IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, INC. d/b/a JOHNSON MATTHEY PHARMA SERVICES, JOHNSON MATTHEY INC. d/b/a JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, and JOHNSON MATTHEY PUBLIC LIMITED COMPANY,	)	Civil Action No. _____
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
INSITE VISION INCORPORATED,	)	
Defendant.	)	

COMPLAINT FOR
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiffs Johnson Matthey Pharmaceutical Materials, Inc. ("JMPMI") d/b/a Johnson Matthey Pharma Services ("JMPS"), Johnson Matthey, Inc. ("JMI") d/b/a Johnson Matthey Pharmaceutical Materials ("JMPM"), and Johnson Matthey Public Limited Company ("JMPLC"), (collectively "Johnson Matthey") hereby bring this action for declaratory relief against the above-named Defendant InSite Vision Incorporated ("InSite") for a declaration that Defendant InSite will infringe the claims of U.S. Patent Nos. 8,299,295 ("the '295 patent"); 8,481,780 ("the '780 patent"); 9,045,388 ("the '388 patent"); and 9,061,968 ("the '968 patent") (collectively, the "patents-in-suit").

NATURE AND SUMMARY OF THIS ACTION

1. Plaintiff Johnson Matthey is a leading and internationally recognized multinational specialty chemicals and sustainable technologies company headquartered in the

United Kingdom with several U.S. subsidiaries and divisions. Specifically, Plaintiff Johnson Matthey is in the business of, *inter alia*, supplying active pharmaceutical ingredients ("API") to the pharmaceutical industry. Pertinent to this case, Plaintiff JMPMS, a d/b/a of JMPMI, manufactures and supplies bromfenac sodium API that is subsequently formulated into various aqueous ophthalmic drops for administration into a human's eye. Bromfenac sodium is a non-steroidal anti-inflammatory drug ("NSAID") used to reduce post-operative inflammation in the eye and to prevent pain following cataract surgery.

2. Plaintiff JMPLC is the owner of the patents-in-suit that cover various polymorphic forms (Forms I-III) of the crystalline bromfenac sodium compound. More specifically, the patents-in-suit recite various types of claims including claims to: crystalline forms of the bromfenac sodium composition; methods of bromfenac sodium's manufacture; formulated dosage forms comprising bromfenac sodium; and methods of treatment using those dosage forms. All four patents-in-suit expire on September 27, 2030.

3. Plaintiff JMPLC has granted exclusive permission to Plaintiffs JMI d/b/a JMPM and JMPMI d/b/a JMPS to practice the inventions claimed in the patents-in-suit, namely to manufacture, use, offer for sale and sell the claimed compositions and to use the claimed processes.

4. Defendant InSite is a U.S.-based developer of ophthalmic products designed to treat common ocular ailments, including pain and inflammation associated with cataract and other eye surgery. On or about June 11, 2015, Defendant InSite submitted, and the United States Food and Drug Administration ("FDA") received, InSite's New Drug Application ("NDA") seeking approval for a bromfenac sodium (0.075%) ophthalmic product ("InSite's NDA"). The product will be sold under the trade name BromSite™.

5. The FDA has accorded Defendant InSite's NDA a Prescription Drug User Fee Act ("PDUFA") action date of April 10, 2016, which is the date by which FDA must complete review of the NDA and issue approval. On information and belief, FDA is expected to grant approval over Defendant InSite's NDA by April 10, 2016; consequently, Defendant InSite will immediately thereafter launch its BromSite™ product on to the market at that time.

6. Recently, Plaintiff Johnson Matthey came to learn of Defendant InSite's research, clinical development, NDA submission to the FDA, and impending commercial launch post-FDA approval for BromSite™. Upon information and belief, the bromfenac sodium API incorporated into BromSite™ likely infringes Plaintiff JMPLC's patent portfolio.

7. On two different occasions, Plaintiff Johnson Matthey requested to purchase representative samples of the BromSite™ product and its bromfenac sodium API from Defendant InSite so that Plaintiff Johnson Matthey could assess and confirm infringement of the patents-in-suit. Specifically, by letters dated August 4, 2015 and August 18, 2015, Plaintiff Johnson Matthey notified Defendant InSite's CEO of potential infringement of the patents-in-suit, as well as one pending U.S. Patent Application Publication No. 2013/0289120. Finally, on August 24, 2015, Defendant InSite replied, alleging only that Plaintiff Johnson Matthey's inquiry is premature, and did not agree to provide the requested samples.

