NO. 14-1522 (L)

United States Court of Appeals

for the

Fourth Circuit

MYLAN PHARMACEUTICALS INC.,
WATSON LABORATORIES, INC.,
and
LUPIN PHARMACEUTICALS, INC.

Plaintiffs-Appellants

– v. –

U.S. FOOD AND DRUG ADMINISTRATION
and
TEVA PHARMACEUTICALS USA, INC.

Defendants-Appellees

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR
THE NORTHERN DISTRICT OF WEST VIRGINIA AT CLARKSBURG

CORRECTED REPLY BRIEF OF APPELLANTS MYLAN PHARMACEUTICALS INC. AND WATSON LABORATORIES, INC.

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INTRODUCTION

The Briefs submitted by the U.S. Food and Drug Administration ("FDA") and Teva Pharmaceuticals USA, Inc. ("Teva") do not, and cannot, undercut the principal reasons that the District Court decision should be overturned. The plain language of the relevant statutory provision dictates that the 2008 Federal Circuit Court decision invalidating U.S. Patent No. 5,760,068 (the "'068 patent" or the "original patent") triggered the running of Teva's marketing exclusivity period tied to that patent, and that Teva's exclusivity period expired 180 days later. FDA *admits* that the 2008 court decision was a final court decision invalidating the '068 patent. FDA and Teva cannot alter that case-dispositive point. FDA's attempt to manufacture ambiguity from clear and unambiguous statutory language should be rejected, as should Teva's mischaracterization of the final court decision as only "partially" invalidating the '068 patent.

There are three elements in the court decision trigger provision that governs this case (21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002)): a marketing exclusivity period expires 180 days after 1) a final court decision in patent litigation brought as a result of a Paragraph IV certification, 2) that relates to a patent that is the subject of that Paragraph IV certification, and 3) that holds the patent invalid or otherwise not infringed. All parties agree on the first element: the 2008 Federal Circuit decision was a final court decision in patent litigation brought in response to Teva's

Paragraph IV certification to the '068 patent. FDA's and Teva's argument focuses on the second element. They argue that the word "patent" in the court decision trigger is ambiguous when the patent involved is an original patent that is later followed by a reissue patent because, they assert, the statute does not explicitly mention reissue patents.

FDA's and Teva's argument confuses generality with ambiguity. Here, the statute is not ambiguous: it employs a comprehensive term – "patent" – that clearly encompasses the patents at issue. Reissue *and* original patents fall within the category of "patents" just as other subcategories do, e.g., continuation patents, divisional patents, and continuation-in-part patents. "Patent" means patent – any patent. Moreover, FDA's and Teva's assertion with respect to reissue patents ignores that Teva's first-filed certification, and thus its exclusivity period, was tied to the original '068 patent – not the reissue patent. Even the District Court found that the court decision trigger applies to an original patent. J.A. 272.

What FDA and Teva really seek is an interpretation of the statute that excludes certain patents under certain circumstances. That exclusion does not exist in the statute, and cannot be created by agency fiat or judicial decision. The statutory definition of a court decision trigger controls this case, whether read in isolation or in its statutory context, and compels reversal of both the District Court

decision and FDA's underlying decision, under Step One of *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

In an obvious attempt to force the argument into more favorable territory, Teva and FDA conflate the two issues presented by this appeal. Both FDA's and Teva's Briefs focus almost exclusively on the second issue before this Court (whether there is a separate, shared exclusivity period tied to the *reissue* patent), and address only in passing the first issue (whether Teva's exclusivity period tied to the *original* patent expired in 2008). They claim these issues are inextricably linked. They are not. Even the underlying FDA decision treated the two issues as separate questions. This Court, after deciding that Teva's exclusivity period tied to the '068 patent expired in 2008 (and therefore no longer blocks Mylan Pharmaceuticals Inc. ("Mylan") and Watson Laboratories, Inc. ("Watson") from receiving final approval to market the generic form of Celebrex®), could still hold that a separate shared exclusivity period does not exist for the reissue patent (U.S. Patent No. RE 44,048, the "'048 patent").

