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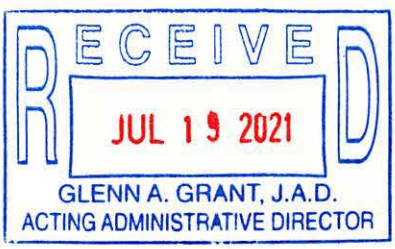
July 16, 2021

VIA FEDERAL EXPRESS
Hon. Glenn A. Grant, J.A.D.
Administrative Director of the Courts
Administrative Office of the Courts
of the State of New Jersey
Richard J. Hughes Justice Complex
25 West Market Street
Trenton, NJ 08625



Re: Request for Multicounty Designation of Elmiron Litigation

Dear Judge Grant:

This letter is submitted on behalf of sixteen (16) plaintiffs represented by my law firm who are amongst the twenty (20) plaintiffs[1] who have cases filed in Mercer, Middlesex and Bergen Counties, New Jersey involving use of the prescription medication Elmiron® and their vision-related injuries resulting from permanent retinal damage. In June 2020, the present holder of the

[1] See **Exhibit A**. Counsel on behalf of the *Gibbs, Kline* and *O'Brien* plaintiffs also supports this application.

New Drug Application issued a change to its package insert to warn of the risk of pigmentary maculopathy, a vision threatening retinal condition. Plaintiffs seek a Multicounty Litigation (MCL) designation in accordance with Rule 4:38A. A Multi-District Litigation (MDL) has already been granted in the federal court system and approximately 310 cases are pending in the District of New Jersey before the Honorable Brian Martinotti, a former MCL Judge before he went to the federal bench.

My firm obtained consent from defendants for this MCL request after speaking with counsel for Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research & Development, LLC, Janssen Ortho, LLC, and Ortho-McNeil Pharmaceuticals, LLC defendants ("Janssen Defendants") and as part of the joint request agreed to not specify any particular venue and instead defer to the AOC for their selection of appropriate venue. Since this application is unopposed by the Janssen Defendants, it is respectfully requested that if possible, the AOC timeline for considering and creating an MCL be expedited because there will be a "Science Day" before Judge Martinotti on September 30, 2021 and it would be beneficial if an MCL Judge (if an MCL is formed) is invited to attend to hear expert presentations. Presently the twenty cases in suit in New Jersey State Court are before seven (7) different judges.

Background

Elmiron® is a brand-name prescription drug also known as pentosane polysulfate sodium ("PPS") which is prescribed to patients suffering from Interstitial Cystitis ("IC"). IC is a chronic medical condition that causes bladder pressure and pain. Elmiron® is a low molecular weight heparin-like compound that was originally granted an "orphan drug"[2] designation by the FDA in 1995 for use in patients suffering from IC. The following year, the FDA approved a New Drug Application ("NDA") submitted by Baker Norton Pharmaceuticals. Since that time, the NDA has been held by various pharmaceutical companies and is currently held by the New Jersey corporation Janssen Pharmaceuticals, Inc.

Due to Elmiron's property of weak oral bioavailability, patients are required to take 100mg doses, three times per day, because only about 6% of the drug is absorbed to the epithelial cells of the bladder. At present, it remains unknown how Elmiron® works to alleviate painful bladder symptoms. While it is believed the medication binds to exposed epithelial cells in the bladder, this also means the medication is absorbed by the retinal epithelial cells. As a result, some users ingesting Elmiron® for multiple years have developed retinal pigmentary damage which results

[2] The Orphan Drug Act (ODA) allows the FDA to grant special status to a drug or biological product ("drug") to treat a rare disease or condition upon request of a sponsor. See https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products

in symptoms such as blurred vision, difficulty reading small print, an inability to see at night, difficulty with light-dark adaptation and the potential for permanent vision loss.

Recent medical literature has supported a causal relationship between long-term use of Elmiron® and a condition now coined as "pigmentary maculopathy." For example, in 2018, physicians with the Emory Eye Care Center reported a case series of patients known to be long term users of Elmiron that presented with an atypical maculopathy that resulted in significant vision loss.[3] They concluded that these patients presented "a novel and possibly avoidable maculopathy associated with chronic exposure to PPS."[4] Numerous studies and articles have since been published documenting similar findings and concluding use of Elmiron® can result in retinal injury. Unfortunately, even after the cessation of Elmiron®, patients can continue to suffer from progression of their retinal disease.[5]

Plaintiffs have alleged the Janssen Defendants[6] knew or should have known of the risks of permanent retinal damage and failed to adequately warn of the risks, failed to design a safe product and failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Elmiron®, among other theories of liability found in traditional products liability cases. Prior to June 2020, Elmiron's label contained no information about pigmentary maculopathy or vision loss.

