UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS END-PAYOR ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:13-cv-9244-RA-SDA
IN RE ACTOS DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:15-cv-3278-RA-SDA

TAKEDA'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO CERTIFY AN INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(b)

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INTRODUCTION

Takeda respectfully requests that this Court certify for interlocutory appeal the September 30, 2019 Opinion and Order denying Takeda's motion to dismiss the End Payor Plaintiffs' Fourth Amended Complaint (Case No. 1:13-cv-9244, ECF No. 272) (the "EPP Order") and the October 8, 2019 Opinion and Order granting in part and denying in part Defendants' motions to dismiss the Direct Purchaser Plaintiffs' Third Amended Complaint (Case No. 1:15-cv-3278, ECF No. 131) (the "DPP Order" and, collectively, the "Orders").[1]

The Orders meet all the requirements for interlocutory review. Prompt appellate review is necessary to address a controlling question of law that could obviate the need for prolonged, costly, and complex litigation, and resolve industry-wide uncertainty concerning a key component of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act")—uncertainty that will be sown by the irreconcilable conflict between the interpretation adopted in the Orders, on the one hand, and the statute's plain language, decades of FDA guidance, and industry practice on the other.

First, the Orders decided an issue of first impression concerning the requirements of Section 355(b)(1) of the Hatch-Waxman Act. This is a controlling question of law because the only claims remaining in this litigation are based on the contention that Takeda's listing of two patents in the Orange Book did not comply with Section 355(b)(1). If Takeda's interpretation of the statute is adopted, Plaintiffs' lawsuits would be dismissed in their entirety.

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[1] The DPP Order adopts the reasoning of the EPP Order with respect to the allegedly improper patent listings in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." (DPP Order 12-13.) Accordingly, for convenience, this memorandum cites to the EPP Order, but the arguments herein apply equally to the DPP Order.

Second, there is at least substantial ground for difference of opinion regarding the proper interpretation of the statutory language. The Court adopted a reading of Section 355(b)(1) that was not advanced by Plaintiffs and that Takeda therefore had no opportunity to address. That interpretation cannot be squared with the plain language of the statute. And, it conflicts with the interpretation given to the statute by the FDA, the expert regulatory agency tasked with administering the statute, and which is entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984); industry participants, including the generic drug defendants in this action; and the Plaintiffs themselves. The weight of this authority confirms Takeda's interpretation of the listing statute; but at a minimum, there are substantial grounds for difference of opinion about the Court's unprecedented interpretation of Section 355(b)(1) that warrant immediate appellate review.

Third, an interlocutory appeal would materially advance the ultimate termination of this lawsuit and resolve industry-wide uncertainty that has been introduced by the Orders. If the Court of Appeals were to agree with Takeda's construction of the statutory language, that would put an end to these lawsuits, and thereby avoid costly and burdensome class action antitrust litigation for the parties and the Court. Interlocutory review is particularly appropriate here because the issue is also of significant importance to the entire pharmaceutical industry. The Hatch-Waxman Act was designed to facilitate appropriate, early entry by generic pharmaceutical manufacturers by, among other things, providing them with notice regarding the potential patents at issue and a mechanism for testing those patents in court before launching potentially infringing generic drugs and thereby exposing themselves to potentially massive liability measured by the innovator companies' lost profits. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008). This is accomplished through the mandatory

listing requirements in Section 355(b)(1) that require innovator drug companies to disclose in the Orange Book all potentially infringed patents relating to a drug when filing an NDA. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). By construing the operative statutory language in a manner that is inconsistent with its plain meaning, industry practice, and the FDA's own interpretation, the Orders have altered the delicate balance struck by Congress in the Hatch-Waxman Act and created significant uncertainty in the industry. A prompt ruling by a federal appellate court on the requirements of Section 355(b)(1) would bring much needed clarity.

As the Supreme Court has explained, "district courts should not hesitate to certify an interlocutory appeal" if the relevant criteria are satisfied and a decision "involves a new legal question or is of special consequence." *Mohawk Indus., Inc. v. Carpenter*, 558 U.S. 100, 110-11 (2009); *see Klinghoffer v. S.N.C. Achille Lauro*, 921 F.2d 21, 25 (2d Cir. 1990) (stating that "exceptional circumstances [will] justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment" (alteration in original)). This case presents exactly the type of exceptional circumstances that warrant interlocutory appeal.