But the Court should also overturn the District Court's decision on the second question, and hold that a shared exclusivity period tied to the '048 patent should be awarded to Mylan, Watson, Teva, and any other first-filers to the '048 patent. In the context of applications for generic drugs considered under the pre-Medicare Modernization Act ("MMA") framework, challenges to separate patents

create separate exclusivity periods. Reissue patents qualify as patents. Although FDA and Teva argue at length about situations requiring interpretation to avoid unacceptable results like "mutually blocking" exclusivity periods, this case presents no such difficulties. The exclusivity period tied to the '068 patent expired nearly six years ago, more than four years before the reissue patent was even issued. Mylan, Watson, and Teva all challenged the reissue patent on the day it was listed in the Orange Book, and they have therefore earned the reward of sharing an exclusivity period commencing when one of the companies launches its celecoxib product, likely in December 2014.

ARGUMENT

I. TEVA'S EXCLUSIVITY PERIOD TIED TO THE '068 PATENT EXPIRED IN 2008.

A. This Court's Analysis Must Begin, and Should End, with the Statutory Language of the Court Decision Trigger.

The statute provides that a marketing exclusivity period begins to run on "the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II)) (2002). Both FDA and Teva largely ignore the text and context of that provision and, instead, move quickly to unsubstantiated assertions of ambiguity, or irrelevant provisions of patent law. *See, e.g.*, Gov't Br. at 18, 26; Teva Br. at 16-19. But, as this Court recently confirmed in *King v. Burwell*, "[i]n construing a statute's meaning, the court 'begin[s], as always, with

the language of the statute.'" No. 14-1158, 2014 WL 3582800, at *5 (4th Cir. July 22, 2014) (quoting *Duncan v. Walker*, 533 U.S. 167, 172 (2001)).

Because this is a statutory construction case, the analysis must begin with the language of the statute. The relevant statutory provision here requires no interpretation, and that clear language should dictate the outcome. A literal reading of statutory language should be rejected only where, as in *King*, the statutory context makes it impossible or absurd to apply the language literally. *Id.* at *6-7. Neither exception applies to this case.

It is undisputed that the 2008 Federal Circuit mandate was a final court decision issued in litigation brought as a result of Teva's Paragraph IV certification to the '068 patent (the first element of the court decision trigger discussed above). Nevertheless, Teva and FDA argue, as to the second element, that the statute is ambiguous as to whether that court decision related to a relevant "patent" – the original patent – because the original patent was later the subject of a reissue. Teva goes further to argue a meritless proposition relating to the third element of the court decision trigger, claiming that its exclusivity period did not expire because the Federal Circuit decision did not fully invalidate the '068 patent or hold that it was not infringed. Teva and FDA are wrong under *Chevron* Step One.

B. The '068 Patent Was a Qualifying Patent for the Court Decision Trigger.

The '068 (original) patent is a patent that is addressed directly by the relevant statutory language. Thus, the Federal Circuit mandate *is*, by the statute's plain terms, a "decision . . . holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002).

FDA and Teva argue that a patent that is later the subject of reissue falls into a gap in the statute as to what "patent" means in the context of the court decision trigger, and that FDA may fill this gap with its "bundle of rights" approach to patents. *See* Teva Br. at 22-23. But the statutory provision refers comprehensively to "the patent which is the subject of the certification," 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002), and need not be more specific in order to unambiguously encompass all instruments that fall within the definition of a "patent," including both original and reissue patents where, as here, either is "the subject of the certification."