Elmiron Litigation in New Jersey

Presently there are at least twenty (20) cases pending in New Jersey state court, all involving allegations of vision-related injuries, including, but not limited to toxic maculopathy, retinal pigmentary changes, blurred vision, distorted vision and other visual dysfunction. Janssen Pharmaceuticals, Inc., Johnson & Johnson and its subsidiaries are New Jersey based companies, and it is thus anticipated that many more cases will be filed. The MDL is in the early stages and Judge Martinotti has expressed a desire to coordinate with existing state court cases. In addition to the New Jersey cases, there are also a number of Elmiron cases filed in the Court of Common Pleas in Philadelphia which may also conduct coordinated discovery. The parties anticipate that all defendant depositions in the MDL will be cross-noticed with the New Jersey state court cases if

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[3] Pearce, William A., M.D., et al, "Pigmentary Maculopathy Associated with Chronic Exposure to Pentosan Polysulfate Sodium," *Ophthalmology,* Vol. 125, No. 11 (Nov. 2018) at 1793-1802, available at https://www.aaojournal.org/article/S0161-6420(17)33695-3/fulltext

[4] Id.

[5] Huckfeldt, R. and Vavvas, D., "Progressive Maculopathy After Discontinuation of Pentosan Polysulfate Sodium," 50 OPHTHALMIC SURGERY, LASERS AND IMAGING RETINA 656–59 (2019), ncbi.nlm.nih.gov/pubmed/31671200.

[6] Defendants named in the cases currently pending include: Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research & Development, LLC, Janssen Ortho, LLC, and Ortho-McNeil Pharmaceuticals, LLC.

this petition is granted. Additionally, there is also an overlap in both plaintiffs' and defendants' counsel in the MDL and the state court cases. I have been appointed to the Plaintiffs' Executive Committee of the MDL and Emily Acosta, counsel for state court plaintiffs *Gibbs, Kline* and *O'Brien* is also a member of the Plaintiffs' Steering Committee. Given Judge Martinotti's experience as a former MCL judge in Bergen County and the involvement of the same counsel in both litigations, it is expected coordination will be both efficient and the best use of judicial resources for the progression of these cases.

Why Coordination is Appropriate

As set forth in the guidelines, Multicounty designation is warranted when a litigation involves a large number of parties; many claims with common, recurrent issues of law and fact that are associated with a single product; there is geographical dispersement of parties; there is a high degree of commonality of injury; there is a value interdependence between different claims; there is a degree of remoteness between court and actual decision makers in the litigation; among other considerations. This litigation meets the above enunciated criteria. There are already at least twenty (20) filed cases before seven (7) different judges in three (3) different counties. All cases will involve the recurrent legal issues of failure to warn, design defect, breach of warranty and other common product liability claims. If an MCL is formed, pursuant to In Re: Accutane Litigation, 235 N.J. 229 (2018) the MCL Judge will apply the New Jersey Products Liability Act to all cases which simplifies matters instead of having seven different judges perform complex choice of law analysis for the cases involving plaintiffs presently from nine (9) different states. Moreover, there are significant overlapping factual liability issues relating to defendants' notice and knowledge of the risk of retinal damage; defendants' failure to warn of the risks of injury; defendants' failure to adequately test and design the product; defendants' failure to assess safety signals; and defendants' failure to conduct post-marketing surveillance.

In light all the factors and information discussed above, plaintiffs respectfully request that the Supreme Court designate the Elmiron® cases for Multicounty Management.

Respectfully submitted,

Danielle Gold

Danielle Gold

cc: Melissa A. Czartoryski, Chief, Civil Court Programs
Michael Zogby, Esq. (Via Email)
Kristen Renee Fournier, Esq. (Via Email)
Adam Slater, Esq. (Via Email)
Emily Acosta, Esq. (Via Email)

Exhibit A

1. *Annis v. Janssen Pharmaceuticals, Inc. et al.* - MER-l001271-21
2. *Annison v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-002338-20
3. *Cates v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-002346-20
4. *Chauvin v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-002347-20
5. *Davis vs. Janssen Pharmaceuticals, Inc. et al.*- MER-L-000326-21
6. *Downey v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-001332-21
7. *Eliasson v. Janssen Pharmaceuticals, Inc. et al.*- BER-L-008001-20
8. *Gibbs v. Janssen Pharmaceuticals, Inc. et al.* – MID-L-004121-20
9. *Gillette v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-000040-21
10. *Gutelius v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-002348-20
11. *Henderson v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-000041-21
12. *Kline v. Janssen Pharmaceuticals, Inc. et al.* – MID-L-004123-20
13. *Kotulski v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-000043-21
14. *McKinzie v. Janssen Pharmaceutical, Inc. et al.*- MER-L-001088-21
15. *O'Donnell v. Janssen Pharmaceuticals, Inc. et al.* – MID-L-004122-20
16. *Strickland v. Janssen Pharmaceuticals, Inc., et al.* - MER-L-001282-21
17. *Sutton v. Janssen Pharmaceuticals, Inc. et al.*- MER-L000044-21
18. *Unyi vs. Janssen Pharmaceuticals, Inc. et al.*- MER-L-000709-21
19. *Walendowski v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-001358-21
20. *West v. Janssen Pharmaceuticals, Inc. et al.*- MER-L-001030-21