UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ELLIOTT ASSOCIATES, L.P., *et al.*, Plaintiffs,	)	
v.	)	Civil Action No. 14-1850 (KBJ)
SYLVIA BURWELL, Secretary of Health and Human Services, *et al*., Defendants.	)	
and	)	
HIKMA PHARMACEUTICALS PLC AND WEST-WARD PHARMACEUTICAL CORP., Intervenor-Defendants.	)	

DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Plaintiffs Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P. (collectively, "Elliott") filed a complaint and moved for summary judgment nearly two months after the similar, and now consolidated, case, *Takeda v. Burwell*, civil action no. 14-1668 (KBL), was initiated. Because the Court is well-versed in the facts and issues raised in *Takeda*, FDA will not repeat those here.[1] The only new challenge Elliott raises regarding FDA's approval of West-Ward's colchicine product, Mitigare, is a statutory interpretation argument. Elliott claims that Section 505(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act ("FDCA"),

[1] The government is cross-moving for summary judgment to provide the Court with a vehicle with which to dispose of the entire case. Because the government does not intend to submit further briefing (unless requested by the Court), this cross-motion should not impact the timing of resolution of the case previously agreed upon by the parties.

21 U.S.C. § 355(b)(2)(A), requires applicants to certify to all patents claiming uses of the active ingredient in the product being submitted for approval. Elliott contends that this certification requirement applies even if the patent is not listed in the Orange Book for the drug product on which the 505(b)(2) application relies, but rather is listed for another drug product (in this instance, Colcrys) that contains the same active ingredient as the listed drug upon which West-Ward relied. FDA's long-standing interpretation of section 505(b)(2)(A), on the other hand, requires applicants to submit certifications only for the patents listed in the Orange Book for the listed drug upon which the applicant relies (here, Col-Probenecid).

Elliott's interpretation finds no support in the language of the FDCA or its implementing regulations, or in the legislative history. Indeed, as the Court noted during oral argument, *see* Transcript of Motions Hearing dated Nov. 19, 2014 ("Transcript") at 82,[2] it is difficult to imagine Congress using such opaque language if it intended the meaning that Elliott attributes to section 505(b)(2)(A). Elliott's interpretation also contravenes the quid pro quo created by the Hatch-Waxman Amendments whereby applicants can rely on FDA's findings of safety and effectiveness for previously-approved drug products so long as those applicants also certify to patents listed for the previously-approved drug products.[3] FDA's interpretation of section 505(b)(2)(A) furthers the dual goals of the Hatch-Waxman Amendments – to get more drugs to market quickly while protecting innovators' patent rights; meanwhile, Elliott's interpretation would confer the benefit of FDCA patent protections on some patent owners without those patent owners having to share their data with other drug manufacturers in return. Because FDA's

[2] The relevant portions of the transcript are attached as Exhibit A.

[3] For the full statutory background on drug applications and patent certifications, see Defs.' Opp'n to Pl.'s Mot. for a TRO and/or PI at 4-7 (Doc. #15).

interpretation easily passes muster under the deferential standard of *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), Elliott's claims lack merit, and judgment should be entered in favor of FDA.

BACKGROUND[4]

Section 505(b)(2) of the FDCA provides:

> An application submitted under [21 U.S.C. § 355(b)(1)] for a drug for which the investigations described in [21 U.S.C. § 355(b)(1)(A)] 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 the subsection and for which information is required to be filed …

21 U.S.C. § 355(b)(2). FDA's implementing regulation, 21 C.F.R. § 314.50(i), mirrors section 505(b)(2). Both the statute and regulation require 505(b)(2) applicants to submit patent certifications to product patents (patents covering the drug product or drug substance that is a component of the drug product) and use patents (patents covering approved methods of using the product). 21 U.S.C. § 355(b)(2)(A); 21 C.F.R. § 314.50(i)(1)(i).