8. Plaintiff Johnson Matthey is left with no other reasonable alternative to obtain details of Defendant InSite's BromSite™ product, bromfenac sodium API used in BromSite™, or to discover the identity of the manufacturer that is making and selling the bromfenac sodium API to Defendant InSite, so as to create the instant cause of action.

9. Additionally, under 35 U.S.C. § 295, this Court may presume that BromSite™ was made by the methods claimed in the '780 and '388 patents since there is a substantial

likelihood that it was so made, and Plaintiff Johnson Matthey has made reasonable efforts to determine the process actually used. Here, there is substantial likelihood that Plaintiff JMPLC's patented methods were used by Defendant InSite's API supplier to make the bromfenac sodium API in BromSite™. Further, Plaintiff Johnson Matthey has requested representative samples from Defendant InSite to identify the methods used by Defendant InSite, but Defendant InSite has not provided them. By requesting representative samples from Defendant InSite, Plaintiff Johnson Matthey has made reasonable efforts to determine the manufacturing process actually used to make the bromfenac sodium API.

10. In addition to the impending FDA approval of Defendant InSite's NDA for BromSite™ and its inevitable commercial launch in the U.S. market, the reality and immediacy of this controversy is further underscored by three additional factors. First, QLT Inc. ("QLT"), a Canadian company that specializes in ocular products, entered into a merger agreement with Defendant InSite in early June 2015 that was expected to close by the end of September 2015. That Merger Agreement was premised on contingencies related to FDA's approval of Defendant InSite's NDA for BromSite™, and QLT extended a secured $9.9 million line of credit to fund Defendant InSite's continuing operations, including, upon information and belief, to assure successful progress for BromSite™.

11. Second, in early August 2015, Defendant InSite received an unsolicited competing bid from a large, unidentified multi-national pharmaceutical company to acquire all outstanding shares of Defendant InSite's common stock at a premium price, which on information and belief, is also directly related to FDA's impending approval of the BromSite™ NDA. Defendant InSite publicly called the competing bid a "Company Superior Proposal" under the terms of its Merger Agreement with QLT sufficient to warrant termination of the same. But,

on August 27, InSite announced that it entered into a revised, and more lucrative (for InSite shareholders) merger agreement with QLT, where a "wholly owned subsidiary of QLT will be merged with and into InSite Vision." See http://phx.corporate-ir.net/phoenix.zhtml?c=86061&p=irol-newsArticle&ID=2082577. QLT's aggressive response to overcome the competing bid to acquire InSite, upon information and belief, directly stems from the lucrative potential from the impending approval and launch of InSite's BromSite™.

12. Third, on information and belief, Defendant InSite entered into an exclusive license agreement with Nicox, S.A., a France-based publicly traded company, to develop and commercialize BromSite™ in Europe (including Eastern Europe), Middle East and Africa ("EMEA"), under which Defendant InSite has already received an upfront payment of $3 million.

13. Accordingly, there exists an actual, substantial, continuing and justiciable controversy between the parties regarding the infringement of Johnson Matthey's bromfenac patents-in-suit.

THE PARTIES

14. Plaintiff Johnson Matthey Public Limited Company ("JMPLC") is a company organized and existing under the laws of England, having a principal place of business at 5th Floor, 25 Farringdon Street, London EC4A 4AB, United Kingdom.

15. Plaintiff Johnson Matthey, Inc. ("JMI") d/b/a Johnson Matthey Pharmaceutical Materials ("JMPM") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 456 Devon Park Drive, Wayne, Pennsylvania 19807.

16. Plaintiff Johnson Matthey Pharmaceutical Materials ("JMPM"), which is a d/b/a entity of Plaintiff JMI, is a corporation organized under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 2003 Nolte Drive, West Deptford, NJ 08066. Plaintiff JMPM is actively involved in the marketing, offer for sale, and sales of bromfenac sodium API both within the United States.