In *William v. Gonzales*, 499 F.3d 329 (4th Cir. 2007), this Court rejected an argument similar to FDA's and Teva's position. The statute in *William* provided that "[a]n alien may file one motion to reopen proceedings under this section . . . ." *Id*. at 330. The government argued that the statute left "a gap which [the government] may fill with a regulation restricting the availability of motion to

reopen to those aliens who remain in the United States," as opposed to those who had left the country. *Id*. at 332. This Court disagreed:

> [I]n providing that '*an alien* may file,' the statute does not distinguish between those aliens abroad and those within the country – both fall within the class denominated by the words 'an alien.' Because the statute sweeps broadly in this reference to 'an alien,' it need be no more specific to encompass within its terms those aliens who are abroad. Thus, the government's view that Congress was silent as to the ability of aliens outside the United States to file motions to reopen is foreclosed by the text of the statute.

Id.

In this case, as in *William*, FDA attempts to manufacture statutory ambiguity. But all patents, original and reissue, fall within the statutory class denominated by the words "*the patent* which is the subject of the certification." 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002) (emphasis supplied). Thus, the statute includes reissue patents as a subset of the statutory classification of "patent" subject to the court decision trigger (just as it includes original patents), and FDA's contrary interpretation is "foreclosed by the text of the statute." *William*, 499 F.3d at 332.

FDA's Brief cites no authority in support of its position that the statute is ambiguous, nor does FDA or Teva address the cases cited by Mylan and Watson in which courts rejected FDA's other attempts to alter plain statutory language in the Hatch-Waxman Amendments. *See* Appellants' Br. at 3 n.2, 29. Under *Chevron* Step One, courts have rejected FDA's attempts to alter the statutory language to

require a "successful defense" to a patent suit, *Mova Pharm. Corp. v. Shalala*, 955 F. Supp 128 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir 1998), or to require that an Abbreviated New Drug Application ("ANDA") applicant be sued to earn an exclusivity period, *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1526 (D.D.C.), *vacated as moot*, 43 F.3d 712 (D.C. Cir. 1989)).

The error of FDA's position is illustrated by its argument that "[t]he Statute does not address what version of the patent is relevant to the court-decision trigger . . . ." Gov't Br. at 31 (emphasis supplied). There are no "versions" of patents, particularly for purposes of an ANDA certification. There are only individual, distinct patents. And, as discussed above, the '068 patent – the original patent – is the basis of Teva's exclusivity period challenged in this appeal. As the District Court found, Congress intended "the patent" to include original patents. J.A. 272.

FDA should not be allowed to twist the definition of "the patent" to mean "the patent, unless it is an original patent that is later superseded by a reissue patent before commercial marketing has commenced." FDA tries to legislate in the guise of interpretation; and FDA has manufactured ambiguity to justify a result. That is impermissible under *Chevron* Step One.

C. *Apotex* Supports Mylan and Watson, Not FDA.

Both FDA and Teva rely heavily on *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61 (D.D.C. 2006), *aff'd*, 226 F. App'x 4 (D.C. Cir. 2007). They argue that because the court in *Apotex* agreed with FDA that particular language of the *exclusivity-creating* provision in the statute at Section 355(j)(5)(B)(iv) is ambiguous, the court decision trigger clause of Section 355(j)(5)(B)(iv) must also be ambiguous. Gov't Br. at 18, 21-22; Teva Br. at 1, 3, 10-16. The latter simply does not follow from the former, however. In fact, the *Apotex* court specifically emphasized the *clarity* of the court decision trigger provision: "The Court can conceive of no reason why, for example, the court-decision trigger clause could not be patent-specific even though the remainder of § 355(j)(5)(B)(iv) is drug-product-specific, *particularly because the language of the court-decision trigger clause is very clearly patent-specific . . . .*" *Apotex*, 414 F. Supp. 2d at 71 (emphasis supplied). Thus, as the *Apotex* court stated, "[t]his clause triggers the 180-day exclusivity clock only if the relevant court decision relates to the same patent that is the subject of the paragraph IV certification." *Id*. Here, there is no question that the 2008 Federal Circuit Court decision related to the same patent, the '068 patent, that was the subject of Teva's first-filed Paragraph IV certification.

