UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) CONTAMINATION PRODUCTS LIABILITY LITIGATION

MDL No. 2875

TRANSFER ORDER

Before the Panel:[*] This litigation arises out of an investigation by the U.S. Food and Drug Administration into impurities found in generic drug products containing valsartan, a medication indicated for the treatment of high blood pressure and other conditions. During the course of the FDA investigation, a number of voluntary recalls of generic valsartan medications were issued. Purchasers of recalled lots of generic valsartan subsequently filed actions alleging economic losses. The initial wave of consumer class actions was followed by actions alleging personal injuries from the ingestion of affected valsartan medications, as well as other related litigation.

Plaintiff in one action moves under 28 U.S.C. § 1407 to centralize 10 actions, as listed on Schedule A, in the District of New Jersey. Each of these actions seeks economic damages and related injunctive relief on behalf of proposed classes of purchasers of generic valsartan. The initial motion for centralization also listed an action alleging individual personal injury (*Gentry*), but the action subsequently was voluntarily dismissed. Since the filing of the motion, the Panel has been notified of 30 related actions.[1] Of these, 17 are individual personal injury actions, and the remainder are putative class actions on behalf of consumers and third-party payors.

Responding plaintiffs in seven actions on the motion and nine potential tag-along actions support centralization of all actions, including the personal injury actions, and request the District of New Jersey as their first or second choice of forum. Their other suggested districts are the Northern District of California, the Northern District of Florida, the District of Massachusetts, the District of Minnesota, and the Western District of Texas. Plaintiffs in two actions on the motion (*Stimma* and *Duffy*) support centralization only of the consumer class actions and seek the District of New Jersey. Plaintiff in one potential tag-along action on behalf of third-party payors (*MSP Recovery*) seeks inclusion of its action and requests the Southern District of Florida or the District of New Jersey.

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[*] Certain 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] These and any other related actions are potential tag-along actions. *See* Panel Rules 1.1(h), 7.1 and 7.2.

The principal common defendants in this litigation – Zhejiang Huahai Pharmaceutical Co., Ltd. (ZHP) and its U.S. affiliates Prinston Pharmaceutical Inc., Solco Healthcare U.S., LLC, and Huahai U.S., Inc. (together, the ZHP defendants) – along with pharmacy defendants Walgreen Co. and Throggs Neck Pharmacy support centralization of the 10 actions on the motion in the District of New Jersey. They ask the Panel to limit the scope of the MDL solely to consumer class actions, though they acknowledged shared factual issues among the personal injury and consumer actions at oral argument.[2] The Mylan defendants[3] – sued in six potential tag-along actions – oppose inclusion of any actions against Mylan or actions involving personal injuries and, alternatively, request the District of New Jersey or the Northern District of West Virginia. The other responding defendants[4] do not oppose centralization of solely the consumer class actions in the District of New Jersey, but Teva and certain other defendants suggest that an MDL may not be warranted on the ground that alternatives to centralization exist, particularly transfer under Section 1404(a). In the event an MDL is established, they strongly oppose inclusion of any personal injury actions. Additionally, Teva opposes inclusion of the *MSP Recovery* third-party payor action.

On the basis of the papers filed and the hearing held, we find that these actions involve common questions of fact, and that centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. All actions involve common factual questions arising out of allegations that plaintiffs purchased or used generic formulations of valsartan medications containing the nitrosamine impurities NDMA and/or NDEA;[5] that these impurities present a risk of cancer and liver damage; and that defendants knew, or should have known, of the impurities as early as 2012. All actions stem from the same FDA investigation and voluntary recall announced in July 2018, and the voluntary recalls are ongoing. Although the investigation, and the earliest-filed actions, focused on ZHP as the source of the alleged impurities, the FDA investigation and the actions before the Panel now encompass alleged industry-wide issues concerning the production of the valsartan active pharmaceutical ingredient (API) which will be

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[2] In the Panel briefing, the ZHP defendants, Walgreens, and Throggs Neck Pharmacy sought to exclude the personal injury actions, subject to revisiting that position if the number of such actions increased. On January 14, 2019, they filed a notice stating that they supported centralization of the personal injury actions. At oral argument, they shifted positions once more, as set forth above.

