BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re Selenious Acid Litigation	MDL No. _____

MEMORANDUM IN SUPPORT OF MOTION
TO TRANSFER TO THE DISTRICT OF NEW JERSEY

Plaintiff American Regent, Inc. ("ARI") sells Selenious Acid Injection in two different strengths. Selenious Acid Injection are trace element products indicated for adult and pediatric patients as a source of selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. Generally speaking, parenteral nutrition refers to the administration of nutritional products to patients in a way that bypasses the patient's digestive tract—for example, directly into the bloodstream through a vein. It can provide life-sustaining nutrients to patients who for some reason are unable to safely obtain nutrition by mouth (oral) or through a feeding tube into the digestive tract (enteral).

The formulas for ARI's Selenious Acid Injection products are protected by U.S. Patent No. 11,998,565 (the "'565 patent"). Fourteen pharmaceutical companies—Accord,[1] Aspiro,[2]

[1] As alleged in the complaint, "Accord" is comprised of Accord Healthcare Inc.

[2] As alleged in the complaint, "Aspiro" is comprised of Aspiro Pharma Ltd.

Cipla,[3] DRL,[4] Fresenius,[5] Gland Pharma,[6] Hikma,[7] Long Grove,[8] RK Pharma,[9] Somerset,[10] Steriscience,[11] Sun,[12] Xiromed,[13] and Zydus[14]—have now submitted Abbreviated New Drug Applications ("ANDAs") to FDA seeking approval to make and sell generic copies of ARI's Selenious Acid Injection products before ARI's '565 patent expires. ARI sued each of these companies for patent infringement under the Hatch-Waxman Act. ARI filed suits against each of the fourteen generic companies in the District of New Jersey (the "New Jersey actions"), and filed two additional suits against Fresenius and Long Grove, respectively, in the District of Delaware (the "Delaware actions"). *See* Ex. A.

To prevent inconsistent rulings, preserve the parties' and judiciary's resources, and ensure the swift resolution of patent litigation related to the potential entry of generic drugs into the market, the Judicial Panel on Multidistrict Litigation (the "Panel") should transfer the two

[3] As alleged in the complaint, "Cipla" is comprised of Cipla USA, Inc. and Cipla Ltd.

[4] As alleged in the complaint, "DRL" is comprised of Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.

[5] As alleged in the complaints, "Fresenius" is comprised of Fresenius Kabi USA, LLC.

[6] As alleged in the complaint, "Gland Pharma" is comprised of Gland Pharma Ltd.

[7] As alleged in the complaint, "Hikma" is comprised of Hikma Pharmaceuticals USA, Inc.

[8] As alleged in the complaints, "Long Grove" is comprised of Long Grove Pharmaceuticals, LLC.

[9] As alleged in the complaint, "RK Pharma" is comprised of RK Pharma, Inc.

[10] As alleged in the complaint, "Somerset" is comprised of Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC.

[11] As alleged in the complaint, "Steriscience" is comprised of Steriscience Pte. Ltd.

[12] As alleged in the complaint, "Sun" is comprised of Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries, Inc.

[13] As alleged in the complaint, "Xiromed" is comprised of Xiromed, LLC and Xiromed Pharma España, S.L.

[14] As alleged in the complaint, "Zydus" is comprised of Zydus Pharmaceuticals (USA) Inc.

Delaware actions to the District of New Jersey where the other fourteen actions are pending in order to centralize the pretrial proceedings—just as it has done in other Hatch-Waxman actions. *See, e.g.*, *In re Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370, 1372 (J.P.M.L. 2019) (centralizing multiple Hatch-Waxman cases).

BACKGROUND

In June of this year, Accord, Aspiro, Cipla, DRL, Fresenius, Gland Pharma, Hikma, Long Grove, RK Pharma, Somerset, Steriscience, Sun, Xiromed, and Zydus separately notified ARI that they had submitted ANDAs to the U.S. Food and Drug Administration ("FDA") seeking approval to market one or more generic forms of ARI's Selenious Acid Injection products before the '565 patent covering those products expires, along with certifications that, in their opinions, the '565 patent is invalid, unenforceable, and/or not infringed. The Hatch-Waxman Act makes the submission of these applications containing such certifications an artificial act of infringement of the '565 patent, permitting ARI to sue the generic filers for patent infringement even though they have not yet commercially launched their products. *See* 35 U.S.C. § 271(e)(2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The Hatch-Waxman Act framework was intended to permit patent owners like ARI the ability to promptly resolve any disputes regarding infringement and validity of patents covering their drug products before generic copies are introduced to the market. *See Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001).

