IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELLIOTT ASSOCIATES, L.P.,
ELLIOTT INTERNATIONAL, L.P., and
KNOLLWOOD INVESTMENTS, L.P.,
40 West 57th Street,
New York, NY 10019

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201

and

MARGARET HAMBURG, M.D., in her official capacity as COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue,
Silver Spring, MD 20993,

Defendants.

Civil Action No. _____

VERIFIED COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiffs Elliott Associates, L.P. ("EA"), Elliott International, L.P. ("EI") and Knollwood Investments, L.P. ("Knollwood") (collectively, "Elliott") hereby bring this Verified Complaint against Defendants Sylvia Mathews Burwell, solely in her official capacity as Secretary of the Department of Health and Human Services ("HHS"), and Margaret Hamburg, M.D., solely in her official capacity as Commissioner of Food and Drugs, head of the Food and Drug Administration ("FDA" or the "agency"), and alleges as follows:

INTRODUCTION

1. This is an action under the Administrative Procedure Act ("APA") to hold unlawful and set aside FDA's recent unlawful approval of Mitigare, a 0.6 mg single-ingredient oral colchicine capsule for the prophylaxis of gout flares. FDA approved Mitigare on September 26, 2014, based on a confidential application submitted by Hikma Pharmaceuticals LLC ("Hikma") under Section 505(b)(2) of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b)(2). FDA's approval of Mitigare constitutes final agency action. *See id.* § 355(q).

2. In taking this final agency action, FDA failed to enforce key provisions of the FDCA that are central to the drug approval process. As a direct result of FDA's failure, necessary participants were cut out of the administrative process and denied their statutory right under the FDCA to challenge Hikma's attempt to launch an unlawful drug product.

3. In particular, FDA failed to enforce the FDCA's provisions requiring Hikma to certify that Mitigare does not infringe the numerous patents that protect the brand drug Colcrys®, a single-ingredient oral colchicine tablet marketed by Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") and approved for the prophylaxis of gout flares. Indeed, the only difference between Hikma's Mitigare product and Takeda's patented Colcrys® product is that Mitigare is in capsule form, while Colcrys® is in tablet form. In all other relevant respects—including active ingredients, indications, and concentration—Mitigare is identical to Colcrys®.

4. FDA's failure to enforce the FDCA's certification requirement stripped Takeda of its statutory rights under the FDCA. FDA's failure to require certification also materially injured parties who have legally-enforceable rights in the sale of Colcrys® in the United States, such as Elliott.

5. Had FDA required Hikma to certify to Takeda's patents covering Colcrys®, as was required under the FDCA, Hikma's approval (if any) would have been contingent upon

Hikma providing notice to Takeda that its patents were invalid or will not be infringed by the manufacture, use, or sale of Mitigare (the "Paragraph IV notice"). *See* 21 U.S.C. § 355(b)(2)(iv), (b)(3) & (c)(3). Upon receipt of the Paragraph IV notice, Takeda could have and would have sued Hikma for patent infringement within 45 days as the FDCA provides.

6. Under the FDCA, Takeda's lawsuit would trigger a statutory stay of further FDA action on Hikma's application for approval of Mitigare. Specifically, FDA would have been statutorily prohibited from approving Hikma's application until 30 months had passed, the patents had expired, or a court found the patents invalid or not infringed. *See* 21 U.S.C. § 355(c)(3)(C), 355(j)(5)(B)(iii).

7. Elliott owns a legally-enforceable right tied to the Colcrys® patents to receive a percentage of royalties from the sale of Colcrys®. On information and belief, Mitigare will compete directly with Colcrys®, and substitution will be rapid and substantial. Within four weeks of Mitigare's launch, it has been estimated that Mitigare will capture 60 to70 percent of the Colcrys® market; within one year of Mitigare's launch, Mitigare is expected to capture 95 to 98 percent of the Colcrys® market. FDA's failure to require Hikma to certify to the Colcrys® patents therefore has directly injured Elliott.