ARGUMENT

The Orders addressed an issue that is without question a matter of first impression: whether "the phrase 'with respect to which a claim of patent infringement could reasonably be asserted'" in Section 355(b)(1) "modifies only the directly preceding phrase, 'claims a method of using such drug,'" or whether it also modifies "the earlier phrase 'claims a drug.'" (EPP Order 12, 15.) The Court adopted an interpretation that neither Takeda nor Plaintiffs had advanced and ruled that "an NDA applicant is required to describe a patent as a drug product patent" *only* "if it claims the NDA drug, that is, it literally reads on the drug." (EPP Order 14, 26.) The Court's decision on this important issue of first impression should be certified for interlocutory appeal

under 21 U.S.C. § 1292(b) because it involves "[1] a controlling question of law [2] as to which there is substantial ground for difference of opinion and . . . [3] an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). Here, not only would an immediate appeal advance this litigation, but it is also necessary to provide guidance on an issue that is at the heart of the Hatch-Waxman Act statutory scheme and the critical balance Congress sought to strike between the intellectual property rights of innovators and the interests of would-be generic competitors. In this regard, clarity on which patents must be listed in the Orange Book is important to both innovators and generic companies.

I. The Proper Interpretation of the Listing Statute Is a Controlling Question of Law That Can Resolve This Litigation.

The requirements of Section 355(b)(1) decided in the Orders is a "controlling question of law." 28 U.S.C. § 1292(b). The requirements of Section 355(b)(1) are purely "a question of statutory interpretation" that the Court of Appeals can resolve "quickly and cleanly without having to study the record." *See Capitol Records, LLC v. Vimeo, LLC*, 972 F. Supp. 2d 537, 551, 552 (S.D.N.Y. 2013) (Abrams, J.). In this case, if the Court of Appeals agrees with the plain-language interpretation that Takeda advanced—and that the FDA itself has adopted—Plaintiffs' claims would be dismissed in their entirety. (*See* EPP Order 2 (noting that "[t]he issues in this case largely revolve around the proper interpretation" of Section 355(b)(1)).) Accordingly, because "reversal of the . . . order would terminate the action," it is "clear that [the] question of law is controlling" within the meaning of Section 1292(b). *See Klinghoffer*, 921 F.2d at 24.

II. There Are, at a Minimum, Substantial Grounds for Difference of Opinion About the Requirements of the Listing Statute.

The requirements of Section 355(b)(1) present a novel issue of first impression in the courts, and the Court implicitly recognized that there are substantial grounds for difference of opinion about the requirements of the statute by noting that Takeda's "strong arguments" made

the issue especially complex to resolve. (EPP Order 12.) Not only does the Court's decision conflict with Takeda's position, but it also conflicts with the (1) plain language of the statute and the applicable canons of construction, (2) long-standing expert interpretation by the FDA, (3) interpretation by industry participants, including generic drug manufacturers named as defendants in this action, and (4) the interpretation offered by Plaintiffs in this case. The difference between the Court's decision and these other sources confirms that, at the very least, there are substantial grounds for difference of opinion as to the proper interpretation of Section 355(b)(1). Because "the issue is particularly difficult and of first impression," certification for interlocutory appeal is appropriate. *Capitol Records*, 972 F. Supp. 2d at 551.

A. The Statute's Plain Language and the Applicable Canons of Construction Support Takeda's Reading of the Listing Statute.

The Court's interpretation of Section 355(b)(1) conflicts with the language of the statute and the applicable canons of statutory interpretation, which support Takeda's position that, under Section 355(b)(1), the '548 and '404 patents were properly listed in the Orange Book as drug product patents.

The starting place for any statutory interpretation question is the statute's plain language. (*See* EPP Order 15 (citing *United States v. Lucien*, 347 F.3d 45, 51 (2d Cir. 2003)).) Here, the plain language of the statute is entirely consistent with Takeda's interpretation. The statute provides in relevant part:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1). The plain meaning of this language is that (1) all patents that claim a drug (including patents that claim components of a drug) or claim a method for using a drug

must be listed in the Orange Book (2) if a reasonable claim of infringement could be asserted against a generic manufacturer that sold a generic copy of a drug without the authority to practice those patents.

