

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF VIRGINIA

NOV 17 2008

JOHN F. CORCORAN, CLERK  
BY: *[Signature]*  
DEPUTY CLERK

\_\_\_\_\_  
ALPHARMA INC., )  
 )  
Plaintiff, )  
 )  
v. )  
 )  
PURDUE PHARMA L.P., )  
 )  
Defendant. )  
 )  
\_\_\_\_\_ )

Civil Action No. 1:08CV00050  
JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Alpharma Inc. ("Alpharma") hereby brings this action for declaratory relief against the above-named Defendant Purdue Pharma L.P. ("Purdue"), and states as follows:

NATURE OF THE ACTION

1. Alpharma brings this complaint against Purdue pursuant to the patent laws of the United States, Title 35 of the United States Code, with a specific remedy sought based upon the laws authorizing actions for declaratory judgment in the courts of the United States, 28 U.S.C. §§ 2201 and 2202.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

3. This Court has personal jurisdiction over Purdue because of Purdue's continuous and systematic contacts with this State. On information and belief, Purdue intentionally markets

and directs its products to this State, maintains a broad distributorship network within this State, and enjoys substantial income from sales in this State.

4. Venue in this Judicial District is proper under 28 U.S.C. §§ 1391(b) and (c) and 1400(b) because Purdue conducts business in this District and is subject to personal jurisdiction in this District.

### **THE PARTIES**

5. Plaintiff Alharma is a corporation organized and existing under the laws of the State of Delaware. Alharma maintains its principal place of business at 440 U.S. Highway 22 East, Bridgewater, NJ 08807. Alharma develops, manufactures, and sells pharmaceutical products for use in humans and animals. Among the products Alharma markets and sells is KADIAN<sup>®</sup>, an FDA-approved extended-release oral formulation of the opioid morphine indicated for the management of moderate to severe pain.

6. On information and belief, Defendant Purdue is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business located at 1 Stamford Forum, 201 Tresser Blvd., Stamford, Connecticut 06901-3431. Purdue is a leading manufacturer and seller of prescription and non-prescription pain medicines, including the prevalent oral formulation of oxycodone known as OxyContin<sup>®</sup>. On information and belief, Purdue is the owner by assignment of one or more of the patents-in-suit (each defined in Complaint paragraphs 7-16 below).

## **THE PATENTS-IN-SUIT**

7. On August 21, 2001, the USPTO issued U.S. Patent No. 6,277,384 (“the ‘384 patent”), entitled “Opioid Agonist/Antagonist Combinations.” Robert F. Kaiko and Robert D. Colucci are the named inventors on the face of the ‘384 patent. On information and belief, the ‘384 patent is assigned to Purdue. A copy of the ‘384 patent is attached hereto as Exhibit 1 and incorporated herein by reference.

8. On April 23, 2002, the United States Patent & Trademark Office (“USPTO”) issued U.S. Patent No. 6,375,957 (“the ‘957 patent”), entitled “Opioid Agonist/Opioid Antagonist/Acetaminophen Combinations.” Robert F. Kaiko and Robert D. Colucci are the named inventors on the face of the ‘957 patent. On information and belief, the ‘957 patent is assigned to Purdue. A copy of the ‘957 patent is attached hereto as Exhibit 2 and incorporated herein by reference.

9. On November 5, 2002, the USPTO issued U.S. Patent No. 6,475,494 (“the ‘494 patent”), entitled “Opioid Agonist/Antagonist Combinations.” Robert F. Kaiko and Robert D. Colucci are the named inventors on the face of the ‘494 patent. On information and belief, the ‘494 patent is assigned to Purdue. A copy of the ‘494 patent is attached hereto as Exhibit 3 and incorporated herein by reference.

10. On February 24, 2004, the USPTO issued U.S. Patent No. 6,696,066 (“the ‘066 patent”), entitled “Opioid Agonist/Antagonist Combinations.” Robert F. Kaiko and Robert D. Colucci are the named inventors on the face of the ‘066 patent. On information and belief, the ‘066 patent is assigned to Purdue. A copy of the ‘066 patent is attached hereto as Exhibit 4 and incorporated herein by reference.

11. On February 6, 2007, the USPTO issued U.S. Patent No. 7,172,767 (“the ‘767 patent”), entitled “Opioid Agonist/Antagonist Combinations.” Robert F. Kaiko and Robert D. Colucci are the named inventors on the face of the ‘767 patent. On information and belief, the ‘767 patent is assigned to Purdue. A copy of the ‘767 patent is attached hereto as Exhibit 5 and incorporated herein by reference.

