IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P. and THE. P.F. LABORATORIES, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
COLLEGIUM NF, LLC and COLLEGIUM PHARMACEUTICAL, INC.,	)	**DEMAND FOR JURY TRIAL**
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. (collectively "Purdue" or "Plaintiffs") for their Complaint against Collegium NF, LLC and Collegium Pharmaceutical, Inc. (collectively "Collegium" or "Defendants"), aver as follows:

NATURE OF THE ACTION

1. This is an action for relief from patent infringement, arising under the patent laws of the United States, Title 35, United States Code. Plaintiffs seek relief from infringement of U.S. Patent Nos. 9,861,583 (the "'583 patent"), 9,867,784 (the "'784 patent") and 9,872,836 (the "'836 patent"), which relate to pharmaceutical formulations containing a gelling agent. The '583, '784 and '836 patents are herein referred to, collectively, as "the Patents." Collegium offers to sell and sells Nucynta® (tapentadol) tablets ("Nucynta IR") and Nucynta® ER (tapentadol) extended-release tablets ("Nucynta ER") from before the expiration of the Patents. Collegium has infringed and continues to infringe the '583, '784 and '836 patents under 35 U.S.C. § 271(b) by inducing Depomed, Inc.'s ("Depomed") direct infringement under

35 U.S.C. § 271(a) and (g) and under 35 U.S.C. § 271(g) by using, selling, and/or offering for sale Nucynta IR and Nucynta ER, products made by processes patented in the United States.

THE PARTIES

2. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. Purdue Pharma is an owner by assignment of the Patents.

3. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner by assignment of the Patents.

4. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. P.F. Labs is an owner by assignment of the Patents.

5. On information and belief, Collegium NF, LLC ("Collegium NF") is a limited liability company organized and existing under the laws of the State of Delaware.

6. On information and belief, Collegium Pharmaceutical, Inc. ("Collegium Pharmaceutical") is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

7. On information and belief, Collegium NF is a wholly owned subsidiary of Collegium Pharmaceutical.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, including 35 U.S.C. § 271.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Collegium NF, and venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because Collegium NF resides in this District and has committed an act of patent infringement in this District.

11. Further, this Court has personal jurisdiction over Collegium NF because of, *inter alia*: Collegium NF's incorporation in Delaware; its continuous and systematic contacts with corporate entities within this District; and its marketing and sales activities in this Judicial District, including, but not limited to, the substantial, continuous, and systematic distribution, marketing and/or sales of Nucynta IR and Nucynta ER to residents of this District. Accordingly, Collegium NF should have reasonably anticipated that its actions would cause injury in Delaware, and that it would be subject to suit in Delaware to redress that injury.

12. This Court further has personal jurisdiction over Collegium NF by virtue of the fact that Collegium NF has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

13. This Court has personal jurisdiction over Collegium Pharmaceutical, and venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because Collegium Pharmaceutical has committed acts of patent infringement in this District and is responsible for the performance and payment of royalties by its wholly owned subsidiary,

Collegium NF, a resident of the State of Delaware, under the Commercialization Agreement set forth in more detail below.

14. Further, this Court has personal jurisdiction over Collegium Pharmaceutical because of, *inter alia*: Collegium Pharmaceutical's marketing and sales activities in this District, including, but not limited to, the substantial, continuous, and systematic distribution, marketing and/or sales of Nucynta IR and Nucynta ER to residents of this District. Accordingly, Collegium Pharmaceutical should have reasonably anticipated that its actions would cause injury in Delaware and that it would be subject to suit in Delaware to redress that injury.

15. This Court further has personal jurisdiction over Collegium Pharmaceutical by virtue of the fact that Collegium Pharmaceutical has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware.

NUCYNTA NDAs

Nucynta IR

16. Depomed is the holder of NDA No N022304 for Nucynta IR.

17. On November 20, 2008, the FDA approved NDA No. 022304 for the manufacture, marketing, and sale of Nucynta IR.

18. Depomed has and continues to manufacture or have manufactured three dosage strengths of Nucynta IR in the U.S.: 50 mg, 75 mg and 100 mg.