By contrast, the Orders interpreted the language of the listing statute in a manner that is inconsistent with its plain meaning. Instead, the Court read the statute as giving the same word—"claims," used as a verb to describe something that the patent does—two different meanings in the same sentence (one meaning that the Court labeled the "plain meaning" and another that it labeled the "infringement meaning"). (EPP Order 25.) The statute requires filing of patent information for any patent "which *claims* the drug for which the applicant submitted the application or which *claims* a method of using such drug." 21 U.S.C. § 355(b)(1) (emphases added). The Court ruled that "the plain meaning of 'claims' in § 355(b)(1) applies in the phrase 'claims the drug,' but the infringement meaning of 'claims' applies in the phrase 'claims a method of using such drug.'" (EPP Order 25.) But it is well-established that "identical words used in different parts of the same statute" usually "have the same meaning;" and that presumption is particularly strong in cases like this when the words appear in a single sentence of a single statutory provision. *Robers v. United States*, 572 U.S. 639, 643 (2014) (internal quotation marks omitted); *see also, e.g.*, *Mohasco Corp. v. Silver*, 447 U.S. 807, 809-10, 818, 826 (1980) ("[W]e cannot accept respondent's position without unreasonably giving the word 'filed' two different meanings in the same section of the statute.").

There are good reasons why the same meaning of the word "claims"—the meaning that the Court labeled the "infringement meaning"—should apply in both instances. The statutory objective as to both is to identify patents relating to a drug as to which a reasonable claim of infringement could be asserted. That is why secondary patents, such as patents on new

formulations and new dosage forms, are frequently listed in the Orange Book for the pioneering drug. *See* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents*, 7 PLOS ONE 1,1 (2012) ("Medicine products may be associated, for example, not only with patents covering the base compound. They may also be covered by patents covering modified forms of that base compound, medical uses of a known chemical compound, combinations of known chemical compounds, particular formulations (tablets, topical forms), dosage regimens, and processes, among others."). But, under the Orders' interpretation of Section 355(b)(1), it is possible that innovators would be prohibited from listing such later developed patents because they are not method of use patents and are not literally infringed by the original NDA drug.[2] That result would frustrate the operation of the Hatch-Waxman Act, which is designed to permit all patent infringement claims related to a drug to be resolved in one suit before a generic product launches, by exposing generic manufacturers to patent infringement suits after launch for patents that were not disclosed. *See Caraco Pharm. Labs.*, 527 F.3d at 1283.[3]

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[2] As just one example, in *Novartis Pharmaceuticals Corp. v. Watson Laboratories, Inc.* the innovator drug company (Novartis) asserted claims for infringing later obtained patents related to dosages of rivastigmine (sold under the brand name Exelon) against manufacturers who filed Abbreviated New Drug Applications ("ANDAs") to produce that drug. 611 F. App'x 988, 990 (Fed. Cir. 2015). The FDA recognizes that new dosages and formulations covered by later obtained patents can be added to an existing NDA. *See* 21 C.F.R. § 314.70 (2019). Because Novartis had disclosed the later obtained dosage patents in the Orange Book as drug product patents, the ANDA applicants were (a) aware that Novartis believed those patents would be infringed by a generic manufacturer and (b) were able to resolve their infringement claims before launching their generic version of that product. 611 F. App'x at 990.

[3] Takeda's inclusion of the '548 and '404 patents as drug product patents in the Orange Book listing for ACTOS was fully consistent with the policies that animate the Hatch-Waxman Act. Those patents contained claims that are directed to a pharmaceutical composition that includes pioglitazone, the active ingredient in ACTOS. (*See* '548 patent at Claim 1; '404 patent at Claim 1.) They were thus "drug product patents"—they related to the active chemical substance and not just a method of using it. And, a claim of infringement could reasonably have been asserted against a company that engaged in the unauthorized manufacture and sale of a generic

In short, by diverging from well-established principles of statutory interpretation and giving the word "claims" two different meanings, the Court departed from the plain meaning of Section 355(b)(1), under which both instances of the word "claims" are tied together by the neighboring phrase "with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1). This shows, at least, that there are substantial grounds for difference of opinion concerning the proper interpretation of the statute.

