197 F.Supp.3d 53
United States District Court,
District of Columbia.

ASTRAZENECA PHARMACEUTICALS LP; IPR Pharmaceuticals, Inc., Plaintiffs,
v.
Sylvia Mathews BURWELL, Secretary of Health & Human Services; Robert Califf, Commissioner of Food and Drugs; Food and Drug Administration, Defendants,
and
PAR Pharmaceutical, Inc.; Apotex Corp.; Apotex Inc.; Sandoz Inc.; Sun Pharma Global FZE; Sun Pharmaceuticals Industries Inc.; Glenmark Pharmaceuticals Inc., USA; Glenmark Pharmaceuticals, Ltd.; Intervenor-Defendants.

Civil Action No. 16-cv-1336 (RDM)
|
Signed 07/11/2016

Synopsis
Background: Name brand drug manufacturer brought action under the Administrative Procedure Act (APA), seeking a temporary restraining order (TRO) barring Food and Drug Administration (FDA) from approving Abbreviated New Drug Applications (ANDAs) for generic versions of its drug. Generic manufacturers intervened as defendants.

Holdings: The District Court, Randolph D. Moss, J., held that:

[1] FDA was required to provide 24 hours' notice before issuing decision on manufacturer's pending citizen petition;

[2] FDA was required to issue its decisions on manufacturer's pending citizen petition at same time as its decision on ANDAs;

[3] manufacturers of generic drug were not required to provide their draft labeling to name brand drug manufacturer;

[4] FDA was not required to produce administrative record at time it issued its decision on pending citizen petition.

Ordered accordingly.

West Headnotes (6)

[1] Health
Judicial review or intervention

To reach the merits of claims to exclusivity before the Food and Drug Administration (FDA) has granted final approval to any Abbreviated New Drug Application (ANDA) concerning the drug at issue, a court must first conclude that such a pre-enforcement action is ripe for judicial review.

Cases that cite this headnote

[2] Administrative Law and Procedure
Finality;ripeness

To show that agency action is ripe for pre-enforcement judicial review, the plaintiff must show that the issue presented is purely legal, that consideration of the issue would not benefit from a more concrete setting, and that the agency's action is sufficiently final.

Cases that cite this headnote

[3] Health
Judicial review or intervention

Exercising its authority under the All Writs Act, District Court required Food and Drug Administration (FDA) to provide it 24 hours' notice before issuing decision on name brand drug manufacturer's pending citizen petition, since notice was necessary to preserve manufacturer's opportunity to present its arguments in action for judicial review, seeking to bar FDA from approving Abbreviated New Drug Applications (ANDAs) for generic versions of its drug, before it suffered irretrievable loss of

six months or more of exclusivity. 28 U.S.C.A. § 1651(a).

Cases that cite this headnote

[4] Health

Judicial review or intervention

In name brand drug manufacturer's action seeking temporary restraining order (TRO) barring Food and Drug Administration (FDA) from approving Abbreviated New Drug Applications (ANDAs) for generic versions of its drug, exercise of District Court's authority under All Writs Act was warranted so as to require FDA to issue its decisions on manufacturer's pending citizen petition at same time as its decision on ANDAs, and thereby provide brief window for judicial review while imposing smallest possible effect on FDA's usual processes and parties' rights and expectations. 28 U.S.C.A. § 1651(a).

Cases that cite this headnote

[5] Health

Generic and orphan drugs;market exclusivity

Health

Preliminary injunctions

In name brand drug manufacturer's action seeking temporary restraining order (TRO) barring Food and Drug Administration (FDA) from approving Abbreviated New Drug Applications (ANDAs) for generic versions of its drug, District Court would not exercise its authority under All Writs Act so as to require manufacturers of generic drug to provide their draft labeling to name brand drug manufacturer; rather, FDA was expected to provide copies of final labeling, if any, at hearing on motion for TRO, along with any other essential material. 28 U.S.C.A. § 1651(a).

