SUPPLEMENTAL APPENDIX

APPENDIX A

No. 18-2209, -2230, -2260, -2273

United States Court of Appeals
for the Federal Circuit

APOTEX INC, *ET AL.*,

Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Appellees.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in IPR No. 2017-00854

DECLARATION OF ANTHONY TABASSO IN SUPPORT OF ARGENTUM'S OPPOSITION TO NOVARTIS'S MOTION TO DISMISS

I, Anthony Tabasso, declare:

1. I am the President and Chief Executive Officer (CEO) for KVK-Tech, Inc. ("KVK"), a leader in the development and manufacture of high quality, FDA-approved drug products based in Newtown, PA. Unless otherwise stated, I have personal knowledge of the facts set forth herein and, if called as a witness, I could and would testify competently thereto.

2. KVK currently has over 50 research scientists working in labs supported with state of the art development and testing equipment. Continuous investments into KVK's Research and Development Center enable us to develop drug products across multiple therapeutic indications and dosage forms. KVK has over 34 approved abbreviated new drug applications ("ANDAs"), and has developed and filed several paragraph IV filings under the Hatch-Waxman Act for approval by the Food and Drug Administration. KVK has a multi-billion tablet and capsule annual capacity.

3. I have reviewed the Declaration of Jeffrey Gardner of September 10, 2018, including paragraphs ¶¶ 4-12. I agree with the contents of this Declaration with regard to all issues relating to KVK. Moreover, the Declaration of Jeffrey Gardner properly characterizes the business relationship between Argentum Pharmaceuticals LLC ("Argentum") and KVK.

4. KVK is committed to expansion, and in 2015 KVK purchased a 461,000-square-foot facility from Lockheed Martin in Newtown, Pennsylvania and a 250,000-square-foot facility in Langhorne, Pennsylvania. Ex. 1, KVK Vision 2020, available at https://www.kvktech.com/our-products/vision-2020/;

Ex. 2, Natalie Kostelni, *Lockheed Martin sells large Newtown site to pharma company,* Philadelphia Business Journal (Mar. 4, 2015). KVK has spent the last three years building out these facilities to make them state-of-the-art pharmaceutical manufacturing facilities. KVK intends to use these facilities to manufacture drugs developed through its joint collaboration with Argentum. The generic version of PAZEO® will be produced in KVK's new manufacturing space which will come online in the next year.

5. Argentum and KVK are jointly pursuing a generic version of GILENYA® (fingolimod) ("fingolimod product"). The ANDA for the fingolimod product will likely be filed within the next 8-10 months. Both KVK and Argentum have been diligent in working to bring the ANDA to readiness for filing.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on September 10, 2018.

Date: September 10, 2018

Anthony Tabasso

/s/ Anthony Tabasso

Exhibit 1

Vision 2020

(http://www.kvktech.net/wp-content/uploads/2015/07/vision2020.png)

"By 2020, KVK will apply its relentless drive to manufacture high-quality, affordable generics in every major dosage form," states Anthony Tabasso, CEO and President of KVK Tech. "And, all of our products will be made in the USA, right here in Pennsylvania."

KVK is committed to expansion through alliances across all phases of operations, which is evidenced by the current construction of a 250,000-square-foot sterile injectable plant in nearby Langhorne and the purchase of the 461,000-square-foot Lockheed-Martin complex in Newtown.

We continue to explore strategic opportunities to add to our expanding portfolio and are aggressively pursuing research and development prospects, including investment in new molecular entities.

And, we continue with developments in oral solids, such as extended or slow release tablets or capsules, all the while maintaining high manufacturing standards and exemplary customer service.

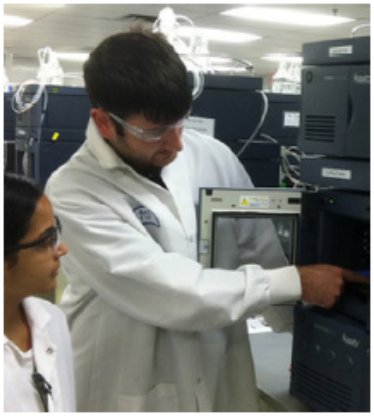

Exhibit 2

Lockheed Martin sells large Newtown site to pharma company

Mar 4, 2015, 8:25am EST

Updated: Mar 4, 2015, 9:07am EST

KVK-Tech Inc., a specialty pharmaceutical company, has entered into an agreement to buy Lockheed Martin's Newtown, Pa., property.

Lockheed put the site up for sale last summer and KVK said in a statement that it has the property under agreement and is scheduled to close on the transaction in June.

The property at 100 Campus Drive has 460,514 square feet of office, lab and high-tech manufacturing space in a series of buildings. It also includes a conference center that was constructed in 2010. The property is approved for an additional 192,000 square feet of office space.

An overhead view of Lockheed Martin's 460,000 square foot property in Newtown, Pa. It has been sold to KVK-Tech Inc.

