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16 FLOW PHARMA, INC.

17 UNITED STATES DISTRICT COURT
18 NORTHERN DISTRICT OF CALIFORNIA – SAN FRANCISCO DIVISION

19 **FLOW PHARMA, INC.,**

20 Plaintiff,

21 v.

22 **BAUSCH HEALTH COMPANIES INC.;**
23 **VALEANT PHARMACEUTICALS**
24 **NORTH AMERICA, LLC**

25 Defendants.

CASE NO.

**COMPLAINT FOR PATENT
INFRINGEMENT**

JURY TRIAL DEMANDED

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COMPLAINT

Plaintiff Flow Pharma, Inc. (“Flow Pharma”) files this Complaint for Patent Infringement of U.S. Patent No. 8,138,157 (the “’157 patent”) against Bausch Health Companies Inc. (“Bausch Health”), formerly Valeant Pharmaceuticals International, Inc., and Valeant Pharmaceuticals North America, LLC (“VPNA”) (together, “Defendants”), and alleges as follows:

Nature of the Action

1. Flow Pharma brings this civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. §§ 271, 281-85.

2. On March 20, 2012, the United States Patent and Trademark Office (“USPTO”) duly and legally issued U.S. Patent No. 8,138,157, titled “Antibiotic Formulation and Method of Treatment,” to inventor Reid M. Rubsamén. A true and correct copy of the ’157 patent is attached as Exhibit A to this Complaint for Patent Infringement.

3. Flow Pharma owns the entire right and title to the ’157 patent.

4. Defendants have infringed and continue to infringe one or more claims of the ’157 patent at least by using their Arestin product in an infringing manner and by knowingly encouraging others to use their Arestin product in an infringing manner, as set forth in detail below. Flow Pharma seeks, among other things, monetary damages.

Parties

5. Flow Pharma is a corporation formed under the laws of Delaware with its principal place of business at 39655 Eureka Dr., Newark, California 94560.

6. Upon information and belief, Bausch Health is a Canadian corporation with its principal place of business at 2150 St. Elzéar Blvd. West, Laval, Quebec H7L 4A8, Canada.

7. Upon information and belief, VPNA is a limited liability company formed under the laws of Delaware with its principal place of business at 400 Somerset Corporate Blvd., Bridgewater, NJ 08807. Upon information and belief, VPNA is a subsidiary of Bausch Health.

Jurisdiction

8. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338.

1 9. This Court has personal jurisdiction over Defendants because Defendants have,
2 directly or through intermediaries, committed acts within this District and the State of California
3 giving rise to this action and/or have established minimum contacts with this District and the
4 State of California such that the exercise of jurisdiction would not offend traditional notions of
5 fair play and substantial justice.

6 10. Defendants transact and conduct business in this District and the State of
7 California. For example, Bausch Health maintains a physical location in Petaluma, California.
8 Defendants promote and sell their products, including their dentistry products, through their
9 websites, including www.orapharma.com and www.arestinprofessional.com, and over the phone.
10 These products are thus available to and accessed by residents of this District and the State of
11 California. On information and belief, Defendants also employ sales persons whose objective is
12 the sales of their products into this District and the State of California. Additionally, Defendants
13 perform and/or direct studies of their new products in this State.

14 11. Flow Pharma's cause of action arises, at least in part, from Defendants' business
15 contacts and activities in this District and elsewhere within the State of California. Defendants'
16 Arestin product can be and is being used to infringe one or more claims of Flow Pharma's '157
17 patent in this District and the State of California. Defendants, directly or through intermediaries,
18 have both: (1) used their Arestin product to infringe one or more claims of Flow Pharma's '157
19 patent in the State of California; and (2) knowingly encouraged and continue to encourage
20 persons in this District and in the State of California to use their Arestin product in a way that
21 infringes one or more claims of the '157 patent. Specifically, on information and belief,
22 Defendants have performed studies, including at the UCLA School of Dentistry in Los Angeles,
23 during which Defendants and/or persons at their direction used Defendants' Arestin product in an
24 infringing manner. Defendants also promote and sell their Arestin product in the State of
25 California, including in this District. For example, Defendants advertise and make available their
26 Arestin product through their websites, including www.orapharma.com/Products and
27 www.arestinprofessional.com. Defendants, directly or through intermediaries, further encourage
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1 purchasers of their Arestin product to use it in an infringing manner in this District and the State
2 of California, including at dental association events in this District.