D. The Patent Law Cited by FDA and Teva Does Not Render Ambiguous the Plain Language of the Court Decision Trigger.

Both FDA and Teva misapply patent law in their doomed attempt to show that the '068 patent is not "the patent which is the subject of the certification," under the Federal Food, Drug, and Cosmetic Act. Not only is FDA's foray into patent law an abrogation of its historical position that it takes only a ministerial role in patent matters, but patent law cannot support FDA's or Teva's argument because it neither contradicts the plain language of the court decision trigger, nor renders it ambiguous.

FDA argues that "the reissued patent and the original patent are closely connected to each other." Gov't Br. at 25. Specifically, FDA notes that no "new matter" can be introduced in the reissue patent application, that the reissue patent is issued "for the unexpired part of the term of the original patent," and that "every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form." *Id.*; 35 U.S.C. §§ 251(a), 252. Teva says the same statutory sections show that "reissue patents are closely tethered to their predecessors." Teva Br. at 17. None of these points furthers FDA's or Teva's argument.

First, Section 252 addresses patent rights "on the trial of actions for causes thereafter arising," not exclusivity periods for those who challenge the validity of patents or who succeed in designing around the patents. Teva tellingly fails to

quote the complete statutory language that limits the "continued existence" of the original patent to "the trial of actions for causes thereafter arising." Further, a statute on the books governing patent rights in the 1920s cannot, without more, trump plain statutory language created to govern generic drug marketing exclusivity periods some 60 years later. Such marketing exclusivity periods did not yet exist in the 1920s. Congress obviously could not have intended that the narrow category of patent rights preserved through 35 U.S.C. §§ 251(a) and 252 would affect marketing exclusivity periods that would not even be created until 1984.

Second, Teva and FDA actually concede critical points demonstrating the separate nature of original and reissue patents: obtaining a reissue patent means surrendering the original patent, Teva Br. at 17, and "reissued patents are, in some respects, new and distinct from the original patents from which they arise," Gov't Br. at 26. Nevertheless, FDA states that it "merely concluded that the relationship between an original and a reissued patent is sufficiently close to justify treating them together . . . ." *Id.* FDA is without authority to reach such a conclusion in the face of unambiguous statutory language to the contrary.

Under the statute, a reissue and original patent together could not possibly constitute "the patent" – singular – since the statute states that the exclusivity period starts running on "the date of a decision of a court . . . holding *the patent*

which is the subject of *the certification* to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002) (emphasis supplied). Because an original and reissue patent are never the subject of a single Paragraph IV certification, and would never be subject to a single lawsuit invalidating both, FDA's and Teva's interpretation would require rephrasing the court decision trigger to read "*the patents,*" "*the certifications,*" and the "*decisions*" of a court, not "the certification" and "a decision of a court."

Though FDA asserts that it "properly took account of the relationship between original and reissued patents," Gov't Br. at 25, patent law and past FDA practice contradict that assertion. Like original and reissue patents, continuation and divisional patents also share the same expiration dates as their predecessors (absent a patent term adjustment or extension), 35 U.S.C. §§ 120, 121, 154, and cannot contain new matter, 37 C.F.R. § 1.53(b). Because FDA treats these patents as separate and distinct, FDA cannot justify different treatment of original and reissue patents.

Teva also asserts that the claims of the '068 and '048 patents are "substantially identical." Teva Br. at 60. This assertion is not supported by anything in the record and, in any event, is irrelevant as a matter of law. FDA's decision on reissue and original patents is not dependent on whether they contain similar claims, and FDA did not – and could not (given its ministerial approach to

patents) – analyze the original and reissue patents to determine whether their claims were similar.