19. Depomed has until on or about January 10, 2018, offered for sale and sold Nucynta IR in the U.S.

Nucynta ER

20. Depomed is the holder of NDA No 200533 for Nucynta ER.

21. On August 25, 2011, the FDA approved NDA No. 200533 for the manufacture, marketing, and sale of Nucynta ER.

22. Depomed has and continues to manufacture or have manufactured five dosage strengths of Nucynta ER in the U.S.: 50 mg, 100 mg, 150 mg, 200 mg and 250 mg.

23. Depomed has until on or about January 10, 2018 offered for sale and sold Nucynta ER in the U.S.

COMMERCIALIZATION AGREEMENT BETWEEN DEFENDANTS AND DEPOMED

24. Upon information and belief, on or about December 4, 2017, Collegium Pharmaceutical, and its wholly-owned subsidiary, Collegium NF, entered into a Commercialization Agreement (the "Commercialization Agreement") with Depomed pursuant to which Depomed granted a sublicense of certain of its intellectual property related to Nucynta ER and Nucynta IR (the "Products") to Collegium NF for commercialization of the Products in the United States of America, the District of Columbia and Puerto Rico.

25. Upon information and belief, on or about January 10, 2018, Collegium Pharmaceutical, Collegium NF and Depomed closed on the Commercialization Agreement.

26. Upon information and belief, pursuant to the Commercialization Agreement, Collegium Pharmaceutical paid a one-time non-refundable license fee of $10 million to Depomed at the closing of the Commercialization Agreement.

27. Upon information and belief, under the Commercialization Agreement, Collegium NF will offer for sale and sell Nucynta IR and Nucynta ER in the U.S.

28. Upon information and belief, under the Commercialization Agreement, Collegium NF will receive the gross revenues from sales of Nucynta IR and Nucynta ER.

29. Upon information and belief, under the Commercialization Agreement, Collegium NF will deposit the gross sales revenue in a lock-box account held in its name.

30. Upon information and belief, under the Commercialization Agreement, Collegium Pharmaceutical will on a daily basis sweep the revenue from the lock-box account of Collegium NF.

31. Upon information and belief, under the Commercialization Agreement, Collegium Pharmaceutical is responsible for all payments to Depomed.

32. Upon information and belief, during the term of the Commercialization Agreement and through December 31, 2021, Collegium Pharmaceutical will be required to pay a minimum royalty of $135,000,000 per year, payable in quarterly payments of $33,750,000, plus (ii) 25% of annual net sales of the Products between $233,000,000 and $258,000,000, plus (iii) 17.5% of annual net sales of the Products above $258,000,000.

33. Upon information and belief, under the Commercialization Agreement, Collegium Pharmaceutical is responsible for and has guaranteed the performance by Collegium NF.

34. Upon information and belief, Collegium NF was formed on or about December 1, 2017, specifically to receive the license rights to Nucynta ER and Nucynta IR from Depomed.

35. Collegium NF has no substantial revenue other than the gross revenue received from the sales of Nucynta ER and Nucynta IR.

THE PATENTS-IN-SUIT

36. Purdue is the lawful owner of all right, title and interest in the ’583 patent, entitled “PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT,” including all right to sue and to recover for past infringement thereof. A copy of the

'583 patent is attached hereto as Exhibit A, which was duly and legally issued on January 9, 2018 naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

37. Upon information and belief, the manufacture of Nucynta IR is covered by one or more claims of the '583 patent, including, but not limited to, independent claim 1, which recites, *inter alia*, a method of preparing an oral dosage form.

38. Purdue is the lawful owner of all right, title and interest in the '784 patent, entitled "PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT," including all right to sue and to recover for past infringement thereof. A copy of the '583 patent is attached hereto as Exhibit B, which was duly and legally issued on January 16, 2018 naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

39. Upon information and belief, the manufacture of Nucynta IR is covered by one or more claims of the '784 patent, including, but not limited to, independent claim 1, which recites, *inter alia*, a method of preparing an abuse deterrent immediate release dosage form.