8. FDA's approval of Mitigare was unlawful, arbitrary, and capricious for at least two separate reasons.

9. *First*, FDA's decision to approve Mitigare without requiring that Hikma certify to the patents covering the use of colchicine for the prophylaxis of gout flares violates the plain text of Section 505(b)(2)(A) of the FDCA, which requires an applicant seeking approval to market a new therapeutic drug to certify that each patent claiming a use for that drug either is expired, invalid, or will not be infringed by the applicant's product. 21 U.S.C. § 355(b)(2)(A).

10. Takeda's Colcrys® patents are listed in FDA's Orange Book as claiming a "[m]ethod of using colchicine for the prophylaxis of gout flares"—exactly the use for which Hikma sought and received FDA approval. Yet FDA did not require Hikma to certify to those patents. FDA therefore circumvented the FDCA's 30-month stay by preventing Takeda from commencing litigation that would have triggered that stay. Accordingly, FDA's decision to approve Hikma's 505(b)(2) application without complying with the patent certification process was in excess of statutory authority and without observance of procedure required by law. 5 U.S.C. § 706(2)(C)-(D).

11. *Second*, FDA acted in an arbitrary and capricious manner by approving Hikma's 505(b)(2) application without requiring a certification as to the Colcrys® patents. Hikma's 505(b)(2) application did not seek approval of a "duplicate" of a previously approved drug product, as is the case when a manufacturer seeks approval of a generic drug under the provisions set forth in Section 505(j) of the FDCA. Had Hikma sought approval of a duplicate drug, Hikma would have been required to submit a 505(j) application and rely explicitly on Colcrys®—and its safety and efficacy data—as the reference listed drug. Instead, Hikma was "seeking approval of *a change to an approved drug* that would not be permitted under 505(j)." FDA, Guidance for Industry: Applications Covered by Section 505(b)(2), at 3 (1999) (emphasis added), http://www.fda.gov/downloads/Drugs/Guidances/ucm079345.pdf.

12. The circumstances plainly show that the previously "approved drug" for which Hikma was seeking a "change" was Colcrys®. The "change" that was being sought was simply a change in dosage form from tablet to capsule. Accordingly, although Hikma was entitled to file a 505(b)(2) application, longstanding FDA policy required Hikma to reference the

pharmaceutically equivalent or most similar alternative drug to the product for which Hikma was seeking approval.

13. There is no "pharmaceutically equivalent" drug to the capsule form of colchicine for which Hikma was seeking approval. However, Colcrys® is the most similar alternative to Mitigare because it is identical in every relevant respect save for dosage form. Thus, Hikma was required to reference Colcrys® in support of Hikma's application for approval of Mitigare. Referencing Colcrys® would have required that Hikma certify to the patents covering Colcrys®. FDA therefore should not have granted final approval unless and until Hikma certified to the Colcrys® patents.

14. In an arbitrary, capricious, and unlawful manner, FDA allowed Hikma to claim that another drug, Col-Probenecid, is the previously-approved drug for which Hikma was seeking a "change." However, FDA and Hikma knew that Col-Probenecid differs from Hikma's product in *four* substantial ways: different dosage form; different active ingredients; different concentration; and different approved indication. In contrast, Colcrys® differs from Hikma's product in only dosage form—and therefore is obviously the most similar reference drug (and the drug to which Hikma was required to reference) under longstanding FDA policy. There is only one reason to reference Col-Probenecid and not Colcrys and that is to circumvent the patent certification process in violation of FDA policy. FDA's sudden and unannounced departure from that policy, without public notice and opportunity for comment, was arbitrary, capricious and unlawful.

PARTIES

15. Plaintiff Knollwood Investments, L.P. is a Delaware limited partnership with its principal place of business at 40 West 57th Street, New York, NY 10019. Knollwood is the

record holder of the contingent value right to receive royalties from the sale of Colcrys® in the United States. Takeda Pharmaceuticals U.S.A., Inc., is the holder of a new drug application for Colcrys®. Takeda or its affiliates hold the Colcrys® patents, which entitle Takeda to protect its market for the sale of Colcrys® against infringers in the United States.

