORIES, INC.,** **Defendant.**	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Patheon Softgels Inc. ("Patheon Softgels"), and Bionpharma Inc. ("Bionpharma") (Patheon Softgels and Bionpharma are collectively referred to herein as "Plaintiffs"), by their attorneys, for their complaint against Apotex Inc. and Apotex Corp. (collectively, "Apotex") allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 9,693,978 (the "'978 patent") and 9,693,979 (the "'979 patent") (collectively, the "Patents-in-suit") under the patent laws of the United States, 35 U.S.C. §100, *et seq*. This action arises from Apotex's filing of Abbreviated New Drug Application ("ANDA") No. 210325 ("the Apotex ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Bionpharma's 220 mg Naproxen Sodium (EQ 200 mg Base) Over-the-Counter ("OTC") drug product ("the Apotex ANDA Product") prior to the expiration of the Patents-in-suit.

THE PARTIES

2. Patheon Softgels is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 4125 Premier Drive, High Point, North Carolina 27265.

3. Bionpharma Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 600 Alexander Road, Suite 2-4B, Princeton, New Jersey 08540.

4. Upon information and belief, defendant Apotex Inc. is a foreign corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. Upon information and belief, defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Weston, Florida 33326.

THE PATENTS-IN-SUIT

6. On July 4, 2017, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '978 patent, entitled "Solvent System for Enhancing the Solubility of Pharmaceutical Agents." Patheon Softgels is the owner and assignee of the '978 patent. A copy of the '978 patent is attached as Exhibit A.

7. Bionpharma has an exclusive license under the '978 patent.[1]

8. On July 4, 2017, the USPTO duly and lawfully issued the '979 patent, entitled "Liquid Dosage Forms of Sodium Naproxen." Patheon Softgels is the owner and assignee of the '979 patent. A copy of the '979 patent is attached as Exhibit B.

9. Bionpharma has an exclusive license under the '979 patent.[2]

BIONPHARMA'S NDA AND NAPROXEN SODIUM DRUG PRODUCT

10. Bionpharma holds approved New Drug Application ("NDA") No. 021920 for 220 mg Naproxen Sodium (EQ 200 mg Base) OTC capsules ("the Bionpharma NDA Product").[3]

11. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '978 and '979 patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NDA No. 021920.

12. Bionpharma sells the Bionpharma NDA Product throughout the United States, including in this Judicial District.

[1] On May 21, 2018, former Plaintiff Bionpharma Healthcare LLC assigned the exclusive license to the '978 patent to Bionpharma.
[2] As with the '978 patent, the exclusive license to the '979 patent has been assigned to Bionpharma.
[3] On May 21, 2018, former Plaintiff Bionpharma Healthcare LLC assigned any residual ownership rights in the NDA to Bionpharma.

13. Patheon Softgels manufactures the Bionpharma NDA Product for Bionpharma.

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

15. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-2202 because this is a case of actual controversy within the Court's jurisdiction.

16. Upon information and belief, Apotex Inc. and Apotex Corp. are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to the Apotex ANDA Product.

17. Upon information and belief, Apotex Inc. and Apotex Corp. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to the Apotex ANDA Product.

18. Upon information and belief, Apotex Inc., alone and/or together with its subsidiary, agent or alter ego Apotex Corp., filed Apotex's ANDA No. 210325 with the FDA.

19. Upon information and belief, Apotex Corp. acts at the direction, and for the benefit, of Apotex Inc., and is controlled and/or dominated by Apotex Inc.

20. This Court has personal jurisdiction over Apotex Inc. because, *inter alia*, upon information and belief: (1) it has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Apotex Corp., a company registered with the State of New Jersey as a drug wholesaler under Registration No. 5003192; (2) it maintains pervasive, continuous, and systematic contacts with the State of New

Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs (for which it is the holder of the approved FDA application) in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Apotex Corp.; (3) Apotex Inc. sent Bionpharma a letter dated November 15, 2017, addressed to Bionpharma in Princeton, New Jersey, where Apotex Inc. states that it is seeking approval to engage in the commercial manufacture, use, sale, and/or importation of the Apotex ANDA Product prior to the expiration of the '978 patent ("the Apotex Notice Letter regarding the '978 patent"), and Apotex Inc. sent Bionpharma a letter dated November 15, 2017, addressed to Bionpharma in Princeton, New Jersey, where Apotex Inc. states that it is seeking approval to engage in the commercial manufacture, use, sale, and/or importation of the Apotex ANDA Product prior to the expiration of the '979 patent ("the Apotex Notice Letter regarding the '979 patent") (collectively, the Apotex Notice Letter regarding the '978 patent and the Apotex Notice Letter regarding the '979 patent are referred to herein as "the Apotex Notice Letters"); (4) when and if Apotex's ANDA No. 210325 is approved, Apotex Inc. and/or Apotex Corp. intend to and will commit acts of infringement in New Jersey by selling and offering to sell the Apotex ANDA Product throughout the United States, including in New Jersey; and (5) the filing of ANDA No. 210325 by Apotex seeking approval to market the Apotex ANDA Product before the expiration of the Patents-in-Suit has caused, and by the sale of the Apotex ANDA Product by Apotex Inc., Apotex Corp. and/or others before the expiration of the Patents-in-Suit will cause, foreseeable harm to Bionpharma, which is headquartered in New Jersey.

21. Additionally, Apotex Inc. has routinely consented to jurisdiction and/or venue in this Court, and availed itself of the protections afforded by this Court, including by asserting Counterclaims in this Court. *See, e.g., Mitsubishi Tanabe Pharma Corp.et al. v. Apotex, Inc. et al.*, No. 17-5278 (PGS) (DEA) (D.N.J. Dec. 11, 2017); *Celgene Corp. v. Hetero Labs Limited et al.*,

No. 17-3387 (ES) (JAD) (D.N.J. Jul. 13, 2017); *Novartis Pharm. Corp. v. Apotex Inc., et al.*, No. 15-3634 (SDW)(LDW) (D.N.J. Aug. 18, 2015); *Astrazeneca AB, et al. v. Apotex Corp., et al.*, No. 15-3379 (FLW)(DEA) (D.N.J. Jul. 20, 2015); *Sanofi-Aventis U.S. LLC, et al. v. Apotex Corp., et al.*, No. 15-287 (MAS)(LHG) (D.N.J. Mar. 20, 2015). Apotex Inc. has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Court. *See, e.g., Apotex Inc. v. Shire LLC*, No. 08-3598 (SRC)(MAS) (D.N.J. Jul. 17, 2008); *Apotex Inc., et al. v. Pharmaceutical Resources, Inc.*, No. 06-1153 (JLL)(MF) (D.N.J. Mar. 10, 2006).

22. Alternatively, to the extent the above facts do not establish personal jurisdiction over Apotex Inc., this Court may exercise jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) the claims asserted herein arise under federal law; (b) Apotex Inc. would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

23. This Court has personal jurisdiction over Apotex Corp. because, *inter alia*, upon information and belief: (1) it has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, securing a New Jersey wholesaler drug distributor's license (Registration No. 5003192); (2) it maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (3) the Apotex Notice Letters, which were addressed to Bionpharma in Princeton, New Jersey, were each signed by a Mr. Kiran Krishnan, an individual identified in the Apotex Notice Letters as the Senior Vice-President, Global Regulatory Affairs for Apotex Corp., and each of the Apotex Notice Letters further identifies Mr. Krishnan as a U.S. agent

authorized to accept service on behalf of Apotex Inc.; (4) when and if ANDA No. 210325 is approved, Apotex Corp. intends to and will commit acts of infringement in New Jersey by selling and offering to sell the Apotex ANDA Product throughout the United States, including in New Jersey; and (5) the filing of ANDA No. 210325 by Apotex seeking approval to market the Apotex ANDA Product before the expiration of the Patents-in-Suit has caused, and by the sale of the Apotex ANDA Product by Apotex Corp. and/or others before the expiration of the Patents-in-Suit will cause, foreseeable harm to Bionpharma, which is headquartered in New Jersey.

24. Additionally, Apotex Corp. has routinely consented to jurisdiction and/or venue in this Court, and availed itself of the protections afforded by this Court, including by asserting Counterclaims in this Court. *See, e.g., Mitsubishi Tanabe Pharma Corp.et al. v. Apotex, Inc. et al.*, No. 17-5278 (PGS) (DEA) (D.N.J. Dec. 11, 2017); *Celgene Corp. v. Hetero Labs Limited et al.*, No. 17-3387 (ES) (JAD) (D.N.J. Jul. 13, 2017); *Novartis Pharm. Corp. v. Apotex Inc., et al.*, No. 15-3634 (SDW)(LDW) (D.N.J. Aug. 18, 2015); *Astrazeneca AB, et al. v. Apotex Corp., et al.*, No. 15-3379 (FLW)(DEA) (D.N.J. Jul. 20, 2015); *Sanofi-Aventis U.S. LLC, et al. v. Apotex Corp., et al.*, No. 15-287 (MAS)(LHG) (D.N.J. Mar. 20, 2015). Apotex Corp. has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Court. *See, e.g., Apotex Inc., et al.v. Pharmaceutical Resources, Inc.*, No. 06-1153 (JLL)(MF) (D.N.J. Mar. 10, 2006).