Furthermore, although both FDA and Teva emphasize the "substantially identical" clause of the reissue statute (Gov't Br. at 25; Teva Br. at 42-43, 46, 50-53), this provision cannot support FDA's bundle of rights approach. Where patent claims have been invalidated, the U.S. Patent and Trademark Office ("PTO") generally will not issue reissue patents with claims that are substantially identical to invalidated original patent claims, based on the doctrine of collateral estoppel. *See* MPEP §§ 2242(III)(C), 2286(II) (applying collateral estoppel within PTO proceedings); *Application Clark*, 522 F.2d 623, 633-37 (C.C.P.A. 1975) (Miller, J., concurring) (upholding the PTO's rejection of reissue claims based on the collateral estoppel effect of a prior invalidity judgment regarding the original patent). Thus, FDA's presumption that the PTO will issue reissue patents with claims that are substantially identical to invalidated claims of the original patent is wrong.

E. The 2008 Federal Circuit Court Decision Was a "Decision of a Court" Invalidating the '068 Patent.

Teva's exclusivity arising from its certification to the '068 patent began to run as of the date of the court decision invalidating that patent. FDA agrees that Teva successfully challenged the '068 patent. *See* Gov't Br. at 2, 9, 24, 31 (Teva "prevailed in patent litigation"). FDA's Brief is consistent with its April 24

decision (the "FDA Decision"), which correctly pointed out (at 1, and at 1 n.1, J.A. 41) that the 2008 Federal Circuit invalidated the original patent or held that it was not infringed. Teva, by contrast, repeatedly claims that the 2008 Federal Circuit decision only "partially invalidated" the '068 patent. Teva Br. at 1-4, 16, 20, 24, 30, 37, 60. Teva argues that the 2008 decision therefore does not qualify as "a decision of a court . . . holding the patent . . . to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002); Teva Br. at 44. This argument is wrong under *Chevron* Step One and was rejected by FDA.

Long-settled law makes clear that FDA's decision must stand or fall based on the rationale that the Agency itself (not Teva in litigation) puts forward. *See SEC v. Chenery Corp.*, 318 U.S. 80, 89-90 (1943) (reasoning that an agency's "action must be judged by the standards which the [agency] itself invoked" in taking that action); *Camp v. Pitts*, 411 U.S. 138, 143 (1973); *Newport News Shipbuilding and Dry Dock Co. v. N.L.R.B.*, 631 F.2d 263, 268, 268 n.9 (4th Cir. 1980). Teva's "partially invalidated" argument asserts a ground of decision upon which the Agency did not rely. This argument is entitled to no consideration.

Moreover, Teva's argument is contrary to the purpose of the statute and to FDA's long-standing interpretation of the statute. Pfizer chose to assert certain of the claims from the '068 patent against Teva, so the remaining claims were not before the court for consideration. *See generally Pfizer Inc. v. Teva Pharms. USA,*

Inc., 482 F. Supp. 2d 390 (D.N.J. 2007), *aff'd in part, rev'd in part*, 518 F.3d 1353 (Fed. Cir. 2008). Additionally, if Teva were correct, patent holders would have a perverse incentive to assert only some of their patent claims in order to manipulate the patent litigation so that a court decision trigger would never be created, and full generic competition could be delayed for months (as it has been here). 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002). And, as a practical matter, long-standing principles of mandatory joinder of claims and *res judicata* compel a patentee to assert its meritorious claims in patent litigation or forfeit the ability to pursue such claims. Thus, the final court decision did not, as Teva claims, leave Claims 5-10 "intact." Teva Br. at 20.

Alternatively, the 2008 Federal Circuit decision qualified as a court decision trigger because the decision effectively held that the unaddressed claims of the '068 patent were "not infringed." Pfizer conceded that Claims 5-10 were not infringed by not pursuing them, and the 2008 Federal Circuit decision implicitly incorporated that concession.

Teva's argument also contradicts FDA's long-established practice. In the Mircette example cited by FDA, FDA Decision at 7, J.A. 47, the triggering court decision on the reissued Mircette patent, U.S. Patent No. RE 35,724, occurred on December 6, 2001, the date the court entered summary judgment of non-infringement on seven of the 28 claims of the reissued patent. *See Bio-Technology*

Gen. Corp. v. Duramed Pharms., Inc., 174 F. Supp. 2d 229, 232 (D.N.J. 2001), *rev'd*, 325 F.3d 1356 (Fed. Cir. 2003). Yet, FDA considered that decision to have held the patent was not infringed.

