UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION MDL No. 2875

TRANSFER ORDER

Before the Panel:* Plaintiffs represented by co-lead counsel in MDL No. 2875 move under 28 U.S.C. § 1407 to expand the scope of the MDL to include additional drugs and alleged contaminants. The MDL, as currently constructed, is limited to generic valsartan drugs that allegedly contain carcinogenic nitrosamine impurities. The motion requests expansion of the MDL (1) to include actions concerning all other drugs in the Angiotensin II Receptor Blockers (ARB) class – namely, losartan, irbesartan, eposartan, azilsartan, candesartan, olmesartan, and telmisartan; and (2) to encompass claims of contamination by any potential carcinogen. Movants accordingly request transfer of four actions involving losartan and irbesartan (listed on Schedule A)[1] to the District of New Jersey for inclusion in MDL No. 2875, and also request inclusion of losartan and irbesartan actions previously filed there but not yet part of the MDL.[2] They also request that MDL No. 2875 be recaptioned "In re ARB Contamination Products Liability Litigation." In their reply brief, movants alternatively propose an expansion for some subset of the ARB drugs, principally losartan and irbesartan.

All responding defendants[3] oppose expanding the MDL's scope to include all drugs in the

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* Judge R. David Proctor took no part in the decision of this matter. One or more Panel members who could be members of the putative classes in this litigation have renounced their participation in the classes and have participated in this decision.

[1] Plaintiffs in the four actions on Schedule A each allege that they consumed generic losartan or irbesartan drugs containing nitrosamine impurities and, as a result, developed cancer. Movants identified one additional action for transfer – *Noe v. Hetero Labs., Ltd., et al.*, No. 19-0054 (W.D. Ky.) – that was voluntarily dismissed and terminated on September 20, 2019.

[2] The New Jersey actions involving generic losartan and irbesartan include four personal injury actions alleging that plaintiffs developed cancer as a result of using both losartan and valsartan; and five putative class actions alleging economic losses from the purchase of allegedly contaminated losartan or irbesartan, with one of those actions also bringing claims as to valsartan. Of these, the multi-drug actions asserting valsartan-related claims have been included in the MDL, while the actions limited to losartan and irbesartan have not.

[3] Zhejiang Huahai Pharmaceutical Co., Ltd. (ZHP), Prinston Pharmaceutical Inc., Solco Healthcare U.S., LLC, and Huahai U.S., Inc. (together, the ZHP defendants); Walgreen Co.;

ARB class and potential carcinogens other than nitrosamines. The ZHP defendants, joined by eight others, also oppose expanding the MDL to include losartan and irbesartan actions, and specifically oppose transfer of the four actions on the motion. Seven defendants – the Humana, Aurobindo, Torrent, and Hetero companies – did not take a position on the inclusion of losartan and irbesartan actions.

Movants argue that expansion of the MDL is warranted at this time because: (1) the FDA investigation into impurities in generic valsartan drugs has grown to cover the entire ARB drug class, and resulted in recalls of over 500 lots of two other ARBs – namely, losartan and irbesartan; (2) the upward trend in ARB recalls has resulted in the filing of additional actions, with more forthcoming, eventually involving all drugs in the class; and (3) the current and to-be-filed ARB actions present common factual questions because (i) the same manufacturing processes that resulted in the presence of nitrosamines in valsartan allegedly have resulted in the presence of nitrosamines and other contaminants in all drugs in this class; and (ii) many of the current defendants in MDL No. 2875 – companies involved in the valsartan supply chain – also manufacture or sell some or all of the other ARB drugs (or the active ingredient in them). Plaintiffs further argue that the MDL should include claims of contamination by any carcinogen, not just nitrosamines, because another carcinogen (N-Dimethylformamide) recently was detected in valsartan drugs.

In opposition, defendants principally argue that expanding the MDL to include all eight drugs in the ARB class is not appropriate because the pending actions concern only valsartan, losartan, and irbesartan. In particular, they assert, without dispute from movants, that the other five ARBs are not the subject of any action in federal or state court, and have not been the subject of any recalls. Defendants also assert that the recalls all have been based on the presence of nitrosamine impurities in the recalled drugs and, thus, movants' request to broaden the MDL to include *any* alleged carcinogen is unsupported. As to an expansion of the MDL just for the pending losartan and irbesartan actions, defendants argue that: (1) the number of losartan and irbesartan actions is minimal, and informal coordination of those actions is practicable; (2) valsartan, losartan, and irbesartan each are distinct drugs, involving drug- and defendant-specific questions that will predominate over any common issues; and (3) the addition of new drugs to the MDL will result in unwieldy and inefficient pretrial proceedings and increase the danger of frivolous filings.

On balance, we have determined that the record warrants expanding the scope of MDL No. 2875 to include the actions involving losartan and irbesartan, but not to include other drugs in the ARB class. Although the record indicates that the FDA is investigating ARBs as a class, the only pending actions arising from that investigation involve valsartan, losartan, and irbesartan. Movants' speculation that actions involving *all* drugs in the ARB class eventually will be filed is insufficient

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Throggs Neck Pharmacy; Teva Pharmaceutical Industries Ltd.; Teva Pharmaceuticals USA, Inc., Actavis LLC; Actavis Pharma, Inc.; Arrow Pharm (Malta) Inc.; Legacy Pharmaceutical Packaging, LLC; Humana Inc.; Humana Pharmacy, Inc.; Aurobindo Pharma USA, Inc.; Aurolife Pharma LLC; Torrent Pharma., Inc.; Torrent Pharmaceuticals, Ltd.; and Hetero USA Inc. A response also was filed by Sandoz Inc., but that brief subsequently was withdrawn.

to support the requested ARB class-wide MDL.[4] In the absence of such actions, their request is premature. We also observe that the claims in the pending actions concern the formation of, and risks from, nitrosamine impurities.[5] Thus, we decline movants' request to expand the MDL to include all potential carcinogens.