12. On September 2, 2008, the USPTO issued U.S. Patent No. 7,419,686 (“the ‘686 patent”), entitled “Opioid Agonist/Antagonist Combinations.” Robert F. Kaiko and Robert D. Colucci are the named inventors on the face of the ‘686 patent. On information and belief, the ‘686 patent is assigned to Purdue. A copy of the ‘686 patent is attached hereto as Exhibit 6 and incorporated herein by reference.

13. On May 8, 2001, the USPTO issued U.S. Patent No. 6,228,863 (“the ‘863 patent”), entitled “Method of Preventing Abuse of Opioid Dosage Forms.” Philip J. Palermo, Robert F. Kaiko, and Robert D. Colucci are the named inventors on the face of the ‘863 patent. On information and belief, the ‘863 patent is assigned to Purdue. A copy of the ‘863 patent is attached hereto as Exhibit 7 and incorporated herein by reference.

14. On September 30, 2003, the USPTO issued U.S. Patent No. 6,627,635 (“the ‘635 patent”), entitled “Method of Preventing Abuse of Opioid Dosage Forms.” Philip J. Palermo, Robert F. Kaiko, and Robert D. Colucci are the named inventors on the face of the ‘635 patent. On information and belief, the ‘635 patent is assigned to Purdue. A copy of the ‘635 patent is attached hereto as Exhibit 8 and incorporated herein by reference.

15. On information and belief, the ‘635 patent expired on September 30, 2007, for failure to pay the required maintenance fee. However, the ‘635 patent may still be reinstated under 37 C.F.R. § 1.378 within thirty months of the date of expiration upon the filing of the

appropriate petition, fees, and statement that the delay in payment of the maintenance fee was unintentional, or at any time by filing of the appropriate petition, fees, and statement that the delay in payment of the maintenance fee was unavoidable. Accordingly, Purdue has until March 30, 2010 to reinstate the '635 patent with only a minimal showing to the U.S. Patent and Trademark Office.

16. On February 24, 2004, the USPTO issued U.S. Patent No. 6,696,088 (“the ‘088 patent”), entitled “Tamper Resistant Oral Opioid Agonist Formulations.” Benjamin Oshlack, Curtis Wright, and J. David Haddox are the named inventors on the face of the ‘088 patent. On information and belief, the ‘088 patent is assigned to Purdue. A copy of the ‘088 patent is attached hereto as Exhibit 9 and incorporated herein by reference.

### **FACTUAL BACKGROUND**

#### ***Abuse Of Prescription Opioid Analgesics In The United States***

17. Opioid analgesics, such as morphine, oxycodone, and hydrocodone, remain physicians’ first choice for treating patients with moderate to severe chronic pain. The legitimate use of opioids can dramatically improve the quality of life in patients who do not respond adequately to other pain management therapies. However, opioids produce euphoria, a mood-altering effect that can lead to drug-seeking behavior and misuse by patients, as well as non-medical or illicit use (i.e., abuse) by non-patients. Because of their high potential for abuse, opioids are listed as Schedule II drugs under the Controlled Substances Act, meaning that they are only available by prescription, and their distribution is carefully controlled and monitored by the Drug Enforcement Administration (DEA). *See* 21 U.S.C. § 812(b)(2).

18. Prescription drug abuse is a major problem in the United States. Between 1992 and 2003, the number of Americans who abuse controlled prescription drugs nearly doubled from 7.8 million to 15.1 million, and abuse among teens more than tripled during that time, according to The National Center on Addiction and Substance Abuse (CASA) at Columbia University. [Exhibit 10 at ii.] The CASA Report found that from 1992 to 2003, while the U.S. population increased 14 percent, the number of 12 to 17 year olds who abused controlled prescription drugs more than tripled and the number of adults 18 and older abusing such drugs climbed 81 percent. [*Id.* at 1-3.]

19. The number of Americans abusing controlled prescription drugs now exceeds the combined number abusing cocaine, hallucinogens, inhalants, and heroin. [*Id.* at 24.] According to Joseph A. Califano, Jr., CASA's chairman and former U.S. Secretary of Health, Education and Welfare, "Our nation is in the throes of an epidemic of controlled prescription drug abuse and addiction. While America has been congratulating itself in recent years on curbing increases in alcohol and illicit drug abuse, and in the decline in teen smoking, abuse of prescription drugs has been stealthily, but sharply, rising." [*Id.* at i.]