How much the company paid couldn't be confirmed but it was listed for $30 million. KVK is now located at 110 Terry Drive in Newtown.

Lockheed will remain in the complex until the end of the year and KVK will begin to fit the space out beginning in January 2016.

In a statement, Anthony Tabasso, president and chief executive officer at KVK, said: "We are excited to add the Lockheed Facility to provide for the next stage of KVK's growth. In doing so, KVK is renewing its commitment to the Newtown business community. We expect to create quality jobs here over the next several years as we continue to manufacture high-quality pharmaceuticals exclusively in the USA."

How many jobs couldn't be determined.

Lockheed used the Newtown complex for its commercial and military satellite work and has undergone a reorganization in which it no longer needs the facility. JLL arranged the sale.

Natalie Kostelni

Reporter

Philadelphia Business Journal

APPENDIX B

No. 18-2209, -2230, -2260, -2273

United States Court of Appeals
for the Federal Circuit

APOTEX INC, *ET AL.*,

Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Appellees.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in IPR No. 2017-00854

DECLARATION OF JEFFREY GARDNER IN SUPPORT OF ARGENTUM'S OPPOSITION TO NOVARTIS'S MOTION TO DISMISS

I, Jeffrey Gardner, declare:

1. I am the Chief Executive Officer (CEO) for Argentum Pharmaceuticals LLC ("Argentum"). I have served in this position since January 1, 2017. Unless otherwise stated, I have personal knowledge of the facts set forth herein and, if called as a witness, I could and would testify competently thereto.

2. As the CEO at Argentum, a pharmaceutical company, I am involved in many aspects of the business. My job responsibilities include, among other things, managing the overall operations and resources of Argentum, developing Argentum's strategy, and creating and implementing Argentum's vision and mission. I have also been actively involved in all aspects of the dispute between Argentum and Novartis AG and now Novartis Pharmaceuticals Corporation (collectively, "Novartis"), including Argentum's challenge to Novartis's U.S. Patent No. 9,187,405 (" '405 patent") (Ex. 1) in IPR2017-01550, which was consolidated in IPR 2017-00854 and the subsequent appeal to the United States Court of Appeals for the Federal Circuit following a final written decision from the Patent Trial and Appeal Board.

3. Argentum was incorporated in May of 2015. Although a young company, Argentum has already pursued generic versions of multiple products to bring to market, including, but not limited to, generic versions of VIMPAT®, PAZEO®, ZYTIGA®, RESTASIS®, AFINITOR®, TRAVATAN Z®, DYMISTA®, JUBLIA® and CIALIS®. *See generally* Ex. 2, Press Release, *Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against UCB's*

VIMPAT® (May 23, 2016); Ex. 3, Press Release, *Argentum Pharmaceuticals and KVK Tech Succeed in Starting Patent Cancellation Trial Against Alcon's PAZEO*® (Aug. 1, 2016); Ex. 4, Press Release, *Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Janssen's ZYTIGA*® (Sept. 19, 2016); Ex. 5, Press Release, *Argentum and Alcon Settle Patent Dispute Over PAZEO*® (Nov. 30, 2016); Ex. 6, Press Release, *Argentum Persists in Challenging the "Evergreening" Patent on UCB's VIMPAT*® (Mar. 23, 2016); Ex. 7, Press Release, *Argentum Pharmaceuticals and Allergan Settle Patent Dispute Over RESTASIS*® (Apr. 18, 2016); Ex. 8, Press Release, *Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Novartis's AFINITOR*® (Sept. 29, 2017); Ex. 9, Press Release, *Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Mylan's DYMISTA*® (Sept. 29, 2017); Ex. 10, Press Release, *Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Alcon's TRAVATAN Z*® (Sept. 29, 2017); Ex. 11, Press Release, *Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Valeant's JUBLIA*® (Nov. 13, 2017); Ex. 12, Press Release, *Argentum Pharmaceuticals Wins Patent Invalidation Trial against the Sole Remaining Patent Protecting Janssen's ZYTIGA*® (Jan, 17, 2018); Ex. 13, Press Release, *Argentum Pharmaceuticals Wins Patent Invalidation Trial Against Patent on Valeant's JUBLIA*® (June 7, 2018); Ex. 14, Press Release, *Argentum Pharmaceuticals and Eli Lilly Settle Patent Dispute Over CIALIS*® (Aug. 22, 2017). Argentum has been granted a license to market generic versions of multiple "Brand name" drugs prior to the expiration of the associated patents listed in the U.S. Food and

Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), including, but not limited to PAZEO®, RESTASIS®, and CIALIS®. *See* Exs. 5, 7, 14. For example, Argentum and Novartis company Alcon Research, Ltd. reached agreement for Argentum to market a generic version of PAZEO® in November of 2016. Ex. 5.

4. Argentum partners with other companies to develop generic drug products and to bring them to market. For example, Argentum has partnered with KVK-Tech Inc. ("KVK") to develop generic versions of multiple generic drug products. KVK is a recognized leader in the development and manufacture of high quality, FDA-approved drug products and possesses operational expertise in packaging, manufacturing, sales, distribution and research and development.