The absurdity of Teva's argument is highlighted by reference to another section of the Hatch-Waxman Amendments. In 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2002), one of the dates set for approval of an ANDA is the date "the court decides that such patent is invalid or not infringed." If Teva were right about the 2008 Federal Circuit mandate, Teva's own ANDA could not have been approved under this subsection, frustrating the Hatch-Waxman Amendments' system for approvals, which FDA applies in practice.

The 2008 Federal Circuit mandate thus fully invalidated the '068 patent, or held it was not infringed.

F. FDA's "Bundle of Rights" Approach Is Not Reasonable.

FDA's bundle of rights approach is impermissible under the statute. Appellants' Br. at 32-38. FDA makes little attempt to tether its bundle of rights approach to the statutory language or to any source of authority. Nor does FDA reconcile its approach here with its proclaimed ministerial role in patent matters; rather, FDA merely asserts that its bundle of rights theory is permissible and reasonable. *See, e.g.*, Gov't Br. at 30, 32, 36.

Even if this Court determines that it must reach *Chevron* Step Two to determine the outcome of this case, and the reasonableness of FDA's decision therefore becomes relevant, any assertion of reasonableness in FDA's application of the court decision trigger only to reissue patents is fundamentally wrong. A decision to revive an original patent's expired exclusivity period unnecessarily creates gross and untenable uncertainty for generic drug manufacturers, rather than predictability.

When a patent is invalidated or held not to be infringed in a final court decision, generic drug manufacturers other than the first-filer to the patent are entitled to certainty that the exclusivity period tied to that patent will expire 180 days later so they can prepare to market their drug upon FDA approval. These preparations include:

- scheduling acquisition of necessary raw materials,
- scheduling manufacturing of the final dosage form of a generic drug,
- investing time and resources in publicizing launch of the product and securing contracts to sell the drug,
- dedicating distribution channels to the drug, and
- ensuring that personnel are available and trained to complete the onerous product sample testing and regulatory monitoring associated with the distribution of a drug under 21 C.F.R. Part 211.

A final court decision invalidated the '068 patent in 2008, and a reissue patent was not issued until five years later (contrary to Teva's misleading "Day 1" and

"Day 2" chart, Teva Br. at 16). From the time of the 2008 court decision until the FDA Decision, Mylan, Watson, and Lupin Pharmaceuticals, Inc. ("Lupin") more than reasonably believed that Teva's exclusivity period had expired (because it had), and Mylan and Watson were preparing to launch the product. In the wake of the FDA Decision, if upheld by this Court, manufacturers of other generic drugs would be unable to predict whether an exclusivity period was triggered by a qualifying court decision, because a reissue patent could be sought and potentially granted at any time on any drug for which an ANDA was submitted prior to the effective date of the MMA.

Further, FDA's interpretation of the court decision trigger language would introduce uncertainty under other related statutory provisions. For example, the holder of a marketing exclusivity period forfeits exclusivity if it does not begin marketing within 75 days of a court decision invalidating the patent. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Under FDA's interpretation, if the patent is reissued after that period, but before competitors receive final approval or the first applicant markets the product, the exclusivity period could potentially be revived. For this reason, as well, FDA's interpretation of the court decision trigger cannot stand.

G. Pfizer's Characterization of the '048 Patent Has No Bearing on this Appeal.

Teva claims that Pfizer's characterization of the reissue patent as a continuation of the original patent, when it listed the '048 patent in the Orange

Book, informs the issue of whether the reissue patent is separate and distinct from the original patent. Teva Br. at 21, 25, 31-32. Teva also suggests that FDA is keeping to its ministerial role by deferring to the patent-holder's (here, Pfizer's) characterization of a reissue patent. Teva is incorrect.

