IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TAKEDA PHARMACEUTICALS U.S.A., INC.

Plaintiff,

and

ELLIOTT ASSOCIATES, L.P., ELLIOTT INTERNATIONAL, L.P., and KNOLLWOOD INVESTMENTS, L.P.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND) HUMAN SERVICES,

and

MARGARET HAMBURG, M.D., in her official capacity as COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

Defendants,

and

HIKMA PHARMACEUTICALS PLC AND WEST-WARD PHARMACEUTICAL CORP.,

Intervenor-Defendants.

Case Nos. 1:14-cv-01668-(KBJ)
1:14-cv-01850-(KBJ)

INTERVENOR-DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF CROSS MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The summary judgment motion filed by the Elliott plaintiffs[1] relies primarily on a novel statutory-interpretation argument—one that is so at odds with the plain reading of the Hatch-Waxman Act that even Takeda could not bring itself to make it. In asking the Court to hold unlawful and set aside FDA's approval of Hikma's[2] colchicine product branded as Mitigare™, Elliott contorts the natural reading of Hatch-Waxman into inconsistency and confusion. As discussed at the last hearing on November 19, 2014, Congress created a simple *quid pro quo* in Section 505(b)(2): where a drug applicant relies on another party's data for a previously approved drug (the "listed drug"), the applicant must certify to any patents associated with that listed drug.

Here, the listed drug for Hikma's 505(b)(2) application for Mitigare is Col-Probenecid—the same listed drug Takeda relied on to support approval of its 505(b)(2) application for Colcrys®. Based on FDA's prior approval of Col-Probenecid, as well as published literature and Hikma's own studies, FDA found Mitigare™ both safe and effective and properly approved Hikma's 505(b)(2) application. Hikma met all of its statutory obligations to certify to patents listed for Col-Probenecid: because there are no such patents, Hikma made no certifications. Hikma never relied on Takeda's Colcrys® as the listed drug, nor was it necessary for Hikma to do so for FDA to approve Mitigare™. Therefore, there is no basis to support Elliott's contention that Hikma was statutorily obligated to certify to the patents Takeda listed for Colcrys®.

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[1] This brief refers to Plaintiffs Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P. collectively as "Elliott."

[2] This brief refers to Defendants Hikma Pharmaceuticals PLC and West-Ward Pharmaceutical Corp. together as "Hikma."

According to Elliott, however, Hatch-Waxman requires that Hikma certify to patents for listed drugs on which it never relied for approval. Under such an interpretation, the *quid pro quo* compromise is rendered a one-way street, providing a windfall for brand companies.

In fact, Elliott's reading of the statute creates a jumble out of it. According to Elliott, Hikma was required to certify to *any* "Orange Book" patents claiming a "method of using colchicine for the prophylaxis of gout flares"—regardless of whether the 505(b)(2) applicant relied on the patentee's data. Dkt. #14-2 at 2. That requires reading the term "drug" in the statutory phrase "or which claims a use for such drug for which the applicant is seeking approval" to mean the drug substance/active ingredient (here, colchicine), rather than the listed drug product (here, Col-Probenecid). FDA has already expressly rejected that interpretation: the statute "requires certifications to patents listed **for the drug product relied on for approval**, but **not** to patents for all other drug products that contain the same drug substance and rely on the same underlying investigations." FDA, Citizen Petition Response Re: Docket No. 2004P-0386/CP1 & RC1, Nov. 30, 2004 ["Fenofibrate CP Response"], Takeda Supp. Br. Ex. i. at 7 (emphasis in original). That interpretation, at minimum, is entitled to *Chevron* deference. Elliott's contrary reading, moreover, requires that the word "drug" have different meanings (drug *product* in some instances and drug *substance* in others) when used at different places within the same statute. That cannot be right.