16. Plaintiff Elliott Associates, L.P. is a Delaware limited partnership with its principal place of business at 40 West 57th Street, New York, NY 10019. EA is an investment vehicle that provides returns to its limited partners based on its investments, which include a substantial investment in the corporate parent of Mutual Pharmaceutical Company, Inc. Mutual's corporate parent developed Colcrys® and was later acquired by Takeda. EA is entitled to receive amounts from Knollwood, including any royalties from the sale of Colcrys® pursuant to the contingent value right.

17. Plaintiff Elliott International, L.P. is a Cayman Islands limited partnership with its principal place of business at 40 West 57th Street, New York, NY 10019. EI is an investment vehicle that provides returns to its limited partners based on its investments. EI is entitled to receive amounts from Knollwood, including any royalties from the sale of Colcrys® pursuant to the contingent value right.

18. Defendant Sylvia Mathews Burwell is the Secretary of HHS and is responsible for administering and enforcing the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Defendant Burwell is being sued in her official capacity only. She maintains an office at 200 Independence Avenue, S.W., Washington, DC 20201.

19. Defendant Margaret Hamburg, M.D., is the Commissioner of Food and Drugs and is responsible for supervising the activities of FDA, an administrative agency within HHS.

Defendant Hamburg is being sued in her official capacity only. She maintains offices at 10903 New Hampshire Avenue, Silver Spring, MD 20993.

JURISDICTION AND VENUE

20. This action arises under the Food Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. § 701-706. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361, and 2201-2202.

21. There exists an actual and justiciable controversy between Elliott and Defendants requiring resolution by this Court, as well as preliminary and permanent injunctive relief to prohibit Defendants from violating laws and regulations.

22. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (e).

23. EA, EI, and Knollwood have Article III standing to bring this action because each has suffered a concrete and particularized injury that is actual or imminent. Knollwood owns a contractual right, known as a contingent value right, to receive a percentage of royalties from the domestic sales of an approved pharmaceutical product, Colcrys®, that is covered by valid and enforceable patents and is entitled to market exclusivity. Knollwood's injury is directly caused by FDA's unlawful decision to approve a competing product without requiring its manufacturer, Hikma, to certify to the Colcrys® patents. As a result of that unlawful approval, Hikma's colchicine product will likely capture the Colcrys® market, thereby diminishing or destroying the value of Knollwood's contingent value right. That loss will be realized by EA and EI, which are entitled to receive amounts from the performance of Knollwood's assets, including the contingent value right, and will cause substantial and irreparable injury to the investment performance and reputation of EA, EI, and Knollwood. This injury is redressable by the Court,

because this Court may set aside FDA's action as contrary to the FDCA, arbitrary, capricious, and otherwise not in accordance with law.

24. Plaintiffs also have standing under the Administrative Procedure Act, 5 U.S.C. §§ 701-706, which allows any person suffering a legal wrong caused by the final action of an administrative agency to challenge that action in federal court and seek equitable relief. Plaintiffs therefore fall within the zone of interests protected by the APA.

NATURE OF THE CASE

I. Statutory And Regulatory Background

25. A manufacturer may not sell a new therapeutic drug in interstate commerce without FDA approval. 21 U.S.C. § 355(a). Innovators of novel drug products must file with FDA a New Drug Application ("NDA") containing detailed information about the drug's safety and efficacy (21 U.S.C. § 355(b)(1)) and proposed method of use (21 C.F.R. § 314.53(b)-(c)).

26. The NDA applicant must also identify "the patent number and the expiration date" of any method of use patent "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G). These reporting requirements encourage broad disclosure and do not require NDA applicants to make extrajudicial determinations of actual infringement.

27. FDA lists this patent information in a publication officially known as the *Approved Drug Products with Therapeutic Equivalence Evaluations* and more commonly known as the "Orange Book," which serves as a reference to applicants seeking approval for a drug who need identify potentially relevant intellectual property. *See* FDA, Orange Book, http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm (last updated Sept. 2014).