[3] Mylan Laboratories Ltd., Mylan Pharmaceuticals Inc., Mylan N.V., and Mylan Inc.

[4] Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd. (together, Teva); Hetero USA Inc.; Connecticut CVS Pharmacy LLC; Torrent Pharma, Inc.; Camber Pharmaceuticals, Inc.; The Harvard Drug Group d/b/a Major Pharmaceuticals; Wal-Mart Stores, Inc.; The Kroger Co.; and Quality Food Centers, Inc. Responses also were filed by Four B Corp. and Hen House Hen House Marketplace, LLC, but they are no longer parties to any related action following dismissal of *Gentry*.

[5] NDMA refers to N-nitrosodimethylamine, and NDEA refers to N-nitrosodiethylamine.

common to all actions.[6] The common questions of fact include: (1) whether the generic valsartan sold by defendants contained NDMA or NDEA; (2) the cause of the alleged impurities, including alleged defects in the manufacturing and sampling process; (3) when defendants knew or should have known of the impurities; (4) how long the NDMA- and NDEA- containing valsartan medications were in circulation; and (5) whether the amounts of NDMA and NDEA in the medications presented a risk of cancer or other injuries. All of the valsartan actions will raise these issues, regardless of whether the alleged supplier of the valsartan API was ZHP, Mylan,[7] Hetero Labs Limited, or some other entity.[8] Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings, including with respect to class certification and *Daubert* motions; and conserve the resources of the parties, their counsel, and the judiciary.

Although all pending actions on the motion before us are putative consumer class actions seeking economic damages, we received extensive briefing and oral argument on whether the MDL should include personal injury actions. Based on this record, we believe that the centralized proceedings should include the related personal injury actions alleging that plaintiffs developed cancer as a result of using valsartan containing NDMA or NDEA impurities. The core factual issues in the personal injury actions will be the same as in the consumer class actions – in particular, the cause of the alleged impurities; the nature and extent of the health risks posed by the NDMA and NDEA levels at issue; defendants' knowledge of the alleged impurities; and the impact of any findings made by the FDA. Additionally, there is significant overlap in defendants in the consumer

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[6] For example, the FDA announced in late 2018 that NDMA was found in valsartan products sourced from a second overseas supplier, Hetero Labs Limited in India, which it noted used a process similar to ZHP's to produce valsartan API. Valsartan sourced from both Hetero and ZHP is at issue in the *Stimma* action on the motion.

[7] In light of the industry-wide issues concerning generic valsartan, we decline Mylan's request to categorically exclude actions involving Mylan from the MDL. We intend to transfer actions involving Mylan's valsartan products through the conditional transfer order process. *See* Panel Rule 7.1(b).

[8] Practical considerations also favor industry-wide centralization of the valsartan actions. The proposed classes in many of the consumer class actions are described as all purchasers of generic valsartan containing the alleged impurities, without regard to the specific API supplier. Additionally, counsel for plaintiffs represented in the Panel briefing and at oral argument that most consumers of generic valsartan were dispensed more than one manufacturer's products, noting the general practice among pharmacies of filling generic prescriptions with any available generic version of the medication.

We express no opinion at this time as to whether this MDL will grow to include actions involving other medications in the same class as valsartan (angiotensin II receptor blockers, or ARBs), such as the irbesartan and losartan actions filed only in recent days. The record on the factual issues involved in those actions is not sufficient for the Panel to make such a determination.

class actions and personal injury actions. Thus, discovery undoubtedly will overlap among these actions. The Panel often has recognized the efficiencies of centralizing economic loss class actions with personal injury actions, explaining that "liability discovery in all the cases will certainly overlap," and that, in our experience, the individual discovery required in personal injury actions is "regularly and successfully coordinated" within MDLs involving both kinds of actions.[9] For these reasons, we intend to include personal injury potential tag-along actions in this MDL through the conditional transfer order process. *See* Panel Rule 7.1(b).