Defendants' objections to the inclusion of losartan and irbesartan actions are unpersuasive. First, there are four actions asserting losartan and irbesartan claims in four geographically dispersed districts, and nine such actions pending in the transferee district – 13 actions in total. The parties are unlikely to be able to effectively informally coordinate among this number of actions and districts, especially in light of the complexity of the issues and international scope of discovery. Second, inclusion of the losartan and irbesartan actions in the MDL is superior to informal coordination given that the transferee court already is presiding over nine actions involving losartan and irbesartan claims. Third, valsartan, losartan, and irbesartan, while distinct, allegedly involve common manufacturing practices by common defendants that have resulted in the same types of impurities in these drugs. A complete identity of factual issues or parties is not a prerequisite to Section 1407 transfer where, as here, the actions arise from a common factual core.[6] Fourth, defendants can raise their concerns about efficiency with the transferee court and propose measures to address these issues.[7] As with any MDL, the transferee judge may account, at his discretion, for any differences among the actions by using appropriate pretrial devices, such as separate tracks for discovery or motion practice for the various products. *See In re Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379-80 (J.P.M.L. 2014).

The Panel has explained that the risk of frivolous filings can be managed efficiently within an MDL:

> [T]he transferee court handling several cases in an MDL likely is in a better position – and certainly is in no worse position than courts in multiple districts handling

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[4] *See In re California Wine Inorganic Arsenic Levels Prods. Liab. Litig.*, 109 F. Supp. 3d 1362, 1363 (J.P.M.L. 2015) ("Although plaintiffs assert that the number of actions is likely to expand, the mere possibility of additional actions does not convince us that centralization is warranted").

[5] N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), and N-Nitroso-N-methyl-4-aminobutyric acid (NMBA).

[6] *See In re 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, 201 F. Supp. 3d 1375, 1378 (J.P.M.L. 2016).

[7] We note that the transferee court has case management procedures in place for the valsartan actions that could be utilized for the losartan and irbesartan actions, such as orders on master and short-form complaints, core discovery, plaintiff fact sheets, and dismissal without prejudice of peripheral defendants.

> individual cases – to properly address meritless claims. There are many tools a transferee court may use to accomplish this task. And importantly, if defendants believe plaintiffs' counsel are filing frivolous claims, it is incumbent upon defense counsel to bring that concern to the attention of the transferee court, and to propose a process to identify and resolve such claims.

See In re Xarelto (Rivaroxaban) Prods. Liab. Litig., 65 F. Supp. 3d 1402, 1405 (J.P.M.L. 2014) (quoting *In re Cook Med., Inc., IVC Filters Mktg., Sales Practices and Prods. Liab. Litig.*, 53 F. Supp. 3d 1379 (J.P.M.L. 2014)).

After considering the argument of counsel, we find that the actions on Schedule A involve common questions of fact with the actions transferred to MDL No. 2875, and that transfer under 28 U.S.C. § 1407 will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. The Panel originally centralized actions alleging that "plaintiffs purchased or used generic formulations of valsartan medications containing the nitrosamine impurities NDMA and/or NDEA." The losartan and irbesartan actions present common questions of fact arising from the allegation that the same or substantially similar manufacturing processes are used in the production of valsartan, losartan, and irbesartan and result in the formation of nitrosamine impurities in the same manner. Thus, the valsartan, losartan, and irbesartan actions will present common factual questions as to the cause of the nitrosamine impurities and, in particular, alleged common defects in the manufacturing process; when defendants knew or should have known of the impurities; and whether the amounts of nitrosamines in the medications presented a risk of cancer or other injuries. Additionally, the actions likely will involve overlapping discovery concerning the FDA investigation, the same scientific studies, common expert witness issues, and duplicative pretrial motions. For these reasons, we hereby expand the scope of MDL No. 2875 to include actions alleging that losartan and irbesartan contain nitrosamine impurities, and rename the MDL "*In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation*."[8]

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the District of New Jersey are transferred to the District of New Jersey and, with the consent of that court, assigned to the Honorable Robert B. Kugler for inclusion in the coordinated or consolidated pretrial proceedings.

IT IS FURTHER ORDERED that MDL No. 2875 is renamed "*In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*"

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[8] Under Panel Rule 7.2(a), the parties should notify the transferee court of losartan and irbesartan actions already in the transferee district that are appropriate for inclusion in the MDL. *See id.* ("Potential tag-along actions filed in the transferee district do not require Panel action. A party should request assignment of such actions to the Section 1407 transferee judge in accordance with applicable local rules.").

PANEL ON MULTIDISTRICT LITIGATION

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IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION MDL No. 2875

SCHEDULE A

Northern District of Alabama

THOMAS v. HETERO DRUGS LTD., ET AL., C.A. No. 6:19-01290

Eastern District of Arkansas

ESTATE OF LARRY BROCK v. TEVA PHARMACEUTICAL INDUSTRIES LTD., ET AL., C.A. No. 4:19-00538

Eastern District of Tennessee

BRANHAM v. HETERO DRUGS, LIMITED, ET AL., C.A. No. 3:19-00265

Western District of Tennessee

BENNETT, ET AL. v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., ET AL., C.A. No. 2:19-02418