40. Purdue is the lawful owner of all right, title and interest in the '836 patent, entitled "PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT," including all right to sue and to recover for past infringement thereof. A copy of the '836 patent is attached hereto as Exhibit C, which was duly and legally issued on January 23, 2018, naming Curtis Wright, Benjamin Oshlack, and Christopher Breder as the inventors.

41. Upon information and belief, the manufacture of Nucynta ER is covered by one or more claims of the '836 patent, including, but not limited to, independent claim 1,

which recites, *inter alia*, a method of preparing an abuse deterrent controlled release dosage form.

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,861,583)

42. Purdue incorporates by reference and realleges paragraphs 1-41 above as though fully restated herein.

43. Depomed has and continues to manufacture (or have manufactured) Nucynta IR.

44. The manufacture of Nucynta IR is covered by one or more claims of the '583 patent, including, but not limited to, independent claims 1 and 7. As shown in the following chart, Depomed has directly infringed and continues to directly infringe at least claim 1 of the '583 patent under 35 U.S.C. § 271(a):

Claim Element	Nucynta IR
1. A method of preparing an oral dosage form comprising: preparing a mixture comprising:	All Dosage Strengths "NUCYNTA IR recently transitioned to a new third party manufacturer in the United States, and based on currently available information…" (Depomed Announces Third Quarter 2017 Financial Results http://investor.depomedinc.com/phoenix.zhtml?c=97276&p=irol-newsArticle&id=2315127) Active Ingredient: TAPENTADOL HYDROCHLORIDE Proprietary Name: NUCYNTA Dosage Form; Route of Administration: TABLET; ORAL * * * Application Number: N022304 Product Number: 001 Approval Date: Nov 20, 2008 Applicant Holder Full Name: DEPOMED INC (Orange Book listing for NDA 022304) (https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=0223040 "In addition, NUCYNTA franchise product sales for the

	three months ended September 30, 2017 were negatively impacted by approximately $2 million due to temporary delays in the packaging and delivery of certain dosage strengths of NUCYNTA resulting from the impact of Hurricanes Irma and Maria at our third party manufacturing facility located in Puerto Rico." (Depomed, Inc. FORM 10-Q 11/09/17) Under Depomed's direction or control, Janssen Pharmaceuticals, Inc. ("Janssen"); an affiliate of Janssen and/or Halo Pharmaceutical, Inc. manufacturers Nucynta IR. Because Depomed directs or controls the performance of all steps of the claim, Depomed directly infringes.
	"NUCYNTA (tapentadol) tablets are a mu-opioid receptor agonist, available in immediate-release film-coated tablets for oral administration, containing 58.24, 87.36 and 116.48 mg of tapentadol hydrochloride in each tablet strength, equivalent to 50, 75, and 100 mg of tapentadol free-base, respectively." (Nucynta IR Full Prescribing Information ["PI"] at 21) "NUCYNTA tablets contain tapentadol, a Schedule II controlled substance. As an opioid, NUCYNTA tablets exposes users to the risks of addiction, abuse, and misuse *[see Drug Abuse and Dependence (9)]*." (Nucynta IR PI at 6)
(ii) a gelling agent comprising microcrystalline cellulose, a cellulosic polymer and polyvinyl pyrrolidone,	<u>Microcrystalline Cellulose</u> "The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) <u>A Cellulosic Polymer</u> "The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) "Croscarmellose sodium, or sodium CMC, is a cross-linked polymer of carboxymethylcellulose sodium. It appears as white, fibrous, free-flowing powder, and is used commonly as an FDA-approved disintegrant in pharmaceutical manufacturing." (Croscarmellose Sodium (Inactive Ingredient) - Drugs.com) <u>Polyvinyl Pyrrolidone</u>