Cases that cite this headnote

[6] Health

Preliminary injunctions

In name brand drug manufacturer's action seeking temporary restraining order (TRO) barring Food and Drug Administration (FDA) from approving Abbreviated New Drug Applications (ANDAs) for generic versions of its drug, District Court would not exercise its authority under All Writs Act so as to require FDA to produce administrative record at time it issued its decision on manufacturer's pending citizen petition; rather, FDA was ordered to bring 15 copies of administrative decision on citizen petition, administrative decisions on ANDAs, final labels for those ANDAs, and any other documents or record material that FDA intended to rely on at hearing on motion for TRO. 28 U.S.C.A. § 1651(a).

Cases that cite this headnote

Attorneys and Law Firms

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Charles John Biro, U.S. Department of Justice, Washington, DC, for Defendants.

MEMORANDUM AND ORDER

RANDOLPH D. MOSS, United States District Judge

This action arising under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, is before the Court on the plaintiffs' motion for a temporary restraining order. Dkt. 22. The plaintiffs, AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals, Inc. ("AstraZeneca"), allege that the Food and Drug Administration ("FDA") "is poised to grant final approval to several Abbreviated New Drug Applications (ANDAs) for generic versions of AstraZeneca's drug Crestor" on the basis of an interpretation of its pediatric-labeling and general carve-out authority that is contrary to law. *Id.* at 1. AstraZeneca seeks a temporary restraining order ("TRO") enjoining the FDA from approving these ANDAs "pending a

hearing on a motion for preliminary injunction and/or ***55** expedited review on the merits." Dkt. 22-1 at 8. AstraZeneca also suggests, alternatively, that the Court exercise its authority under the All Writs Act, 28 U.S.C. § 1651, to retain jurisdiction over the case and to preserve the possibility of meaningful judicial review. *See* Dkt. 46 at 14–15. Six generic drug manufacturers, each of which asserts that it has received tentative approval of an ANDA for a generic version of Crestor, have intervened as defendants. *See* Dkts. 6, 9, 15, 21, 35, 47. The FDA, along with the intervenors, oppose AstraZeneca's motion. *See* Dkts. 42, 43. The Court held a hearing on AstraZeneca's motion on July 7, 2016.

In its opposition brief and at the motion hearing, the FDA argued that the Court currently lacks jurisdiction over this matter because the agency has yet to issue a final decision and, in fact, has yet to decide whether to permit the manufacturers of the generic form of Crestor to enter the market. Dkt. 43 at 17–30. Although the FDA concedes that it is likely to issue decisions in the near future, it argues that as the record now stands, there is nothing for the Court to review. In response, AstraZeneca argues that existing FDA precedent, and the preparations that the intervenors assert that they are making for "an imminent launch of [their] product[s]," leaves little doubt that the FDA has already decided to approve the ANDAs. Dkt. 46 at 6. AstraZeneca argues, in addition, that it can obtain meaningful judicial consideration of its motion for a TRO only *before* the ANDAs are approved because "there is every reason to believe" that the generic manufacturers will "flood the market immediately with at least six months' worth of generic product," causing "AstraZeneca's market share [to] drop precipitously." Dkt. 22-1 at 45.

As the Court noted at the hearing, there is merit to portions of both the FDA's and AstraZeneca's arguments. As the FDA correctly observes, AstraZeneca has submitted a citizen petition to the agency, *see* 21 U.S.C. § 355(q), which among other things raises the same substantive arguments AstraZeneca makes in this case. The Federal Food, Drug, and Cosmetic Act, however, provides that where a citizen petition remains pending before the Secretary and raises an issue that the petitioner also seeks to raise in a civil action, the district court "shall dismiss without prejudice the action for failure to exhaust administrative remedies." 21 U.S.C. § 355(q)(2)(B). Moreover, even if AstraZeneca had not submitted a citizen petition, it would still face a substantial ripeness problem: the FDA contends that its evaluation of the pending ANDAs "is ongoing, and it is possible that the agency would agree with AstraZeneca on one or more of the issues it has raised or find another basis for non-approval." Dkt. 43 at 34.