Nor did FDA act arbitrarily or capriciously when approving Hikma's 505(b)(2) application because—as Hikma addressed in opposing Takeda's briefs—FDA did not violate its prior policies and procedures. *See* Opposition to Motion for Preliminary Injunction, 1:14-cv-01668-(KBJ), Dkt. 16, at 18–21. The Court should see Elliott's motion for what it is—a last ditch effort to protect Colcry®'s monopoly of the U.S. colchicine market and Elliott's "hundreds

of millions of dollar[]" royalty stream. Dkt. #14-2 at 11. Elliott's motion for summary judgment should be denied, and summary judgment should be entered on behalf of defendants.[3]

STATEMENT OF MATERIAL FACTS NOT IN DISPUTE

Hikma does not materially dispute Elliott's account of the statutory background and other facts regarding FDA's approval of Takeda's Colcrys® and Hikma's Mitigare™ drug products in its Statement of Facts section. Dkt. #14-2 at 4–11. Those facts are well known to this Court and have been presented in previous papers and arguments to date.[4] But Hikma disputes Elliott's interpretation of Hatch-Waxman and its application to these facts.

ARGUMENT

I. Under Chevron step one, Hatch-Waxman unambiguously requires a 505(b)(2) applicant to certify only to patents associated with the listed drug on which the applicant relies for approval.

The meaning of a statute is a legal question and courts do not defer to an agency's interpretation if it violates a clear congressional command. *See Chevron, USA, Inc. v. NRDC, Inc.*, 467 U.S. 837, 842–43 (1984); *see also Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005) ("A court's prior judicial construction of a statute trumps an agency construction otherwise entitled to Chevron deference only if the prior court decision holds that its construction follows from *the unambiguous terms of the statute and thus leaves no room for agency discretion*.") (emphasis added).

[3] Hikma is cross-moving for summary judgment to give the Court a procedural vehicle to terminate this case if the Court rejects the legal arguments raised in Elliott's complaint and summary judgment motion. Although Hikma is entitled to file a reply brief in support of its cross-motion, it is mindful of the briefing schedule set by the Court. As a result, Hikma is not requesting that the Court delay its ruling on Elliott's motion and Hikma's cross-motion pending the filing of Hikma's reply brief. Hikma will file any such reply brief as soon as possible after receiving Elliott's opposition brief.

[4] Hikma incorporates in its entirety the Regulatory and Factual Background from its Opposition to Motion for Preliminary Injunction, 1:14-cv-01668-(KBJ), Dkt. 16, at 5–16.

Hatch-Waxman is unambiguous on the issues presented here. A plain reading of § 355(b)(2)(A) instructs a 505(b)(2) applicant to certify only to patents associated with the listed drug *product* relied upon for approval. That is precisely what Hikma did, and thus FDA's approval of Mitigare™ was lawful. The only way Elliott can get around the statute's structure and purpose is to make contorted statutory interpretation arguments. But when the smoke is cleared and the mirrors shattered, Elliott's attempt to transform Hatch-Waxman into something it is not fails from the start.

A. FDA's approval of Mitigare™ is consistent with the plain language of Hatch-Waxman.

The *Chevron* analysis begins, and in this case ends, with the words of the statute itself. *Chevron*, 467 U.S. at 842–43 ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). The relevant portion of the statute provides:

> (2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—
>
> (A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c) of this section—
>
> (i) that such patent information has not been filed,
>
> (ii) that such patent has expired,
>
> (iii) of the date on which such patent will expire, or
>
> (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and
>
> (B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this

> subsection, a statement that the method of use patent does not claim such a use.

21 U.S.C. § 355(b)(2) (emphasis added); *see also* Tr. Hearing, Nov. 19, 2014, Ex. 2, at slide 42.

Under the statute, a 505(b)(2) applicant is required to make a certification to product patents listed in FDA's "Orange Book" that claim the listed drug product, *i.e.* "the drug for which such investigations were conducted," as well as patents that claim a use for *such* listed drug. *Id.* This plain reading of the statute gives the term "drug" the same meaning throughout. "A standard principle of statutory construction provides that identical words and phrases within the same statute should normally be given the same meaning." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232 (2007). "That maxim is doubly appropriate" where the word or phrase was inserted at the same time, *id.*, as they were here.