Following notification of the Selenious Acid Injection ANDAs submitted to FDA, ARI filed the fourteen New Jersey actions against each of the generic filers, as well as the two

additional Delaware actions against Fresenius and Long Grove on July 16, 2024.[15] *See* Ex. A.

The New Jersey and Delaware actions involve numerous common issues of law and fact. All defendants are seeking FDA approval to market generic versions of one or more of ARI's Selenious Acid Injection products. All of the actions involve the same asserted patent—the '565 patent. The infringement of the generics' ANDAs will be a common issue in all the cases. The validity of ARI's '565 patent will also be a common issue to all the cases, as will be any construction or interpretation of the claim terms of the patent. Additionally, ARI is seeking the same relief in each of the cases (*i.e.*, injunctive relief) under the Hatch-Waxman Act. The cases, moreover, are in an ideal posture to take advantage of the benefits of centralization. All actions are in their earliest stages. Only one of the defendants has responded to the complaint. No conferences have been held, no case schedules have been entered, no substantive orders have been issued, and no discovery has occurred.

LEGAL STANDARD

28 U.S.C. § 1407(a) provides that transfer and centralization of pretrial proceedings in a single District is appropriate where the movant establishes that: (1) "common questions of fact" exist; (2) centralization will "be for the convenience of [the] parties and witnesses"; and (3) centralization "will promote the just and efficient conduct of [the] actions." *See In re Auryxia (Ferric Citrate) Pat. Litig.*, 412 F. Supp. 3d 1347, 1348 (J.P.M.L. 2019).

Applying this standard, the Panel has frequently centralized Hatch-Waxman cases in a single District where, as here, "the complexity of the allegations and regulatory framework" involved and "the need for swift progress in litigation involving the potential entry of generic

[15] For clarity, ARI sued Accord, Aspiro, Cipla, DRL, Gland Pharma, Hikma, Pharma, Somerset, Steriscience, Sun, Xiromed, and Zydus only in the District of New Jersey, and sued Fresenius and Long Grove in both the District of New Jersey and the District of Delaware.

drugs into the market" make centralization appropriate. *See In re: Kerydin (Tavaborole) Topical Sol. 5% Patent Litig.*, 366 F. Supp. 3d at 1371; *In re Nebivolol ('040) Patent Litig.*, 867 F. Supp. 2d 1354, 1355 (J.P.M.L. 2012); *In re Auryxia (Ferric Citrate) Patent Litig.*, 412 F. Supp. 3d at 1349. Indeed, the drafters of the Hatch-Waxman Act recommended transfer and centralization "[i]n the event of multiple ANDA's" because it would "avoid hardship on the parties and witnesses and [] promote the just and efficient conduct of the patent infringement actions." H.R. Rep. No. 98-857, Pt. 1, at 28 & n.14 (1984) (emphasis added).

ARGUMENT

I. The panel should centralize the New Jersey and Delaware actions.

Transfer and centralization of ARI's patent infringement lawsuits regarding its Selenious Acid Injection products is appropriate under the three-part test set forth in 28 U.S.C. § 1407(a).

A. The actions present common questions of fact.

When the same patents are asserted in separate, parallel actions, the actions can "be expected to share factual and legal questions concerning such matters as the technology underlying the patents, prior art, claim construction and issues of infringement involving the patents." *In re Pharmastem Therapeutics, Inc., Patent Litig.*, 360 F. Supp. 2d 1362, 1364 (J.P.M.L. 2005). That is the case here, as common questions of fact exist with respect to the '565 patent's validity and whether the proposed generic products infringe the patent.

First, all sixteen actions involve the same asserted patent—the '565 patent. The patented technology, and the relevant documents and witnesses, will thus substantially overlap between the actions. The same claim construction or interpretation issues will also be common to all sixteen actions.

Second, there are common questions of fact concerning whether the asserted patent is infringed. All of the accused products are generic copies of ARI's Selenious Acid Injection

products. And while the generic defendants may contend that they do not infringe the patent because they have changed certain aspects of their respective generic products, the infringement issues will still be common across all sixteen actions. *See In re Nebivolol ('040) Patent Litig.*, 867 F. Supp. 2d at 1355 ("While there may be some variances in the proposed formulations of defendants' respective drugs, this does not weigh strongly against centralization because all defendants are anticipated to raise similar arguments concerning non-infringement defenses . . . ."). Here, it is anticipated that all ANDA defendants' non-infringement arguments will be similar.