Contrary to the conclusion reached in the Orders, the canon against surplusage does not conflict with Takeda's, or the FDA's, interpretation of Section 355(b)(1). The Court stated that "[i]f Congress intended the infringement meaning of 'claims' to apply *both* to drug product and method-of-use claims, then § 355(b)(1) could simply state that a patent must be listed if it contains a claim for which a reasonable claim of patent infringement could be asserted against the unauthorized manufacture, sale, or use of the NDA drug." (EPP Order 22.) But that conclusion is incorrect and would impermissibly broaden the scope of the statute. For example, it would sweep in a patent that neither "claims the drug" nor "a method of using the drug," such as patents on manufacturing processes, patents on packaging, and patents on metabolites, which current regulations clarify are not covered by the listing requirements. *See, e.g.*, 21 C.F.R. § 314.53(b)(1) (2019). Moreover, the surplusage canon asks whether a particular interpretation of the statute renders language in that statute, as the statute is actually written, mere surplusage—not whether it is possible to hypothesize a differently-worded statutory provision that would be more concise such that certain language would be unnecessary. *See, e.g.*, *Obduskey v. McCarthy & Holthus LLP*, 139 S. Ct. 1029, 1037 (2019). An interpretation of Section 355(b)(1) that reads

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version of ACTOS containing pioglitazone, and thereby indirectly infringe the patents. *See* 35 U.S.C. § 217(b) and (c). By listing those patents, would-be generic competitors were able to certify against them and address potential infringement claims before launching their products.

the "with respect to" clause as applying to both of the "which claims" phrases earlier in the sentence does not make any language in the statute as written superfluous, because the phrase "which claims the drug" is doing important work under that interpretation: it differentiates the types of patents to which the listing statute applies (drug and method patents) and those to which it does not.[4] Even if the statutory language could be rewritten to be more efficient, that does not mean that Takeda's interpretation (and that of the FDA) violates the surplusage canon.

The Court also suggested that Takeda's interpretation "arguably" runs counter to the last antecedent rule. (EPP Order 22.) But, as the Court acknowledged, that rule is usually applied where there is a "list of terms or phrases." (EPP Order 22-23 (citing *Lockhart v. United States*, 136 S. Ct. 958, 962 (2016)).) No such list exists here. And the rule has force only when the alternative "would stretch[] the modifier too far by asking it to qualify a remote or otherwise disconnected phrase." *Cyan, Inc. v. Beaver Cty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1077 (2018) (alteration in original) (citation and internal quotation marks omitted). It is not awkward or difficult to read the last part of the relevant statutory sentence in Section 355(b)(1) to apply both to the phrase "which claims the drug" and to the phrase "which claims a method of using such drug," particularly because those two phrases are written in an entirely parallel fashion and are not disconnected by punctuation or otherwise. Indeed, that is exactly how the FDA has interpreted the statute, which indicates that Takeda's construction is appropriate, or at least that there are substantial grounds for difference of opinion such that prompt appellate review is warranted.

[4] Regardless, the surplusage canon is "not an absolute rule." *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 385 (2013). Congress may affirmatively choose redundancy as part of a belt-and-suspenders approach, to add extra clarity—and may be particularly likely to do so in a statute like this regarding complex, technical issues. *See, e.g.*, *id.*

B. The FDA Has Consistently Interpreted Section 355(b)(1) in a Manner That Required the '548 and '404 Patents To Be Listed as Drug Product Patents.

The conflict between the FDA's own interpretation of Section 355(b)(1), which is entitled to *Chevron* deference,[5] and the result that the Court reached underscores that there are substantial grounds for difference of opinion about the statute's interpretation requiring immediate appellate review.

First, the FDA's regulation implementing Section 355(b)(1), states that the listing requirement applies to "each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted." 21 C.F.R. § 314.53(b) (2001).[6] Under that regulation, the phrase "with respect to which a claim of patent infringement could reasonably be asserted" plainly applies to "drug" claims as well as "method" claims. That is because the verb "claims" appears only one time: to encompass not only patents that claim a drug but also patents that claim a method of using the drug. The verb "claims" therefore can have only one meaning, and "with respect to which" must be read to refer equally to "each patent"—regardless of the nature of what the patent "claims."