	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) Povidone (polyvinylpyrrolidone, PVP) is used in the pharmaceutical industry as a synthetic polymer vehicle for dispersing and suspending drugs. It also acts as a disintegrant and tablet binder. (https://www.drugs.com/inactive/povidone-169.html)
the gelling agent in an effective amount to impart a viscosity unsuitable for parenteral administration when the dosage form is subjected to tampering by dissolution in from about 0.5 ml to about 10 ml of an aqueous liquid;	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) "In certain embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent, various gelling agents can be employed including, for example and without limitation, … cellulose derivatives, such as microcrystalline cellulose, sodium cahoxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose, … polyvinylpyrrolidone …." ('583 patent, 7:1-14) "A gelling agent may be added to the formulation in a ratio of gelling agent to opioid agonist of from about 1:40 to about 40:1 by weight, preferably from about 1:1 to about 30:1 by weight, and more preferably from about 2:1 to about 10:1 by weight of the opioid agonist. ('583 patent, 7:36-40) "In certain other embodiments, the dosage form forms a viscous gel after the dosage form is tampered with, dissolved in an aqueous liquid (from about 0.5 to about 10 ml and preferably from 1 to about 5 ml), causing the resulting mixture to have a viscosity of at least about 10 cP." ('583, 7:46-50)
(iii) lactose; and	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21)
(vi) magnesium stearate;	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21)

compressing the mixture into a tablet; and	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21)
coating the tablet with a coating comprising polyvinyl alcohol, polyethylene glycol and talc,	"The film coatings for all tablet strengths contain polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and the colorant FD&C Yellow #6 aluminum lake; the film coatings for the 50 mg and 75 mg tablets also contain the additional colorant D&C Yellow #10 aluminum lake." (Nucynta IR PI at 21)
the oral dosage form having a ratio of gelling agent to opioid agonist from about 8:1 to about 1:8;	"-DOSAGE FORMS AND STRENGTHS Tablets: 50 mg, 75 mg, 100 mg (3)" (Nucynta IR PI at 1) "The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) Upon information and belief this claim element would be met. For the 100 mg dosage strength the gelling agent has a range of 12.5 mg to 800 mg which includes the gelling agent to agonist ratio of Nucynta IR.
the oral dosage form providing an immediate release when orally administered to a human patient.	"NUCYNTA (tapentadol) tablets are a mu-opioid receptor agonist, available in immediate-release film-coated tablets for oral administration, containing 58.24, 87.36 and 116.48 mg of tapentadol hydrochloride in each tablet strength, equivalent to 50, 75, and 100 mg of tapentadol free-base, respectively." (PI at 21).

45. Nucynta IR is made by the processes claimed in the '583 patent, including at least the process of claim 1. Prior to its offer for sale or sale by Defendants, Nucynta IR was not materially changed by subsequent processes or become a trivial and nonessential component of another product.

46. Since at least January 10, 2018, Defendants have been infringing the '583 patent in violation of 35 U.S.C. § 271(g) by using, offering for sale, selling, and/or distributing Nucynta IR.

47. Since at least January 10, 2018, Defendants have been infringing the ’583 patent in violation of 35 U.S.C. § 271(b) by inducing Depomed’s direct infringement of the ‘583 patent.

48. Defendants have known of the ’583 patent since at least as early as January 9, 2018, and no later than the filing date of this Complaint.

49. As of the time they learned of the ’583 patent, Defendants knew that Depomed’s process for manufacturing Nucynta IR infringed at least claim 1 of the ’583 patent.

50. Alternatively, Defendants were willfully blind as to the fact that Depomed’s process for manufacturing Nucynta IR infringed at least claim 1 of the ’583 patent given that the infringement is apparent from Depomed’s NDA and other public information.

51. On information and belief, since the date that the ’583 patent issued, Defendants have had knowledge that the induced acts would constitute infringement of the ’583 patent and have specifically intended to cause such infringement.

52. On information and belief, Defendants’ affirmative acts, including their commercial sale, offer for sale, and/or their entering into the Commercial Agreement to sell or offer for sale Nucynta IR manufactured by Depomed according to the claims of the ‘583 patent have induced and/or caused, and continue to induce and/or cause, direct infringement by Depomed.