Third, there are common facts regarding the anticipated invalidity defenses. The vast majority of the defendants have indicated in their notice letters to ARI that they believe the asserted patent is invalid as obvious. Evaluating the obviousness of the claimed inventions requires inquiring into, among other things, the level of ordinary skill in the art, the scope and content of prior art, whether the person of ordinary skill in the art would have been motivated to combine the prior art references, and whether the person of ordinary skill in the art would have had a reasonable expectation of success in achieving the claimed invention. *See, e.g.*, *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1051 (Fed. Cir. 2016) (*en banc*). Many other generic defendants have also indicated in their notice letters to ARI that the asserted patent is invalid as anticipated, and/or lacking written description and enablement. Like obviousness, these defenses similarly involve a factual inquiry into the teachings of the prior art and the knowledge of a person of ordinary skill in the art. *See, e.g.*, *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (regarding anticipation); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (regarding written description); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (regarding enablement). Thus, the Delaware and New Jersey

actions will share many common invalidity-related factual inquiries.

B. Centralization will serve the convenience of the parties and witnesses.

Centralization will make the litigation more convenient for the parties and witnesses because it will ensure a common pretrial schedule, common fact and expert discovery, and a streamlined and consistent approach to schedule modifications, motions practice, claim construction, and summary judgment. This will reduce the burdens on the parties to engage in duplicative tasks in different jurisdictions at different times, and will obviate the need for witnesses to appear and participate in more than one proceeding. *See In re: Kerydin (Tavaborole) Topical Sol. 5% Patent Litig.*, 366 F. Supp. 3d at 1371 ("[c]entralization is warranted to prevent…overlapping pretrial obligations [and] reduce costs").

C. Centralization will promote the just and efficient conduct of the actions.

Centralizing will also promote justice and efficiency. "Given the complexity of the allegations and regulatory framework . . . as well as the need for swift progress in litigation involving the potential entry of generic drugs into the market, placing all actions before a single judge should foster the efficient resolution of all of the actions." *Id.* Centralization will also eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel, and the judiciary. *See id*.

Defendants may contend that informal coordination is an adequate alternative to formal centralization. Not so. Unlike informal coordination, transfer and centralization "will have the salutary effect of assigning the . . . actions and any future tag-along actions to a single judge who can formulate a pretrial program that ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties and the courts." *In re Metoprolol Succinate Patent Litig.*, 329 F. Supp. 2d 1368, 1370

(J.P.M.L. 2004). Having a single decision-maker set the schedule and oversee the proceedings is necessarily more efficient than burdening multiple courts with ongoing coordination. That efficiency is particularly important in Hatch-Waxman cases because of the recognized concern for prompt resolution of validity and infringement issues before FDA approval and launch of the accused generic products. It is also of particular importance given the large number of pending cases. *Compare, e.g.*, *In re Valsartan N-Nitrosodimethylamine (NDMA) Contamination Prod. Liab. Litig.*, 363 F. Supp. 3d 1378, 1382 (J.P.M.L. 2019) (alternatives to centralization "not practicable … given the number of actions"), *with In re Eli Lilly & Co. (Cephalexin Monohydrate) Pat. Litig.*, 446 F. Supp. 242, 243 (J.P.M.L. 1978) (denying transfer because "only three actions are involved").

Further, transfer and centralization, unlike informal coordination, serves the important purpose of preventing inconsistent rulings on a variety of critical pre-trial issues present in a Hatch-Waxman patent infringement case like this one, such as claim construction, *Daubert* issues, and summary judgment. *See In re Neo Wireless, LLC, Pat. Litig.*, 610 F. Supp. 3d 1383, 1385 (J.P.M.L. 2022).

II. The Panel should centralize the actions in the District of New Jersey before Judge Brian R. Martinotti.

There can be little doubt that the United States District Court, District of New Jersey is the most appropriate forum for a centralized action, and that District Judge Brian R. Martinotti is the most appropriate judge to preside over these actions. *First*, almost all of the pending cases—fourteen out of sixteen—are already pending in the District of New Jersey, and each of these cases is already assigned to Judge Martinotti. *See In re Ozempic (Semaglutide) Pat. Litig.*, 621 F. Supp. 3d 1354, 1356 (J.P.M.L. 2022) (centralizing before a judge who was already presiding over many of the pending actions).