17. Plaintiff Johnson Matthey Pharmaceutical Materials, Inc. ("JMPMI") d/b/a Johnson Matthey Pharma Services ("JMPS") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2711 Centerville Road, Suite 400, Wilmington 19808.

18. Plaintiff Johnson Matthey Pharma Services ("JMPS"), which is a d/b/a entity of Plaintiff JMPMI, is a corporation having a principal place of business at 25 Patton Road, Devens, MA 01434. JMPS is the exclusive manufacturer of the bromfenac sodium API embodied in the patents-in-suit.

19. Upon information and belief, Defendant InSite is a corporation organized and existing under the laws of Delaware, having a principal place of business at 965 Atlantic Avenue, Alameda, California 94501, and having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

JURISDICTION AND VENUE

20. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 U.S.C. §§ 1 *et seq.*, and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

21. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq.*), as well as under the Declaratory Judgment Act (28 U.S.C. §§ 2201 and 2202) because this action involves an actual case or controversy concerning the infringement of the patents-in-suit.

22. This Court has personal jurisdiction over Defendant InSite because, among other reasons, it is incorporated in the State of Delaware and has designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

23. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Defendant InSite is a Delaware corporation and has its appointed process server in Delaware. Plaintiff JMPMI is a Delaware corporation, which d/b/a JMPS, which in turn manufactures bromfenac sodium API at its Devens, MA location, the product embodied by the patents-in-suit. Additionally, JMPM (located in Deptford, NJ) and JMI (located in Wayne, PA) are within an hour from this Court.

FACTUAL BACKGROUND

The Patents-in-Suit

24. On October 30, 2012, the U.S. Patent and Trademark Office duly and legally issued the ’295 patent, entitled “Polymorphs of Bromfenac Sodium and Methods for Preparing Bromfenac Sodium Polymorphs.” The ’295 patent contains 20 claims (8 independent and 12 dependent) covering a polymorphic form (Form I) of bromfenac sodium, a pharmaceutical compound comprising Form I, and an aqueous liquid preparation comprising Form I of bromfenac sodium. The ’295 patent expires on September 27, 2030. Plaintiff JMPLC is the

assignee of the ’295 patent, and holds all right, title, and interest therein. A true and correct copy of the ’295 patent is attached hereto as **Exhibit A**.

25. On July 9, 2013, the U.S. Patent and Trademark Office duly and legally issued the ’780 patent, a continuation of the ’295 patent, entitled “Polymorphs of Bromfenac Sodium and Methods for Preparing Bromfenac Sodium Polymorphs.” The ’780 patent contains 32 claims (4 independent and 28 dependent) covering methods of preparing Form I of bromfenac sodium, methods of treating a disease or condition (e.g., inflammation) by administering a pharmaceutical formulation comprising Form I of bromfenac sodium, as well as compounds comprising Form I of bromfenac sodium made by the claimed process for making bromfenac sodium (product-by-process claims). The ’780 patent expires on September 27, 2030. Plaintiff JMPLC is the assignee of the ’780 patent, and holds all right, title, and interest therein. A true and correct copy of the ’780 patent is attached hereto as **Exhibit B**.

26. On June 2, 2015, the U.S. Patent and Trademark Office duly and legally issued the ’388 patent, entitled “Polymorphs of Bromfenac Sodium and Methods for Preparing Bromfenac Sodium Polymorphs.” The ’388 patent contains 17 claims (2 independent and 15 dependent) covering methods of converting from Form I bromfenac sodium and/or Form II bromfenac sodium to, and preparing, Form III of bromfenac sodium. The ’388 patent expires on September 27, 2030. Plaintiff JMPLC is the assignee of the ’388 patent, and holds all right, title, and interest therein. A true and correct copy of the ’388 patent is attached hereto as **Exhibit C**.