20. The CASA Report's analysis of emergency room data confirms the sharp increase in drug abuse and its consequences. In 2002, controlled prescription drugs were implicated in 30 percent of drug related emergency room deaths. [*Id.* at 40.] Opioids were implicated in the majority of those deaths. [*Id.*] Between 1994 and 2002, prescription drug-related emergency room mentions increased by nearly 80 percent, with opioid mentions jumping 168 percent, far more sharply than the increases for heroin and cocaine. [*Id.* at 42.]

*Abuse Of Prescription Opioid Analgesics In This Judicial District*

21. While prescription drug abuse impacts the entire United States, some areas of the country, such as Virginia—and this Judicial District especially—have been disproportionately affected. The annual cost of substance abuse in Virginia is staggering. According to a 2008 report issued by the Joint Legislative Audit and Review Commission of the General Assembly of Virginia, substance abuse costs state and local governments in Virginia nearly three-quarters of a billion dollars in 2006 (roughly \$613 million for public safety agencies and health care costs, and an additional \$102 million for substance abuse services). [Exhibit 11 at ii.]

22. In the past decade, there has been a dramatic increase in the abuse of opioid drugs such as methadone and oxycodone in this Judicial District. [Exhibits 12 and 13] In southwestern Virginia, physically demanding and dangerous working conditions—most notably in the mining industry—have resulted in a significant segment of the population suffering from injuries that require treatment with prescription opioid painkillers. [Exhibits 14 and 15.] As a result, certain opioid painkillers such as OxyContin<sup>®</sup> are prescribed in southwestern Virginia 500 percent more frequently than the national average. [Exhibit 16 at 1.] The increased availability of these potent and potentially addictive drugs in southwestern Virginia has resulted in a subset of the population inclined to abuse opioid painkillers, often to tragic effect.

23. In 2006, more than 240 individuals died from drug overdoses in southwestern Virginia, representing nearly a tripling in overdose deaths in southwestern Virginia since 1996. [Exhibit 15] Of these fatalities, at least 200 were caused by prescription drugs. [*Id.*] Drug overdose fatalities in the region during this period occurred at nearly six times the rate experienced in Northern Virginia counties such as Loudoun and Fairfax. [Exhibit 14.] According to Lt. Richard Stallard, Director of the southwest Virginia Drug Task Force, “the

abuse and misuse of painkillers is the worst I've seen in the sixteen years I have worked narcotics in [southwestern Virginia]" [Exhibit 14.] Some even go so far as to say that prescription drug abuse is "almost a way of life" in southwestern Virginia. [Exhibit 15.]

24. Beyond the loss of life, the other local costs of substance abuse in southwestern Virginia are also significant. In 2007, for example, over half of the approximately 1,700 children placed in foster care or with relatives in southwestern Virginia were displaced from their families because of substance abuse. [Exhibit 17.] Health care costs have also risen sharply due to prescription drug abuse. For example, a 2005 study suggests that average health care costs for opioid abusers are over eight times those of non-abusers. [Exhibit 18 at 473.] The work force in southwestern Virginia is adversely affected by opioid abuse as well. According to one employer in the region, only one out of every eleven applicants for certain manufacturing jobs in southwestern Virginia is employable, often because of drug addiction. [Exhibit 17.]

#### **The Importance Of Developing Less Abusable Forms Of Prescription Pain Medications**

25. The United States Food and Drug Administration ("FDA") is responsible for ensuring that all new drugs are safe and effective. Since 2000, the FDA has been aware of the growing problem with the abuse and misuse of OxyContin<sup>®</sup> and other opioid drugs. [Exhibit 19 at § 2, p. 1.] In July 2006, the Deputy Director of the Office of New Drugs for the FDA testified before Congress that the "FDA is concerned about the increasing abuse of prescription drugs, including opioid drugs. Abuse of opioid analgesics ... has risen steadily over the past five years. By contrast, overall rates of abuse of illicit drugs have been generally stable over the same time period." [Exhibit 20 at 2.] The FDA has taken many steps to combat this problem, such as requiring strong warnings about the misuse and abuse of opioids. [Exhibit 21 at 34.] The FDA



has also encouraged drug companies “to develop novel interventions to prevent this abuse ...”  
[Exhibit 19 at §1, p. 1.]