28. For method of use patents, FDA also requires innovators to draft and submit a short "use code" describing the claimed method of use that FDA publishes in the Orange Book. 21 C.F.R. § 314.53(c)(2)(ii)(P), (e).

29. Generic manufacturers seeking to market a copy of an innovator's proprietary drug can file with FDA an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). The ANDA seeks to rely on the innovator's safety and efficacy data by showing that the generic drug has the same active ingredients as, and is equivalent to, the innovator's drug. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv). The brand-name drug on which the generic applicant relies is known as a Reference Listed Drug, or RLD.

30. Because FDA cannot approve a generic drug that would infringe an innovator's patents listed in the Orange Book, a generic company must include with its ANDA a certification or statement that those patents are invalid, that the proposed generic drug will not infringe those patents, or that the use for which the applicant is seeking approval is not covered by those patents. In the latter case, FDA relies exclusively on the innovator's use code when determining whether to approve a proposed generic product.

31. A third approval pathway is available where a new prescription drug differs only slightly from an already approved drug, as is the case, for example, where a new drug has a different dosage form than the approved drug. In those cases, the manufacturer may submit a type of NDA governed by Section 505(b)(2) of the FDCA. These so-called 505(b)(2) applications allow manufacturers to rely on the studies and investigations conducted by the NDA holder of the previously approved drug to establish the safety and efficacy of the new prescription drug.

32. As with ANDA applicants, a 505(b)(2) applicant must include with its application a statement or certification that its proposed drug will not infringe the patents claiming the reference drug or patents that claim the use for which the applicant is seeking approval. *See* 21 U.S.C. § 355(b)(2). Moreover, FDA requires that applicants who file a 505(b)(2) certification also provide notice of that certification to the patent holder. *See* 21 C.F.R. § 314.52. As it does in the ANDA context with method of use patents, FDA relies on use codes to determine whether to approve a 505(b)(2) application. *See* 21 C.F.R. § 314.53(c)(2)(ii).

II. Factual Background

33. Takeda's Colcrys® is the only single-ingredient colchicine product designated as an RLD. On July 29, 2009, FDA approved a 505(b)(2) application filed by Mutual Pharmaceutical Company ("Mutual") for Colcrys® oral tablets in 0.6 mg strength for the treatment of Familial Mediterranean Fever. On July 30, 2009, FDA approved Mutual's 505(b)(2) application for the use of Colcrys® for the treatment of acute gout flares. And on October 16, 2009, FDA approved Mutual's 505(b)(2) application for the use of Colcrys® for the prophylaxis of gout flares. In its applications, Mutual relied on published literature, a previously-approved drug product, and its own clinical trials.

34. As a result of its innovation, Mutual or its affiliates received numerous patents directed to colchicine. Seventeen of these patents are listed in FDA's Orange Book for Colcrys®. Moreover, four of the listed patents—referred to herein as the Colcrys® patents—list as their use code a "[m]ethod of using colchicine for the prophylaxis of gout," designated as use code U-1020. *See* U.S. Patent No. 7,619,004 ("the '004 patent"); U.S. Patent No. 7,820,681 ("the '681 patent"); U.S. Patent No. 8,097,655 ("the '655 patent"); U.S. Patent No. 8,440,722 ("the '722 patent").

35. All manufacturers who submit ANDAs or 505(b)(2) applications citing to Colcrys® as the RLD and seeking approval for a method of using colchicine for the prophylaxis of gout must also certify that their proposed products will not infringe the Colcrys® patents.

36. In the fall of 2010, public reports stated that Hikma's U.S. manufacturer, West-Ward Pharmaceutical Corp. ("West-Ward"), had submitted an application for a single-ingredient oral colchicine product. Mutual filed a Citizen Petition with FDA requesting confirmation that any duplicate version of Colcrys® would need to be submitted as an ANDA, rather than a 505(b)(2) application. In its response, FDA granted Mutual's request and confirmed that West-Ward had inappropriately submitted a 505(b)(2) application for approval of a duplicate version of Colcrys®.