53. Defendants’ infringement of the ’583 patent has been willful, egregious, and in disregard of the ’583 patent.

54. Since at least January 10, 2018, when Defendants offered Nucynta IR for sale following the issuance of the ’583 patent, Defendants had knowledge that they had no good-faith non-infringement and invalidity positions.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,867,784)

55. Purdue incorporates by reference and realleges paragraphs 1-54 above as though fully restated herein.

56. Depomed has and continues to manufacture (or have manufactured) Nucynta IR.

57. The manufacture of Nucynta IR is covered by one or more claims of the '784 patent, including, but not limited to, independent claim 1. As shown in the following chart Depomed has directly infringed and continues to directly infringe at least claim 1 of the '784 patent under 35 U.S.C. § 271(a):

Claim Element	Nucynta IR
1. A method of preparing an abuse deterrent immediate release dosage form comprising:	All Dosage Strengths "NUCYNTA IR recently transitioned to a new third party manufacturer in the United States, and based on currently available information…" (Depomed Announces Third Quarter 2017 Financial Results http://investor.depomedinc.com/phoenix.zhtml?c=97276&p=irol-newsArticle&id=2315127) Active Ingredient: TAPENTADOL HYDROCHLORIDE Proprietary Name: NUCYNTA Dosage Form; Route of Administration: TABLET; ORAL Strength: EQ 50MG BASE * * * Application Number: N022304 Product Number: 001 Approval Date: Nov 20, 2008 Applicant Holder Full Name: DEPOMED INC (Orange Book listing for NDA 022304) (https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=022304) "In addition, NUCYNTA franchise product sales for the three months ended September 30, 2017 were negatively impacted by approximately $2 million due to temporary delays in the packaging and delivery of certain dosage

	strengths of NUCYNTA resulting from the impact of Hurricanes Irma and Maria at our third party manufacturing facility located in Puerto Rico." (Depomed, Inc. FORM 10-Q 11/09/17) Under Depomed's direction or control, Janssen Pharmaceuticals, Inc. ("Janssen"); an affiliate of Janssen and/or Halo Pharmaceutical, Inc. manufacturers Nucynta IR. Because Depomed directs or controls the performance of all steps of the claim, Depomed directly infringes.
(i) preparing a mixture comprising an opioid agonist and	"NUCYNTA (tapentadol) tablets are a mu-opioid receptor agonist, available in immediate-release film-coated tablets for oral administration, containing 58.24, 87.36 and 116.48 mg of tapentadol hydrochloride in each tablet strength, equivalent to 50, 75, and 100 mg of tapentadol free-base, respectively." (Nucynta IR Full Prescribing Information ["PI"] at 21) "NUCYNTA tablets contain tapentadol, a Schedule II controlled substance. As an opioid, NUCYNTA tablets exposes users to the risks of addiction, abuse, and misuse *[see Drug Abuse and Dependence (9)]*." (Nucynta IR PI at 6) "NUCYNTA tablets contain tapentadol, a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone." (PI at 18)
a gelling agent comprising microcrystalline cellulose and sodium carboxymethylcellulose;	<u>Microcrystalline Cellulose</u> "The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) <u>Sodium Carboxymethylcellulose</u> "The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) "Croscarmellose sodium, or sodium CMC, is a cross-linked polymer of carboxymethylcellulose sodium. It appears as white, fibrous, free-flowing powder, and is used commonly as an FDA-approved disintegrant in pharmaceutical manufacturing." (Croscarmellose Sodium (Inactive