26. The Centers for Disease Control and Prevention (CDC) has also urged drug manufacturers to “modify opioid painkillers so that they are more difficult to tamper with and/or combine them with agents that block the effect of the opioid if it is dissolved and injected.” [Exhibit 22 at 5.] But “[u]nfortunately, successful new formulations have been elusive due to difficulties related to manufacturing, biopharmaceutical concerns and clinical failures in early studies,” according to Bob A. Rappaport, Director of the Division of Anesthesia at the FDA.  
[Exhibit 19 at §1, p. 1.]

**Alpharma Has Developed A Less Abusable Opioid Analgesic**

27. In an effort to reduce prescription drug abuse, Alpharma has developed a new type of opioid-based pain medicine to reduce the likelihood of abuse, referred to by Alpharma personnel as ALO-01. Like its predecessor KADIAN<sup>®</sup>, ALO-01 provides an extended-release oral formulation of morphine indicated for the management of moderate to severe pain. But unlike KADIAN<sup>®</sup>, ALO-01 contains a sequestered opioid antagonist called naltrexone. An opioid antagonist is a molecule that binds to opioid receptors with higher affinity than opioids but does not activate the receptors; this effectively blocks the receptor, preventing the body from responding to opioids. In ALO-01, the naltrexone is sequestered using a proprietary technology that Alpharma has developed and for which it has applied for a patent. When taken as directed, the drug provides long lasting pain relief. However, when abused (e.g., crushed or chewed), the naltrexone is immediately released, mitigating the euphoric effects of the morphine. ALO-01 will provide an important public health benefit by providing doctors with a prescription pain

reliever whose pain abatement equals that of current products and which can be prescribed with measurably less risk of substance abuse.

28. Alharma is pursuing approval for ALO-01 from the FDA, and plans to manufacture and market the drug in the United States upon receiving FDA approval. On June 30, 2008, Alharma re-submitted a New Drug Application (“NDA”) for ALO-01 to the FDA. On September 2, 2008, Alharma announced that the FDA had accepted its NDA for priority review, which provides for a review period of six months from the date of submission. On September 9, 2008, Alharma reported results from its Phase III pivotal efficacy trial showing that ALO-01 provided significant pain relief in patients with moderate to severe hip and knee pain, yet was safe and well-tolerated. On November 14, 2008, the FDA reviewed Alharma’s NDA for ALO-01 at a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. Based on the outcome of that meeting, Alharma is confident that it will obtain final FDA approval for ALO-01 by the six-month review deadline of December 30, 2008. Once approved, ALO-01 would be one of the first prescription opioid pain medicines of its kind, treating patients with chronic pain while also being less abusable .

29. Alharma has begun producing commercial quantities of ALO-01 and establishing a marketing and sales force. To date, Alharma has spent over \$40 million researching, developing, testing, and commercializing its proprietary naltrexone sequestering technology, including ALO-01.

**Existence Of An Actual Controversy Between Alharma And Purdue**

30. By at least the Fall of 2006, Alharma was aware that Purdue’s patents and published patent applications in the field of abuse-resistant opioids posed a potential impediment

to Alharma's freedom to develop its naltrexone sequestering technology, and to market less abusable drugs utilizing that technology, such as ALO-01.

31. Alharma was also aware that Purdue is extremely litigious. For example, in 1996, Purdue sued Faulding, Inc., a company that Alharma acquired in 2002—along with several other companies—charging that its KADIAN<sup>®</sup> drug product infringed a Purdue patent relating to controlled-release opioid formulations. Faulding successfully invalidated Purdue's asserted patent. More recently, Purdue has sued several companies for infringing its patents relating to OxyContin<sup>®</sup>, including Teva Pharmaceuticals, Endo Pharmaceuticals, KV Pharma, Impax Laboratories, Boehringer Ingelheim, Roxane Laboratories, Actavis Totowa, and Mallinckrodt, Inc. In October 2006, after obtaining a consent judgment of patent infringement from Teva, Michael Friedman, Purdue's President and CEO, announced that Purdue would “continue to enforce our patents vigorously against all infringers.” [Exhibit 23.]

32. On June 23, 2008, Purdue filed a Citizen Petition requesting that the FDA deny approval to Remoxy<sup>®</sup>, an extended-release oxycodone formulation described as tamper-resistant being co-developed by Pain Therapeutics, Inc. and King Pharmaceuticals, Inc. [Exhibit 24.] The FDA accepted the application for Remoxy<sup>®</sup>, and on October 15, 2008, Purdue filed a Supplemental Citizen Petition. [Exhibit 25.] Purdue's apparent object in filing these Citizen Petitions is to prevent companies like King—and Alharma—from developing and marketing products that Purdue believes will compete with OxyContin<sup>®</sup>.