37. Three years later, without warning, FDA approved Hikma's single-ingredient colchicine product, Mitigare, as a 0.6 mg capsule indicated for the prophylaxis of gout flares. Apparently, instead of resubmitting its previous application as an ANDA, Hikma reformulated its product to be delivered as a capsule, rather than a tablet, and filed a new 505(b)(2) application. FDA approved this new application on September 26, 2014. Hikma publicly announced the approval on or about September 30, 2014.

38. Despite owning 17 Orange Book-listed patents for Colcrys®—four of which are for a "[m]ethod of using colchicine for the prophylaxis of gout"—Takeda never received notice of a patent certification as required under Section 505(b)(2)(A).

39. Had FDA required Hikma to certify to the Colcrys® patents, and provide notice of the certification to Takeda, Takeda would have sued Hikma for patent infringement, thus triggering a 30-month stay of any FDA approval of Hikma's application. Indeed, just four days after learning of FDA's approval of Hikma's Mitigare product, Takeda sued Hikma and West-

Ward in federal Court for infringement of several patents claiming the use of Colcrys®, including the '655 patent and the '722 patent. *See* Complaint, *Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268 (D. Del. filed Oct. 3, 2014).

III. FDA's Approval Of Mitigare Without Requiring Hikma To Certify To The Colcrys® Patents Violates The FDCA

40. FDA has purported to approve Hikma's product under Section 505(b)(2). Section 505(b)(2)(A) requires a drug applicant, such as Hikma, using the truncated process to certify to any patents listed in the Orange Book that claim a use for the applicant's drug. Specifically, the applicant must certify "to each patent which claims a use for such drug for which the applicant is seeking approval." 21 U.S.C. § 355(b)(2)(A).

41. Here, the Colcrys® patents claim the use of colchicine—*i.e.*, for the prophylaxis of gout flares—for which Hikma sought approval. Hikma therefore was required to certify that the Colcrys® patents either were expired, not infringed, or invalid, and to provide notice of that certification to Takeda.

42. Had Hikma certified to the Colcrys® patents and provided notice as Section 505(b)(2)(A) requires, Takeda would have sued Hikma for patent infringement—as indeed Takeda quickly did after learning that FDA had approved Hikma's application.

43. Moreover, under the FDCA, Takeda's lawsuit would have prohibited FDA from approving Hikma's application for 30 months. The 30-month stay is a centerpiece of the FDCA's provisions governing approval of generic drugs, because it creates a window of time in which the patent holder may sue the generic applicant for patent infringement and obtain a judicial determination of rights. During that period, the patent holder—as well as its assignees and any other parties who possess a legal right to sales of the patent holder's drug—would be

entitled to enjoy market exclusivity, revenues, and royalties from the sale of the patented, proprietary product.

44. As a consequence of FDA's unlawful decision to allow Hikma to circumvent the certification requirement, Takeda and its assignees, including Elliott, have been deprived of the statutory benefits to which they are legally entitled under the FDCA.

45. FDA has either ignored the plain language of the statute or has read the phrase "such drug" in Section 505(b)(2)(A) to refer to the "drug for which such investigations were conducted," rather than the drug for which a use is claimed by the listed patent. The FDA's reading is contrary to the statutory text because it would render portions of the statute superfluous. *See, e.g.*, 21 U.S.C. § 355(b)(2)(B). In Section 505(b)(2)(A), by modifying the phrase "such drug" with the additional phrase "for which the applicant is seeking approval," Congress unambiguously conveyed that it was requiring certification to any patents claiming a use for the drug *for which the applicant is seeking approval*.

46. Even if the certification requirement of Section 505(b)(2)(A) could be viewed as ambiguous—and it cannot—the legislative history makes clear that certification is required in precisely the circumstances presented here. Any contrary interpretation would not be entitled to deference and would be contrary to longstanding FDA policy.