The inclusion of the term "such" to modify "drug" in the latter clause makes doubly clear that the term "drug" is the same as the term "the drug" in the former clause. *See* "Such," Merriam-Webster Online Dictionary, www.merriam-webster.com (last visited Nov. 26, 2014) ("of the same class, type, or sort <other *such* clinics throughout the state>."); *see also, e.g.*, *United States v. Chi Tong Kuok*, 671 F.3d 931, 945 (9th Cir. 2012) ("Without a phrase that limits or defines the merchandise, the second clause's use of the word 'such' is meaningless."); *id.* at n.8 ("'Such' in this context means 'of the sort or degree previously indicated or implied.'"); *Fleming v. Moberly Milk Products Co.*, 160 F.2d 259, 274 (D.C. Cir. 1947) ("'Such production' means 'that sort of production'; production of the sort which is expanded in accordance with the preceding sentence . . . ."). That term, of course, is the same as "a drug" "relied upon by the applicant for approval" in § 355(b)(2). Moreover, the phrase "for which the applicant seeks approval" most naturally refers to the "use," not "such drug," for which the applicant is seeking approval.

Subsection 355(b)(2)(B) further illustrates the statute's consistent use of the term "drug" to mean the listed drug product. In lieu of making a § 355(b)(2)(A) certification to a method of use patent that claims a use for the listed drug product, that paragraph allows an applicant to omit an indication from its labeling by making "a statement that the method of use patent does not claim" "a use for which the applicant is seeking approval." 21 U.S.C. § 355(b)(2)(B). Thus, to address method of use patents that claim a use for the listed drug, an applicant must either include a certification under § 355(b)(2)(A) or include what is generally called a "carve-out statement" or "skinny label" under § 355(b)(2)(B). *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677(2012). In either case, it is clear that the statute is referring to method patents that claim a use for the listed drug product. *See* § 355(b)(2)(B) ("with respect to *the drug* for which investigations . . . were conducted").

The statute should be read as a whole. *Cf. Powerex Corp.*, 551 U.S. at 232; *see also Gonzales v. Oregon*, 546 U.S. 243, 274 (2006) (holding that a provision should be interpreted by "the illumination of the rest of the statute"). Instead of doing so, Elliott's reading parses the § 355(b)(2)(A) certification requirement into two *separate* clauses. Dkt. #14-2 at 16. The first requires certification with respect to each patent "which claims the drug for which such investigations were conducted," which Elliott refers to as product patents. Elliott concedes that these product patents are those associated with the listed drug on which the applicant relies for approval. Dkt #14-2 at 16 ("The first is to each patent 'which claims the drug for which such investigations were conducted,' the product patents."); *see also* Tr. Hearing, Nov. 19, 2014, at 75:19–23. The second requires certification to each patent "which claims a use for such drug for which the applicant is seeking approval," which Elliott refers to as method of use patents. Here, Elliott posits that these method of use patents can include patents associated with listed drugs on

which the applicant never relied. Thus, according to Elliott's logic, Hikma "was seeking approval for the use of colchicine for the prophylaxis of gout" and, therefore, Hikma was required to certify to *any patents* listed in the Orange Book—including the Colcrys® method of use patents—that purport to claim a use of colchicine for prophylaxis of gout.

Elliott's reading makes a jumble out of the statute. It would require reading the term "drug" to have different meanings at different times in the same subsection. *Cf. Powerex Corp.*, 551 U.S. at 232. Specifically, Elliott's reading requires that "such drug"—in the phrase "or which claims a use for such drug for which the applicant is seeking approval"—refer to the drug *substance* "colchicine." Hence, Elliott argues "there can be no dispute that Hikma was seeking approval for the use of colchicine for the prophylaxis of gout." Dkt. #14-2 at 16. But if "such drug" refers to the drug substance colchicine (as opposed to a drug product), then so should the word "drug" in the first clause addressing product patents. But not even Elliott is willing to argue that; even it recognizes that the "drug for which such investigations were conducted" is the drug *product* Col-Probenecid, not the drug *substance* colchicine. Dkt. #14-2 at 16; Tr. Hearing, Nov. 19, 2014, at 75:19–23.