3 **Venue**

4 12. Venue is proper in this District as to Bausch Health because it is a foreign
5 corporation. *See* 28 U.S.C. § 1391(c)(3); *In re HTC Corp.*, No. 2018-130, slip op. at 7 (Fed. Cir.
6 May 9, 2018).

7 13. Venue is proper as to VPNA under 28 U.S.C. § 1400(b), because VPNA has
8 committed acts of infringement in this District and has a regular and established place of business
9 in this District. For example, on information and belief, VPNA employs sales persons who are
10 located within this District and who are required, as a part of their job, to maintain a home office
11 and samples of VPNA products, including Arestin. On information and believe, those sales
12 persons promote the infringing use of Defendants' Arestin product in this District.

13 **Intradistrict Assignment**

14 14. This action for patent infringement is assigned on a district-wide basis under Civil
15 L.R. 3-2(c).

16 **Background**

17 15. Flow Pharma was founded in 2000 with the goal of discovering new and
18 innovative ways to combat disease. Flow Pharma's founder, Reid Rubsamen, M.D., has
19 extensive experience in the areas of medicine, biochemistry, and computer science. He is a
20 Board-Certified anesthesiologist who received his M.D. from Stanford University and his medical
21 training at both the Pacific Medical Center in San Francisco and Massachusetts General Hospital.
22 Additionally, Dr. Rubsamen earned bachelor's degrees in Biochemistry and Computer Science
23 from the University of California, Berkeley, and a master's degree in Computer Science from
24 Stanford. Dr. Rubsamen is a named inventor on more than 65 issued U.S. patents.

25 16. One of Flow Pharma's early focuses in combatting disease was on developing
26 technology relating to delivery of drugs to a patient's body over a controlled period of time. By
27 2001, Flow Pharma had filed a provisional patent related to formulations of small spherical
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1 particles (“microspheres”) that would dissolve inside the body, delivering drugs to the patient
2 consistently over a set period of time as they dissolved.

3 17. By 2009, Flow Pharma had created microspheres, made out of an FDA-approved
4 biodegradable polymer, that carried an antibiotic called gentamicin. In a study published in Spine,
5 those microspheres, when delivered to the sites of surgical implants in rabbits, were shown to
6 significantly decrease the incidence of implant-associated post-operative wound infections. Stall
7 AC, Becker E, Ludwig SC, *et al.*, *Reduction of Postoperative Spinal Implant Infection Using*
8 *Gentamicin Microspheres*, SPINE, Volume 34, Number 5, pp. 479-483 (March 2009); *see also*
9 Poelstra KA, Vaccaro AR, Albert TA, Lampro S, Adams C, Rubsamen R, & Albert TJ,
10 *Gentamicin microspheres for infection prophylaxis in the rabbit spine*, 53rd Orthopaedic Research
11 Society (ORS) Meeting, San Diego, CA (February 10-14, 2007).

12 18. Flow Pharma continues to develop its microsphere technology for drug and
13 vaccine delivery. Flow Pharma’s lead product under current development is FlowVax HPV, for
14 treating women with cervical cancer. Flow Pharma manufactures its microspheres out of the
15 same biodegradable polymer that is used in absorbable sutures. Flow Pharma makes its
16 precision-sized microspheres using retrofitted, commercial spray drying equipment with a
17 proprietary nozzle system, and continuously samples the output of the spray drier using laser
18 particle analysis. Flow Pharma’s microsphere manufacturing process is capable of manufacturing
19 at volumes and quality consistent with that required for human clinical trials. Flow Pharma has
20 recently manufactured additional gentamicin microspheres for experiments using orthopedic
21 implant animal models.

22 19. Flow Pharma filed for the ’157 patent, entitled “Antibiotic Formulation and
23 Method of Treatment,” in April 12, 2010. That patent is a continuation or continuation-in-part of
24 several patents filed before it, dating back to 2001. The ’157 patent issued on March 20, 2012.