[1] **[2]** At the same time, AstraZeneca is correct that the FDA's position leaves both the parties and the Court "in an awkward bind." *Teva Pharmaceuticals USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311 (D.C.Cir.2010). Because generic manufacturers are at times poised to ship their products within hours of approval, *see* Dkt. 22-2 at 7–8, and because the FDA maintains that there is nothing for the Court to review until it issues such an approval, the window for review is not only small, but "more or less instantaneous[ ]" with the FDA's issuance of its decision. *Teva*, 595 F.3d at 1311. For this reason, "[d]istrict courts in this circuit routinely reach the merits of ... claims to exclusivity before the FDA has granted final approval to any ANDA concerning the drug at issue." *Id.* But to do so, a court must first conclude that such a pre-enforcement action is ripe for judicial review. Putting aside the "hardship" prong to that test for present purposes, the plaintiff must show that the ***56** dispute is "fit" for review—that is, that the issue presented is "purely legal," that "consideration of the issue would [not] benefit from a more concrete setting," and that "the agency's action is sufficiently final." *Id.* at 1308. (internal quotation marks omitted). Here, however, the FDA contends that its consideration of AstraZeneca's legal argument is intertwined with a factual inquiry relating to the safety of the proposed labels for the generic versions of Crestor and that its consideration of the citizen petition and ANDAs is ongoing. *See* Dkt. 43 at 13.

The fact that this case may fall short of the mark for pre-enforcement review, however, does not mean that AstraZeneca and other manufacturers in similar circumstances are simply without recourse to prevent an asserted loss of six months or more of exclusivity. Rather, as AstraZeneca suggests in its reply brief, the Court is authorized under the All Writs Act, 28 U.S.C. § 1651, to issue those orders necessary to preserve the availability of meaningful judicial review. The All Writs Act authorizes federal courts to issue "all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a). The Act has long been recognized to encompass a federal

court's power "to preserve [its] jurisdiction or maintain the status quo by injunction pending review of an agency's action through the prescribed statutory channels." *F.T.C. v. Dean Foods Co.*, 384 U.S. 597, 604, 86 S.Ct. 1738, 16 L.Ed.2d 802 (1966) (quoting *Arrow Transp. Co. v. Southern R.R. Co.*, 372 U.S. 658, 671 n. 22, 83 S.Ct. 984, 10 L.Ed.2d 52 (1963)). The D.C. Circuit has further explained that, "[i]f the court may eventually have jurisdiction of the substantive claim, the court's incidental equitable jurisdiction, despite the agency's primary jurisdiction, gives the court authority to impose a temporary restraint in order to preserve the status quo pending ripening of the claim for judicial review." *Wagner v. Taylor*, 836 F.2d 566, 571 (D.C.Cir.1987); *see also Nat'l Treasury Employees Union v. King*, 961 F.2d 240, 245 (D.C.Cir.1992).

Against this background, the Court concludes—as it suggested at the July 7 hearing—that it is appropriate to devise some mechanism to ensure that three goals are satisfied: First, AstraZeneca should have some opportunity to present its arguments to the Court before it suffers an irretrievable loss of six months or more of exclusivity. Second, that mechanism should not deprive the intervenors of their right to market generic versions of Crestor as soon as lawfully allowed to do so. Third, the Court should not unnecessarily or unduly interfere with the usual operation of the administrative process.

Rather than simply impose such a mechanism on the parties, at the July 7 hearing the Court invited the parties to meet and confer to determine whether they could reach an agreement regarding how best to proceed. Pursuant to the Court's direction, the parties have now filed a status report addressing two aspects of this issue, along with two additional issues raised by AstraZeneca. *See* Dkt. 49. The four issues are (1) whether the FDA should be required to provide advance notice to the Court or to the parties before issuing its decision on the citizen petition; (2) whether the FDA should issue a decision on the citizen petition before issuing decisions on the pending ANDAs; (3) whether the intervenors should be required to produce copies of their draft labels to AstraZeneca in order to expedite any further briefing or argument on AstraZeneca's motion for a TRO; and (4) when the Court should require the FDA to file the administrative record. *Id.* The Court will address each of these issues in turn.