Second, as the FDA explained more than 25 years ago, the statutory provision "requires an applicant to file 'the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application * * * and with respect to which a claim of

[5] The FDA is part of the Department of Health and Human Services ("HHS"), which is the agency charged with administering Section 355. *See* 21 U.S.C. § 355 (referring to the "Secretary"); 21 U.S.C. § 321(d) (defining "Secretary" as "the Secretary of Health and Human Services" for purposes of the chapter in which Section 355 is found).

[6] The regulations in effect in 2001 are relevant here because the patent submissions at issue were made between 1999 and 2002.

patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'" 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994) (omission in original). The FDA's choice, for purposes of that discussion, to insert ellipses into the statutory language demonstrates that the FDA understands the "with respect to" clause as modifying the language about a "patent which claims the drug." As in the regulation itself, the FDA's statement reflects the view that, contrary to the interpretation in the Orders, the "with respect to" clause does not apply only to a "patent which claims a method of using the drug."

Third, the FDA has twice reaffirmed this interpretation. *See* 60 Fed. Reg. 3398, 3398 (Jan. 17, 1995) (notice of public hearing, stating that "an NDA applicant is required to submit to FDA information on any patent which claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party (*see* 21 U.S.C. 355(b)(1) and (c)(2))"); 67 Fed. Reg. 65,448, 65,449 (Oct. 24, 2002) (stating, in connection with 2002 proposal to amend patent listing requirements, that "both the act and our regulations establish two distinct criteria for a patent intended for listing in the Orange Book: (1) The patent must claim the approved drug product or a method of using the approved drug product; and (2) the patent must be one with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner sought to engage in the drug's manufacture, use, or sale"). The FDA's interpretation is consistent with Takeda's plain-language interpretation of Section 355(b)(1) that a patent is properly described as a drug product for an NDA drug so long as one of the patent's claims is directed to a component of the drug, such that the unauthorized sale of the NDA drug would infringe the claim (either directly or indirectly).

The FDA's reasonable interpretation of Section 355(b)(1) is entitled to *Chevron* deference from the Courts. *See Chevron*, 467 U.S. at 843; *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004) (giving the FDA's interpretation of Section 355 *Chevron* deference); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2124 (2016) (explaining that "[i]n the usual course, when an agency is authorized by Congress to issue regulations and promulgates a regulation interpreting a statute it enforces, the interpretation receives deference if the statute is ambiguous and if the agency's interpretation is reasonable"). That is true regardless of whether the Court regards the agency's interpretation as the best reading of the statute, or the one that the Court would choose if it were writing on a blank slate. *See, e.g.*, *Skubel v. Fuoroli*, 113 F.3d 330, 336 (2d Cir. 1997).

The FDA's longstanding interpretation of Section 355(b)(1) is reasonable, entitled to deference, and in Takeda's view, correct. The incongruity between the FDA's expert interpretation and the Court's construction shows that there are, at a minimum, substantial grounds for difference of opinion regarding the Orders.[7]

C. Industry Participants Interpret Section 355(b)(1) in a Manner That Required the '548 and '404 Patents To Be Listed as Drug Product Patents.

As the Court and the Second Circuit acknowledged, nine generic drug companies filed Paragraph IV certifications to the '584 and '404 patents. *In re Actos End-Payor Antitrust Litig.*,

[7] The Federal Circuit's decision in *Apotex, Inc. v. Thompson*, 347 F.3d 1335 (Fed. Cir. 2003), does not dictate the result the Court reached. As the Court acknowledged, *Apotex* discusses the interpretive question at issue here only in dicta. (EPP Order 19.) The Federal Circuit did not need to, and did not, consider the arguments raised in this case about how the final clause of Section 355(b)(1) should be read. Furthermore, *Apotex* states that "[t]he listing decision thus requires what amounts to a finding of patent infringement." *Id*. at 1344. Consistent with the FDA's interpretation, that statement suggests that an analysis of infringement is appropriate with respect to a patent "which claims the drug" as well as with respect to a patent "which claims a method of using [the] drug." 21 U.S.C. § 355(b)(1).