As discussed above, Elliott's reading is completely at odds with the plain reading of the statute that uses the term "drug" consistently to mean the listed drug product. Indeed, there is *no other way* to read the § 355(b)(2)(A) provision to embrace Congress' intended *quid pro quo* exchange of reliance on previous investigations for patent certifications, or square it with the surrounding provisions of § 355(b)(2) and § 355(b)(2)(B). Worse yet, if Congress had intended what Elliott argues, surely it would have chosen a more direct way of saying so.

Elliott has no basis to argue that Hikma's (and FDA's) reading of the statute renders superfluous the phrase "for which the applicant is seeking approval." Dkt. #14-2 at 17. That

phrase most naturally refers to the *use* for which the applicant is seeking approval—here, the prophylaxis of gout flares. This phrase is not superfluous. It specifies that a certification is required for method of use patents covering an FDA-indication for the listed drug *only* if the 505(b)(2) applicant is seeking approval for that indication (i.e., the patented use). This is a plain, and common-sense, reading.

For example, as explained at the last hearing, if Hikma had referenced Colcrys® as a listed drug and sought approval for the acute gout flare indication, Takeda's patents "would claim[] a use for such drug [i.e., the listed drug, Colcrys®] for which the applicant is seeking approval [i.e., the acute gout flare indication in the Colcrys® label]." *See* Tr. Hearing, Nov. 19, 2014, at 96:1–7. Indeed, § 355(b)(2)(B)'s recitation of the phrase "which does not claim *a use for which the applicant is seeking approval*" confirms that the phrase "for which the applicant is seeking approval" in § 355(b)(2)(A) modifies the term "use," not the term "such drug."

This reading also resolves Elliott's remaining statutory argument—namely, that "[w]here Congress wished to refer back to a drug previously mentioned, and to no other drug, it simply used the phrase 'such drug' in isolation without any further modification or explanation," whereas here Congress modified the language with the additional phrase "for which the applicant is seeking approval." Dkt. #14-2 at 18. What this argument misses is that this additional phrase modifies *use*; it does not modify "such drug" at all. Indeed, Elliott recognizes only a paragraph later that the phrase modifies "use" after all. *Id.* at 18–19 ("Subparagraph 505(b)(2)(B) makes doubly clear that subparagraph 505(b)(2)(A) necessarily requires applicants to certify to patents claiming uses 'for which the applicant is seeking approval' . . . . In other words, subparagraph

(B) provides a pathway for the applicant to carve the patented use out of its label if—and only if—the applicant is not seeking approval for that patented use.").[5]

B. Legislative history and congressional intent confirm the statute's plain language.

Because the statute is unambiguous, "recourse to legislative history is unnecessary." *Saratoga Sav. & Loan Ass'n v. Fed. Home Loan Bank Bd.*, 879 F.2d 689, 693 (9th Cir. 1989). Nevertheless, the legislative history confirms Hikma's reading of the statute and Elliott's contrary arguments are entirely question-begging and incorrect. Relying on a single House Committee Report, Elliott alleges that the Committee explained that "the applicant must certify" with respect to "all product patents which claim the listed drug and all use patents which claim *an indication for the drug for which the applicant is seeking approval*." Dkt. #14-2 at 19–20 (quoting H.R. Rep. No. 98-857, pt. 1 at 32 (1984) ["House Report"]) (emphasis in brief). Further, Elliott argues that the Committee referred to these latter patents as "controlling use patents," which "claim an indication for the drug for which the applicant is seeking approval." *Id.* at 20 (quoting House Report 32).

But that language in the House Report merely replaces the word "use" from § 355(b)(2)(A) with the word "indication." In no sense is the meaning changed. The phrase "the drug" still refers to the listed drug *product*. Elliott again merely assumes that "the drug" somehow means the *colchicine* drug substance, not the listed drug product, and substitutes colchicine (i.e., the active pharmaceutical ingredient in Takeda's and Hikma's respective drug products) for "the drug" repeatedly in its legislative history discussion.

[5] Elliott's citation to *Ethypharm S.A. France v. Abbott Labs*, 707 F.3d 223, 227 (3d Cir. 2013) is beside the point. *See* Dkt. #14-2 at 15. The court there mentioned that a 505(b)(2) applicant "must certify whether its drug will infringe any patents listed in the Orange Book," but it did so in passing and in dicta without any analysis. The statute, of course, requires certification only with respect to patents associated with the listed drug on which the applicant relies.