47. Accordingly, FDA plainly exceeded its statutory authority, in violation of the FDCA, when it approved Hikma's 505(b)(2) application without requiring Hikma to certify to the Colcrys® patents.

IV. FDA's Decision To Approve Mitigare Without Requiring Hikma To Certify To The Colcrys® Patents Arbitrarily And Capriciously Violated Longstanding FDA Policy

48. Reading Section 505(b)(2)(A) to require Hikma to certify to the Colcrys® patents is also compelled by longstanding FDA policy. FDA's unexplained decision to depart from that

policy without prior public notice and an opportunity for comment was arbitrary, capricious, and contrary to law.

49. FDA has expressly endorsed and adopted the reading set forth in the Hatch-Waxman Act's legislative history. For example, in FDA's response to the 2004 Fenofibrate Citizen Petition, FDA explained that "'[w]ith respect to all product patents which claim the listed drug and use patents which claim an indication for which the applicant is seeking approval . . . the applicant must certify'" to the listed patents. FDA Response to Citizen Petition (Docket No. 2004P-0386/CP1 & RC1) at 7 n.6 (Nov. 30, 2004) (quoting H.R. Rep. No. 98-857(II) (1984)) ("Fenofibrate Response").

50. FDA also has made clear that 505(b)(2) applicants may not "circumvent" the certification requirement by referencing a drug that is not the drug most similar to the drug for which approval is sought. *Id.* at 9 & n.13. FDA has arbitrarily and capriciously departed from that policy by failing to require Hikma to reference Colcrys®, and instead to reference a drug (Col-Probenecid) that is substantially dissimilar to Hikma's product. Col-Probenecid has different active ingredients, a different dosage form, different indications, and a different concentration of colchicine than Hikma's Mitigare. In contrast, the most similar drug is Colcrys®, which not coincidentally is claimed by the patents to which Hikma was required to certify. Colcrys® differs from Hikma's product only in dosage form—Colcrys® is a tablet, whereas Hikma's product is a capsule. Had FDA adhered to its longstanding policy, it would have required Hikma to reference Colcrys® and, therefore, to certify to the Colcrys® patents.

51. FDA knows of and expressly acknowledged the Colcrys® patents in its 2011 response to a Citizen Petition filed by Mutual. *See* FDA Response to Citizen Petition, Docket No. FDA-2010-P-0614, at 8 (May 25, 2011). In that response, FDA acknowledged that West-

Ward had previously submitted an erroneous 505(b)(2) application that sought approval of a "duplicate drug" but did not cite Colcrys® as the RLD. *See id.* at 17. Moreover, it did not certify to the Colcrys® patents, two of which covered a "Method of using colchicine for the prophylaxis of gout flares." *Id*. at 8. FDA concluded that because Hikma was seeking approval of a duplicate drug, Hikma was required to file a 505(j) application and reference Colcrys® even though Hikma was relying on publicly available information for safety and efficacy. *Id.* at 11-12.

52. Hikma's apparent response to that letter was to reformulate its product from tablet to capsule form, so that it was no longer a "duplicate drug," and resubmit its 505(b)(2) application for a 0.6 mg single-ingredient colchicine product. Notwithstanding that minor change, however, the correct and mandatory reference drug remains Colcrys®, which differs only as to dosage form, and not Col-Probenecid. Hikma's actions evidence a clear intent to circumvent Section 505(b)(2)'s certification requirement and yet longstanding FDA policy makes clear that it will not allow a 505(b)(2) applicant to use the 505(b)(2) process to end-run patent protections. *See, e.g.*, Fenofibrate Response at 9. FDA's approval of Hikma's colchicine product on September 26, 2014, arbitrarily and capriciously departed from longstanding FDA policy and denied the public prior notice and an opportunity for comment.