25. Pursuant to 28 U.S.C. § 1391(c)(3), venue as to Apotex Inc. is proper in this Court because, as set forth above, Apotex Inc. is a foreign corporation and thus does not reside in the United States.

26. Pursuant to 28 U.S.C. §§ 1391 and/or 1400(b), venue as to Apotex Corp. is proper in this Court because, *inter alia*, as set forth above, this Court has personal jurisdiction over Apotex Corp. and Apotex Inc. and thus all defendants reside in New Jersey within the meaning of 28 U.S.C.

§ 1391, and Apotex Corp. has committed and will commit further acts of infringement in New Jersey, and, upon information and belief, does business in New Jersey through a permanent and continuous presence in the State of New Jersey. For example, Apotex Corp. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5003192 and continuously sells its products in New Jersey. Upon information and belief, Apotex Corp. employs a sales force that includes personnel that regularly and continuously work in New Jersey and, if Apotex Inc. succeeds in obtaining FDA approval of the Apotex ANDA, Apotex Corp. will use its sales force to sell the Apotex ANDA Product in the State of New Jersey.

27. Moreover, neither Apotex Inc. nor Apotex Corp. contested venue in at least 14 actions brought in this Judicial District under the Hatch-Waxman Act, including on several occasions after the Supreme Court's decision in *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S.Ct. 1514 (2017). *See*, *e.g.*, Civ. Action Nos. 17-5399, 17-5278, 17-2423, 15-8492, 15-7880, 15-5909, 15-3634, 15-3379, 15-2384, 15-668, 15-287, 14-8074, 14-4409, and 14-2550. Moreover, Apotex Inc. and Apotex Corp. admitted that venue is proper in at least two actions brought in this Judicial District under the Hatch-Waxman Act. *See*, *e.g.*, Civ. Action Nos. 14-1975 and 07-3770.

APOTEX'S INFRINGING ANDA SUBMISSION

28. On or about November 16, 2017, Patheon Softgels received from Apotex's counsel a letter, dated November 15, 2017, stating that Apotex Inc. had submitted the Apotex ANDA to the FDA seeking approval to market the Apotex ANDA Product before the expiration of the '978 patent, and stating that the Apotex ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) (a "Paragraph IV certification") as to the '978 patent. Bionpharma received the Apotex Letter regarding the '978 patent no earlier than November 16, 2017.

29. On or about November 16, 2017, Patheon Softgels received from Apotex's counsel

a letter, dated November 15, 2017, stating that Apotex Inc. had submitted the Apotex ANDA to the FDA seeking approval to market the Apotex ANDA Product before the expiration of the '979 patent, and stating that the Apotex ANDA contains a Paragraph IV certification as to the '979 patent. Bionpharma received the Apotex Letter regarding the '979 patent no earlier than November 16, 2017.

30. Apotex specifically directed the Apotex Notice Letters to Bionpharma's headquarters in Princeton, New Jersey.

31. The Apotex ANDA Product is intended to be a generic version of Bionpharma's 220 mg Naproxen Sodium (EQ 200 mg Base) OTC drug product, which was approved via NDA No. 021920.

32. This action is being commenced before the expiration of 45 days from the date Patheon Softgels and Bionpharma received the Apotex Notice Letters.

COUNT I

Infringement of U.S. Patent No. 9,693,978 by Apotex Under 35 U.S.C. § 271(e)(2)

33. Plaintiffs repeat and reallege paragraphs 1-32 above as if fully set forth herein.

34. By filing its ANDA No. 210325 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Apotex ANDA Product before the expiration of the '978 patent, Apotex committed an act of infringement under 35 U.S.C. § 271(e)(2).

35. Apotex Inc. has had knowledge of the '978 patent since at least the date it submitted a Paragraph IV certification to the '978 patent to FDA in connection with its ANDA No. 210325, which was on or before November 15, 2017, the date that it sent the Apotex Notice Letter regarding the '978 patent to Patheon Softgels and Bionpharma. Upon information and belief, Apotex Corp.

has had knowledge of the '978 patent since at least November 15, 2017, the date that the Apotex Notice Letter regarding the '978 patent – which was signed by an officer of Apotex Corp. – was sent to Patheon Softgels and Bionpharma, and Apotex Corp. will have had knowledge of the '978 patent at least upon the date of service of the initial Complaint, dated December 29, 2017.

36. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or importation of the Apotex ANDA product, if approved by the FDA, prior to the expiration of the '978 patent would infringe the '978 patent under 35 U.S.C. § 271.

37. Plaintiffs will be substantially and irreparably harmed if Apotex's infringement of the '978 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

38. Plaintiffs are entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of the approval of the Apotex ANDA be a date that is not earlier than the expiration date of the '978 patent.

COUNT II

Declaratory Judgment of Infringement of U.S. Patent No. 9,693,978 by Apotex

39. Plaintiffs repeat and reallege paragraphs 1-38 above as if fully set forth herein.

40. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

41. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

42. Upon information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Apotex ANDA Product.

43. The Apotex Notice Letter regarding the '978 patent indicates Apotex's refusal to change the course of its actions directed to obtaining FDA approval for and commercially marketing the Apotex ANDA Product prior to the expiration of the '978 patent.

44. If Apotex commercially makes, uses, offers to sell, or sells the Apotex ANDA Product within the United States, or imports the Apotex ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '978 patent, Apotex would infringe one or more claims of the '978 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

45. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product will infringe the '978 patent.

COUNT III

Infringement of U.S. Patent No. 9,693,979 by Apotex Under 35 U.S.C. § 271(e)(2)

46. Plaintiffs repeat and reallege paragraphs 1-45 above as if fully set forth herein.

47. By filing its ANDA No. 210325 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Apotex ANDA Product before the expiration of the '979 patent, Apotex committed an act of infringement under 35 U.S.C. § 271(e)(2).

48. Apotex Inc. has had knowledge of the '979 patent since at least the date it submitted a Paragraph IV certification to the '979 patent to FDA in connection with its ANDA No. 210325, which was on or before November 15, 2017, the date that it sent the Apotex Notice Letter regarding the '979 patent to Patheon Softgels and Bionpharma. Upon information and belief, Apotex Corp. has had knowledge of the '979 patent since at least November 15, 2017, the date that the Apotex Notice Letter regarding the '979 patent – which was signed by an officer of Apotex Corp. – was

sent to Patheon Softgels and Bionpharma, and Apotex Corp. will have had knowledge of the '979 patent at least upon the date of service of the initial Complaint, dated December 29, 2017.

49. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or importation of the Apotex ANDA product, if approved by the FDA, prior to the expiration of the '979 patent would infringe the '979 patent under 35 U.S.C. § 271.

50. Plaintiffs will be substantially and irreparably harmed if Apotex's infringement of the '979 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of the approval of the Apotex ANDA be a date that is not earlier than the expiration date of the '979 patent.

COUNT IV

Declaratory Judgment of Infringement of U.S. Patent No. 9,693,979 by Apotex

52. Plaintiffs repeat and reallege paragraphs 1-51 above as if fully set forth herein.

53. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

54. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

55. Upon information and belief, Apotex has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import the Apotex ANDA Product.

56. The Apotex Notice Letter regarding the '979 patent indicates Apotex's refusal to change the course of its actions directed to obtaining FDA approval for and commercially marketing

the Apotex ANDA Product prior to the expiration of the '979 patent.

57. If Apotex commercially makes, uses, offers to sell, or sells the Apotex ANDA Product within the United States, or imports the Apotex ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '979 patent, Apotex would infringe one or more claims of the '979 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

58. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the Apotex ANDA Product will infringe the '979 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Apotex has infringed one or more claims of the '978 patent by filing ANDA No. 210325;

B. A Declaratory Judgment that Apotex's making, using, selling, offering to sell, or importing the Apotex ANDA Product before the expiration of the '978 patent would constitute infringement of one or more claims of the '978 patent, and/or induce or contribute to infringement of one or more claims of the '978 patent pursuant to 35 U.S.C. § 271(a), (b), (c), and/or (g);

C. A permanent injunction restraining and enjoining Apotex, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Apotex ANDA Product until after the expiration of the '978 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of ANDA No. 210325 relating to the Apotex ANDA Product be a date that is not earlier than the expiration date of the

'978 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Apotex has infringed one or more claims of the '979 patent by filing ANDA No. 210325;