848 F.3d 89, 95 (2d Cir. 2017); (EPP Order 5). The nature and scope of those patents, and what they claimed, was in the public domain and known to those companies. Accepting Plaintiffs' allegations as true, the decisions to certify against those patents in connection with their ANDAs demonstrates that those companies understood the listing statute as Takeda does, *i.e.*, that the patents were required to be listed as claiming the drug product because a reasonable claim of infringement could be asserted against a generic manufacturer. (*See* EPP Fourth Consol. Am. Class Action Compl., ECF No. 255 (Mar. 14, 2018) ¶ 81 (alleging that "all generic applicants faced with the choice of addressing the Patents' method-of-use claims with either Paragraph IV Certifications or Section viii Statements would have elected Section viii Statements exclusively").) This evidence of sophisticated pharmaceutical companies—that are the intended beneficiaries of the listing statute—interpreting the statute contrary to the Orders shows, at least, substantial grounds for difference of opinion over the requirements of Section 355(b)(1).

D. Plaintiffs Interpreted Section 355(b)(1) Differently Than the Court Did.

Finally, Plaintiffs had every incentive to read the statute as the Court has, but none advanced the reading of Section 355(b)(1) that the Court adopted. (*See* EPP Order 15 (adopting a "third reading" of Section 355(b)(1)).) That fact underscores that there is substantial ground for difference of opinion regarding the Court's decision on this novel interpretation that was not briefed.[8] *Cf. Lewis v. Rosenfeld*, 145 F. Supp. 2d 341, 343 (S.D.N.Y. 2001) (granting motion for reconsideration of opinion that was based on an issue not fully briefed by the parties); *Kai Wu*

[8] Of course, the Court also has the authority to reconsider its decision *sua sponte*, with full briefing on its novel interpretation of the statute and in light of the fact that that interpretation is inconsistent with the long-standing interpretation of the FDA and the industry. *See, e.g.*, *Chartis Seguros Mexico, S.A. de C.V. v. HLI Rail Rigging, LLC*, No. 11 Civ. 3238 (ALC) (GWG), 2015 WL 545565, at *2 (S.D.N.Y. Feb. 9, 2015).

Chan v. Reno, 932 F. Supp. 535, 540 (S.D.N.Y. 1996) (inviting motion under Federal Rule of Civil Procedure 60 because the court *sua sponte* decided an issue not briefed by either party).

III. An Immediate Appeal Will Advance the Ultimate Termination of the Litigation and Resolve Industry-Wide Uncertainty.

Certifying this matter for interlocutory appeal "may materially advance the ultimate termination of the litigation," 28 U.S.C. § 1292(b), and resolve uncertainty that risks harming the careful balance set by the Hatch-Waxman Act to promote the entry of generic drugs, and, in turn, competition in the pharmaceutical industry while respecting innovators' intellectual property.

A. An Immediate Appeal Could Lead to the Prompt End of This Litigation.

If the Court of Appeals interprets Section 355(b)(1) as Takeda believes it should, that will materially advance the litigation by completely ending it, and thereby avoid the significant expense and burdens attendant to this type of complex, class action litigation. The material advancement prong of Section 1292(b) is satisfied when a decision by the Court of Appeals would resolve all of a plaintiff's claims, or even "most" of them. *Capitol Records*, 972 F. Supp. 2d at 554; *see also, e.g.*, *In re Duplan Corp.*, 591 F.2d 139, 148 n.11 (2d Cir. 1978) (material advancement prong satisfied if appeal has "the potential for substantially accelerating the disposition of the litigation"); *Transp. Workers Union of Am., Local 100 v. New York City Transit Auth.*, 358 F. Supp. 2d 347, 352-53 (S.D.N.Y. 2005) (certifying order because "[i]f the Court of Appeals reverses . . . the litigation will end"). Indeed, the Committee of the Judicial Conference of the United States that proposed Section 1292(b) specifically recognized that antitrust cases such as this are exactly the kind of "protracted and expensive litigation" as to which certification for immediate appeal may well be warranted so as to pretermit further proceedings. S. Rep. No. 85-2434, 85th Cong., 2d Sess., at 5260 (1958). Accordingly, certification is an appropriate use of judicial resources to materially advance this litigation.