5. As part of the collaboration, KVK and Argentum meet regularly to collaborate on choice of products for development and marketing. Considerations for choice of project are the same as any pharmaceutical company would face, including market size, technical considerations, regulatory considerations and patent considerations.

6. In 2015, the same year that Argentum was incorporated, it is my understanding that KVK purchased a 250,000-square-foot facility in Langhorne, Pennsylvania, and a 461,000-square-foot facility from Lockheed Martin in Newtown, Pennsylvania. Ex. 15, KVK Vision 2020, available at https://wwvv.kvktech.com/our-products/vision-2020/; Ex. 16, Natalie Kostelni, *Lockheed Martin sells large*

Newtown site to pharma company, Philadelphia Business Journal (Mar. 4, 2015). It is my understanding that KVK has spent the last three years building out these facilities to make them state-of-the-art pharmaceutical manufacturing facilities. Products developed from the joint collaboration with KVK will be manufactured at these locations, benefiting Argentum which does not have manufacturing facilities of its own. In 2015, Argentum was looking for manufacturing space to produce products.

7. In 2015 Argentum and KVK began negotiations for a collaboration, which culminated in a collaboration agreement between Argentum and KVK, executed January 29, 2016, which calls for the following joint activities: (i) collaborate using their internal resources to develop and commercialize pharmaceutical products, including generic drug products and authorized-generic drug products; (ii) prepare, prosecute and defend IPRs and litigation under the Hatch-Waxman Act and other patent-related strategies germane to the availability and cost of pharmaceutical products using internal and external resources; (iii) engage in settlement discussions and settle legal proceedings; (iv) share in external costs; and (v) share in any financial benefits.

8. External costs are shared by Argentum and KVK on an opportunity-by-opportunity basis. Resulting revenues from the collaboration are distributed between the parties.

9. A number of products are currently being jointly developed by Argentum and KVK. Argentum is currently partnered with KVK to collaborate on the development and marketing of a generic version of

JUBLIA® (efinaconazole). Part of the responsibilities of Argentum included requesting, organizing and participating in Pre-ANDA meetings with the FDA, and participating on a Joint Development Committee that is responsible for overseeing the development and activities relating to the development of the Product formulations at all stages of development.

10. As part of the Argentum-KVK collaboration, in 2017, Argentum and KVK agreed to jointly develop and bring to market a generic version of GILENYA® (fingolimod).[1]

11. On behalf of the generic fingolimod drug product opportunity, the Abbreviated New Drug Application ("ANDA") for a generic version of GILENYA® will be filed by KVK, Argentum's manufacturing and marketing partner. KVK has represented to me that the ANDA will likely be filed within the next 8-10 months. Both KVK and Argentum have been diligent in working toward FDA submission of the ANDA. Argentum has invested significant manpower and resources to the endeavor.

12. Argentum and KVK intend to market their generic fingolimod product upon approval of the

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[1] Novartis lists three patents in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as protecting its GILENYA® 0.5 mg dosage strength drug product: U.S. Patent Nos. 8,324,283 (" '283 patent"), 5,604,229 (" '229 patent"), and the '405 patent. Ex. 17, Orange Book listing. According to the Orange Book, the '229 patent will expire next year on February 18, 2019, or August 18, 2019 with six months of pediatric exclusivity, and the '405 patent will expire June 25, 2027, or December 25, 2027, with six months of pediatric exclusivity. *Id.*

ANDA by FDA. Argentum has prepared marketing projections for a variety of scenarios, and revenues from the generic fingolimod product are projected to be about $10-50 million per year, with a positive profit margin. Novartis reported $3.185 billion in net sales of GILENYA® in 2017. Ex. 18, Excerpts from Novartis Annual Report 2017 at 206.

13. It is my understanding that when an ANDA is filed, an applicant must certify to FDA in the opinion of the applicant and the best of applicant's knowledge with respect to each patent which claims the reference listed drug or which claims a use for the reference listed drug for which the applicant is seeking approval that (1) such patent information has not been filed, (2) that such patent has expired, (3) the date on which such patent will expire, or (4) such patent is invalid or will not be infringed by the manufacture, use, or sale of the generic product ("paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii). It is also my understanding that when an applicant includes a paragraph IV certification, the applicant must give notice to each owner of the patent that is subject of the paragraph IV certification, and the New Drug Application ("NDA") holder for the reference listed drug that states, among other things, a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed ("notice letter"). 21 U.S.C. § 355(j)(2)(B). It is also my understanding that where an applicant's ANDA includes a paragraph IV certification and the applicant sends a notice letter to the patent owner and NDA holder, if a patent infringement suit is brought within 45-days after the date of receipt of the notice letter, the ANDA will not be approved by FDA until

expiration of the 30-month period beginning on the date of receipt of the notice letter ("30-month stay"), unless before the expiration of the 30-month stay a district court decides that the patent is invalid or not infringed, the FDA approval is effective on the date the court enters judgment reflecting that decision, or the date of a settlement order or consent decree signed and entered by the court saying that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii).