53. Moreover, FDA has addressed similar situations in the ANDA context and stated that "[I]f a tablet and a capsule are approved for the same moiety with patents listed for the tablet and none listed for the capsule an ANDA applicant seeking approval for a tablet should cite the approved tablet as the reference listed drug. *It should not circumvent the patents on the tablet by citing the capsule as the reference listed drug and filing a suitability petition under section 505(j)(2)(C) of the Act and 21 CFR 314.93 seeking to change to a tablet dosage form.*"

Fenofibrate Response at 9 n.13. Although this example arises in the ANDA context, FDA has made clear that its "approach ensures that patent certification obligations for 505(b)(2) applications and for ANDAs are parallel." *Id*. at 10.

54. Here, patented Colcrys® and unpatented Col-Probenecid are both reference drugs in tablet form. However, FDA has permitted Hikma to circumvent Takeda's patents and reference unpatented Col-Probenecid, despite the fact that it differs in active ingredients, concentration, dose form, and indication from Mitigare, whereas Colcrys® differs only in dose form. Col-Probenecid is not "the most similar alternative to the product for which approval is sought"; Colcrys is. The only reason to permit Hikma to reference Col-Probenecid and not Colcrys is to allow Hikma to circumvent the patent certification process. FDA's approval of those actions arbitrarily and capriciously violated longstanding FDA policy.

V. FDA's Actions Will Cause Immediate And Irreparable Harm To Elliott

55. Elliott owns a legally-enforceable right to receive a percentage of royalties from sales of Colcrys® in the United States.

56. In 2012, Takada acquired Mutual's corporate parent, including the rights to Colcrys®. At the time of the acquisition, EA owned a substantial investment in Mutual's corporate parent. As part of the acquisition, a significant portion of the consideration for such investment was a contingent value right that entitles the holder to receive a percentage of royalties on the United States sales of Colcrys® so long as the Colcrys® patents remain in force. The record holder of that contingent value right is Knollwood, which entity distributes its income to EA and EI. Thus, a material portion of the value of Elliott's investment is inextricably tied to the exclusivity guaranteed by the Colcrys® patents, which do not expire until 2028 and 2029.

57. FDA's approval of Mitigare without certifying to Takeda's Colcrys® patents permits Hikma to launch its colchicine product into the market at any moment. New drug entrants into the market have an immediate and precipitous effect upon the market share and pricing of the brand name drugs upon which they are based. Such competition from Mitigare would markedly decrease revenue from the sale of Colcrys®, thereby directly harming the interests of Elliott.

58. It has been reported that Mitigare is expected to capture 60 to 70 percent of the Colcrys® market within four weeks of Mitigare's launch, and 95 to 98 percent of the Colcrys® market within twelve months of Mitigare's launch. The lost market share for Colcrys® will be unrecoverable.

59. In the absence of immediate injunctive relief, Elliott will suffer irreparable injury. EA and EI are investment vehicles that provide income to their partners based on their strategic investments. As a direct result of FDA's unlawful decision, the value of a significant asset—namely, the contingent value right—has been greatly diminished, if not destroyed altogether. FDA's unlawful action therefore is causing, and has caused, irreparable harm to the goodwill of Elliott and unrecoverable loss to the value of Elliott's investment.

COUNT I
(Administrative Procedure Act: Violation Of The FDCA)

60. Elliott realleges, reasserts, and incorporates by reference herein each of the allegations contained in paragraphs 1 through 59 of the Verified Complaint as though set forth fully herein.

61. FDA's approval of Hikma's 505(b)(2) application for Mitigare was unlawful and in violation of the plain text of the FDCA, 21 U.S.C. § 355(b)(2).

62. FDA's approval of Hikma's 505(b)(2) application for Mitigare constitutes final agency action for which Elliott has no other adequate remedy within the meaning of 5 U.S.C. § 704.

63. FDA's approval of Hikma's 505(b)(2) application for Mitigare was not in accordance with federal law and therefore violates 5 U.S.C. § 706(2)(A).

64. FDA's approval of Hikma's 505(b)(2) application for Mitigare constitutes agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, in violation of 5 U.S.C. § 706(2)(C).

65. Elliott will be irreparably harmed unless FDA is required to withdraw its approval of Hikma's 505(b)(2) application for Mitigare.