Courts have repeatedly rejected agency interpretations that would allow an NDA holder, like Pfizer, to manipulate events allowing the brand company to deprive a generic applicant of a period of marketing exclusivity. *See Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 126 (D.C. Cir. 2006), *abrogated on other grounds by Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303 (D.C. Cir. 2010) (rejecting an FDA policy that "allows an NDA holder, by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity"); *Teva*, 595 F.3d at 1317-18. Pfizer's characterization of the patent is simply irrelevant. In addition, FDA did not rely on Pfizer's characterization in making its decision, and Pfizer's statement therefore cannot now be used to uphold FDA's decision. Moreover, the language quoted from the cover letter that Pfizer filed with the reissue patent is directly contradicted by the language in the actual FDA form that Pfizer submitted to FDA to list the '048 patent. *See* D. Ct. Dkt. No. 71-1, at 2, Form FDA 3542: Patent Information Submitted Upon and After Approval of an NDA or Supplement. At the bottom of page 1 of the form, it asks "Is the patent referenced above [in this case, the reissue patent] a patent that has been submitted

previously for the approved NDA or supplement referenced above?" Pfizer answered "no" to that question. Teva also fails to disclose that the six different use codes Pfizer submitted on this FDA form for the '048 patent were all different from the single use code associated with the '068 patent ("Treatment of Inflammation or an Inflammation-Associated Disorder"). *See id*. at 4; D. Ct. Dkt. No. 47-1, at 3.[1] Looking solely at the use codes for the '068 and '048 patents, which are intended to provide an accurate description of the relevant method claims, Pfizer clearly did not consider the reissue patent to be the same as the original patent, and FDA could not have concluded that the reissue patent was the same as the original patent.

H. The Court Should Ignore Teva's Argument that Ambiguity Is Demonstrated by Five Parties' Taking Three Different Positions.

Teva argues that the relevant statutory provision is ambiguous because five different parties in this appeal take three different positions as to exclusivity periods. *See, e.g.*, Teva Br. at 1, 3. Yet, with regard to other court decisions on the Hatch-Waxman Amendments, Teva candidly admitted that, "[n]ot surprisingly, the applicants in such cases advocated different positions on exclusivity." *Id*. at 12.

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[1] Where a patent containing method claims is submitted for listing in the Orange Book, and some of the method claims are approved conditions of use of the drug, the NDA holders must submit a brief description of the relevant method claims ("use codes") to be published in the Orange Book. *See* 21 C.F.R. § 314.53(c)(2)(i)(O)

By definition, parties in litigation have different positions. That natural phenomenon does not, however, create statutory ambiguity where none exists. Predictably, Teva's argument has been rejected in other cases. "[S]tatutory ambiguity cannot be determined by referring to the parties' interpretations of the statute. Of course their interpretations differ. That is why they are in court." *John v. United States*, 247 F.3d 1032, 1041 (9th Cir. 2001) (Kozinski, J., dissenting); *see also Wetzler v. F.D.I.C.*, 38 F.3d 69, 73 (2d Cir. 1994).

II. MYLAN, WATSON, AND TEVA EARNED A PERIOD OF SHARED EXCLUSIVITY TIED TO THE '048 PATENT.

A. Shared Exclusivity Is a Separate Issue in this Case.

As discussed above, both FDA and Teva distort this case by merging the distinct issues of (1) expiration of the exclusivity period tied to the '068 patent, and (2) shared exclusivity as to the '048 patent.

The first question is whether Teva's exclusivity tied to the '068 patent expired in 2008. Because it did, as argued in Section I, *supra*, other generic manufacturers should have received approval to begin marketing on May 30, 2014, the day that Mylan, Watson, and Lupin all received tentative approval letters for celecoxib. Contrary to FDA's mischaracterization, Gov't Br. at 14, Mylan and Watson do not argue that they were entitled to go to market on May 30, 2014 because they were entitled to shared exclusivity but, rather, *because Teva's exclusivity tied to the '068 patent had expired*.