	Ingredient) - Drugs.com)
(ii) compressing the mixture into a tablet; and	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21)
(iii) coating the tablet with a coating comprising polyvinyl alcohol and polyethylene glycol,	"The film coatings for all tablet strengths contain polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and the colorant FD&C Yellow #6 aluminum lake; the film coatings for the 50 mg and 75 mg tablets also contain the additional colorant D&C Yellow #10 aluminum lake." (Nucynta IR PI at 21)
wherein the abuse deterrent dosage form forms a gel unsuitable for parenteral administration when the dosage form is subjected to tampering comprising dissolution in from about 0.5 ml to about 10 ml of an aqueous liquid;	"The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21) "In certain embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent, various gelling agents can be employed including, for example and without limitation, … cellulose derivatives, such as microcrystalline cellulose, sodium cahoxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose, … polyvinylpyrrolidone …." ('583 patent, 7:1-14) "A gelling agent may be added to the formulation in a ratio of gelling agent to opioid agonist of from about 1:40 to about 40:1 by weight, preferably from about 1:1 to about 30:1 by weight, and more preferably from about 2:1 to about 10:1 by weight of the opioid agonist. ('583 patent, 7:36-40) "In certain other embodiments, the dosage form forms a viscous gel after the dosage form is tampered with, dissolved in an aqueous liquid (from about 0.5 to about 10 ml and preferably from 1 to about 5 ml), causing the resulting mixture to have a viscosity of at least about 10 cP." ('583, 7:46-50)
the dosage form having a ratio of gelling agent to opioid agonist from about 8:1 to about 1:8;	"-DOSAGE FORMS AND STRENGTHS Tablets: 50 mg, 75 mg, 100 mg (3)" (Nucynta IR PI at 1) "The inactive ingredients in NUCYNTA tablets include: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone." (Nucynta IR PI at 21)

	Upon information and belief this claim element would be met. For the 800 mg dosage strength the gelling agent has a range of 12.5 mg to 800 mg which includes the gelling agent to agonist ratio of Nucynta IR.
the dosage form providing an immediate release of the opioid agonist when orally administered to a human patient; and	"NUCYNTA (tapentadol) tablets are a mu-opioid receptor agonist, available in immediate-release film-coated tablets for oral administration, containing 58.24, 87.36 and 116.48 mg of tapentadol hydrochloride in each tablet strength, equivalent to 50, 75, and 100 mg of tapentadol free-base, respectively." (Nucynta IR PI at 21).
wherein the opioid agonist is the sole active agent in the dosage form.	"NUCYNTA (tapentadol) tablets are a mu-opioid receptor agonist, available in immediate-release film-coated tablets for oral administration, containing 58.24, 87.36 and 116.48 mg of tapentadol hydrochloride in each tablet strength, equivalent to 50, 75, and 100 mg of tapentadol free-base, respectively." (Nucynta IR PI at 21) "NUCYNTA tablets contain tapentadol, a Schedule II controlled substance. As an opioid, NUCYNTA tablets exposes users to the risks of addiction, abuse, and misuse *[see Drug Abuse and Dependence (9)]*." (Nucynta IR PI at 6)

58. Nucynta IR is made by the processes claimed in the '784 patent, including at least the process of claim 1. Prior to its offer for sale or sale by Defendants Nucynta IR has not been materially changed by subsequent processes or has become a trivial and nonessential component of another product.

59. Since at least January 16, 2018, Defendants have been infringing the '784 patent in violation of 35 U.S.C. § 271(g) by using, offering for sale, selling, and/or distributing Nucynta IR.

60. Since at least January 16, 2018, Defendants have been infringing the '784 patent in violation of 35 U.S.C. § 271(b) by inducing Depomed's direct infringement of the '784 patent.

61. Defendants have known of the '784 patent since at least as early as January 16, 2018, and no later than the filing date of this complaint.

62. As of the time they learned of the ’784 patent, Defendants knew that Depomed’s process for manufacturing Nucynta IR infringed at least claim 1 of the ’784 patent.

63. Alternatively, Defendants were willfully blind as to the fact that Depomed’s process for manufacturing Nucynta IR infringed at least claim 1 of the ’784 patent given that the infringement is apparent from Depomed’s NDA and other public information.

64. On information and belief, since the date that the ’784 patent issued, Defendants have had knowledge that the induced acts would constitute infringement of the ’784 patent and have specifically intended to cause such infringement.