27. On June 23, 2015, the U.S. Patent and Trademark Office duly and legally issued the ’968 patent, entitled “Polymorphs of Bromfenac Sodium and Methods for Preparing Bromfenac Sodium Polymorphs.” The ’968 patent contains 28 claims (2 independent and 26 dependent) covering Form II of bromfenac sodium, methods of making pharmaceutical

compositions comprising Form II of bromfenac sodium, and methods of treating (e.g., reducing pain) by administering a pharmaceutical formulation comprising Form II of bromfenac sodium. The ’968 patent expires on September 27, 2030. Plaintiff JMPLC is the assignee of the ’968 patent, and holds all right, title, and interest therein. A true and correct copy of the ’968 patent is attached hereto as **Exhibit D**.

28. Plaintiff JMPLC has granted exclusive permission to Plaintiffs JMI d/b/a JMPM and JMPMI d/b/a JMPS to practice the inventions claimed in the patents-in-suit, namely to manufacture, use, offer for sale and sell the claimed compositions and to use the claimed processes.

29. The inventors of the patents-in-suit all have been employed by Plaintiff Johnson Matthey. For instance, one inventor of the patents-in-suit currently is an employee of Plaintiff JMPS in Devens, MA, the entity that manufactures the bromfenac sodium API. Two other inventors were previously employed by Plaintiff JMPS and another inventor previously worked for JMPM in West Deptford, NJ, an entity involved in the offer for sale/sale of the bromfenac sodium API.

30. Plaintiff JMPM includes bromfenac sodium API on its product list and is actively involved in the marketing of bromfenac sodium API within the United States.

BromSite™’s FDA-Approval is Imminent

31. On or about June 11, 2015, as a consequence of positive results from two Phase III clinical trials, InSite submitted an NDA pursuant to 21 U.S.C. § 355 with the FDA seeking approval to commercially market a bromfenac sodium ophthalmic product, to be marketed and sold under the trade name BromSite™. By submitting the NDA, InSite has affirmed to the FDA

that any preclinical and clinical testing to support the safety and efficacy is complete, and that its BromSite™ product is fit and ready for commercial use by humans.

32. According an August 17, 2015 press release, Defendant InSite announced that FDA, in a Day-74 letter, has accepted Defendant InSite's NDA for review and that FDA had assigned Defendant InSite's NDA a Prescription Drug User Fee Act ("PDUFA") action date of April 10, 2016. http://www.businesswire.com/news/home/20150817006205/en/InSite-Vision-Announces-FDA-Acceptance-NDA-Filing#.VdT3n3fD-M8. PDUFA dates are target deadlines for FDA to finish its review of an NDA (typically ten (10) months from filing). However, FDA can, and has in the past, announced its decision on drug product approval prior to a PDUFA date.

33. Upon information and belief, Defendant InSite's NDA will be approved on or before April 10, 2016 and commercial launch of BromSite™ will immediately follow thereafter.

34. On June 8, 2015, Defendant InSite entered into an Agreement and Plan of Merger with QLT, pursuant to which QLT would acquire Defendant InSite in an all-stock transaction, causing Defendant InSite to become an indirect, wholly-owned subsidiary of QLT. According to Defendant InSite's press release, the Merger Agreement is expected to "create an ophthalmic specialty pharmaceutical company with a diversified portfolio of products, full R&D capabilities and innovative platform technologies … [t]he combined company expects to have approximately $70 million in cash after the closing of the transaction". *Business Wire* (June 8, 2015), *accessible at* http://www.businesswire.com/news/home/20150608006051/en/InSite-Vision-Merge-Canadian-Biotechnology-Company-QLT#.Vc43iXfD-M8.

35. The Merger Agreement contained conditions precedent which require, *inter alia*, that: (i) FDA not issue a written communication refusing to file Defendant InSite's NDA for review by August 10, 2015 (the 60th day following FDA's receipt of the same); and (ii) FDA not

assert a deficiency by August 24, 2015 (the 74th day following FDA's receipt of the same) that is reasonably likely to require one or more additional clinical studies with respect to BromSite™ to be conducted prior to initiating the marketing and sale of BromSite™ in the U.S. for its indicated treatment. As such, upon information and belief, QLT's desire to acquire Defendant InSite is directly related to Defendant InSite's development of BromSite™, the filing of Defendant InSite's NDA and the impending commercial launch and marketing of BromSite™ post-FDA approval.