We also intend to include the *MSP Recovery* third-party payor class action through the conditional transfer order process. The *MSP Recovery* action makes substantially the same factual allegations as the consumer class actions – essentially, that defendants sold valsartan medications that they knew or had reason to know contained NDMA or NDEA. The handful of case-specific issues raised by Teva in opposition to transfer – plaintiff's standing to sue and the assertion of an allegedly unique legal claim – do not warrant exclusion of the action considering the common factual core.

We find that Section 1404 transfer is not a practicable alternative to centralization, given the number of actions, districts, and counsel for plaintiffs and defendants. There are presently a total of 40 related actions pending in 22 districts, which involve over a dozen distinct slates of plaintiffs' counsel and some 20 defendants, most of whom do not share counsel. These circumstances portend significant inefficiencies and obstacles to Section 1404 transfer of the related actions to a single district.[10] The number of involved districts and counsel also would make efforts to informally coordinate discovery and pretrial motions impracticable.

The District of New Jersey is an appropriate transferee district for this litigation. Five actions on the motion and seven potential tag-along actions are pending in this district. Many of the defendants have their U.S. headquarters in New Jersey, including ZHP's U.S. affiliates, which are named in nearly all actions, as well as Hetero USA Inc., Camber Pharmaceuticals, Inc., and Torrent

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[9] *See In re: Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig.*, 704 F. Supp. 2d 1379, 1382 (J.P.M.L. 2010) (centralizing 11 economic loss actions, and explaining the basis for eventually including personal injury potential tag-along actions); *see also In re Johnson & Johnson Talcum Powder Mktg., Sales Practices, & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1357 (J.P.M.L. 2016) (centralizing nine personal injury actions and two consumer class actions; "[a]ll the actions involve factual questions relating to the risk of cancer posed by [defendant's product] . . . [and] whether the defendants knew or should have known of this alleged risk"); *In re Yasmin, Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 655 F. Supp. 2d. 1343, 1344 (J.P.M.L. 2009) ("the Panel has frequently combined actions involving claims relating to sales and marketing of medications with actions involving personal injury claims from use of the same pharmaceutical products").

[10] Section 1404 transfer is not a practicable alternative even if the related actions are limited to the consumer class actions, as there are 19 consumer class actions pending in 10 districts.

Pharma, Inc. Thus, common documents and witnesses likely will be located in this district. Nearly all responding parties support, or do not oppose, the District of New Jersey as their first or second choice. Judge Robert B. Kugler is an experienced transferee judge with the willingness and ability to manage this litigation. We are confident that he will steer this litigation on a prudent course.

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 coordinated or consolidated pretrial proceedings.

IT IS FURTHER ORDERED that, in light of this opinion, MDL No. 2875 is renamed *In re: Valsartan Products Liability Litigation.*

PANEL ON MULTIDISTRICT LITIGATION

Sarah S. Vance
Chair

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IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) CONTAMINATION PRODUCTS LIABILITY LITIGATION

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SCHEDULE A

Eastern District of California

JUDSON, ET AL. v. PRINSTON PHARMACEUTICAL, INC., ET AL., C.A. No. 1:18-01405

Northern District of Illinois

KRUK v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., ET AL., C.A. No. 1:18-05944

Eastern District of Missouri

JONES v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., ET AL., C.A. No. 4:18-01525

District of New Jersey

ERWIN v. PRINSTON PHARMACEUTICALS, INC., ET AL., C.A. No. 3:18-13447
STIMMA, ET AL. v. TORRENT PHARMA, INC., ET AL., C.A. No. 3:18-14318
O'NEILL v. SOLCO HEALTHCARE U.S., LLC, ET AL., C.A. No. 3:18-14840
GONTESKI v. HUAHAI US, INC., ET AL., C.A. No. 3:18-14858
DUFFY, ET AL. v. SOLCO HEALTHCARE U.S., LLC, ET AL., C.A. No. 3:18-15076

Western District of New York

BORKOWSKI v. PRINSTON PHARMACEUTICAL, INC. D/B/A SOLCO HEALTHCARE LLC, ET AL., C.A. No. 1:18-01150

Eastern District of Tennessee

LEWIS v. ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., ET AL., C.A. No. 1:18-00247