Meanwhile, the House Report offers no suggestion at all that the term "drug" means drug substance rather than drug product. Quite the opposite. Elliott conveniently cherry picks a single sentence from page 32 of the House Report, and again ignores the surrounding text that demonstrates that the term "drug" means the listed drug product. The entire paragraph provides:

> *Patent certifications in paper NDA's for listed drugs*
>
> When a Paper NDA's [*sic*] is submitted for a listed drug [i.e., a drug product] under section 505(j)(6), it must include a certification by the applicant regarding the status of certain patents applicable to the listed drug if such information has been provided to the FDA. With respect to all product patents which claim the listed drug, and all use patents which claim an indication for the drug for which the applicant is seeking approval (hereinafter described as a controlling use patent), the applicant must certify, in his opinion and to the best of his knowledge, as to one of four circumstances.

House Report at 32 (emphasis added). Thus, when taken in context, the House Report supports Hikma's reading of the statute. The product patents and controlling use patents must all be "applicable to the listed drug"—the patents must claim the listed drug product or claim a use for the listed drug product. Further, the paragraph explains that it is the listed drug *for which an applicant submitted an application*; it does not refer to *any* listed drug, let alone any drug substance. Again, the phrase "for which the applicant is seeking approval" modifies the entire phrase "an indication for the drug"—not just "the drug."

Elliott's additional references to the House Report get them nowhere. Elliott insists that the Committee "made clear that those submitting applications under Section 505(b)(2) must 'make *the same* certifications regarding patents as mandated in the filing of ANDA's.'" Dkt. #14-2 at 21 (quoting House Report 32) (emphasis in brief). To "underscore" this point, the Committee "warned" that applicants should not "be permitted to circumvent" this notice requirement "by filing sham Paper NDA's." *Id.* (quoting House Report 33). But if the listed drug was properly Col-Probenecid—which it was—then Hikma *has* made the same certifications

as it would need to make under an ANDA application, i.e., none. That is because Col-Probenecid has no patents associated with it. As for not circumventing the requirements, that is, of course, question-begging. Elliott assumes wrongdoing on the part of Hikma, which in fact did no wrong under the natural reading of the statute.

Elliott also argues that its reading is supported by the overall structure and purpose of Hatch-Waxman, which, Elliott claims, struck a balance "between providing incentives for investment and innovation and facilitating the entry of low-cost alternatives to brand name drugs." Dkt. #14-2 at 24. To strike this balance, Congress "incorporated an important new mechanism designed to guard against infringement of patents relating to pioneer drugs." *Id.* (citing *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–77 (1990)). We agree. But where *old* drugs are involved—indeed, those that have been used for millennia, and which were used in the United States without FDA approval for several decades—Congress quite naturally intended to allow drug manufacturers to rely on those prior-approved drug products. The most significant innovation thus happened decades, if not centuries, ago. And the only impact Takeda's monopolistic takeover had was to *prevent* the entry of low-cost alternatives that had already existed for decades. In short, unless Hikma seeks to rely on Takeda's data (which Hikma does not do), Hikma has no statutory obligation to certify to Takeda's patents. *That* is the balance Congress struck in Hatch-Waxman.

As already explained, Congress created a symmetry in Hatch-Waxman. Only if a particular drug product is relied upon for approval must the applicant certify to patents with respect to *that drug product*. But where the applicant does not rely on a particular drug product (here Colcrys®), there is no requirement or policy justification that it must certify to patents listed for that product. Reading "drug" to mean "drug substance" would undermine the *quid pro*

quo envisioned by Congress, as the generic or 505(b)(2) applicant would have to certify to drugs on which it did not rely at all.

Public policy and common sense further support the proposition that "drug" must refer to the drug product and not to the drug substance. Elliott's interpretation sweeps so much more broadly and would make the statute inadministrable. For example, it can often be the case that there are *several* approved drug products that use the same drug substance or active ingredient. More than one hundred drug products contain the drug substance acetaminophen. In such cases, there is no evidence that Congress intended that a 505(b)(2) applicant certify to *all* patents listed in the Orange Book for drug products that have nothing to do with its application.