25 20. On information and belief, Defendants are a sprawling healthcare and
26 pharmaceutical company that, in 2012, decided to enter the field of oral healthcare by acquiring
27 OraPharma. OraPharma’s website states that it was founded in 1996 as a specialty
28 pharmaceutical company dedicated to oral healthcare. According to OraPharma’s website, its

1 flagship product, *ARESTIN* (minocycline HCl) Microspheres, 1 mg, was approved by the FDA in
2 2001 for the treatment of periodontal disease.

3 21. From the beginning of 2012 through the end of 2014, OraPharma and then
4 Defendants sponsored studies of the safety and effectiveness of their Arestin product in a new
5 application: the treatment of peri-implantitis. On information and belief, these studies were
6 performed on over 400 persons, in locations such as the UCLA School of Dentistry, the
7 University of Florida College of Dentistry, the University of Maryland School of Dentistry, Tufts
8 University School of Dental Medicine, and elsewhere.

9 22. Defendants' use of the Arestin product to treat peri-implantitis, rather than to treat
10 periodontal disease, infringed and infringes at least Claim 1 of the '157 patent, and Flow Pharma
11 promptly notified Defendants of that fact. On June 16, 2015, Dr. Rubsamén, President and CEO
12 of Flow Pharma, wrote a letter to the then-president of OraPharma, stating the relevance of
13 the '157 patent to OraPharma's studies related to using Arestin to treat peri-implantitis. Ten days
14 later, OraPharma responded that it was not interested in having discussions with Flow Pharma
15 about the '157 patent.

16 23. Flow Pharma followed up. After multiple conversations to discuss the matter, on
17 September 24, 2015, counsel for Flow Pharma sent to counsel for Defendants a letter stating
18 clearly that "the '157 patent covers the use of Arestin to treat osteomyelitis which is a known
19 sequ[e]lae of peri-implantit[i]s, the prevention of which is to be covered by OraPharma's planned
20 NDA to be filed later [t]his year." The letter continues:

21 You agreed to review the patent, with an eye towards possible
22 future discussion of assignment or license of the '157 patent from
23 Flow Pharma to OraPharma. During our most recent call, however,
24 you stated that OraPharma, has or is about to abandon work on
[trials] directed to supporting the NDA for the second indication of
Arestin, and therefore has no need for, or interest in, assignment or
license of the '157 patent.

25 After our last phone conversation, however, my client had a
26 telephone call, on August 25, 2015, with Ms. Laurie Little,
27 Valeant's SVP of Investor Relations. She indicated that the NDA
28 was still scheduled to be filed in the second half of 2015. This
seems to contradict your last statement that efforts to obtain
approval on this second indication had been dropped.

...

Given the seemingly inconsistent information, I believe it would be useful to both my client and OraPharma . . . to begin new discussions, or for you to identify an individual in the business development space who can engage in a broader discussion about the '157 Patent.

Based on our conversations, it was also my understanding that neither OraPharma nor any of its agents are currently promoting the use of Arestin for delivering antibiotics in biodegradable polymers for the purpose of prevention and treatment of peri-implantitis, and is not planning to do so in the future.

The letter closed by stating: "We trust you and your agents will continue to respect my client's intellectual property and avoid any off-label promotion which would constitute an inducement to infringe the '157 patent."

24. Counsel for Defendants responded a day later, stating that "the clinical trial was a failure and . . . the project has been abandoned."

25. Flow Pharma has learned that, despite Flow Pharma's warning and Defendants' representation that the clinical trial was a failure, Defendants and their agents have promoted and continue to promote the use of Arestin for delivering antibiotics in biodegradable polymers for the purpose of prevention and treatment of peri-implantitis, including in presentations made in this District.

26. As an example, on March 19, 2016, the late Ricardo P. Teles, DDS, DMSc, the OraPharma Distinguished Professor at University of North Carolina Chapel Hill Dental School, released the findings of a study in which he claimed results that demonstrated that "adjunctive minocycline microspheres decrease periodontal pathogens around implants with peri-implantitis." Notably, according to OpenPaymentsData.CMS.gov, Defendants paid a \$4,000 "Consulting Fee" to Professor Teles just six days before he released those findings. Earlier, in 2014, Defendants paid to Professor Teles over \$120,000 for "Research."

