UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION MDL No. 2642

TRANSFER ORDER

Before the Panel: Plaintiffs in eight actions move under 28 U.S.C. § 1407 to centralize pretrial proceedings in this litigation in the Southern District of Illinois. This litigation currently consists of 20 actions pending in 15 districts, as listed on Schedule A.[1] The actions allege that fluoroquinolone antibiotics – principally, Levaquin, Avelox, and Cipro – cause or substantially contribute to the development of irreversible peripheral neuropathy and that defendants' warnings concerning the alleged risks were inadequate.[2] The involved manufacturers and distributors are Bayer (Cipro and Avelox), Janssen (Levaquin), and McKesson (a distributor). Since the filing of the motion, the parties have notified the Panel of 58 related actions pending in 23 additional districts.[3]

Responding plaintiffs in six actions on the motion and 18 potential tag-along actions support centralization, arguing in favor of either the Southern District of Illinois or the District of Minnesota. Defendants oppose centralization.

The primary arguments advanced against centralization are that (1) centralization of actions involving different manufacturers and different medications is inappropriate because of the different factual issues involved in the composition, development, testing, and regulatory history of each medication; and (2) individualized facts concerning each plaintiff's case, such as medical history, the condition treated, the patient's overall risk-benefit profile, and diagnosis, will predominate over common factual issues. There are undoubtedly individualized factual issues presented by these actions, but after careful review of the record, we have determined that those considerations do not outweigh the benefits of centralization.

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[1] There were 24 actions listed on plaintiffs' motion for centralization, but four actions have been terminated since the filing of the motion.

[2] The defendants are: Bayer HealthCare Pharmaceuticals, Inc., Bayer Corporation, Merck & Co., Inc., and Schering Corporation (collectively, Bayer); Johnson & Johnson, Janssen Research & Development, LLC, Janssen Pharmaceuticals, Inc., and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (collectively, Janssen); and the McKesson Corporation.

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

A true copy In 6 sheet(s)
of the record in my custody,
CERTIFIED, August 17, 2015
Richard D. Sletten, Clerk
BY: Deputy Clerk

On August 15, 2013, the U.S. Food and Drug Administration announced that it had required a revised label for the entire class of oral and injectable fluoroquinolone antibacterial drugs concerning the risk of irreversible peripheral neuropathy. The warning labels of Levaquin, Avelox, and Cipro allegedly were revised to contain virtually identical warnings with respect to that risk. Plaintiffs' actions followed the FDA announcement, relying on the same regulatory history and scientific background to support the allegation that fluoroquinolone antibiotics, as a class, are causally linked to the development of irreversible peripheral neuropathy. Thus, while we typically are hesitant to centralize litigation on an industry-wide basis, here all fluoroquinolone actions, regardless of the manufacturer, will share factual questions regarding general causation (in particular, the biological mechanism of the alleged injury), the background science, and common regulatory issues.[4]

In these circumstances, the existence of individualized factual issues does not negate the efficiencies gained by centralization. Almost all personal injury litigation involves questions of causation that are plaintiff-specific. Those differences are not an impediment to centralization when common questions of fact are multiple and complex. *See, e.g., In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, 65 F. Supp. 3d 1402, 1403 (J.P.M.L. 2014). Once discovery and other pretrial proceedings related to the common issues have been completed, the transferee judge may suggest Section 1407 remand of actions to their transferor courts for more individual discovery and trial, if necessary. *See In re: Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011).

Defendants also argue that informal coordination among the involved courts and counsel is preferable to creation of an MDL. But there are now 78 actions pending in 38 districts. Even if additional actions are not filed, the present number of cases, districts, and involved counsel warrants centralization, especially considering the complexity of the issues presented.

Additionally, defendants raise a number of arguments concerning the appropriateness of centralization where the viability of plaintiffs' claims allegedly is in question. They argue, for example, that plaintiffs are unlikely to prevail in light of the products' 2004 warning labels on the risk of peripheral neuropathy, that the majority of actions are "facially time-barred," and that recovery against Janssen and Bayer is largely unavailable to users of the generic versions of the medications which are in predominant use.[5] Those allegations do not justify a different outcome. The Panel is not authorized to engage in an assessment of the merits of the actions. *See In re: Maxim*

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[4] Our decision here is in keeping with our past decisions in similar circumstances. We recently centralized litigation involving multiple manufacturers of testosterone replacement therapies. *See In re: Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378 (J.P.M.L. 2014). We also have centralized litigation involving multiple manufacturers of incretin-based diabetes drugs. *See In re: Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345 (J.P.M.L. 2013).

[5] Defendants contend that, in the vast majority of states, a brand name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product, citing *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013). There is only one such action on the motion.

Integrated Prods., Inc., Patent Litig., 867 F. Supp. 2d 1333, 1335 (J.P.M.L. 2012) ("'[t]he framers of Section 1407 did not contemplate that the Panel would decide the merits of the actions before it and neither the statute nor the implementing Rules of the Panel are drafted to allow for such determinations'") (quoting *In re: Kauffman Mut. Fund Actions*, 337 F. Supp. 1337, 1339-40 (J.P.M.L.1972)). Moreover, placing those common issues before the transferee judge further serves the just and efficient conduct of this litigation, in contrast to allowing them to proceed separately in dozens of different districts.