Congress intended that a 505(b)(2) applicant that relies upon a listed drug should have an easy way to identify any patents it needs to clear or certify. Thus, the statute requires the sponsor of a New Drug Application to list in the Orange Book all applicable patents for the drug product subject to that application. If "drug" meant "drug substance," it may become exceedingly challenging for a generic or 505(b)(2) applicant even to identify the relevant patents. Currently, FDA's process for administering patent certifications is straightforward: if the 505(b)(2) applicant relies on data for another party's drug product, the applicant must certify to patents listed for that drug product. Elliott's effort to read the certification process more broadly would cause FDA to take on an active role in determining what patents require a certification. But FDA has only a ministerial role. *See Caraco Pharm. Labs.*, 132 S. Ct. at 1677 (FDA "lacks 'both [the] expertise and [the] authority' to review patent claims" and thus views "its own 'role with respect to patent listing [a]s ministerial'" (quoting 68 Fed. Reg. 36683 (2003)).

II. Under Chevron step two, even if the statute were ambiguous, FDA's reasonable interpretation of Hatch-Waxman would be entitled to deference.

Where the statute is ambiguous, an agency's reasonable interpretation is entitled to deference. "In a suit challenging agency action, it is not for the court to choose between competing meanings of an ambiguous statute . . . ." *Teva Pharm. USA, Inc., v. FDA*, 441 F.3d 1, 4 (D.C. Cir. 2006). If Congress left gaps for agencies to fill, "any ensuing regulation is binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001). "Such deference is justified because '[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones,' and because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000) (internal citation omitted); *see also Am. Bar Ass'n v. FTC*, 430 F.3d 457, 468 (D.C. Cir. 2005) ("[W]e will then uphold the agency's interpretation of the ambiguous statute if that interpretation is 'permissible,' that is, if it is 'reasonable.'").

Hatch-Waxman is not ambiguous on the issue here: on that point we agree with Elliott. But the only way Elliott could claim the statute is unambiguous in its favor is by contorting the statute into inconsistency and absurdity. Even if Elliott's interpretation were marginally colorable (it is not), that interpretation would render the statute ambiguous, at best. And so long as an agency's interpretation of its own statute is reasonable in light of ambiguity, its interpretation must prevail. *Teva Pharm.*, 441 F.3d at 4.

FDA's interpretation of the statute is entirely consistent with the text as construed by Hikma. In a 2004 citizen petition decision, FDA specifically concluded that the "language of

section 505(b)(2) of the Act *links the drug relied on for approval to the drug for which the patent certifications must be made. . . .* FDA interprets drug in section 505(b)(2) to refer to drug product, not active ingredient." Fenofibrate CP Response, at 6–7 (emphasis added). In other words, 505(b)(2) "requires certifications to patents listed **for the drug product relied on for approval**, but **not** to patents for all other drug products that contain the same drug substance and rely on the same underlying investigations." *Id.* at 7 (emphasis in original); *see also id.* at 10–11 fn. 15 ("505(b)(2) applicants are not obligated to certify to patents for other drug products on whose findings of safety and effectiveness they do not seek to rely."). This enforces the statute's "relationship between reliance and certification." *Id.* at 7.

In a 2013 decision, FDA explained that an applicant's "patent certification obligations are limited to those patents that claim the *specific listed drug* upon which the applicant has relied for FDA's finding of safety and effectiveness to support the approval of the NDA." FDA, Citizen Petition Response Re: Docket Nos. FDA-2011-P-0869 and FDA-2013-P-0995, Sept. 18, 2013 ["2013 CP Response"], Takeda Reply, Ex. C at 4 (emphasis in original). That is also consistent with FDA's 2011 citizen petition decision to Mutual/Takeda, in which it explained that a hypothetical 505(b)(2) applicant would not need to certify to patents related to Colcrys® if the applicant did not rely on Colcrys® as the listed drug for approval. FDA, Citizen Petition Response Re: Docket No. FDA-2010-P-0614, May 25, 2011 ["Mutual CP Response"], Wong Decl. Ex. A at 21.