27. As another example, between 2012 and 2016, Jon B. Suzuki, DDS, PhD, MBA, Professor of Periodontology and Oral Implantology at Temple University School of Dentistry, provided numerous presentations, including in this District, promoting the use of Arestin in treating peri-implantitis. Dr. Suzuki's presentation promotes the infringing use of Arestin, and

1 even educates attendees on how best to bill the patient’s dental insurance to ensure that insurance
2 will pay for the Arestin prescription. On information and belief, Dr. Suzuki has been paid more
3 than \$100,000 since 2013 by BioHorizons Implant Systems, Inc. BioHorizons, Inc., in turn, is
4 majority-owned by Henry Schein, Inc., the sole U.S. distributor of Arestin.

5 28. On information and belief, sales of Arestin substantially increased in or around
6 2015, due to the infringing use of Arestin to treat peri-implantitis. Peri-implantitis is a common
7 complication of placing a dental implant. On information and belief, Arestin has become the de
8 facto standard for preventing and/or treating this complication.

9 29. On information and belief, the infringing use of Arestin to treat peri-implantitis
10 accounts for the majority of Arestin sales in the United States.

11 **FIRST CAUSE OF ACTION**

12 **Infringement of U.S. Patent No. 8,138,157**

13 30. Flow Pharma repeats and incorporates the allegations set forth in paragraphs 1-29
14 above.

15 31. Defendants have infringed and continue to infringe at least Claim 1 of the ’157
16 patent under 35 U.S.C. § 271, literally or under the doctrine of equivalents, by making, using,
17 selling, and/or offering for sale in the United States, and/or importing into the United States,
18 products and/or methods that infringe the ’157 patent, including but not limited to by using their
19 Arestin product to treat and/or combat peri-implantitis.

20 32. In addition to the foregoing and/or in the alternative, Defendants indirectly
21 infringe at least Claim 1 of the ’157 patent by inducing infringement by others, including dentists
22 and researchers, in accordance with 35 U.S.C. § 271(b), in this District and elsewhere in the
23 United States. Defendants are actively, knowingly, and intentionally inducing infringement of
24 the ’157 patent by advocating the methods set forth therein and by selling, offering to sell, and/or
25 importing into the United States their Arestin product, with the knowledge and specific intent that
26 third parties will practice the patented methods and use, sell, offer for sale, and/or import the
27 Arestin product to infringe the ’157 patent, and with the knowledge and specific intent to
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1 encourage and facilitate the infringement through the dissemination of the Arestin product and the
2 dissemination of information relating to the Arestin product and the infringing uses thereof.

3 33. In addition to the foregoing, Defendants have performed all their infringing actions
4 since June 16, 2015, with full knowledge of the '157 patent and Flow Pharma's allegations herein.
5 For that reason, Defendants are liable for willful infringement.

6 34. Defendants' acts of infringement have caused damage to Flow Pharma, and flow
7 Pharma is entitled to recover from Defendants the damages it has sustained as a result of
8 Defendants' wrongful acts in an amount subject to proof at trial.

9 **DEMAND FOR JURY TRIAL**

10 35. Flow Pharma hereby demands a jury trial for all issues so triable.

11 **PRAYER FOR RELIEF**

12 WHEREFORE, Flow Pharma prays for judgment as follows:

13 A. Declaring that Defendants have infringed the '157 patent and/or induced
14 infringement of the '157 patent;

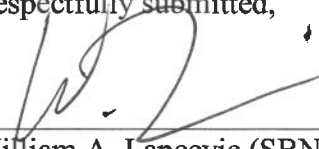
15 B. Awarding damages arising out of Defendants' infringement of the '157 patent,
16 including enhanced damages pursuant to 35 U.S.C. § 284, to Flow Pharma, together with
17 prejudgment and post-judgment interest, in an amount according to proof;

18 C. Awarding attorneys' fees to Flow Pharma pursuant to 35 U.S.C. § 285 or as
19 otherwise permitted by law; and

20 D. Awarding such other costs and further relief as the Court may deem just and
21 proper.

22 Dated: September 20, 2018

Respectfully submitted,

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