66. There is no mechanism by which Elliott can be made whole for the injury that would result from the entry into the marketplace of an unlawful colchicine product. Elliott is without an adequate remedy at law because of the unique nature of the harm.

67. The intent of Congress will be served by an Order directing FDA to withdraw its approval of Hikma's 505(b)(2) application for Mitigare.

COUNT II
(Administrative Procedure Act: FDA's Conduct Was Arbitrary, Capricious, An Abuse Of Discretion And Otherwise Not In Accordance With Law)

68. Elliott realleges, reasserts, and incorporates by reference herein each of the allegations contained in paragraphs 1 through 67 of the Verified Complaint, as though set forth fully therein.

69. The APA prohibits FDA from implementing the FDCA in a manner that is arbitrary, capricious, or an abuse of discretion. 5 U.S.C. § 706(2)(A). FDA acted arbitrarily, capriciously, and contrary to law by departing from its longstanding policy of requiring

505(b)(2) applicants to reference the most similar alternative drug, and to certify to the patents covering that most similar alternative drug.

70. FDA's approval of Hikma's 505(b)(2) application for Mitigare was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

71. FDA's approval of Hikma's 505(b)(2) application for Mitigare was premised on agency determinations that represented abrupt departures from longstanding agency practice and the treatment of similarly-situated entities. FDA's conduct was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

72. FDA's approval of Hikma's 505(b)(2) application for Mitigare constitutes final agency action for which Elliott has no other adequate remedy within the meaning of 5 U.S.C. § 704.

73. Elliott will be irreparably harmed unless FDA is required to withdraw its approval of Hikma's application.

74. There is no mechanism by which Elliott can be made whole for the injury that would result from the entry into the marketplace of Hikma's product. Elliott is without an adequate remedy at law because of the unique nature of the harm.

75. The intent of Congress will be served by an Order directing FDA to withdraw its approval of Hikma's 505(b)(2) application for Mitigare.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that FDA's approval of Hikma's 505(b)(2) application for Mitigare, without requiring Hikma to certify to the Colcrys® patents

and provide contemporaneous notice of that certification to Takeda, was in excess of statutory authority and otherwise unlawful the FDCA, 21 U.S.C. § 355(b)(2);

B. A declaration pursuant to 28 U.S.C. § 2201 that FDA's approval of Hikma's 505(b)(2) application for Mitigare was arbitrary, capricious, and unlawful under the APA and the FDCA;

C. A declaration pursuant to 28 U.S.C. § 2201 that FDA's refusal to require Hikma's 505(b)(2) application to reference Colcrys® was arbitrary, capricious, and unlawful under the APA and the FDCA;

D. Temporary, preliminary and permanent injunctive relief requiring FDA to rescind or, at a minimum, stay its approval of Hikma's 505(b)(2) application for Mitigare;

E. An order awarding plaintiff's costs, expenses and attorneys' fees pursuant to 28 U.S.C. § 2412; and

F. Such other and further relief as the Court deems just and proper.

Respectfully Submitted,

Dated: November 4, 2014

/s/ Matthew D. McGill

MATTHEW D. MCGILL, D.C. Bar No. 481430
MMcGill@gibsondunn.com
MITHUN MANSINGHANI, D.C. Bar No. 1010818
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, NW
Washington, DC 20036
Telephone: 202-955-8500
Facsimile: 202-467-0539

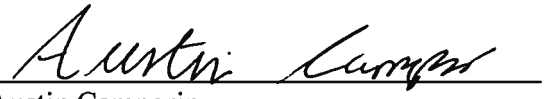
MICHAEL A. STIZMAN, Cal. Bar No. 156667
(*pro hac vice application to be filed*)
MSitzman@gibsondunn.com
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street, Suite 3000

San Francisco, CA 94105
Telephone: 415-393-8200
Facsimile: 415-393-8306

VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct based on my personal knowledge and on information derived from the business records of Elliott Associates L.P. and its affiliates. I further declare that matters asserted upon information and belief are believed to be true and correct.

Executed this 4th day of November, 2014



Austin Camporin