33. In early 2007, believing that a mutually beneficial business arrangement might be reached between Alharma and Purdue, Alharma's CEO, Dean Mitchell, instructed Stephan Aigner, the Executive Vice-President of Corporate and Business Development at Alharma, to meet with representatives of Purdue to discuss such an arrangement. On May 3, 2007, Mr.

Aigner's subordinate, Darren Pincus, Head of Pharmaceutical Business Development at Alharma, met with Purdue representatives James Dolan and Allen Downs at Purdue's headquarters in Stamford, Connecticut. The meeting between Messrs. Pincus, Dolan, and Downs was informal in nature and no confidential information was exchanged between the parties.

34. In the following weeks, Mr. Aigner tried to arrange another, more formal meeting with Purdue. A meeting was scheduled for July 12, 2007, between Mr. Aigner and Messrs. Dolan and Downs of Purdue. Before the meeting, the parties executed a Confidential Disclosure Agreement ("CDA"), which stated in part that the two companies "will be discussing confidential and proprietary information relating to a potential business relationship involving certain of the Company's [Alharma's] potential products (the 'Possible Relationship'), controlled-release oxycodone and/or morphine formulations containing a sequestered opioid antagonist (the 'Technology')." "

35. After the meeting on July 12, 2007, Purdue learned of Alharma's agreement with another company to market the Flector<sup>®</sup> patch to topically treat acute pain. On August 21, Mr. Downs of Purdue e-mailed Mr. Pincus to congratulate Alharma on its "agreement reached with IBSA for FLECTOR patch indicated for topical treatment of acute pain and TIROSCINT [*sic*] gel capsules indicated for thyroid hormone replacement therapy." In his e-mail, Mr. Downs stated that "Purdue remains interested in exploring a potential co-promotion alliance with Alharma," and asked what assumptions Purdue should make "regarding the targets that Purdue consider[s] in such a co-promotion with Alharma."

36. On September 14, 2007, Alharma's CEO, Mr. Mitchell, met with several representatives of Purdue, including John Sackler, Mortimer Sackler, Richard Sackler, and Peter

Boer. At the meeting, Mr. Mitchell reiterated Alharma's interest in establishing a collaborative business arrangement with Purdue. The parties discussed Alharma's proprietary naltrexone sequestering technology, among other issues. At one point in the conversation, one of Purdue's representatives stated that Alharma must be aware of Purdue's "extensive intellectual property rights" in the field of abuse-resistant opioid formulations. Mr. Mitchell responded that Alharma was aware of Purdue's patents, but that based on its internal analysis of those patents, it believed it had the freedom to practice in this area. Mr. Sackler of Purdue disagreed, stating his company's position that its patents were broad enough to encompass Alharma's naltrexone sequestering technology, and that it would be "necessary to let the lawyers work [the dispute] out." Mr. Sackler's reference to letting "the lawyers work it out" was a threat of litigation; that is, if Alharma continued to develop and market its naltrexone sequestering technology, including ALO-01, Purdue would sue Alharma for patent infringement.

37. Another meeting between the companies was arranged, and on September 21, 2007, the parties executed an expanded CDA. The CDA stated that the two companies "will be discussing confidential and proprietary information relating to a potential business relationship involving certain of the Company's [Alharma's] potential products (the 'Possible Relationship') involving (a) certain of Company's potential products, including its controlled-release oxycodone formulations containing a sequestered opioid antagonist and (b) Company's diclofenac epolamine product known as Flector Patch (collectively, the 'Technology')."

38. On September 24, 2007, the parties met at Alharma's headquarters in Bridgewater, New Jersey. The attendants included Messrs. Aigner and Pincus of Alharma and Messrs. Dolan and Downs of Purdue. Alharma shared with Purdue its preliminary data regarding its sequestered opioid antagonist drug combinations containing oxycodone and/or

morphine, including therapeutic efficacy, common adverse effects, naltrexone pharmacokinetic data, and phase III study designs.

39. After the meeting, Alharma pressed Purdue for a business proposal that would encompass Alharma's naltrexone sequestering technology. Alharma considered the receipt of such a proposal from Purdue to be important given Purdue's earlier statement that Alharma's ALO-01 technology infringed one or more of Purdue's patents. On October 8, 2007, Mr. Downs of Purdue e-mailed Mr. Pincus to inform him that Purdue's management was still considering Alharma's "economic proposal regarding Flector and ALO-01 (oxycodone NT) [*sic*]" On October 9, 2007, Mr. Downs again e-mailed Mr. Pincus that Purdue would provide Alharma with an "updated response in the next couple of days following further discussions with our management." Mr. Downs also stated, "Jim [Dolan] offered to arrange for our VP & Chief IP Counsel to be available to your patent counsel if it would be helpful to your understanding the IP we have in the field."