36. Upon information and belief, QLT's desire to acquire rights to the BromSite™ NDA is further evidenced by QLT granting Defendant InSite a first priority secured line of credit, up to $9.9 million at 12%-14% interest per annum, to fund Defendant InSite's continuing operations, including the BromSite™ NDA, through the completion of the merger. Further, according to QLT's most recent 10-Q (filed with SEC on June 30, 2015), $3.5 million debt remains outstanding to QLT. Upon information and belief, QLT's desire to acquire Defendant InSite is directly related to the development of BromSite™, the filing of the NDA, and the expectation of imminent commercial launch and marketing of BromSite™ post-FDA approval.

37. On August 17, 2015, Defendant InSite announced receipt of FDA's Day-74 letter stating that FDA formally accepted for review Defendant InSite's NDA, consequently satisfying two critical Merger Agreement obligations, as described above in ¶ 35. According to Defendant InSite's CEO, such FDA notification was "an important milestone for the BromSite NDA." *Business Wire,* (Aug. 17, 2015), *accessible at*: http://www.businesswire.com/news/home/20150817006205/en/InSite-Vision-Announces-FDA-Acceptance-NDA-Filing#.VdT3n3fD-M8.

38. But on August 10, 2015, Defendant InSite announced that it received an unsolicited competing proposal from a multi-national pharmaceutical company to acquire all outstanding shares of Defendant InSite common stock at a price of $0.25 per share in cash. http://www.businesswire.com/news/home/20150810005237/en/InSite-Vision-Receives-Unsolicited-Proposal-Multi-National-Pharmaceutical#.VdTU8nfD-M8. Upon information and belief, Defendant InSite's receipt of this unsolicited proposal is a direct result of Defendant InSite's research and development of the bromfenac sodium ophthalmic product, of the filing of the NDA for BromSite™, as well as its imminent FDA approval and immediate commercial launch and marketing post-FDA approval.

39. On August 21, 2015, QLT announced that Defendant InSite, under the terms of their Merger Agreement, considers the competing unsolicited all-cash offer of $0.25 per share from the unidentified bidder to be a "Company Superior Proposal" than QLT's all-stock offer, and that InSite intends on terminating its Merger Agreement with QLT and entering into a merger with the new competing bidder, subject to QLT's contractual right under the existing Merger Agreement to match or exceed the new offer by 5:00PM PDT on August 26, 2015. http://www.firstwordpharma.com/print/1309055?tisd=17). This more lucrative unsolicited proposal is a direct result of Defendant InSite's research and development of the bromfenac sodium ophthalmic product, of the filing of the NDA for BromSite™, as well as its imminent FDA approval and immediate commercial launch and marketing post-FDA approval.

40. However, on August 27, InSite announced that QLT exercised its rights to match the competing bid, and InSite and QLT entered into a revised, and more lucrative (for InSite shareholders) merger agreement with QLT, where a "wholly owned subsidiary of QLT will be merged with and into InSite Vision." See http://phx.corporate-

ir.net/phoenix.zhtml?c=86061&p=irol-newsArticle&ID=2082577. QLT's aggressive response to overcome the competing bid to acquire InSite, upon information and belief, directly stems from the lucrative potential from the impending approval and launch of InSite's BromSite™.

InSite's Planned Expansion of BromSite™
Into European, Middle East and African Markets

41. Confident in the impending successful approval of its U.S. development program for BromSite™, Defendant InSite has already planned to expand BromSite™ into other markets abroad, including Europe, the Middle East, and Africa, and InSite executed a contract agreement with another pharmaceutical company to carry out its expansion strategy.

42. According to a February 2015 press release, InSite signed an exclusive license agreement with France-based Nicox, S.A. to commercialize BromSite™ in Europe (including Eastern Europe), Middle East and Africa ("EMEA"). MAAs for BromSite™. http://www.businesswire.com/news/home/20150202005026/en/InSite-Vision-Announces-License-Agreement-AzaSite%C2%AE-AzaSite#.VdtopHfD-M8.

43. According to Nicox, S.A.'s website, Defendant InSite already received an upfront $3 million payment and potentially $13.75 million in milestone payments, depending on Nicox, S.A's sponsorship and management of the further development required for product registration in EMEA. Upon product launch, Defendant InSite will also receive tiered, mid-single digit to double-digit royalties. http://www.nicox.com/about-nicox/partnerships/insite-vision/.