***57 1. Advance Notice**

[3] As an initial matter, AstraZeneca requests that the Court order that the FDA provide the parties with 48 hours' notice before issuing a decision on AstraZeneca's citizen petition "in order to ensure the availability of lead counsel for the hearing." Dkt. 49 at 2. The FDA and the intervenors "strenuously oppose" this request. *Id.* They argue that AstraZeneca has sought emergency relief from the Court and that the company should be able to "assemble attorneys in time for a hearing." *Id.* And although not raised by AstraZeneca in this context, they argue that "no further briefing is necessary." *Id.*

As explained further below, the Court will set a further hearing on this matter in due course. Given the need to ensure immediate review of the FDA's final decision on AstraZeneca's citizen petition and the need to ensure that the effect of that decision is not unnecessarily or materially delayed, lead counsel for all parties should be prepared to appear in Court on two hours' notice. Although the Court may provide the opportunity for further briefing at or following the hearing, for the reasons discussed below, there will be no need for further briefing in advance of the hearing.

2. Timing and Procedures for Release of the FDA's Decision

[4] The most substantial disagreement among the parties involves the procedures for the release and review of the FDA's decision on AstraZeneca's citizen petition. AstraZeneca argues that the Court should order the FDA to issue its decision on the citizen petition 48 hours before final approval of any of the ANDAs at issue. It contends that this delay will provide the parties with an opportunity to review the decision and will provide the Court with an opportunity to conduct a hearing and to render a decision on AstraZeneca's (renewed) motion for a TRO. *See* Dkt. 49 at 3–4. Alternatively, AstraZeneca seems to suggest that the FDA be permitted to issue its ANDA decisions at the same time that it issues a decision on the citizen petition but that the Court stay any approvals for 48 hours. *See id.* at 4.

The FDA disagrees. It argues that it "is bound by its statutory mandate not to delay approval of an ANDA once it determines that the approval criteria have been met." *Id.* at 5. It does, however, point to three approaches taken by other judges in order to "provide for timely review of final agency action on ANDAs." *Id.* First, it points to *Teva Pharmaceutical Industries, Ltd. v. Sebelius*,

Civ. No. 14–0786, 2014 WL 2600217 (D.D.C. May 9, 2014), where Judge Huvelle dismissed an action as unripe but required the FDA to provide the Court—and only the Court—with advance notice that a decision on an ANDA was imminent so that the Court could be prepared to rule promptly in the event the ANDA was challenged. Dkt. 49 at 5; Dkt. 49-1 at 112–13. Second, it points to *Otsuka Pharmaceutical Co., Ltd v. Burwell*, Civ. No. 15–852, 2015 WL 1962240 (D.Md. Apr. 29, 2015), where Judge Hazel retained jurisdiction over the matter pending issuance of a final FDA decision on the ANDAs and, according to the FDA, required the FDA to provide notice to the Court—and only the Court—with 24 hours' advance notice that a decision was imminent so that the Court could be prepared promptly to rule on the pending motion for a TRO. Judge Hazel did not enjoin issuance of the ANDA decisions but held a hearing within an hour- and-a-half of the agency's final action. Dkt. 49 at 5–6. Third, the FDA discusses, but does not endorse, Judge Bates's approach in *Hi–Tech Pharmacal Co. Inc. v. FDA*, 587 F.Supp.2d 1 (D.D.C.2008), where the Court retained jurisdiction over the matter pending the FDA's issuance of its final decision and directed that the FDA provide at least 12 ***58** hours' notice to the Court—and to the parties—that the issuance of its decision on exclusivity was imminent. Then, at a previously scheduled status conference, the FDA issued its decision in the courtroom, where, according to the FDA, Judge Bates ordered that the decision "not be publicly disclosed." Dkt. 49 at 6.