ARGUMENT

The plain text of section 505(b)(2) is ambiguous because it does not define the term "drug," and the word itself could mean active ingredient or finished drug product. FDA has interpreted "drug" in this provision to mean drug product rather than active ingredient. Despite the ambiguity in section 505(b)(2) and FDA's long-standing interpretation of that term, Elliott

[4] For the full statutory and factual background, see Defs.' Opp'n to Pl.'s Mot. for a TRO and/or PI at 4-10 (Doc. #15).

nonetheless argues that the statutory provision is unambiguous and means the opposite of FDA's stated interpretation. For Elliott's argument to succeed, one would have to interpret "drug" to mean finished drug product in the first half of section 505(b)(2)(A) (regarding product patents) and "such drug" to mean active ingredient in the second half of section 505(b)(2)(A) (regarding use patents). And Elliott claims that this convoluted interpretation somehow stems from the "plain text" of the FDCA. Not only is it hard to comprehend why Congress would give different meanings to the same word in the same sentence of a statute without explicitly noting the definition change, but Elliott's contention also disrupts the delicate balance between generic and innovator manufacturers that Congress established with the Hatch-Waxman Amendments. FDA's interpretation, on the other hand, logically gives the word "drug" the same meaning throughout section 505(b)(2), and also furthers the goals of the Hatch-Waxman Amendments.

I. Standard of Review

The usual summary judgment standard does not apply in cases involving review of final agency action under the APA "because of the limited role of a court in reviewing the administrative record." *ViroPharma, Inc. v. Hamburg*, 916 F. Supp. 2d 76, 79 (D.D.C. 2013). In such cases, "the agency resolves factual issues to arrive at a decision that is supported by the administrative record," and summary judgment is "the mechanism for deciding whether as a matter of law the agency action is supported by the administrative record and is otherwise consistent with the [Administrative Procedure Act] standard of review." *Coal. for Common Sense in Gov't Procurement v. United States*, 821 F. Supp. 2d 275, 280 (D.D.C. 2011), *aff'd*, 707 F.3d 311 (D.C. Cir. 2013); *see also Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 13, 18 (D.D.C. 2008) (same); *Fund for Animals v. Babbitt*, 903 F. Supp. 96, 105 (D.D.C. 1995) (summary judgment is "an appropriate procedure for resolving a challenge to a federal agency's

administrative decision" when, as here, "review is based upon the administrative record.") (citing *Richards v. INS*, 554 F.2d 1173, 1177 (D.C. Cir. 1977)).

Under the highly deferential APA standard of review, FDA's administrative decisions may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Indeed, the agency's administrative decision is entitled to a presumption of validity. *American Wildlands v. Kempthorne*, 530 F.3d 991, 997 (D.C. Cir. 2008); *AT&T Corp. v. FCC*, 349 F.3d 692, 698 (D.C. Cir. 2003). Elliott, as "the party challenging an agency's action as arbitrary and capricious[,] bears the burden of proof." *San Luis Obispo Mothers for Peace v. NRC*, 789 F.2d 26, 37 (D.C. Cir. 1986); *see also City of Olmsted Falls v. FAA*, 292 F.3d 261, 271 (D.C. Cir. 2002). The reviewing court considers whether the agency's decision was based upon consideration of the relevant factors and whether there has been a clear error of judgment. *Overton Park*, 401 U.S. at 416. However, a reviewing court is "not empowered to substitute its judgment for that of the agency," *id.,* and must uphold the agency's action so long as it is "rational, based upon consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute." *Motor Vehicle Mfrs. Ass'n, Inc., v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

Moreover, in reviewing the FDA's interpretation of the FDCA, the Court is governed by the familiar two-step analysis of *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). The first question under *Chevron* is "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If, however, as here, the statute "is silent or ambiguous with respect to the specific issue," the Court proceeds to the second prong of *Chevron*, under which "the question for the court is whether the agency's answer is based on a permissible

construction of the statute." *Chevron*, 467 U.S. at 843. The court need not find that the agency construction was the only one it permissibly could have adopted or even the reading the court would have reached; so long as the agency's reading is permissible, it must be sustained. *See Chevron*, 467 U.S. at 843-44 & n.11; *Mylan Pharms., Inc. v. Sebelius*, 856 F. Supp. 2d 196, 208 (D.D.C. 2012). The Supreme Court has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *United States v. Mead Corp.*, 533 U.S. 218, 227-28 (2001) (quoting *Chevron*, 467 U.S. at 844); *see also Udall v. Tallman*, 380 U.S. 1, 16 (1965); *Sara Lee Corp. v. Am. Bakers Ass'n Retirement Plan*, 512 F. Supp. 2d 32, 37 (D.D.C. 2007).