14. Based upon the foregoing, Argentum believes that Novartis will inevitably sue Argentum's manufacturing and marketing partner KVK for patent infringement upon KVK's filing an ANDA for a generic version of GILENYA® with FDA with a paragraph IV certification for the '405 patent, and sending a notice letter to Novartis. Argentum therefore believes that invalidating the '405 patent in the IPR proceeding that is the subject of this appeal is imperative to removing that patent as an obstacle to approval of KVK's ANDA, and manufacturing and selling the generic version of GILENYA® that is the subject of that ANDA. If KVK cannot gain FDA approval for the ANDA to market the generic fingolimod product, Argentum and KVK will suffer severe financial harm, because of its investment in time and resources.

15. It is my understanding that an IPR petitioner or real party in interest or privy of the IPR petitioner in an IPR that results in a final written decision from the Patent Trial and Appeal Board is prohibited from asserting that a patent claim is invalid on any ground that the petitioner raised or reasonably could have raised during that IPR in a civil action or proceeding before the International Trade Commission. 35 U.S.C. § 315(e). If Argentum is not permitted

to remain a party to this appeal, it will also be harmed because it will be estopped from raising at least the arguments made in the IPR in another forum. Argentum, as a party in the IPR, will be precluded from later re-raising the patentability questions at issue here, and may be estopped from challenging the '405 patent at all. Applying the estoppel provision will forever bar Argentum from challenging the patentability of the '405 patent on these grounds, even though Novartis is virtually certain to bring an infringement suit against Argentum's marketing and manufacturing partner KVK once its ANDA is filed, which may still result in millions of dollars of lost profits to Argentum.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on September 10th, 2018 .

Date: 10 SEP, 2018

Jeffrey Gardner

/s/ Jeffrey Gardner

Exhibit 1 (U.S. Patent No. 9,187,405)
Intentionally Omitted,
Available at:
Appeal No. 18-2209, ECF 44-3, at 11-20

Exhibit 2

Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against UCB's VIMPAT®

NEWS PROVIDED BY
Argentum Pharmaceuticals →
May 23, 2016, 07:20 ET

NEW YORK, May 23, 2016 /PRNewswire/ —

Today, the U.S. Patent & Trademark Office (PTO) granted Argentum Pharmaceuticals LLC's petition for *inter partes* review (IPR) against all claims of the sole remaining patent listed as covering UCB Inc.'s VIMPAT® (lacosamide) drug in the Food & Drug Administration's Orange Book. The PTO concluded that Argentum has established a "reasonable likelihood that it would prevail in showing that claims 1-13 of the '551 patent [U.S. Patent RE 38,551] are unpatentable." The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board. A final decision on patentability in the IPR is due within 1 year.

Argentum Pharmaceuticals. Balancing the rights of pharmaceutical innovators and consumers.

In addition to Argentum's instituted IPR, Argentum also filed an *ex parte* reexamination request against this same patent that raises additional grounds of unpatentability than those in the IPR. A decision by the PTO on Argentum's reexamination request is due no later than July 29, 2016.

Unlike today's successful institution of Argentum's IPR petition, a prior IPR petition filed by a group of generic companies against this same patent was denied in January 2015. Those companies were Actavis, Inc., Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC, Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Vennoot Pharmaceuticals, LLC, Sandoz Inc., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Ltd.

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescrip-

tion drugs by challenging patents that are not innovative and which artificially support high drug prices. http://www.argentumpharmaceuticals.com

Exhibit 3

Argentum Pharmaceuticals and KVK Tech Succeed in Starting Patent Cancellation Trial Against Alcon's PAZEO®

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Aug 01, 2016, 06:35 ET

NEW YORK, Aug. 1, 2016 /PRNewswire/ —

The U.S. Patent & Trademark Office (PTO) granted a petition for *inter partes* review (IPR) filed by Argentum Pharmaceuticals LLC and its manufacturing partner KVK Tech, against all challenged claims of the sole patent listed as covering Alcon's PAZEO® (0.7% olopatadine hydrochloride ophthalmic solution) drug in the Food & Drug Administration's Orange Book. Argentum and KVK challenged claims 1-4, 8, 12, 13, 21 and 22 of Alcon's U.S. Patent No. 8,791,154, and on July 18, 2016 the PTO concluded there is a "reasonable likelihood that [petitioner] would prevail in showing that the claims it challenges are unpatentable". The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board (PTAB). A final decision on patentability in the IPR is due within 1 year. The successful institution of this petition marks the first time the PTAB has instituted an IPR against this patent.

Argentum Pharmaceuticals. Balancing the rights of pharmaceutical innovators and consumers.