44. Moreover, according to InSite's most recent 10-Q (filed with SEC on August 13, 2015), in May 2014, the Swedish Medical Products Agency ("MPA") concluded that the success and positive results from the then-existing U.S. FDA Phase III clinical data for BromSite™ was likely sufficient to support the filing of a Marketing Authorization Application ("MAA") with

the Swedish MPA, and that no further clinical studies were expected to be required prior to the filing of a MAA over BromSite™ in Europe.

Johnson Matthey's Good-Faith Efforts to Obtain Information on InSite's BromSite™ Product and the Bromfenac Sodium API Used in the Product

45. On August 4, 2015, Plaintiff Johnson Matthey sent, and on August 5, 2015 Defendant InSite received, actual notice of the patents-in-suit, alerting InSite to its potential infringement. Plaintiff Johnson Matthey also requested to purchase representative samples of Defendant InSite's BromSite™ product and the bromfenac sodium API used in BromSite™ to assess whether the product and its API infringe the patents-in-suit. Defendant InSite never responded. True and correct copies of the August 4, 2015 Notice Letter and its FedEx shipment notification are attached hereto as **Exhibit E**.

46. On August 18, 2015, Plaintiff Johnson Matthey's counsel sent, and on August 20, 2015 Defendant InSite received, a second letter again requesting representative samples from Defendant InSite to assess whether Defendant InSite's BromSite™ product and its bromfenac sodium API infringe the patents-in-suit. True and correct copies of the August 18, 2015 Notice Letter and its FedEx shipment notification are attached hereto as **Exhibit F.**

47. On August 24, 2015, InSite responded by calling Johnson Matthey's investigative efforts a "premature inquiry," and did not agree to produce the requested samples or provide any information about the suspected infringing bromfenac API used to be used in its proposed Bromsite™ product. A true and correct copy of InSite's August 24, 2015 letter is attached hereto as **Exhibit G.**

48. Upon information and belief, there is substantial likelihood that Plaintiff JMPLC's patented methods were used by Defendant InSite to make the API in BromSite™. Further, Plaintiff Johnson Matthey has requested representative samples from Defendant InSite

to characterize its crystalline structure and to discern the methods used to manufacture them, but Defendant InSite has failed to provide any samples. Plaintiff Johnson Matthey, therefore, has made reasonable efforts to determine the manufacturing process actually used.

49. Notably, InSite's letter suggests that Johnson Matthey's inquiry is premature because the NDA submission is protected under the safe harbor of 35 U.S.C. § 271(e)(1). But that safe harbor provision is irrelevant here because this is a declaratory judgment action targeting impending post-approval activities. More telling is InSite's conspicuous silence regarding Johnson Matthey's request for API and product samples. If InSite was confident that it would not infringe, it could have provided the requested samples and potentially obviated the need for this suit. But InSite did not. InSite's response further demonstrates the immediate and real controversy between the parties.

50. Additionally, under 35 U.S.C. § 295, this Court may presume that BromSite™ was made by the methods claimed in the '780 and '388 patents since there is a substantial likelihood that it was so made, and Plaintiff Johnson Matthey has made reasonable efforts to determine the process actually used.

An Actual Case and Controversy Exists Between the Parties

51. There is a continuing, ripe, and justiciable controversy between the parties as to infringement of the patents-in-suit given the following: (i) Defendant InSite's research and development of its bromfenac sodium ophthalmic product, leading up to its NDA filing for BromSite™ as well as Defendant InSite and Nicox, S.A's signed exclusive license agreement for the development and commercialization over BromSite™ in EMEA; (ii) Defendant InSite's NDA filing; (iii) FDA's acceptance of Defendant InSite's NDA and the imminent FDA approval of Defendant InSite's NDA given FDA's grant of a PDUFA date of April 16, 2015; (iv) the

likely immediate commercial launch and marketing of BromSite™ post-FDA approval; (v) the third party interest in FDA approval of Defendant InSite's NDA, described in ¶¶ 31-40; (vi) Defendant InSite's refusal to supply Plaintiff Johnson Matthey with, and adequately respond to its requests for, representative samples of BromSite™ and its bromfenac sodium API; and (vii) the substantial likelihood that Plaintiff Johnson Matthey's methods claimed in the patents-in-suit were used to make the bromfenac sodium API in BromSite™, and Plaintiff Johnson Matthey's reasonable efforts to determine the methods used by Defendant InSite. Therefore, an actual case and controversy exists between the parties within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201.