40. Mr. Down's e-mail, combined with Mr. Sackler's statement that Purdue's patents covered Alharma's technology, confirmed that Purdue would assert its patents against Alharma if it tried to bring ALO-01 to market. Purdue's assertion of rights puts Alharma in an intolerable position. It must either abandon its efforts to develop less abusable forms of opioid medicines, such as ALO-01, or continue to develop these allegedly infringing drugs, while potentially accruing liability, and risking a patent infringement suit. Unless and until Purdue sues Alharma for patent infringement, Alharma faces continued uncertainty. This uncertainty irreparably injures Alharma, for example, by adversely affecting the marketplace's acceptance of ALO-01 and by decreasing Alharma's attractiveness to potential investors. This uncertainty

also harms the public interest by delaying (and possibly even preventing) Alpharma's ability to bring to market its less abusable forms of opioids.

41. Alpharma has always contended, and continues to contend, that it has the legal right to manufacture, offer to sell, and sell ALO-01 without license to any of Purdue's patents or published patent applications. Alpharma denies that any of the patents-in-suit is or will be infringed by ALO-01, and Alpharma disputes the validity of the patents-in-suit.

42. Accordingly, an actual and justiciable controversy exists between Alpharma and Purdue within the jurisdiction of this Court under 28 U.S.C. §§ 2201 and 2202. This controversy is real and immediate. Absent a declaration of invalidity and/or non-infringement, Purdue will continue to use its patents as a means to intimidate and threaten Alpharma from entering the market, and thereby cause Alpharma irreparable injury and damage.

**Reasons Why This Case Should Be Tried In This Judicial District**

43. This patent infringement action should be tried in this Judicial District. First, this District has an acutely local interest in the subject matter of this case, which relates to the development and commercialization of less abusable forms of prescription pain medicines. As detailed in Complaint paragraphs 21-26 above, this Judicial District has seen an astonishing increase in the abuse of opioid drugs in recent years. Certain opioid painkillers, such as OxyContin<sup>®</sup>, are prescribed in this District 500 percent more frequently than the national average. The increased availability of, and exposure to, these drugs in this District has had tragic consequences, including significant numbers of drug overdoses and deaths, the displacement of children from their families, and spiking health care costs.

44. Second, because of this District's well-documented problems with prescription drug abuse, particularly OxyContin<sup>®</sup>, its residents have an increased need for less abusable prescription painkillers, such as ALO-01. Although Alpharma intends to market and sell ALO-01 nationwide, it intends to concentrate its energies on particularly hard hit communities, such as this District. Accordingly, the economy and residents of this District will be impacted more significantly by the products and technology at issue in this case than just about any other district in the United States.

45. Third, it is critically important that Alpharma's dispute with Purdue be resolved quickly in order that the public—particularly this District's residents—gain access to less abusable forms of prescription pain medicine, like ALO-01, as soon as possible. Moreover, resolution of this dispute is likely to be hastened in this Judicial District because it has a less congested docket than other districts in which this suit could have been filed, such as New Jersey or Connecticut. [Exhibit 26 (the Western District of Virginia had 758 pending cases, while the District of Connecticut had 2,509 pending cases and the District of New Jersey had 5,791 pending cases).] Moreover, new filings in the Western District of Virginia were down 10.6 percent last year, while new filings in Connecticut and New Jersey were up 7.3 and 7.8 percent, respectively. [*Id.*] Finally, in 2007 the median length of time from filing to trial in the Western District of Virginia was about half that of Connecticut and New Jersey—16 months compared to 33 and 31.3 months, respectively. [*Id.*]