When a court is evaluating an agency's interpretation of its own regulations, the agency is entitled to "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *United States Air Tour Ass'n v. FAA*, 298 F.3d 997, 1005 (D.C. Cir. 2002); *see also Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006) ("We have held on a number of occasions that FDA interpretations of the [FDCA] receive deference, as do its interpretations of its own regulations unless plainly erroneous or inconsistent with the regulations."). A court's task "is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Thomas Jefferson Univ.*, 512 U.S. at 512 (internal quotation and citation omitted). Deference is especially appropriate when the statutory and regulatory regimes implemented by the agency are complex. *See Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 766 (D.C. Cir. 2010).

II. Elliott's Statutory Interpretation Argument Fails at Chevron Step 1 Because the Term "Such Drug" is Ambiguous

Section 505(b)(2)(A) requires an applicant to submit a certification "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." 21 U.S.C. § 355(b)(2)(A). Elliott claims that the words "for which the applicant is seeking approval" modifies "such drug" rather than "use," and therefore that section 505(b)(2)(A) requires applicants to certify to product patents listed for the approved drug for which the relied-upon investigations were conducted and to method-of-use patents listed for the active ingredient in the product being proposed for approval. *See*, *e.g.*, Elliott Br. at 1-2, 12-14. Moreover, Elliott argues that these patent certification requirements are clear from the plain text of the statute. *Id*. Elliott is wrong.

The word "drug" can have different meanings in different contexts, *see* 21 U.S.C. § 321(g)(1), and can refer to a finished drug product or an active ingredient. *See*, *e.g.*, *Pfizer Inc. v. FDA*, 753 F. Supp. 171, 176 (D. Md. 1990). Not surprisingly, then, courts have found the term "drug" as used in the FDCA to be ambiguous. *See Baker Norton Pharms. v. FDA*, 132 F. Supp. 2d 30, 36 (2001) ("Given the multiple definitions of the term 'drug,' and the differing purposes that various statutory provisions can serve, the Court cannot find that the definition of 'drug' in § 360cc(a) is clear and unambiguous. The Court finds it more likely that Congress left it to the FDA to determine which definition fits a particular statutory section."); *Nat'l Pharm. Alliance v. Henney*, 47 F. Supp. 2d 37, 39-40 (D.D.C. 1999).

Despite the ambiguity of the word "drug" in section 505(b)(2)(A), Elliott nonetheless contends that this is a Chevron step 1 case. *See*, *e.g.*, Transcript at 80. The crux of Elliott's argument is that "the drug for which such investigations were conducted" refers to the listed drug

relied upon in the 505(b)(2) application (here, Col-Probenecid) and "a use for such drug for which the applicant is seeking approval" refers to the active ingredient in the product for which approval is being sought (here, colchicine). *See*, *e.g.*, Elliott Br. at 2, 12, 15-16. In other words, Elliott is not only asking this Court to conclude that Congress intended the word "drug" to have two very different meanings in the same sentence of a single statutory provision, but also that such distinction is unambiguous from the plain language of the statute.[5] As this Court noted, if that was what Congress meant, "they came up with a very sort of opaque way of expressing it in the statute." Transcript at 82.

The following section, 505(b)(2)(B), confirms FDA's interpretation of Section 505(b)(2)(A) – and in particular the agency's reasonable conclusion that the phrase "for which the applicant is seeking approval" modifies "use" rather than "such drug." Section 505(b)(2)(B) provides, "if with respect to the drug for which investigations . . . were conducted information was filed . . . for a method of use patent which does not claim a use for which the applicant is