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. www.argentumpharmaceuticals.com

About KVK Tech

KVK is a recognized leader in the development and manufacture of high-quality, FDA-approved medicines, and possesses operational expertise in pharmaceutical manufacturing, packaging, sales, distribution, research & development, and customer service. KVK's expertise runs the gamut and includes solid oral, powder, liquid, and proprietary dosage technologies. KVK has expanded its capabilities into sterile products as well, with a 225,000 sq./ft., state-of-the-art sterile injectable facility being qualified later this year. KVK takes pride in its ability to advance medical care and offer low-cost, high-quality alternatives in response to today's healthcare challenges. KVK is

one of the few manufacturers of generic pharmaceuticals who handles all of its manufacturing, packaging, and distribution in the United States. www.kvktech.com

Exhibit 4

Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Janssen's ZYTIGA®

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Sep 19, 2016, 11:00 ET

NEW YORK, Sept. 19, 2016 /PRNewswire/ —

Today, the U.S. Patent & Trademark Office (PTO) granted Argentum Pharmaceuticals LLC's petition for *inter partes* review (IPR) against all claims of the sole unexpired patent listed as covering Janssen Oncology, Inc.'s ZYTIGA® (abiraterone acetate) drug in the Food & Drug Administration's Orange Book that will remain after Janssen's initial patent on the drug expires later this year. Argentum challenges claims 1-20 of Janssen's U.S. Patent No. 8,822,438, which the Orange Book states will expire in 2027.

Argentum Pharmaceuticals. Balancing the rights of pharmaceutical innovators and consumers.

The PTO concluded that Argentum has established a "reasonable likelihood that it will prevail with respect to its challenge to claims 1-20 of the '438 patent on the asserted grounds." The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board. A final decision on patentability in the IPR is due within 1 year.

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. http://www.argentumpharmaceuticals.com

Exhibit 5

Argentum and Alcon Settle Patent Dispute Over PAZEO®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Nov 30, 2016, 02:31 EST

NEW YORK, Nov. 30, 2016 /PRNewswire/ —

Argentum Pharmaceuticals LLC, a generic pharmaceutical company, announced today that it has reached a settlement with Alcon Research, Ltd., related to Argentum's generic version of PAZEO® (0.7% olopatadine hydrochloride ophthalmic solution).

Under the terms of the settlement agreement, Alcon has granted Argentum a license to its U.S. patent covering PAZEO® for a generic version of PAZEO®. The agreement generally provides that Argentum may commence marketing its generic equivalent product sometime prior to the expiration of the patents covering PAZEO®. The specific date on which Argentum may launch its generic product and other details concerning the settlement have not been disclosed.

PAZEO® is a registered trademark of Novartis AG Corporation.

Exhibit 6

Argentum Persists in Challenging the "Evergreening" Patent on UCB's VIMPAT®

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Mar 23, 2017, 12:09 ET

NEW YORK, March 23, 2017 /PRNewswire/ —

In addition to reaching settlements granting Argentum Pharmaceuticals LLC rights to market lower-cost generics of other patented drugs, Argentum continues to challenge the sole remaining patent covering UCB's VIMPAT® drug in the U.S. Patent & Trademark Office. Argentum's challenge of the VIMPAT® patent is consistent with Argentum's mission of seeking to invalidate patents that are not innovative and that artificially support high drug prices.

After obtaining successful institution of its challenge at the PTO where other challengers previously failed, Argentum was subsequently joined in its effort at the PTO to invalidate the VIMPAT® patent (U.S. Patent RE 38,551) by three other generic manufacturers: Mylan Pharmaceuticals, Inc., Breckenridge Pharmaceutical, Inc., and Alembic Pharmaceuticals, Ltd.

On March 22, 2017, the PTO's Patent Trial & Appeal Board ("PTAB") issued a final written decision that rejected nearly all of UCB's so-called "objective indicia of nonobviousness"—giving little to no weight to UCB's arguments of "unexpected results," "industry praise," "skepticism," "failure of others," and "copying." Those issues are currently the subject of a pending appeal, filed by other generic challengers, from the District of Delaware's August 2016 decision that upheld the validity of the VIMPAT® patent based in part on these same "objective indicia" arguments. While the PTAB's final written decision found insufficient motivation to modify a "lead compound" via "bioisosteric replacement" from an amine to a methyl, the pending appeal of the district court decision does not involve this specific replacement chemistry, because the "lead compound" in the appeal already contains a methyl.

The latter "lead compound" was disclosed in a master's thesis written by a student of the patent's inventor at the University of Houston, which was not disclosed to the PTO during prosecution. In response to a Texas Public Information Act request that Argentum filed seeking evidence of the public's access to the thesis, the University refused to turn over that evidence. The University stated that its "revenue stream will be lost or severely diminished ... as a result of the requested information being produced," and that "it is critical that this information be withheld in order to protect the University from competitive interests." The University receives royalties from UCB based on sales of VIMPAT®.