46. This Judicial District is the best forum to try this case also because of its extensive experience with defendant Purdue and with the relevant technology, i.e., prescription pain medicines. In fact, at least ten published decisions involving Purdue have issued from the Western District of Virginia in the past few years. These decisions stem from at least eight



different cases, most of which involved Purdue's Oxycontin® drug product. *See, e.g.*, (1) *Boysaw v. Purdue Pharma*, No. 1:07CV00079; (2) *Cook v. Purdue Pharma*, No. 1:08CV272; (3) *In re Oxycontin Antitrust Litigation*, No. MDL 1603 (Jud. Pan. Mult. Lit.); (4) *Boysaw v. Purdue Pharma*, No. CIV A 707-CV-00394; (5) *Ewing v. Purdue Pharma*, No. 2:01 CV 00080, 2:02 CV 00054; (6) *Ewing v. Purdue Pharma*, No. 2:02CV00150; (7) *Cordill v. Purdue Pharma*, No. 1:02CV00121; and (8) *McCauley v. Purdue Pharma*, No. 2:01CV00080. By contrast, only four published decisions involving Purdue have collectively issued from Connecticut and New Jersey, and all stem from just a single case: *In re Oxycontin Antitrust Litigation*, No. MDL 1603, (Jud. Pan. Mult. Lit.). A Westlaw search identifies just two decisions involving Alharma, both from New Jersey, and neither of which involved Alharma's technology. Accordingly, this Court appears to be as familiar, if not more familiar, with the parties and technology at issue in this case than any other appropriate forum.

## COUNT I

### DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '384 PATENT

47. The allegations contained in paragraphs 1-46 of this Complaint are incorporated as if fully set forth herein.

48. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '384 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

49. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '384 patent.

50. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '384 patent.

## **COUNT II**

### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '384 PATENT**

51. The allegations contained in paragraphs 1-50 of this Complaint are incorporated as if fully set forth herein.

52. Each claim of the '384 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

53. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '384 patent.

54. Alharma therefore requests a declaratory judgment that each claim of the '384 patent is invalid.

## **COUNT III**

### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '957 PATENT**

55. The allegations contained in paragraphs 1-54 of this Complaint are incorporated as if fully set forth herein.

56. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '957 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

57. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '957 patent.

58. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '957 patent.

#### **COUNT IV**

##### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '957 PATENT**

59. The allegations contained in paragraphs 1-58 of this Complaint are incorporated as if fully set forth herein.

60. Each claim of the '957 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

61. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '957 patent.

62. Alharma therefore requests a declaratory judgment that each claim of the '957 patent is invalid.

#### **COUNT V**

##### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '494 PATENT**

63. The allegations contained in paragraphs 1-62 of this Complaint are incorporated as if fully set forth herein.

64. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '494 patent under any theory of infringement, including direct

infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

65. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '494 patent.

66. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '494 patent.

### **COUNT VI**

#### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '494 PATENT**

67. The allegations contained in paragraphs 1-66 of this Complaint are incorporated as if fully set forth herein.

68. Each claim of the '494 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

69. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '494 patent.

70. Alharma therefore requests a declaratory judgment that each claim of the '494 patent is invalid.

### **COUNT VII**

#### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '066 PATENT**

71. The allegations contained in paragraphs 1-70 of this Complaint are incorporated as if fully set forth herein.

72. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '066 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

73. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '066 patent.

74. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '066 patent.

### **COUNT VIII**

#### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '066 PATENT**

75. The allegations contained in paragraphs 1-74 of this Complaint are incorporated as if fully set forth herein.

76. Each claim of the '066 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

77. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '066 patent.

78. Alharma therefore requests a declaratory judgment that each claim of the '066 patent is invalid.

## **COUNT IX**

### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '767 PATENT**

79. The allegations contained in paragraphs 1-78 of this Complaint are incorporated as if fully set forth herein.

80. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '767 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

81. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '767 patent.

82. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '767 patent.

## **COUNT X**

### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '767 PATENT**

83. The allegations contained in paragraphs 1-82 of this Complaint are incorporated as if fully set forth herein.

84. Each claim of the '767 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

85. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '767 patent.

86. Alharma therefore requests a declaratory judgment that each claim of the '767 patent is invalid.

### **COUNT XI**

#### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '686 PATENT**

87. The allegations contained in paragraphs 1-86 of this Complaint are incorporated as if fully set forth herein.

88. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '686 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

89. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '686 patent.

90. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '686 patent.

### **COUNT XII**

#### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '686 PATENT**

91. The allegations contained in paragraphs 1-90 of this Complaint are incorporated as if fully set forth herein.

92. Each claim of the '686 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

93. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '686 patent.

94. Alharma therefore requests a declaratory judgment that each claim of the '384 patent is invalid.

### **COUNT XIII**

#### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '863 PATENT**

95. The allegations contained in paragraphs 1-94 of this Complaint are incorporated as if fully set forth herein.

96. Alharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '863 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

97. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the alleged infringement of the '863 patent.

98. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '863 patent.

