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J. Michael Pearson, CEO
Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

Yukoh Yoshida, President & CEO
Senju Pharmaceutical Co., Ltd.
2-5-8, Hirano-machi, Chuo-ku
Osaka, Japan

Re: Paragraph IV certifications, notice letter, and offer of confidential access for Bromfenac Sodium Ophthalmic Solution/Drops EQ 0.07% Acid, Paddock Laboratories, LLC ANDA No. 207584.

Dear Sir:

I am writing to inform you that Paddock Laboratories, LLC ("Paddock") has submitted an abbreviated new drug application to the United States Food and Drug Administration (FDA) containing one or more "paragraph IV" certifications in order to obtain approval to engage in the commercial manufacture, use, or sale of bromfenac sodium ophthalmic solution/drops, EQ 0.07% acid ("the Paddock product").

Paddock's abbreviated new drug application ("Paddock's ANDA" or "the application") was submitted pursuant to 21 U.S.C. § 355(j) and received by the FDA. Paddock's ANDA contains any required bioavailability or bioequivalence data or information.

Paddock's ANDA has been assigned No. 207584.

The established name of the drug product is bromfenac sodium ophthalmic solution/drops. The active ingredient, strength, and dosage forms of the proposed drug product are: bromfenac sodium EQ 0.07% acid, ophthalmic solution/drops.

patent") and United States Patent No. 8,871,813 ("the '813 patent"). Paddock has certified that in its opinion and to the best of its knowledge, the claims of the '431, '290, '131 and '813 patents will not be infringed by Paddock's proposed manufacture, use, or sale of its product that is the subject of its application, and/or those claims are invalid or unenforceable. According to Bausch and Lomb's entry in the FDA's electronic Orange Book, the '431 patent expires September 11, 2025, the '290 patent expires January 16, 2024, the '131 patent expires January 16, 2024, and the '813 patent expires on January 16, 2024.

As required by 21 U.S.C. § 355(j)(2)(B)(ii), a detailed statement of the factual and legal bases for Paddock's opinion is set forth below. Furthermore, this enclosure also contains an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(iii).

Pursuant to 21 C.F.R. § 314.95(e), Paddock requested and received from the FDA permission to send this notice to the NDA holder and patent owner by means other than registered or certified mail. The FDA granted Paddock's request prior to this notice being sent.

The name and address of an agent authorized to accept service of process for Paddock is:

Shane A. Brunner, Edward J. Pardon, Jeffrey S. Ward, or Wendy M. Ward
Merchant & Gould PC
10 E. Doty Street, Suite 600
Madison, WI 53703-3376

DETAILED STATEMENT

I. Legal Standards

General legal standards utilized here are discussed below. More detailed law is discussed in the analysis sections as needed.

A. Claim Construction

The first step in an infringement or invalidity analysis is to construe the claims. Claim construction is an issue of law, performed by the court, even in a jury trial. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The interpretation to be given a claim is formed by the

generally given their ordinary and established meanings to one of ordinary skill in the art. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

The specification is the primary basis for construing the claims, because that is where the inventor provides a full and exact description of the invention. *Phillips*, 415 F.3d at 1315-17. The claims themselves, both asserted and unasserted, are also a valuable source with respect to claim construction. *Id.* at 1314. The prosecution history should also be consulted. *Id.* at 1317. Review of the prosecution history can reveal whether there are any express limitations made regarding the scope and meaning of the claims. *Bell Atlantic Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001). In addition, extrinsic evidence such as dictionaries, technical treatises, articles that are publicly available at the time the patent issued, and expert testimony may also be considered, but this evidence is less significant than the patent itself and its prosecution history. *Phillips*, 415 F.3d at 1317-19.

B. Infringement

After the claim is interpreted, it must be compared to the accused device or process to determine whether the claim's scope encompasses the accused device or process. *North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1574 (Fed. Cir. 1993). If the properly interpreted terms of the claim read on the accused device or process, literal infringement is established. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1468 (Fed. Cir. 1993). Because each element of a claim is material and essential, the patent owner must show the presence of each and every element in the accused device to establish literal infringement. *Charles Greiner & Co. v. Mari-Med Mfg., Inc.*, 962 F.2d 1031, 1034 (Fed. Cir. 1992). The patentee has the burden to show infringement by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Laboratories Corp.*, 859 F. 2d 878, 889 (Fed. Cir. 1988).