Nor are we persuaded by defendants' related argument that an MDL will generate the filing of voluminous claims without due diligence by plaintiffs' counsel, in an attempt to create pressure to settle. We have rejected essentially this same argument in the past, and do so again here. We reiterate that if defense counsel has grounds to believe that frivolous claims are being filed, it is incumbent upon them to raise that concern with the transferee judge, and to propose a process for identifying and disposing of those claims. *See, e.g., In re: Cook Med., Inc., IVC Filters Mktg., Sales Practices and Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014).

On the basis of the papers filed and the hearing session held, we find that the actions listed on Schedule A 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. These actions share common factual questions arising out of allegations that oral and injectable fluoroquinolone antibiotics cause or substantially contribute to the development of irreversible peripheral neuropathy and that the warnings provided by defendants concerning that risk were inadequate. These actions, in particular, focus on Levaquin (levofloxacin), Avelox (moxifloxacin), and Cipro (ciprofloxacin). Issues concerning general causation, the background science, regulatory history, and labeling will be common to all actions. Centralization will reduce potentially costly expert discovery, facilitate the establishment of a uniform pretrial approach to these cases, reduce the potential for inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary. As with any MDL, the transferee judge may account, at his discretion, for any differences among the actions through the use of appropriate pretrial devices, such as separate tracks for discovery or motion practice for the various products. *See, e.g., In re: Androgel Prods. Liab. Litig.*, 24 F. Supp. 3d at 1379-80.

The District of Minnesota is an appropriate transferee district for this litigation. This district provides a geographically central and convenient forum for this nationwide litigation. Selection of the District of Minnesota also enables us to assign this litigation to the Honorable John R. Tunheim. Judge Tunheim is an experienced transferee judge familiar with the scientific and regulatory background of Levaquin in his capacity as transferee judge for a separate Levaquin MDL concerning tendon rupture injuries. *See* MDL No. 1943, In re: Levaquin Products Liability Litigation. In our view, Judge Tunheim's experience in overseeing MDL No. 1943 will benefit the parties and facilitate the just and efficient conduct of this litigation.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the District of Minnesota are transferred to the District of Minnesota and, with the consent of that court, assigned to the Honorable John R. Tunheim for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Sarah Vance

Sarah S. Vance
Chair

Marjorie O. Rendell
Lewis A. Kaplan
R. David Proctor
Charles R. Breyer
Ellen Segal Huvelle
Catherine D. Perry

IN RE: FLUOROQUINOLONE PRODUCTS LIABILITY LITIGATION MDL No. 2642

SCHEDULE A

District of Arizona

STREET v. JOHNSON & JOHNSON, ET AL., C.A. No. 3:15-08065 15-3283 JRT

Central District of California

LOMBARD v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3284 JRT
C.A. No. 2:15-03120

Northern District of California

KELLERMAN v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3285 JRT
C.A. No. 3:14-03680
LAMPARD, ET AL. v. JOHNSON & JOHNSON, ET AL., C.A. No. 3:14-04983 15-3286 JRT
HIGLEY v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3288 JRT
C.A. No. 3:14-05254
DESALVO v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3290 JRT
C.A. No. 3:14-05670
REIMAN v. JOHNSON & JOHNSON, ET AL., C.A. No. 3:15-01610 15-3291 JRT

District of District of Columbia

HELLER v. BAYER HEALTHCARE PHARMACEUTICALS, INC., C.A. No. 1:14-01953 15-3292 JRT

Northern District of Georgia

PRESLEY v. JOHNSON & JOHNSON, ET AL., C.A. No. 1:15-01293 15-3293 JRT

Southern District of Illinois

BULLARD v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3294 JRT
C.A. No. 3:15-00038
BUSH v. JANSSEN RESEARCH & DEVELOPMENT, LLC, ET AL., C.A. No. 3:15-00452 15-3295 JRT

Western District of Kentucky

BAUM v. JOHNSON & JOHNSON, ET AL., C.A. No. 3:15-00293 15-3296 JRT

District of Maryland

GROSSMAN v. JOHNSON & JOHNSON, ET AL., C.A. No. 1:15-01082 15-3297 JRT

District of Minnesota

SMITH v. JOHNSON & JOHNSON, ET AL., C.A. No. 0:14-05021

District of Nebraska

BLACKMON v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3298 JRT
C.A. No. 4:15-03020

Southern District of New York

SPIEGEL v. JOHNSON & JOHNSON, ET AL., C.A. No. 1:15-03021 15-3299 JRT

Western District of North Carolina

KING v. BAYER CORPORATION, ET AL., C.A. No. 3:15-00194 15-3301 JRT

Middle District of Pennsylvania

HEFFELFINGER, ET AL. v. BAYER HEALTHCARE PHARMACEUTICALS, INC., 15-3302 JRT
ET AL., C.A. No. 1:15-00479

District of South Carolina

MORRIS v. BAYER HEALTHCARE PHARMACEUTICALS, INC., ET AL., 15-3303 JRT
C.A. No. 4:15-01322

Western District of Washington

BAUGHN v. JOHNSON & JOHNSON, ET AL., C.A. No. 3:15-05283 15-3304 JRT