Elliott argues that these interpretations conflict with FDA's own regulation. Not so. The relevant regulation promulgated by FDA is at 21 C.F.R. § 314.50(i)(1), and it tracks exactly with the plain reading of § 355(b)(2)(A). This regulation states that "[a] 505(b)(2) application is required to contain the following":

> *Patent claiming drug, drug product, or method of use.*
>
> Except as provided in paragraph (i)(2) of this section, a certification with respect to each patent… that … claims a drug (the drug product or drug substance that is a component of the drug product) on which investigations that are relied upon by the applicant for approval of its application were conducted or that claims an approved use for such drug and for which information is required to be filed under section 505(b) and (c) of the act and 314.53.

§ 314.50(i)(1)(i) (emphasis added). The regulation again makes clear that the applicant must certify to method of use patents that claim an approved use for "such drug"—*i.e.*, the listed drug product "on which investigations that are relied upon by the applicant for approval" were conducted. Moreover, the regulation recites "that claims an approved use for such drug," revealing that FDA interprets the clause "for which the applicant is seeking approval" in the statute to modify the term "use," not "such drug."

Elliott altogether ignores § 314.50(i)(1)(i), and instead relies solely on § 314.50(i)(1)(iii). Dkt. #14-2 at 26–27. But such reliance is misguided. Section 314.50(i)(1)(iii) makes clear that if an applicant chooses to make a patent certification, such "applicable certification" must be submitted under the rules of § 314.50(i)(1)(i). And, again, subsection (1)(i) requires certification to method of use patents that claim an approved use for the *listed drug product*.

Elliott also conveniently disregards FDA's Guidance on 505(b)(2) applications, which is entirely consistent with Hikma's reading of the statute and regulations. The Guidance states that a 505(b)(2) applicant must make a patent certification "with respect to any relevant *patents that claim the listed drug* and that claim any other drugs *on which the investigations relied on by the applicant for approval* were conducted, *or that claim a use for the listed* or other *drug* (21 CFR 314.54(a)(1)(vi))." FDA, Guidance For Industry: Applications Covered by Section 505(b)(2), Oct. 1999, Tsien Decl. Ex. E, at 8 (emphasis added). The Guidance further defines "listed drug"

as the drug product, not the drug substance. *Id.* at 11. Thus, certification is only required to patents that claim the listed drug product itself, or a use for the listed drug product.

Whether in its regulations, guidance, or citizen petition decisions, FDA has consistently interpreted § 355(b)(2)(A) of Hatch-Waxman to require that a 505(b)(2) applicant make a patent certification only to patents that claim the listed drug product or uses of that listed drug product. Far from being merely a convenient litigating position (*see* Dkt. #14-2 at 26–27), FDA's interpretation is fair and reasonable, and thus entitled to agency deference. *Mead Corp.*, 533 U.S. at 227 ("[An agency] regulation [interpreting an ambiguous statute] is binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute.").

III. FDA did not act arbitrarily or capriciously in approving Hikma's 505(b)(2) application—the agency did not deviate from any existing policies or regulations.

Elliott makes four arguments as to how FDA allegedly violated its own policies and practices: (1) FDA does not permit "circumvention" of the patent protections of the ANDA process; (2) FDA requires that the applicant rely on the "most similar" prior drug; (3) FDA requires certification to method of use patents for a particular indication; and (4) FDA regulations in 21 C.F.R. § 314.50(i)(1)(iii)(B) require an applicant to submit an "applicable" certification for an indication "claimed by a use patent." Dkt. #14-2 at 28–36. All four arguments are meritless. In fact, Hikma has already addressed similar arguments raised by Takeda. Opposition to Motion for Preliminary Injunction, 1:14-cv-01668-(KBJ), Dkt. 16, at 18–21.