52. Based on Defendant InSite's activities and meaningful preparations directed to making, using, selling, offering for sale, or importing a product that likely infringes the patents-in-suit, and based on Defendant InSite's filing of its NDA and refusal to supply, or adequately respond to Plaintiff Johnson Matthey's requests for, samples of its BromSite™ product and bromfenac sodium API, Defendant InSite is indicating its refusal to change the course of its actions so as to further demonstrate a continuing, ripe, and justiciable controversy between the parties as to infringement of the patents-in-suit—further indicating that an actual case and controversy exists between the parties within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201. The controversy requirement for a declaratory judgment action is satisfied here by the immediacy and reality of impending BromSite™ approval and launch.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Infringement of the '295 Patent)

53. Plaintiff Johnson Matthey realleges paragraphs 1 to 52 above as if fully set forth herein.

54. There is an actual, substantial, and continuing justiciable case or controversy between Plaintiff Johnson Matthey and Defendant InSite regarding the infringement of the ’295 patent. Defendant InSite has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import BromSite™ and its bromfenac sodium API.

55. Defendant InSite will infringe one or more claims of the ’295 patent by manufacturing, using, offering to sell, and selling BromSite™ and its bromfenac sodium API in the United States and/or importing BromSite™ and its bromfenac sodium API into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

56. Plaintiff Johnson Matthey is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and/or importation of BromSite™ infringes, either directly, contributorily, or by inducement, one or more claims of the ’295 patent, either literally or under the doctrine of equivalents.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment of Infringement of the ’780 Patent)

57. Plaintiff Johnson Matthey realleges paragraphs 1 to 56 above as if fully set forth herein.

58. There is an actual, substantial, and continuing justiciable case or controversy between Plaintiff Johnson Matthey and Defendant InSite regarding the infringement of the ’780 patent. Defendant InSite has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import BromSite™ and its bromfenac sodium API.

59. Defendant InSite will infringe one or more claims of ’780 patent by manufacturing, using, offering to sell, and selling BromSite™ and its bromfenac sodium API in the United States and/or importing BromSite™ and its bromfenac sodium API into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) and/or (g).

60. Plaintiff Johnson Matthey is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and/or importation of BromSite™ infringes, either directly, contributorily, or by inducement, one or more claims of the ’780 patent, either literally or under the doctrine of equivalents.

61. Under 35 U.S.C. § 295, this Court may presume that BromSite™ and its bromfenac sodium API was made by the methods claimed in the ’780 patent since there is a substantial likelihood that it was so made, and Plaintiff Johnson Matthey has made reasonable efforts to determine the process actually used.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment of Infringement of the ’388 Patent)

62. Plaintiff Johnson Matthey realleges paragraphs 1 to 61 above as if fully set forth herein.

63. There is an actual, substantial, and continuing justiciable case or controversy between Plaintiff Johnson Matthey and Defendant InSite regarding the infringement of the ’388 patent. Defendant InSite has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import BromSite™ and its bromfenac sodium API.

64. Defendant InSite will infringe one or more claims of ’388 patent by manufacturing, using, offering to sell, and selling Defendant InSite’s BromSite™ product and its

bromfenac sodium API in the United States and/or importing Defendant InSite's BromSite™ product and its bromfenac sodium API into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) and/or (g).

65. Plaintiff Johnson Matthey is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and/or importation of Defendant InSite's BromSite™ product infringes, either directly, contributorily, or by inducement, one or more claims of the '388 patent, either literally or under the doctrine of equivalents.

66. Under 35 U.S.C. § 295, this Court may presume that BromSite™ and its bromfenac sodium API was made by the methods claimed in the '388 patent since there is a substantial likelihood that it was so made, and Plaintiff Johnson Matthey has made reasonable efforts to determine the process actually used.