F. A Declaratory Judgment that Apotex's making, using, selling, offering to sell, or importing the Apotex ANDA Product before the expiration of the '979 patent would constitute infringement of one or more claims of the '979 patent, and/or induce or contribute to infringement of one or more claims of the '979 patent pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Apotex and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Apotex ANDA Product until after the expiration of the '979 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of ANDA No. 210325 relating to the Apotex ANDA Product be a date that is not earlier than the expiration date of the '979 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled; and

I. Such other and further relief as the Court may deem just and proper.

Dated: November 12, 2018

By: */s/ Liza M. Walsh*
Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA
One Riverfront Plaza
1037 Raymond Blvd, Suite 600
Newark, NJ 07102

(973) 757-1101
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Of Counsel for Patheon Softgels, Inc.:
Peter Armenio
Anne Toker
Sky Adams
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000
peterarmenio@quinnemanuel.com
annetoker@quinnemanuel.com
skyadams@quinnemanuel.com

Megan Y. Yung
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Huntington Ave, Suite 520
Boston, MA 02199
(617) 712-7100
meganyung@quinnemanuel.com

Rip Finst
THERMO FISHER SCIENTIFIC INC.
5781 Van Allen Way
Carlsbad, CA 92008
rip.finst@thermofisher.com

Of Counsel for Bionpharma Inc.:
J.C. Rozendaal
Dennies Varughese, Pharm.D.
Josh Miller
STERNE KESSLER GOLDSTEIN & FOX, PLLC
1100 New York Avenue, NW, Suite 600
Washington, D.C. 20005
202-772-8747
jcrozendaal@sternekessler.com
dvarughe@sternekessler.com
jmiller@sternekessler.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

I certify that, to the best of my knowledge, the following related action is pending:

- *Patheon Softgels Inc. and Bionpharma Inc. v. PuraCap Pharmaceutical LLC*, Civil Action No. 18-cv-14693 (MAS) (LHG) (D.N.J. Oct. 5, 2018).

Dated: November 12, 2018

By: */s/ Liza M. Walsh*

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA
One Riverfront Plaza
1037 Raymond Blvd, Suite 600
Newark, NJ 07102
(973) 757-1101
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Of Counsel for Patheon Softgels, Inc.:
Peter Armenio
Anne Toker
Sky Adams
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000
peterarmenio@quinnemanuel.com
annetoker@quinnemanuel.com
skyadams@quinnemanuel.com

Megan Y. Yung
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Huntington Ave, Suite 520
Boston, MA 02199
(617) 712-7100
meganyung@quinnemanuel.com

Rip Finst
THERMO FISHER SCIENTIFIC INC.
5781 Van Allen Way

Carlsbad, CA 92008
rip.finst@thermofisher.com

Of Counsel for Bionpharma Inc.:
J.C. Rozendaal
Dennies Varughese, Pharm.D.
Josh Miller
STERNE KESSLER GOLDSTEIN & FOX, PLLC
1100 New York Avenue, NW, Suite 600
Washington, D.C. 20005
202-772-8747
jcrozendaal@sternekessler.com
dvarughe@sternekessler.com
jmiller@sternekessler.com

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: November 12, 2018

By: */s/ Liza M. Walsh*

Liza M. Walsh
Katelyn O'Reilly
William T. Walsh, Jr.
WALSH PIZZI O'REILLY FALANGA
One Riverfront Plaza
1037 Raymond Blvd, Suite 600
Newark, NJ 07102
(973) 757-1101
lwalsh@walsh.law
koreilly@walsh.law
wwalsh@walsh.law

Of Counsel for Patheon Softgels, Inc.:
Peter Armenio
Anne Toker
Sky Adams
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000
peterarmenio@quinnemanuel.com
annetoker@quinnemanuel.com
skyadams@quinnemanuel.com

Megan Y. Yung
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
111 Huntington Ave, Suite 520
Boston, MA 02199
(617) 712-7100
meganyung@quinnemanuel.com

Rip Finst
THERMO FISHER SCIENTIFIC INC.
5781 Van Allen Way
Carlsbad, CA 92008
rip.finst@thermofisher.com

Of Counsel for Bionpharma Inc.:
J.C. Rozendaal
Dennies Varughese, Pharm.D.
Josh Miller
STERNE KESSLER GOLDSTEIN & FOX, PLLC
1100 New York Avenue, NW, Suite 600
Washington, D.C. 20005
202-772-8747
jcrozendaal@sternekessler.com
dvarughe@sternekessler.com
jmiller@sternekessler.com