Second, the remaining two cases against Fresenius and Long Grove are pending in the United States District Court, District of Delaware, which is adjacent to the District of New Jersey, and its Wilmington, Delaware courthouse is only about 110 miles from the courthouse in Newark, New Jersey. Fresenius and Long Grove, like the other defendant entities, regularly transact business in New Jersey; indeed, Fresenius is registered as a business operating in New Jersey. Both Fresenius and Long Grove (like many of the other defendant entities) have also repeatedly appeared in the District of New Jersey, including by filing patent litigation complaints or counterclaims in the District. The District of New Jersey is thus a geographically convenient forum both for the fourteen actions already pending in that District, as well as the two Delaware actions. *See In re: TransData, Inc., Smart Meters Pat. Litig.*, 830 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011) (centralizing cases in a "geographically central" district); *In re: TLI Commc'ns LLC Pat. Litig.*, 26 F. Supp. 3d 1396, 1397 (J.P.M.L. 2014) (transferee district appropriate where defendants were "located in or relatively close to" that district).

Third, the District of New Jersey and Judge Martinotti have extensive experience with both the procedural and substantive issues in this litigation. Over the last ten years, Judge Martinotti has presided over more than 70 Hatch-Waxman cases. *See* Ex. B. He has also presided over multiple multidistrict litigations involving drug products.[16] Indeed, Judge Martinotti is currently presiding over four other ARI litigations that involve the same '565 patent that is asserted in the Delaware and New Jersey actions here.[17] This familiarity with related technology

[16] *See In re Allergan BIOCELL Textured Breast Implant Prod. Liab. Litig.*, 412 F.Supp.3d 1361 (J.P.M.L. 2019); *In re Elmiron (Pentosan Polysulfate Sodium) Prod. Liab. Litig.*, 513 F.Supp.3d 1406 (J.P.M.L. 2020); *In re Insulin Pricing Litig.*, MDL No. 3080, 2023 WL 5065090 (J.P.M.L. Aug 3., 2023).

[17] *See American Regent, Inc. v. Somerset Therapeutics, LLC, et al.*, 2:24-cv-01022 (D.N.J.); *American Regent, Inc. v. RK Pharma, Inc., et al.*, 2:24-cv-01169 (D.N.J.); *American Regent, Inc.*

and procedural issues will promote faster resolution of both the New Jersey and Delaware actions. *See In re Effexor (Venlafaxine Hydrochloride) Prod. Liab. Litig.*, 959 F. Supp. 2d 1359, 1360 (J.P.M.L. 2013) (citing transferee court's familiarity with the subject matter of the cases as a factor in favor of centralization with that court); *In re Iron Oak Techs., LLC, Pat. Litig.*, 325 F. Supp. 3d 1371, 1373 (J.P.M.L. 2018) (noting transferee judge's "experience" in MDL litigation).

Finally, centralization in the District of New Jersey will increase the likelihood that this litigation will be complete before the FDA approves the defendants' ANDAs and they launch their generic products. The District of New Jersey is the second-most popular venue for Hatch-Waxman litigation and has more bandwidth to handle this case than the District of Delaware. The District of New Jersey has only 136 active ANDA cases, compared to 222 in the District of Delaware. *See* Exs. C, D. For cases filed in the last 10 years, the median time to resolution in ANDA cases in New Jersey was 6 months, compared to 10 months in Delaware. *See* Exs. E, F. The District of New Jersey and Judge Martinotti are therefore eminently capable of ensuring these cases proceed fairly and efficiently through the pre-trial process.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that the Panel transfer *American Regent, Inc. v. Fresenius Kabi USA, LLC*, 1:24-cv-00824 (D.Del.) and *American Regent, Inc. v. Long Grove Pharms., LLC*, 1:24-cv-00825 (D.Del.), pending in the District of Delaware, to Judge Martinotti in the District of New Jersey and order coordinated and centralized pretrial proceedings for each of the sixteen actions in question.

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v. Apotex Inc., et al., 2:24-cv-02268 (D.N.J.); *American Regent, Inc. v. Gland Pharma Ltd.*, 2:24-cv-07756 (D.N.J.).

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Respectfully submitted,

By: s/ Charles H. Chevalier
Charles Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Adam LaRock (*pro hac vice* to be filed)
Uma Everett (*pro hac vice* to be filed)
Alex Alfano (*pro hac vice* to be filed)
Ryan Conkin (*pro hac vice* to be filed)
Christopher Coleman (*pro hac vice* to be filed)
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
alarock@sternekessler.com
ueverett@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com
ccoleman@sternekessler.com
Attorneys for Plaintiff
American Regent, Inc.