65. On information and belief, Defendants’ affirmative acts, including its commercial sale, offer for sale, and/or its entering into the Commercial Agreement to sell or offer for sale Nucynta IR manufactured by Depomed according to the claims of the ‘784 patent have induced and/or caused, and continue to induce and/or cause, direct infringement by Depomed.

66. Defendants’ infringement of the ’784 patent has been willful, egregious, and in disregard of the ’784 patent.

67. Since at least January 16, 2018, when Defendants offered Nucynta IR for sale following the issuance of the ’784 patent, Defendants had knowledge that they had no good-faith non-infringement and invalidity positions.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,872,836)

68. Purdue incorporates by reference and realleges paragraphs 1-67 above as though fully restated herein.

69. Depomed has and continues to manufacture (or have manufactured) Nucynta ER.

70. The manufacture of Nucynta ER is covered by one or more claims of the '836 patent, including, but not limited to, independent claim 1 and dependent claims 2, 8, 10 and 12. As shown in the following chart Depomed has directly infringed and continues to directly infringe at least claim 1 of the '836 patent under 35 U.S.C. § 271(a):

Claim Element	Nucynta ER
[p][1] 1. A method of preparing an abuse deterrent controlled release dosage form comprising:	All Dosage Strengths The Prescribing Information accompanying Nucynta ER states that Nucynta ER is "[m]anufactured for: Depomed, Inc." (Nucynta ER PI at 31). As described below, Nucynta ER is made by the recited process.
[1] preparing a mixture comprising an opioid agonist and a gelling agent comprising polyethylene oxide, polyethylene glycol and hydroxypropylmethylcellulose;	"In addition to the active ingredient tapentadol HCl, tablets also contain the following inactive ingredients: alpha-tocopherol (vitamin E), hypromellose, polyethylene glycol, and polyethylene oxide." (Nucynta ER PI at 21) "NUCYNTA® Extended-Release tablets are composed of a hydrophilic matrix system with demonstrated extended-release properties obtained through the use of the specific melt extrusion manufacturing process and the polymer polyethylene oxide." (PRODUCT MONOGRAPH NUCYNTA® Extended-Release http://www.paladin-labs.com/our_products/Nucynta_ER_EN.pdf?ver=3.0) "Nucynta® ER (Ortho-McNeil-Janssen Pharmaceuticals, Titusville, NJ; Tzschentke et al., 2007; 2009), which is tapentadol with a polyethylene oxide matrix that has been designed to be crush-resistant (INTAC™, Grünenthal GmbH, Aachen, Germany); and reformulated Opana®, which is oxymorphone HCl (Endo Pharmaceuticals Inc., Chadds Ford, PA) containing the same INTAC™ matrix as Nucynta® ER." (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3654549) "INTAC® uses polyethylene oxide (PEO) of high molecular weight and a proprietary hot melt extrusion (HME) process—no aversive chemicals or excess excipients are added" (http://www.intac.com/about-intac/intac-technology)
[2] heating the mixture to a temperature to at least soften	See claim element [1]

[1] Bracketed element labels are added.

the mixture;	
[3] extruding the heated mixture to form an extrudate;	See claim element [1]
[4] formulating the extrudate into a tablet; and	See claim element [1]
[5] coating the tablet with a coating comprising polyvinyl alcohol, polyethylene glycol and talc,	"The film coating is comprised of polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, and the colorant FD&C Blue #2 aluminum lake is used for 100, 150, 200, and 250 mg strengths; and additionally, yellow iron oxide is used in 150 mg tablets. Printing inks contain shellac glaze and propylene glycol for all strengths, and black iron oxide (50, 100, 150 and 200 mg tablets) or titanium dioxide (250 mg tablets)." (Nucynta ER PI at 21)
[6] wherein the dosage form forms a gel when subjected to tampering comprising dissolution in from about 0.5 ml to about 10 ml of an aqueous liquid;	"NUCYNTA® Extended-Release should be swallowed whole with sufficient liquid. When exposed to a small volume of water, particles or whole tablets become viscous (gel-like)." (PRODUCT MONOGRAPH NNUCYNTA® Extended-Release http://www.paladin-labs.com/our_products/Nucynta_ER_EN.pdf?ver=3.0)
[7] the dosage form having a ratio of gelling agent to opioid agonist from about 8:1 to about 1:8;	See claim element [1]
[8] the dosage form providing a therapeutic effect for about 12 hours or longer when orally administered to a human patient.	"Take your prescribed dose every 12 hours, at the same time every day." (Nucynta ER PI at 32)