[5] Moreover, Elliott's interpretation of the statutory provision (i.e., "drug" meaning both finished drug product and active ingredient in the same sentence) would lead to unreasonable results at odds with the purpose of the patent listing and certification requirements. In other words, assuming *arguendo* that Elliott were correct that "for which the applicant is seeking approval" modifies "such drug" rather than "use" and therefore refers to the drug being submitted for approval rather than the listed drug relied on in the 505(b)(2) application, that drug would be Mitigare, not colchicine. FDA previously explained, in a 2004 citizen petition response concerning fenofibrate, that "[a]pplications are submitted for drug products, not drug substances or active ingredients." Fenofibrate CP response at 7.[5] In this matter, West-Ward did not seek approval for "colchicine" in its 505(b)(2) application but rather sought approval for Mitigare, a 0.6 mg colchicine capsule (with additional inactive ingredients) indicated for the prophylaxis of gout flares. But of course because Mitigare was not yet approved when its application for approval was submitted, there were no method-of-use patents listed because patents are only listed for approved drug products. The same would be true for every product seeking approval with a 505(b)(2) application. The objective of the patent listing and certification scheme under the FDCA is notice, and Elliott's reading of section 505(b)(2)(A), taken to its logical conclusion, would eliminate that notice for use patents. Moreover, why would a manufacturer certify to its own patent?

seeking approval," then the applicant must file "a statement that the method of use patent does not claim such a use." 21 U.S.C. § 355(b)(2)(B). Thus, section 505(b)(2)(B) operates in parallel to section 505(b)(2)(A) by requiring the applicant to indicate when it is not seeking approval for a use claimed by a patent listed for the approved drug upon which it relied. Notably, section 505(b)(2)(B) does not include the term "such drug" but does include the phrase "for which the applicant is seeking approval" when discussing use patents. When subparagraphs (A) and (B) are read in conjunction under FDA's interpretation, the certification requirements and "not-seeking-approval" statement together cover all use patents listed for the approved drug relied on, whether or not the 505(b)(2) applicant is seeking approval for a patented use. Under Elliott's interpretation, however, the certification requirement of section 505(b)(2)(A) would apply to use patents listed for the approved drug relied on and any other drug products that contain the same active ingredient, while the requirement of section 505(b)(2)(B) to file a statement when not seeking approval for a patented use applies only to use patents listed for the approved drug relied on – a disjointed and nonsensical result.

Elliott's reliance on the legislative history of the Hatch-Waxman Amendments to support its Chevron step one argument, Elliott Br. at 19-22, fares no better. Nothing Elliott cites even suggests, much less establishes, that the use patents discussed by Congress are tied to active ingredient rather than finished drug product. For example, Elliott repeatedly mentions "controlling use patents," claiming that the Colcrys patents are the controlling use patents here. Elliott Br. at 20. But Elliott itself defines controlling use patents as patents that "'claim an indication for the drug for which the applicant is seeking approval[.]'" *Id.* (quoting the House Committee on Energy and Commerce Report at 32). As with the nearly identical language in section 505(b)(2)(A), this language could refer to patents listed in the Orange Book for the

approved drug relied on that cover an indication for which an applicant is seeking approval, and does not unambiguously mean all method-of-use patents listed in the Orange Book that cover the active ingredient in the product for which an applicant is seeking approval.

Elliott's discussion of the purpose of the Hatch-Waxman Amendments and patent protections fails to answer the one question that this Court posed more than once at oral argument: Why would an applicant have to certify to a patent that is listed for a drug product on whose information the applicant does not rely for approval? *See* Transcript at 72, 75, 89, 103, 105-07. There is no quid pro quo in the scenario that Elliott proposes; there is only a benefit for patent owners whose data is not being relied on by another manufacturer. Elliott's recitation of the patent certification and infringement lawsuit process explains the interplay between patent protections and the timing of approval of drug applications that rely for approval on previously-approved drug products, *see* Elliott Br. at 23-25, but fails to address the situation here, where an applicant has not relied on a drug product for which patents are listed. In other words, Elliott has failed to show that the "overall structure and purpose of the Hatch-Waxman Amendments" support Elliott's argument that an applicant must certify not only to those patents listed for the drug product on which the applicant relies for approval, but also all patents listed for the active ingredient in the drug product for which the applicant is seeking approval. Indeed, FDA stated in the fenofibrate CP response:[6] "To divorce patent certification obligations from reliance and require [petitioner] to certify to patents on additional drug products on which FDA did not rely for approval would upset the delicate balance struck by the Hatch-Waxman Amendments." *See* Exhibit B at 11.