Commenting on the PTAB's March 22 decision, Argentum's CEO Jeffrey Gardner stated, "Given the numerous factual rulings against UCB's 'objective indicia' and the differences between 'lead compounds' at the PTAB and district court appeal, Argentum believes the PTAB decision hurts, rather than helps, UCB's chances in the pending appeal of the district court case. The PTAB recognized that UCB was already awarded two earlier, now-expired U.S. patents for VIMPAT®, which UCB is 'evergreening' with this third patent that Argentum is challenging."

Separately, Argentum is also challenging the VIMPAT® patent through an *ex parte* reexamination the PTO agreed to institute based on "obviousness-type double patenting," which is not at issue in the PTAB decision. The PTO has preliminarily agreed with all of Argentum's unpatentability positions, and the reexamination remains pending.

Mr. Gardner stated, "We look forward to reasonable prices for this drug being available to Americans, once the VIMPAT® patent is revoked, whether through Argentum's IPR, the district court appeal, or the reexamination."

Exhibit 7

Argentum Pharmaceuticals and Allergan Settle Patent Dispute Over RESTASIS®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Apr 18, 2017, 16:01 ET

NEW YORK, April 18, 2017 /PRNewswire/ —

Argentum Pharmaceuticals LLC, a generic pharmaceutical company, announced that it has reached a settlement and license agreement with Allergan, Inc. related to Argentum's generic version of RESTASIS® (0.05% cyclosporine ophthalmic emulsion).

The agreement generally provides that Argentum may commence marketing its generic equivalent product sometime prior to the expiration of the patents covering RESTASIS®. The specific date on which Argentum may launch its generic product and other details concerning the settlement have not been disclosed.

RESTASIS® is a registered trademark of Allergan, Inc.

Exhibit 8

Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Novartis's AFINITOR®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Sep 29, 2017, 13:42 ET

NEW YORK, Sept. 29, 2017 /PRNewswire/ —

The U.S. Patent & Trademark Office (PTO) on September 25, 2017 granted Argentum Pharmaceuticals LLC's petition for *inter partes* review (IPR) against all claims of the last-expiring patent listed as covering Novartis Pharmaceuticals' AFINITOR® (everolimus tablet) drug in the Food & Drug Administration's Orange Book. Argentum challenges claims 1-3 of Novartis's U.S. Patent No. 9,006,224, which the Orange Book states will expire in 2028. The PTO concluded that Argentum has established a "reasonable likelihood that [Argentum] would prevail with respect to claims 1-3" of the patent. The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board. A final decision on patentability in the IPR is due within 1 year.

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic

pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. http://www.argentumpharmaceuticals.com

Exhibit 9

Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Mylan's DYMISTA®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Sep 29, 2017, 14:05 ET

NEW YORK, Sept. 29, 2017 /PRNewswire/ —

The U.S. Patent & Trademark Office (PTO) granted a petition for *inter partes* review (IPR) filed by Argentum Pharmaceuticals LLC and its manufacturing partner KVK Tech, against all challenged claims of the last-expiring patent listed as covering Mylan Specialty LP's DYMISTA® (azelastine hydrochloride/fluticasone propionate nasal spray) drug in the Food & Drug Administration's Orange Book. Argentum and KVK challenged claims 1, 4-6, 24-26, 29, and 42-44 of U.S. Patent No. 8,168,620, and on August 21, 2017 the PTO concluded there is a "reasonable likelihood that [Argentum] would prevail in showing that claims 1, 4-6, 24-26, 29, and 42-44 of the '620 patent are unpatentable". The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board (PTAB). A final decision on patentability in the IPR is due within 1 year. This institution decision marks the first time the PTAB has instituted an IPR against any Orange Book listed patent covering DYMISTA®.

MADE IN AMERICA. All KVK Tech products are made in the USA in strictest accordance with FDA, DEA, and DEP guidelines. (PRNewsfoto/Argentum Pharmaceuticals)

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. www.argentumpharmaceuticals.com

About KVK Tech

KVK is a recognized leader in the development and manufacture of high-quality, FDA-approved medicines, and possesses operational expertise in pharmaceutical manufacturing, packaging, sales, distribution, research & development, and customer service. KVK's expertise runs the gamut and includes solid oral, powder, liquid, and proprietary dosage technologies. KVK is in the process of expanding its capabilities into aseptic products as well with a 225,000 sq./ft. sterile injectable facility being qualified this year. KVK takes pride in its ability to advance medical care and offer low-cost, high-quality alternatives in response to today's healthcare challenges. KVK is one

of the few manufacturers of generic pharmaceuticals which does all its manufacturing, packaging, and distribution in the United States. www.kvktech.com

Exhibit 10

Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Alcon's TRAVATAN Z®

Ag Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Sep 29, 2017, 13:47 ET

NEW YORK, Sept. 29, 2017 /PRNewswire/ —

The U.S. Patent & Trademark Office (PTO) granted a petition for *inter partes* review (IPR) filed by Argentum Pharmaceuticals LLC and its manufacturing partner KVK Tech, against all claims of the last-expiring patent listed as covering Alcon's TRAVATAN Z® (0.004% travoprost solution) drug in the Food & Drug Administration's Orange Book. Argentum and KVK challenged claims 1-28 of Alcon's U.S. Patent No. 8,268,299, and on September 22, 2017 the PTO concluded there is a "reasonable likelihood that [Argentum] would prevail at trial". The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board (PTAB). A final decision on patentability in the IPR is due within 1 year. The successful institution of this petition marks the first time the PTAB has instituted an IPR against this patent.