71. Nucynta ER is made by the processes claimed in the '836 patent, including at least the process of claim 1. Prior to its offer for sale or sale by Defendants, Nucynta ER was not materially changed by subsequent processes or become a trivial and nonessential component of another product.

72. Since at least January 23, 2018, Defendants have been infringing the '836 patent in violation of 35 U.S.C. § 271(g) by using, offering for sale, selling, and/or distributing Nucynta ER.

73. Since at least January 23, 2018, Defendants have been infringing the ’836 patent in violation of 35 U.S.C. § 271(b) by inducing Depomed’s direct infringement of the ‘836 patent.

74. Defendants have known of the ’836 patent since at least as early as January 23, 2018 and no later than the filing date of this complaint.

75. As of the time they learned of the ’836 patent, Defendants knew that Depomed’s process for manufacturing Nucynta ER infringed at least claim 1 of the ’836 patent.

76. Alternatively, Defendants were willfully blind as to the fact that Depomed’s process for manufacturing Nucynta ER infringed at least claim 1 of the ’836 patent given that the infringement is apparent from Depomed’s NDA and other public information.

77. On information and belief, since the date that the ’836 patent issued, Defendants have had knowledge that the induced acts would constitute infringement of the ’836 patent and have specifically intended to cause such infringement.

78. On information and belief, Defendants’ affirmative acts, including their commercial sale, offer for sale, and/or its entering into the Commercial Agreement to sell or offer for sale Nucynta ER manufactured by Depomed according to the claims of the ‘836 patent have induced and/or caused, and continue to induce and/or cause, direct infringement by Depomed.

79. Defendants’ infringement of the ’836 patent has been willful, egregious, and in disregard of the ’836 patent.

80. Since at least January 23, 2018, when Defendants continued to offer Nucynta ER for sale following the issuance of the ’836 patent, Defendants had knowledge that they had no good-faith non-infringement and invalidity positions

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for judgment:

A. Adjudging that the commercial sale, offer for sale, use, manufacture, and/or importation of Nucynta IR infringes and/or induces infringement of the ’583 patent;

B. Adjudging that Defendants have infringed the ’583 patent, and that Defendants’ commercial sale, offer for sale, use, manufacture, and/or importation of Nucynta IR infringes and/or induces infringement of the ’583 patent;

C. Adjudging that the commercial sale, offer for sale, use, manufacture, and/or importation of Nucynta IR infringes and/or induces infringement of the ’784 patent;

D. Adjudging that Defendants have infringed the ’784 patent, and that Defendants’ commercial sale, offer for sale, use, manufacture, and/or importation of Nucynta IR infringes and/or induces infringement of the ’784 patent;

E. Adjudging that the commercial sale, offer for sale, use, manufacture, and/or importation of Nucynta ER infringes and/or induces infringement of the ’836 patent;

F. Adjudging that Defendants have infringed the ’836 patent, and that Defendants’ commercial sale, offer for sale, use, manufacture, and/or importation of Nucynta ER infringes and/or induces infringement of the ’836 patent;

G. Awarding, pursuant to 35 U.S.C. § 284, damages to Plaintiffs resulting from Defendants’ importation into the United States, offer for sale, or sale of Nucynta IR and Nucynta ER prior to the expiration of the Patents, increased to treble the amount found or assessed, together with interest;

H. Declaring this an exceptional case and awarding Plaintiffs their attorneys’ fees, as provided by 35 U.S.C. § 285; and

I. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Bruce J. Koch
PURDUE PHARMA LP
201 Tresser Blvd.
Stamford, CT 06901

February 7, 2018