[6] The fenofibrate CP response is attached as Exhibit B.

III. FDA's Interpretation Easily Satisfies Chevron Step 2

At Chevron step 2, an agency's interpretation "is given controlling weight unless it is manifestly contrary to the statute." *ViroPharma*, 916 F. Supp. 2d at 79 (internal quotation and citation omitted). FDA's interpretation of "such drug" in section 505(b)(2) to mean drug product rather than active ingredient is reasonable and furthers the underlying goals of the Hatch-Waxman Amendments. As FDA explained in the fenofibrate CP response:

> [t]he language of section 505(b)(2) of the Act explicitly links the *drug* relied on for approval to the *drug* for which patent certifications must be made. Consistent with its interpretation of section 505(b)(1) discussed above, FDA interprets *drug* in section 505(b)(2) to refer to *drug product*, not *active ingredient*.

Exhibit B at 6-7 (emphasis in original).

Moreover, "[t]he FDA's interpretation of the term 'drug' in § 355 as meaning a particular drug product is consistent with the intent of Congress in enacting both a streamlined approval process for generic drugs and additional marketing protection for pioneer drugs, under certain circumstances." *Pfizer Inc. v. FDA*, 753 F. Supp. 171, 177 (D. Md. 1990). Indeed,

> The legislative history of the 1984 Amendments indicates that Congress was concerned about extending patent protection for pioneer drugs where the necessary regulatory delay to obtain FDA approval before marketing had effectively shortened the period of protection otherwise afforded by the patent. Congress also wished to compensate pioneer manufacturers for the public benefit provided by allowing generic copiers to rely on the pioneer's safety and effectiveness data.

Id. (citing H.R.Rep. No. 857 at 2648). Elliott has not shown, and cannot show, that FDA's interpretation is unreasonable or contrary to congressional intent.

Elliott claims that FDA is "rewriting the statute and is conflating two separate certification requirements in Section 505(b)(2)(A)," namely the product patent and use patent certification requirements. Elliott Br. at 16. Elliott contends that the certification requirement

for use patents focuses "on the uses for the drug for which the applicant is seeking approval, not the investigations upon which the applicant relies." *Id.* There is no dispute that the use patent certification provision focuses on uses for which the applicant is seeking approval, as opposed to the investigations upon which the applicant relied, or patented uses for which the applicant is not seeking approval. Elliott's undisputed restatement of the statute, however, does not address the question at issue, namely, whether "such drug" refers to drug product (i.e., Col-Probenecid or Colcrys) or active ingredient (i.e., colchicine).

Elliott contends that FDA's interpretation deletes the language "for which the applicant is seeking approval" from the statute, Elliott Br. at 17, but FDA's interpretation in fact distinguishes patented uses for which the applicant is seeking approval from patented uses for which the applicant is not seeking approval. Although neither of the patent certification requirements from section 505(b)(2)(A) apply here because no patents are listed for Col-Probenecid (the listed drug upon which West-Ward relied), if, hypothetically, there were two method-of-use patents listed for Col-Probenecid, one concerning prophylaxis of gout flares and one concerning treatment of acute gout flares, and West-Ward were seeking approval of Mitigare only for prophylaxis of gout flares, then West-Ward would only have to file a certification to the patent concerning that use (i.e., the use of Col-Probenecid "for which the applicant is seeking approval").[7] FDA agrees with Elliott that section 505(b)(2)(B) makes the meaning of section 505(b)(2)(A) abundantly clear: section 505(b)(2)(B) dictates what an applicant must file when not seeking approval of a use covered by a relevant patent, while 505(b)(2)(A) dictates what an

[7] In that hypothetical situation, West-Ward would also have had to file a statement pursuant to section 505(b)(2)(B) explaining that the use patent listed for Col-Probenecid for treatment of acute gout flares does not claim a use for which the applicant is seeking approval.

applicant must file when seeking approval of a use covered by a relevant patent. Elliott Br. at 18-19.[8]