MADE IN AMERICA. All KVK Tech products are made in the USA in strictest accordance with FDA, DEA, and DEP guidelines.

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. www.argentumpharmaceuticals.com

About KVK Tech

KVK is a recognized leader in the development and manufacture of high-quality, FDA-approved medicines, and possesses operational expertise in pharmaceutical manufacturing, packaging, sales, distribution, research & development, and customer service. KVK's expertise runs the gamut and includes solid oral, powder, liquid, and proprietary dosage technologies. KVK is in the process of expanding its capabilities into aseptic products as well with a 225,000 sq./ft. sterile injectable facility being qualified this year. KVK takes pride in its ability to advance medical care and offer low-cost, high-quality alternatives in response to today's healthcare challenges. KVK is one of the few manufacturers of generic pharmaceuticals

which does all its manufacturing, packaging, and distribution in the United States. www.kvktech.com

Exhibit 11

Argentum Pharmaceuticals Succeeds in Starting Patent Cancellation Trial Against Valeant's JUBLIA®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Nov 13, 2017, 20:02 EST

NEW YORK, Nov. 13, 2017 /PRNewswire/ —

Today, the U.S. Patent & Trademark Office (PTO) granted Argentum Pharmaceuticals LLC's petition for *inter partes* review (IPR) against all patent claims in the first patent listed in the Food & Drug Administration's Orange Book as covering Valeant Pharmaceuticals' JUBLIA® (efinaconazole topical solution 10%). Argentum is challenging all claims of U.S. Patent No. 7,214,506 ('506 patent).

In granting Argentum's petition, the PTO concluded that Argentum "has established a reasonable likelihood that it would prevail in showing the unpatentability of each of the challenged claims of the '506 patent." The decision marks the beginning of an IPR trial that will be conducted by three specialist patent judges within the PTO's Patent Trial & Appeal Board. A final decision on patentability in the IPR is due by May 1, 2018.

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical

operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. http://www.argentumpharmaceuticals.com

Exhibit 12

Argentum Pharmaceuticals Wins Patent Invalidation Trial against the Sole Remaining Patent Protecting Janssen's ZYTIGA®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Jan 17, 2018, 08:23 EST

NEW YORK, Jan. 17, 2018 /PRNewswire/ —

Today, the U.S. Patent & Trademark Office (PTO) issued a final written decision in Argentum Pharmaceuticals LLC's *inter partes* review (IPR) against the sole unexpired patent listed as covering Janssen Oncology, Inc.'s ZYTIGA® (abiraterone acetate) drug in the Food & Drug Administration's Orange Book. Janssen Oncology, Inc. is a subsidiary of Johnson & Johnson. Argentum challenged all claims (claims 1-20) of Janssen's U.S. Patent No. 8,822,438, which the Orange Book states will expire in August 24, 2027.

In today's decision, the PTO concluded that Argentum "satisfied its burden of demonstrating, by a preponderance of the evidence, that the subject matter of claims 1-20 would have been obvious," and therefore ordered "that claims 1-20 are held *unpatentable.*"

Argentum Pharmaceuticals' CEO Jeffrey Gardner issued the following statement regarding the ruling:

"We are pleased that the PTO has ruled in Argentum's favor by holding all claims of the last remaining Orange Book patent for Zytiga to be obvious. The *inter partes* review process is an important tool by which generic and biosimilar companies can create prescription drug savings by ensuring that non-innovative patents do not block competition. Argentum's core mission is to lower the cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. We believe that the PTO's decision will be upheld if appealed by Janssen, and will save the US healthcare system billions of dollars over the next decade. Those savings will inure to the benefit of American patients by improving their access to the high quality, safe, and effective FDA-approved generic alternatives that they deserve."

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. http://www.argentumpharmaceuticals.com

Exhibit 13

Argentum Pharmaceuticals Wins Patent Invalidation Trial Against Patent on Valeant's JUBLIA®

Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals →
Jun 07, 2018, 10:51 ET

NEW YORK, June 7, 2018 /PRNewswire/ —

On June 6, 2018, the U.S. Patent & Trademark Office (PTO) issued a final written decision in favor of Argentum Pharmaceuticals, finding all claims of U.S. Patent No. 7,214,506 (" '506 patent") to be unpatentable for obviousness. The '506 patent is listed in the Food & Drug Administration's Orange Book as covering Valeant Pharmaceuticals' JUBLIA® (efinaconazole 10% solution) drug. According to the Orange Book, the '506 patent will not expire until October 5, 2021.

On May 12, 2017, Argentum filed an *inter partes* review (IPR) petition challenging all claims (claims 1 and 2) of the '506 patent.