B. An Immediate Appeal Would Resolve Industry-Wide Uncertainty.

Certifying the Orders for interlocutory appeal is appropriate for the additional reason that the Court's interpretation of the listing statute will have substantial ramifications across the pharmaceutical industry. Courts recognize that the interlocutory appeal procedure is appropriate when "[r]esolution of the[] arguments will have far-reaching implications" for an entire industry. *See Capitol Records*, 972 F. Supp. 2d at 551-54 (noting "important ramifications" of case for industry participants). As explained above, the Orders interpret Section 355(b)(1) contrary to how the FDA and industry participants have long understand the requirements of this statute. (*See* Sections II.B-C, *supra*.) Courts have recognized that the interlocutory review process is appropriate when the issue "raises a novel issue of great importance to many other" entities. *See Transp. Workers Union of Am.*, 358 F. Supp. 2d at 353. Here, if review is delayed, there will be potentially years of uncertainty as innovator drug companies must decide whether to (1) adhere to the FDA's guidance and long-standing industry practice, and potentially face class action antitrust lawsuits for treble damages, or (2) follow this Court's interpretation of Section 355(b)(1), and thereby risk failing to comply with the patent disclosure obligations in the Hatch-Waxman Act and forfeit valuable rights under the Act—all while certifying under penalty of perjury that the information they submit to the FDA is "accurate and complete." *See* 21 C.F.R. § 314.53(R). Absent clarification from the Court of Appeals, an innovator drug company that follows industry practice and FDA guidance when disclosing patents under Section 355(b)(1) may nevertheless be subject to expensive and burdensome class action antitrust lawsuits depending on how it discloses patents that cover an innovator drug product used in combination with other compounds.

This double-bind circumstance for innovator drug companies is all the more perilous given the Orders' other conclusion—*i.e.*, that an innovator firm can be held liable for violating

the antitrust laws based on an improper Orange Book listing even without allegations or evidence of subjective bad faith.[9] (EPP Order 36.) In other words, absent immediate appellate intervention, an incorrect, albeit innocent, choice by an NDA holder such as Takeda—against the backdrop of conflicting interpretations of the listing statute by this Court on the one hand and the FDA and decades of industry practice on the other—could give rise to a claim under the Sherman Act. The existence of such serious potential consequences highlights why certifying the Orders for interlocutory appeal is warranted.

The uncertainty created by delaying appellate review of this important issue also risks upsetting the carefully calibrated goals of the Hatch-Waxman Act. The Hatch-Waxman Act "sought to facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products." *Apotex*, 347 F.3d at 1338. Central to that goal is the requirement that innovative drug companies disclose, as part of an NDA, "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). Those patents are listed in the Orange Book so that a generic drug manufacturer can make informed decisions about whether, and how, to bring a generic product to market and the patent litigation risks that they will face by doing so. *Apotex*, 347 F.3d at 1338. By changing the way in which patents are required to be listed in the Orange Book, the Orders will change the

[9] This question also presents a (1) controlling question of law, (2) as to which there is substantial ground for difference of opinion, and (3) the resolution of which would materially advance the litigation. *See* 28 U.S.C. § 1292(b).

balance set in the Hatch-Waxman Act and risk subjecting generic drug manufacturers to unexpected patent infringement suits after they have launched their products.

CONCLUSION

Because an interlocutory appeal will advance the ultimate termination of this lawsuit, and resolve industry-wide uncertainty, the controlling question of law over the interpretation of Section 355(b) presents the "rare exception to the final judgment rule that generally prohibits piecemeal appeals," *Koehler v. Bank of Bermuda Ltd.*, 101 F.3d 863, 865 (2d Cir. 1996), and warrants certifying the Orders for interlocutory appeal.

Accordingly, Takeda respectfully requests that this Court Certify the Orders for interlocutory appeal pursuant to 28 U.S.C. § 1292(b). Within ten days of such a certification, Takeda will ask the Second Circuit for permission to take an appeal from those Orders. *See* 28 U.S.C. § 1292(b).

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Respectfully submitted,

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