FOURTH CLAIM FOR RELIEF
(Declaratory Judgment of Infringement of the '968 Patent)

67. Plaintiff Johnson Matthey realleges paragraphs 1 to 66 above as if fully set forth herein.

68. There is an actual, substantial, and continuing justiciable case or controversy between Plaintiff Johnson Matthey and Defendant InSite regarding the infringement of the '968 patent. Defendant InSite has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import BromSite™ and its bromfenac sodium API.

69. Defendant InSite will infringe one or more claims of '968 patent by manufacturing, using, offering to sell, and selling BromSite™ and its bromfenac sodium API in the United States and/or importing BromSite™ and its bromfenac sodium API into the United

States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c).

70. Plaintiff Johnson Matthey is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and/or importation of BromSite™ infringes, either directly, contributorily, or by inducement, one or more claims of the ’968 patent, either literally or under the doctrine of equivalents.

FIFTH CLAIM FOR RELIEF
(Declaratory Judgment for Injunctive Relief under 35 U.S.C. § 283)

71. Plaintiff Johnson Matthey realleges paragraphs 1 to 70 above as if fully set forth herein.

72. Plaintiff Johnson Matthey will be irreparably harmed by Defendant InSite’s infringing activities unless those activities are enjoined by this Court. Plaintiff Johnson Matthey does not have an adequate alternative remedy at law.

73. Plaintiff Johnson Matthey is entitled to a declaratory judgment under 35 U.S.C. § 283 permanently enjoining the future commercial manufacture, use, offer for sale, sale, and/or importation of BromSite™ and its bromfenac sodium API by Defendant InSite, prior to the expiration of the patents-in-suit.

JURY TRIAL DEMAND

In accordance with Fed. R. Civ. P. 38(b) and 39, and Local Civ. R. 38.1, Plaintiff Johnson Matthey hereby asserts its rights under the Seventh Amendment to the United States Constitution and demands a trial by jury on all issues so triable.

PRAYER FOR RELIEF

Plaintiff Johnson Matthey respectfully prays for the following relief:

A. A declaration that the commercial manufacture, use, offer for sale, sale and/or importation of Defendant InSite's BromSite™ and its bromfenac sodium API will infringe the claims of one or more of the patents-in-suit under 35 U.S.C. § 271(a)-(c) and/or (g);

B. A judgment that Defendant InSite will infringe the patents-in-suit under 35 U.S.C. § 271(a)-(c) and/or (g);

C. An injunction under 35 U.S.C. § 283 restraining and enjoining Defendant InSite, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendant InSite's BromSite™ product and its bromfenac sodium API;

D. An Order that the effective date of any approval of Defendant InSite's NDA for BromSite™ be a date that is not earlier than the expiration of the infringed patents-in-suit, including any extensions thereof and any later expiration of exclusivity associated with the patent;

E. Damages or other monetary relief to Plaintiff Johnson Matthey under 35 U.S.C. § 284 as appropriate;

F. A judgment that this is an exceptional case under 35 U.S.C. § 285, awarding reasonable attorneys' fees and costs to Plaintiff Johnson Matthey; and

G. That this Court awards such other and further relief as it deems just and proper.

Dated: August 31, 2015

Of Counsel:

H. Keeto Sabharwal
Dennies Varughese
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 New York Ave., N.W.
Washington, DC 20005
(202) 371-2600
keetos@skgf.com
dvarughe@skgf.com

STAMOULIS & WEINBLATT LLC

/s/ Stamatios Stamoulis
Stamatios Stamoulis (#4606)
Richard C. Weinblatt (#5080)
Two Fox Point Centre
6 Denny Road, Suite 307
Wilmington, DE 19809
(302) 999-1540
stamoulis@swdelaw.com
weinblatt@swdelaw.com

Attorneys for Plaintiffs JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, INC. d/b/a JOHNSON MATTHEY PHARMA SERVICES, JOHNSON MATTHEY INC. d/b/a JOHNSON MATTHEY PHARMACEUTICAL MATERIALS, and JOHNSON MATTHEY PUBLIC LIMITED COMPANY