In its final written decision, the Patent Trial & Appeal Board concluded that Argentum "has shown by a preponderance of the evidence that claims 1 and 2 of the '506 patent are unpatentable."

Commenting on the Board's decision, Argentum's CEO Jeffrey Gardner stated:

> *"Argentum is pleased with the Board's thorough and detailed decision holding all claims of the '506 claims to be unpatentable. This decision once again shows that the IPR process is an efficient and effective tool to obtain expert agency review of Orange Book listed patents that should not have been granted in the first place.*
>
> *Argentum's core mission is to lower the cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. The IPR process has been shown to work for the benefit of American patients by improving their access to the high quality, safe, and effective FDA-approved generic alternatives that they deserve."*

About Argentum Pharmaceuticals

Argentum is a generic drug company with core competencies in intellectual property and pharmaceutical operations. By working with branded and generic pharmaceutical companies and healthcare payors, Argentum intends to reduce the overall cost of prescription drugs by challenging patents that are not innovative and which artificially support high drug prices. http://www.argentumpharmaceuticals.com

Exhibit 14

Argentum Pharmaceuticals and Eli Lilly Settle Patent Dispute Over CIALIS®

Ag Argentum Pharmaceuticals

NEWS PROVIDED BY
Argentum Pharmaceuticals LLC →

NEW YORK, Aug. 22, 2017 /PRNewswire/ —

Argentum Pharmaceuticals LLC, a generic pharmaceutical company, announced that it has reached a settlement and license agreement with Eli Lilly and Company related to Argentum's generic version of CIALIS® (tadalifil).

The agreement generally provides that Argentum may commence marketing its generic product no earlier than September 27, 2018. The specific date on which Argentum may launch its generic product and other details concerning the settlement have not been disclosed.

CIALIS® is a registered trademark of Eli Lilly and Company.

Exhibit 15

Vision 2020

(http://www.kvktech.net/wp-content/uploads/2015/07/vision2020.png)

"By 2020, KVK will apply its relentless drive to manufacture high-quality, affordable generics in every major dosage form," states Anthony Tabasso, CEO and President of KVK Tech. "And, all of our products will be made in the USA, right here in Pennsylvania."

KVK is committed to expansion through alliances across all phases of operations, which is evidenced by the current construction of a 250,000-square-foot sterile injectable plant in nearby Langhorne and the purchase of the 461,000-square-foot Lockheed-Martin complex in Newtown.

We continue to explore strategic opportunities to add to our expanding portfolio and are aggressively pursuing research and development prospects, including investment in new molecular entities.

And, we continue with developments in oral solids, such as extended or slow release tablets or capsules, all the while maintaining high manufacturing standards and exemplary customer service.

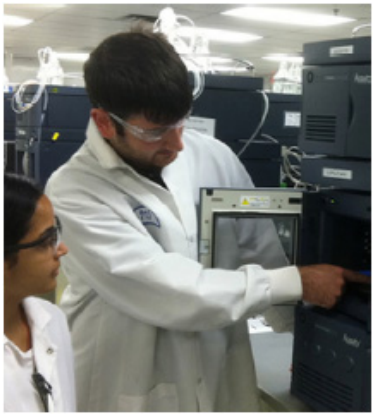

Exhibit 16

Lockheed Martin sells large Newtown site to pharma company

Mar 4, 2015, 8:25am EST

Updated: Mar 4, 2015, 9:07am EST

KVK-Tech Inc., a specialty pharmaceutical company, has entered into an agreement to buy Lockheed Martin's Newtown, Pa., property.

Lockheed put the site up for sale last summer and KVK said in a statement that it has the property under agreement and is scheduled to close on the transaction in June.

The property at 100 Campus Drive has 460,514 square feet of office, lab and high-tech manufacturing space in a series of buildings. It also includes a conference center that was constructed in 2010. The property is approved for an additional 192,000 square feet of office space.

An overhead view of Lockheed Martin's 460,000 square foot property in Newtown, Pa. It has been sold to KVK-Tech Inc.

How much the company paid couldn't be confirmed but it was listed for $30 million. KVK is now located at 110 Terry Drive in Newtown.

Lockheed will remain in the complex until the end of the year and KVK will begin to fit the space out beginning in January 2016.

In a statement, Anthony Tabasso, president and chief executive officer at KVK, said: "We are excited to add the Lockheed Facility to provide for the next stage of KVK's growth. In doing so, KVK is renewing its commitment to the Newtown business community. We expect to create quality jobs here over the next several years as we continue to manufacture high-quality pharmaceuticals exclusively in the USA."

How many jobs couldn't be determined.

Lockheed used the Newtown complex for its commercial and military satellite work and has undergone a reorganization in which it no longer needs the facility. JLL arranged the sale.

Natalie Kostelni

Reporter

Philadelphia Business Journal

Exhibit 17 (Orange Book Listing)
Intentionally Omitted,
Available at:
Appeal No. 18-2209, ECF 44-3, at 71-73