Finally, some of the intervenors agree with the FDA that the approach taken in *Otsuka* is appropriate, while others argue that the Court should require the FDA to file its decision on the citizen petition by 8 a.m. on the day it issues and that the agency postpone issuance of its decision on the ANDAs until the earlier of 4 p.m. that day or an order of the Court denying AstraZeneca's motion for a TRO. *Id.* at 7.

The Court appreciates the parties' efforts to find a workable solution to the dilemma described above and, exercising its authority under the All Writs Act, 28 U.S.C. § 1651, will adopt a variation on the parties' competing proposals. As an initial matter, the Court agrees with the FDA and intervenors that the 48-hour delay proposed by AstraZeneca is more than is necessary to provide a window for judicial review. As explained above, the Court's goal is to impinge as little as possible on the FDA's normal practices and the normal operation of the statute and regulations, while protecting AstraZeneca's right to be heard before it is too late to avoid significant injury. For this same reason, the Court will also reject AstraZeneca's proposal (and the similar, although more limited proposal raised by some of the intervenors) that the FDA issue its decision on the citizen petition before it renders decisions on the ANDAs. The FDA represents that it lacks statutory authority to agree to this approach, although it does not suggest that the Court would lack authority to order the agency to proceed in this manner. But it is evident that doing so would constitute a substantial break with FDA practice, and the Court will not require that the agency depart from its usual practice in this area, which is fraught with the risk of consequences that may be unforeseen by the Court.

At the same time, however, the Court is unconvinced by the FDA's suggestion that the Court merely require that the FDA provide it with advance notice of the agency's impending action. The FDA states that it "understand[s] that litigation involving challenges to the approval process for generic drugs can be grueling," and it expresses its "sympath[y]" to the Court. Dkt. 49 at 5. But that observation, and the FDA's proposed solution, both misperceive the Court's concern. The Court's worry is that the APA, and general principles of administrative law, favor the availability of judicial review of agency action and that the FDA's proposed approach would permit up to a half-dozen manufacturers each to ship a supply of six months or more of the generic form of Crestor into the marketplace before AstraZeneca has an opportunity to be heard on the legality of the agency's action in approving the ANDAs—if, in fact, that is what the agency decides to do.

This, then, leaves a version of the approach Judge Bates applied in *Hi–Tech Pharmacal*, which the FDA does not endorse but seems to favor over the approaches that AstraZeneca and some of the intervenors recommended. The *Hi–Tech Pharmacal* approach permits the FDA to issue its decisions on the citizen petition and the ANDAs at the same time—as the agency favors—and permits the expeditious resolution of AstraZeneca's motion for a TRO. As the FDA explains, this "approach would allow the court to preserve the status quo while doing the least damage to the integrity of FDA's approval and decision-making processes and be most consistent with the statutory ***59** authority." *Id.* at 7. The FDA does request, however, that "in the event the Court proceeds

in this manner, any required notice and any subsequent proceedings should be under seal" in order to avoid adverse consequences on the stock market. *Id.*

As set forth in greater detail below, the Court will adopt a variation on this approach in order to provide a brief window for judicial review while imposing the smallest possible effect on the FDA's usual processes and the rights and expectations of all of the parties to the proceeding. The Court will require that the FDA provide the Court—and the Court alone—with 24 hours' notice before issuing its decision on AstraZeneca's citizen petition. The Court will then schedule a closed hearing at which all counsel of record may appear, and the FDA will be required to issue its decision on the citizen petition and any decision that it may have reached on any of the ANDAs at that closed hearing.