First, Elliott's circumvention argument is circular. Hikma did not circumvent the statute. It undertook a statutorily approved pathway and certified to all applicable patents, i.e., none. Elliott attempts to analogize to the ANDA context described in FDA's Fenofibrate CP Response,

where FDA explained that "an ANDA applicant seeking approval for a tablet should cite the approved tablet as the reference listed drug," and not the capsule. Dkt. #14-2 at 29 (citing Fenofibrate CP Response at 9 n.13). FDA already addressed this authority in the context of Mutual's citizen petition, however. In that context, FDA ruled that Hikma could not file a 505(b)(2) application for a "duplicate" of Colcrys®, i.e., a tablet. That is, if Hikma sought approval of a colchicine tablet, it had to file an ANDA referencing the Colcrys® tablet. But this authority has no application here because Hikma obtained approval for a different dosage form, i.e., a *capsule*, which was not a duplicate of any listed drug. *See also* Mutual CP Response, at 2–3.

Second, as had been addressed repeatedly throughout this litigation, there is simply no requirement that a 505(b)(2) applicant choose the "most similar" drug to rely on in the FDA approval process. In its 2013 Citizen Petition decision, FDA made clear that it is the "*sponsor* interested in submitting a 505(b)(2) application" that "*should determine* which listed drug(s) is most appropriate for its development program, and must establish that such reliance is scientifically appropriate." 2013 CP Response, at 3 (emphasis added). Indeed, FDA allows an applicant to rely on any listed drug "to the extent such reliance is *scientifically justified*." FDA, Citizen Petition Response Re: Dockets Nos. 2011P-0323/CP1 & C5, 2002P-0447/CP1, and 2003-0408/CP1, Oct. 14, 2003, Wong Suppl. Decl. Ex. B at 12 (emphasis added). FDA only requires that the "505(b)(2) application must include sufficient data to support any differences between the proposed drug and the listed drug(s) and demonstrate that the proposed drug product meets the statutory approval standard for safety and efficacy." 2013 CP Response at 3; *see also* 21 C.F.R. § 314.54 (requiring 505(b)(2) applications to include only "information needed to support the modification(s) of the listed drug").

Although FDA suggested in the 2004 Citizen Petition decision that a "505(b)(2) applicant should choose the listed drug or drugs that are most similar to the drug for which approval is sought," Fenofibrate CP Response at 9, it later clarified that "this suggested approach *does not reflect a statutory or regulatory requirement*," 2013 CP Response at 7 (emphasis added). Indeed, there is no such requirement because the "determination of which listed drug is 'most similar' to the proposed product may be difficult . . . and dependent on the sponsor's approach to its development program." *Id.* at 3. "Accordingly, a sponsor . . . should determine which listed drug(s) is most appropriate" for its development program. *Id.* If that program were designed to limit costs, the applicant could choose the "most similar" drug. But if that program were designed to expedite approval by avoiding patents, the applicant would have discretion to choose a different drug, as long as the applicant could meet the approval requirements.

Elliott's contrary reading would turn FDA into a patent police. But FDA has specifically disclaimed that role. Again, FDA "lacks 'both [the] expertise and [the] authority' to review patent claims" and thus views "its own 'role with respect to patent listing [a]s ministerial.'" *Caraco Pharm. Labs.*, 132 S. Ct. at 1677 (quoting 68 Fed. Reg. 36683 (2003)). The agency has thus limited its role in patent disputes as much as possible and, indeed, even decided that it was not its role to determine whether patents submitted by NDA holders were properly listed in the Orange Book. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003).

Finally, Elliott's last two arguments tread old ground. Both rely on the erroneous notion that FDA requires certification for *any* method of use patent that claims the drug *substance* for that use. But that is not the case: the statute is clear, as is FDA's statutory interpretation. A patent certification is required only for patents that claim the listed drug product or a use for such listed drug product *on which the applicant relied* for approval. Again, 505(b)(2) "requires

certifications to patents listed **for the drug product relied on for approval**, but **not** to patents for all other drug products that contain the same drug substance and rely on the same underlying investigations." Fenofibrate CP Response, at 7 (emphasis in original). That drug product here is Col-Probenecid, not the drug substance colchicine—and certainly not Takeda's drug product, Colcrys®. Thus, there is no basis to require that Hikma certify to any of Takeda's patents.

CONCLUSION

For these reasons, the Court should deny Elliott's motion for summary judgment, grant Hikma's cross-motion for summary judgment, and dismiss Elliott's complaint with prejudice.

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