The second question in this case is whether Teva, Mylan, and Watson are entitled to a shared period of exclusivity – *vis-à-vis* other ANDA filers – because they were first-filers to the reissue patent.

These two questions are separate, and the distinction is important. As recognized by the court in *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61 (D.D.C. 2006), *aff'd*, 226 F. App'x 4 (D.C. Cir. 2007), the statutory provisions that create a period of exclusivity are distinct and different from those that dictate when a period of exclusivity *begins* (and, thus, expires). *See id.* at 71.

B. The Court Should Order FDA To Recognize a Separate, Shared Period of Exclusivity Tied to the Reissue Patent.

Mylan and Watson will not repeat here all the reasons that FDA's decision to deny shared exclusivity to the first-filers to the reissue '048 patent is both an impermissible construction of the statute under *Chevron* Step One, and unreasonable under *Chevron* Step Two. Appellants' Br. at 39-44. Notably, though, FDA's Brief devotes a mere paragraph to the critical fact that, as FDA acknowledges, its long-standing interpretation of the statute requires NDA holders to list with FDA "any patent," including reissue patents, that claims the drug, and ANDA applicants to certify to "each patent," including reissue patents, that claims the drug. Gov't Br. at 27. But, FDA would arbitrarily and unlawfully exclude reissue patents from the term "patent" only with respect to the court decision trigger, but not the listing and certification provisions. Even if FDA had discretion

to disallow separate exclusivity periods for reissue patents, FDA relinquished that discretion by requiring the separate listing of, and certification to, reissue patents.

Moreover, even Teva's Brief (*see* the chart at page 12) establishes that, in the pre-MMA structure applicable here, a second patent on the same drug can be the basis of a separate period of exclusivity. A separate period of exclusivity for reissue patents comports with incentives behind the Hatch-Waxman Amendments, and with FDA's own admissions and prior practice. In fact, FDA concedes that the Amendments were intended to incentivize patent challenges. Gov't Br. at 23 (citing *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008)). Watson and Mylan, in addition to Teva, were first-filing challengers to the validity of the '048 patent, were sued by Pfizer on the same day as Teva, and litigated the validity of this patent in district court. *See Teva*, 548 F.3d at 105 ("The point of paragraph IV, the Agency argues, is to reward risk when an applicant challenges a patent that would otherwise preclude price competition.") Under FDA's pre-MMA patent-by-patent approach to exclusivity, FDA has consistently interpreted the statute to incentivize prompt challenges to later-listed patents. *See Apotex Inc. v. FDA*, 414 F. Supp. 2d at 73 (D.D.C. 2006).

Accordingly, the Court should order FDA to recognize a shared exclusivity period for first-filers to the reissue patent.

CONCLUSION

For the foregoing reasons, and those in Mylan and Watson's opening brief, this Court should reverse the District Court decision.

Respectfully Submitted,

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CERTIFICATION OF COMPLIANCE UNDER FED. R. APP. P. 32(A)(7)

Pursuant to Fed. R. App. P. 32(a)(7)(C)(i), I hereby certify that the foregoing Corrected Brief for Plaintiffs-Appellants Mylan Pharmaceuticals Inc. and Watson Laboratories, Inc. complies with Fed. R. App. P. 32(a)(7)(B)(i), because it contains 5643 words, excluding the Table of Contents, Table of Authorities, Certificate of Service, and this Certificate of Compliance. I also certify that this Brief complies with the typeface and style requirements of Fed. R. App. P. 32(a)(5) and (6), because it has been prepared using Microsoft Word with a proportionally spaced 14-point Times New Roman font.

/s/ Douglas B. Farquhar	September 19, 2014
(signature)	(date)

CERTIFICATE OF SERVICE

I certify that on September 19, 2014, the foregoing document was served on all parties or their counsel of record through the CM/ECF system.

/s/ Douglas B. Farquhar September 19, 2014