Elliott contends that one subsection of an FDA regulation, 21 C.F.R. § 314.50(i)(1)(iii)(B), constitutes FDA's interpretation of section 505(b)(2) and that this subsection comports with Elliott's interpretation. Elliott Br. at 26-27. Elliott provides no authority for its claim that subsection 314.50(i)(1)(iii)(B), and only that subsection, is FDA's interpretation of section 505(b)(2)(A). The regulation details the information that must be contained in drug applications, and subsection (i) discusses patent certifications. 21 C.F.R. § 314.50(i). The language of subsection (i)(1)(i) is very similar to section 505(b)(2)(A) of the FDCA, requiring patent certifications for each patent that claims a drug "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." 21 C.F.R. § 314.50(i)(1)(i)(A). The subsection on which Elliott relies, subsection (i)(1)(iii)(B), itself refers back to subsection (i)(1)(i), which discusses patent certifications using the same language as section 505(b)(2)(A). Despite Elliott's attempt to do so, subsection (i)(1)(iii)(B) cannot be read in isolation from the remainder of the regulation. More importantly, the regulation supports FDA's interpretation that only use patents listed for the approved drug relied on must be certified to by 505(b)(2) applicants.

[8] Elliott's reliance on other provisions of the FDCA that use the phrase "such drug" without modification, Elliott Br. at 18, is similarly misplaced. Neither of the provisions that Elliott cites needed to differentiate between use(s) for which an applicant is and is not seeking approval because the difference is not relevant to those provisions.

IV. FDA Did Not Otherwise Act in an Arbitrary and Capricious Manner in Approving Mitigare

Elliott raises several other claims alleging that FDA acted in an arbitrary and capricious manner when approving Mitigare. All of these claims lack merit.

FDA followed the agency policy that Elliott claims FDA violated – requiring 505(b)(2) applicants to comply with the same patent certification requirements with which ANDA applicants must comply. Consistent with the 2004 fenofibrate CP response cited by Elliott (*see* Elliott Br. at 29), FDA, in its 2011 citizen petition response on colchicine, refused to allow West-Ward to submit a duplicate to Colcrys under section 505(b)(2). *See* AR at 12. The suboxone citizen petition response[9] on which Elliott also relies, Elliott Br. at 30, echoes the same general rule: "if there is a listed drug that is a 'pharmaceutical equivalent' [i.e., duplicate] to the proposed drug product, FDA advises that a sponsor should identify the pharmaceutically equivalent product as a listed drug relied upon and provide patent certifications for the patents listed for the pharmaceutically equivalent drug." *See* Exhibit C at 3-4. The fenofibrate CP response noes that the patent certification requirements are the same for 505(b)(2) and ANDA applicants:

> Just as ANDAs need only certify to patents on the listed drugs they reference and on which they rely for approval (and not to patents on other products in the product lines that reference the same underlying investigations that supported the approval of the listed drug referenced), so too, are 505(b)(2) applicant's patent certification obligations correlated to patents on the listed drug or drugs relied on for approval.

See Exhibit B at 8.

[9] The suboxone CP response is attached as Exhibit C.

Elliott claims that 505(b)(2) applicants must make the same patent certifications as ANDA applicants. Elliott Br. at 21. Notably, however, ANDAs need only include certifications for each patent "which claims a use for such listed drug for which the applicant is seeking approval under this subsection." 21 U.S.C. § 355(j)(2)(A)(vii). By the express terms of the statute, the certification requirement for ANDAs applies only to method-of-use patents for which patent information is required to be filed for the RLD, which is the very interpretation that FDA has adopted and that Elliott is challenging in this case. FDA did not fail to apply or otherwise violate any agency policy that prohibits 505(b)(2) applicants from "circumventing the FDCA's patent certification requirements," Elliott Br. at 29, but rather consistently applied its well-established policy by not requiring West-Ward to certify to the Colcrys patents because Colcrys is not the listed drug relied on by Mitigare.[10]

Like Takeda, Elliott argues that because FDA requires 505(b)(2) sponsors to choose the "most similar" listed drug to reference, West-Ward was required to reference Colcrys. Elliott Br. at 32-33. Both Takeda and Elliott are mistaken. The suboxone CP response explains:

> The Fenofibrate CP response describes a suggested approach intended to enhance the efficiency of a prospective 505(b)(2) applicant's development program. An applicant choosing to rely on FDA's finding of safety and/or effectiveness for a listed drug very similar to the proposed product submitted in the 505(b)(2) application would generally need to submit less additional data to support the differences between the proposed product and the listed drug for approval in the 505(b)(2) application. However, as stated in the Fenofibrate CP response, this suggested approach does not reflect a statutory or regulatory requirement. Further, the determination of which listed drug is "most similar" to a proposed product may be difficult (except in cases in which a pharmaceutical equivalent previously has been approved) and dependent on the sponsor's approach to its development program. Accordingly, a sponsor interested in submitting a

[10] Elliott states, "[n]otwithstanding this superficial change [from tablet to capsule], it is obvious that the reference drug [for Mitigare] is still Colcrys." Elliott Br. at 31. There is no doubt that Elliott would like Colcrys to be the reference drug for Mitigare, but the listed drug relied on for approval in the Mitigare application was in fact Col-Probenecid, not Colcrys.

> 505(b)(2) application that relies upon FDA's finding of safety and/or effectiveness for one or more listed drugs should determine which listed drug(s) is most appropriate for its development program.

Exhibit C at 7; *see also id.* at 3 ("A sponsor interested in submitted a 505(b)(2) application that relies upon FDA's finding of safety and/or effectiveness for one or more listed drugs should determine which listed drug(s) is most appropriate for its development program, and must establish that such reliance is scientifically appropriate.").

As the above response makes clear, so long as a sponsor provides the necessary data and information to support the difference(s) between the reference drug and its proposed drug, and so long as the proposed drug is not an exact duplicate of the reference drug, a sponsor is free to choose the listed drug that *it* deems most appropriate for reliance in its 505(b)(2) application. Here, FDA concluded that Mitigare is safe and effective, based on West-Ward's reliance on FDA's prior safety and effectiveness finding for Col-Probenecid, as well as data and information submitted in West-Ward's application. *See* AR at 119-120, 97-98. West-Ward determined that Col-Probenecid was in fact the "most appropriate" listed drug for Mitigare to rely upon, and Elliott has not provided, and cannot provide, any authority for its contention that West-Ward was required to reference Colcrys in the Mitigare 505(b)(2) application.

Finally, Elliott claims that "longstanding FDA policy makes clear that patents claiming the indication for which approval is sought must be addressed through the certification process." Elliott Br. at 33-35. The regulations Elliott cites to support this notion contain the technical aspects (including the "use codes" mentioned by Elliott) regarding how FDA, an agency lacking patent expertise, administers the listing of, and certifications to, patents in the Orange Book. At bottom, however, Elliott is making the same argument that it has made throughout its brief: that the patent certification requirements for method-of-use patents are not limited to patents listed

for the reference drug. But the discussion of use codes and indications provides no more support for this contention than Elliott has provided previously, and thus this argument should similarly be rejected by the Court.

CONCLUSION

In sum, FDA's approval of Mitigare was fully consistent with the FDCA and its implementing regulations. FDA's interpretation of section 505(b)(2)(A) is reasonable and easily passes muster under Chevron step 2. Moreover, FDA did not depart from any established policy or otherwise act in an arbitrary and capricious manner when the agency approved Mitigare. Elliott's belated effort to preserve its profits by challenging FDA's expert opinion that Mitigare met the statutory approval standards must be rejected. For the foregoing reasons, as well as those detailed in FDA's prior filings, judgment should be entered in favor of the government.

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December 9, 2014

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CERTIFICATE OF SERVICE

I certify that on December 9, 2014, I caused a true and correct copy of the above-entitled Defendants' Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment to be served via the Court's Electronic Case Filing system to counsel for all plaintiffs and counsel for intervenors in Case Nos. 1:14-cv-01668-(KBJ) and 1:14-cv-01850-(KBJ).

s/ JESSICA R. GUNDER
JESSICA R. GUNDER