3. Production of Draft Labeling

[5] AstraZeneca also requests that the Court issue an order directing the intervenors to provide it with copies of their draft labeling, subject to a protective order, by midnight on July 8, 2016. Dkt. 49 at 7–8. In particular, AstraZeneca argues that access to the *draft* labeling will assist it in preparing any further briefing and will assist it and the Court in their preparation for the hearing. *Id.* at 8. The FDA and the intervenors disagree, arguing that the *final* labeling will be included in the administrative record and that the FDA is precluded from disclosing the *draft* labeling. *Id.*

AstraZeneca seeks the draft labeling as a window into the FDA's tentative assessment of the issue presented in AstraZeneca's citizen petition and in this litigation. Draft labeling that includes the type of information that the FDA is authorized to require on certain pediatric carve-out labels under 21 U.S.C. § 355a(o)(2), for example, might reasonably inform AstraZeneca's arguments. But the Court is unconvinced that this type of discovery is appropriate in this APA case. Receiving the requested information might assist AstraZeneca in preparing for the upcoming hearing, but the company has not established any right to it and, as discussed below, it will have the opportunity to review the *final* labeling at the hearing.

The Court, accordingly, will not require the intervenors to produce their draft labeling to AstraZeneca. The Court will, however, promptly enter a protective order to govern future proceedings. To the extent the FDA or the intervenors have any comments on the proposed protective order submitted by AstraZeneca, *see* Dkt. 50, they shall file their comments with the Court by 2 p.m. on July 11, 2016. As explained below, the Court contemplates that the FDA will provide copies of the final labeling, if any, at the hearing on AstraZeneca's motion for a TRO, along with any other essential material.

4. Preparation of the Administrative Record

[6] Finally, AstraZeneca asks that the Court order the FDA to produce the administrative record at the time it issues its decision on AstraZeneca's citizen petition—which, as noted above, will occur at the hearing to be scheduled by the Court. Dkt. 49 at 8. The FDA and intervenors oppose this request, noting that "[i]t will take some time to assemble and properly redact the [a]dministrative [r]ecord to protect confidential commercial information" and arguing that "the underlying [a]dministrative [r]ecord is not necessary for the Court to rule on any motion for a TRO." *Id.* at 9. The Court recognizes that it may take several days for the FDA to assemble ***60** and to redact the administrative record and will not order that the agency produce the record at the hearing. It will, however, order that the FDA bring to the hearing fifteen copies of the administrative decision on the citizen petition, the administrative decisions on the intervenors' ANDAs, the final labels for those ANDAs (if they are approved), and any other documents or record material that the FDA intends to rely on at the hearing in support of its position.

CONCLUSION

For the reasons discussed above, the Court orders that (1) the FDA shall provide the Court with 24 hours' notice before issuing a decision on the pending citizen petition; (2) the FDA may issue decisions on any or all of the pending ANDAs simultaneously with its decision on the citizen petition but shall not issue a decision on any of the pending ANDAs before it issues a decision on the citizen petition; (3) the FDA shall issue its decision on the citizen petition at a hearing before the Court, which the Court will promptly schedule upon receiving notice from the FDA that the decision is forthcoming; (4) all counsel shall be prepared to appear for a hearing on two hours' notice; (5) neither the FDA's decision on the citizen petition nor its decision on any of the pending ANDAs shall be

disclosed or released prior to their issuance at the hearing before the Court, and they shall not otherwise be disclosed or released without prior authorization from the Court at the hearing; (6) the hearing will be closed and those proceedings shall be sealed pending further order from the Court; (7) the FDA is authorized to contact the Court's deputy clerk *ex parte* for purposes of notifying the Court of an impending decision of AstraZeneca's pending citizen petition; (8) if the FDA requests, the Court will issue its order setting the hearing under seal; (9) the Court will not require that the intervenors produce copies of their draft labeling to AstraZeneca in advance of the hearing, but the FDA should bring fifteen copies of any final, approved labeling to the hearing; (10) the FDA should also bring fifteen copies of its decision on the citizen petition to the hearing, fifteen copies of any final decisions respecting the intervenors' ANDAs, and fifteen copies of any other documents or record material that the agency intends to rely upon at the hearing; and (11) the Court will otherwise address the timing of production of the administrative record at the hearing.

SO ORDERED.

All Citations

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