### **COUNT XIV**

#### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '863 PATENT**

99. The allegations contained in paragraphs 1-98 of this Complaint are incorporated as if fully set forth herein.



100. Each claim of the '863 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

101. Accordingly, there exists an immediate, real, and justiciable controversy between Alpharma and Purdue with respect to the validity of the '863 patent.

102. Alpharma therefore requests a declaratory judgment that each claim of the '863 patent is invalid.

#### **COUNT XV**

#### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '635 PATENT**

103. The allegations contained in paragraphs 1-102 of this Complaint are incorporated as if fully set forth herein.

104. Alpharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '635 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

105. Accordingly, there exists an immediate, real, and justiciable controversy between Alpharma and Purdue with respect to the alleged infringement of the '635 patent.

106. Alpharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, any claim of the '635 patent.

## **COUNT XVI**

### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '635 PATENT**

107. The allegations contained in paragraphs 1-106 of this Complaint are incorporated as if fully set forth herein.

108. Each claim of the '635 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

109. Accordingly, there exists an immediate, real, and justiciable controversy between AlphaPharma and Purdue with respect to the validity of the '635 patent.

110. AlphaPharma therefore requests a declaratory judgment that each claim of the '635 patent is invalid.

## **COUNT XVII**

### **DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '088 PATENT**

111. The allegations contained in paragraphs 1-110 of this Complaint are incorporated as if fully set forth herein.

112. AlphaPharma denies that it currently infringes, has ever infringed, or will ever infringe, any claim of the '088 patent under any theory of infringement, including direct infringement, indirect infringement, literal infringement, or infringement under the doctrine of equivalents.

113. Accordingly, there exists an immediate, real, and justiciable controversy between AlphaPharma and Purdue with respect to the alleged infringement of the '088 patent.

114. Alharma therefore requests a declaratory judgment that it does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '088 patent.

### **COUNT XVIII**

#### **DECLARATORY JUDGMENT OF INVALIDITY OF THE '088 PATENT**

115. The allegations contained in paragraphs 1-114 of this Complaint are incorporated as if fully set forth herein.

116. Each claim of the '088 patent is invalid and/or unenforceable for failure to comply with the conditional requirements for patentability as set forth in Part II of Title 35 of the United States Code, including §§ 101, 102, 103, and 112.

117. Accordingly, there exists an immediate, real, and justiciable controversy between Alharma and Purdue with respect to the validity of the '088 patent.

118. Alharma therefore requests a declaratory judgment that each claim of the '088 patent is invalid.

### **PRAYER FOR RELIEF**

WHEREFORE, Alharma prays for judgment against Purdue as follows:

1. For an order declaring that Alharma has not infringed and will not infringe, directly, indirectly or contributorily, any claims of the patents-in-suit;
2. For an order declaring that each of the claims of the patents-in-suit is invalid;
3. For an order declaring that Purdue and each of their officers, employees, agents, alter egos, attorneys, and any persons in active concert or participation with them be restrained and enjoined from further prosecuting or instituting any action against Alharma, claiming that

the patents-in-suit are valid or infringed, or from representing that any of Alharma's products or services, or others' use thereof, infringes the patents-in-suit;

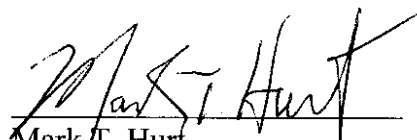
4. For an order declaring this case exceptional under 35 U.S.C. § 285 and awarding Alharma its attorney fees and costs in connection with this case;

5. For an order declaring awarding Alharma such other and further relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Alharma hereby demands a jury trial on all issues.

Dated: November 17, 2008



Mark T. Hurt  
(VSB# 36380)  
159 West Main Street  
Abingdon, VA 24210  
(276) 623-0808 Phone  
(276) 623-0212 Fax

Thomas G. Slater, Jr.  
**HUNTON & WILLIAMS LLP**  
Riverfront Plaza, East Tower  
951 East Byrd Street  
Richmond, VA 23219  
(804) 788-8475 Phone

Rodger L. Tate  
Robert M. Schulman  
**HUNTON & WILLIAMS LLP**  
1900 K Street, N.W.  
Washington, DC 20006  
(202) 419-2069 Phone

David A. Kelly  
**HUNTON & WILLIAMS LLP**  
Bank of America Plaza, Suite 4100  
600 Peachtree Street, NE  
Atlanta, Georgia 30308  
(404) 888-4280 Phone

*Counsel for Plaintiff*