Absent literal infringement, a legal doctrine termed the doctrine of equivalents may apply to bring an accused device or process under the web of infringement. *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed. Cir. 1983). Under the doctrine of equivalents, a patent owner may be successful in an infringement action, even if the claims are not literally infringed, if "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997). In applying the doctrine of equivalents, one considers

1517-18 (Fed. Cir. 1995), *rev'd on other grounds and remanded*, 520 U.S. 17 (1997). It is often enough to assess whether the accused device or process performs substantially the same function in substantially the same way to obtain substantially the same result as the claim element(s) missing from the accused structure or process under the literal infringement analysis. *Hilton Davis*, 62 F.3d at 1518. Furthermore, a patent owner must show the presence of every element or its substantial equivalent in the accused device or process to prove infringement under the doctrine of equivalents. *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935 (Fed. Cir. 1987).

Application of the doctrine of equivalents can be precluded in certain situations as a matter of law. For example, a patent owner cannot obtain, under the doctrine of equivalents, coverage that could not lawfully have been obtained from the USPTO by literal claims. *Pennwalt*, 833 F.2d at 938. In other words, a claim cannot be read to cover an accused device under the doctrine of equivalents if that claim would then be unpatentable in view of prior art. *Wilson Sporting Goods Co. v. David Geoffrey and Assocs.*, 904 F.2d 677, 684 (Fed. Cir. 1990). In addition, a patentee is precluded from capturing subject matter under the doctrine of equivalents that was disclosed in the patent specification but not claimed by the patentee. *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (en banc). Furthermore, a patentee cannot assert the doctrine of equivalents where to do so would "vitiate" or completely read a limitation out of a claim. *Warner-Jenkinson Co.*, 520 U.S. at 39 n.8; *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1017 (Fed. Cir. 2006).

Where an accused activity does not include particular limitations of an independent claim or their substantial equivalents, it follows that, for the same reason, the dependent claims will not be infringed. *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000) ("dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed") (citation omitted).

C. Obviousness

A claimed invention in an issued patent is invalid if it would have been obvious to one of ordinary skill in the art at the time the invention was made when viewed in light of the prior art. 35 U.S.C. § 103. Obviousness is a question of law, based on underlying fact issues. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). These fact issues are: (1) the scope and content of the prior art; (2) the

results and commercial success. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406 (2007).

To prove obviousness based on a combination of references, it can be helpful to identify whether there must be some reason to combine those references. *KSR*, 550 U.S. at 418-19. The reason to combine references can be provided by any need or problem that is known in the field of endeavor at the time of the invention and addressed by the patent at issue. *Id.* at 420. In addition, where there is a need to solve a problem, and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue those solutions. If this leads to anticipated success, it is likely the product of ordinary skill and common sense, and is not inventive. *Id.* at 421.

II. Description of the '431 Patent

A. Background

The '431 patent is entitled "Aqueous Liquid Preparation Containing 2-Amino-3(4-Bromobenzoyl)Phenylacetic Acid." The patent issued on March 6, 2012 from U.S. application No. 10/525,006 ("the '006 application"). The '006 application was the U.S. national phase of PCT application PCT/JP2004/000350, filed on January 16, 2004. The PCT application claimed priority to a Japanese patent application filed on January 21, 2003. The '431 patent lists Shirou Sawa and Shuhei Fujita as inventors. It is assigned to Senju Pharmaceutical Co., Ltd. ("Senju"). The '431 patent expires September 11, 2025, according to the entry in the Orange Book.

B. Claims

The '431 patent contains twenty-two claims, two of which are independent: claims 1 and 18. These claims are reproduced below.

> 1. An aqueous liquid preparation consisting essentially of the following two components, where the first component is [bromfenac] or a pharmaceutically acceptable salt or a hydrate thereof, where the hydrate is at least one selected from a ½ hydrate, 1 hydrate and 3/2 hydrate and the second component is tyloxapol, wherein said liquid preparation is formulated for ophthalmic administration, and wherein when a quaternary ammonium compound is included in said liquid preparation, the quaternary ammonium compound is benzalkonium chloride.

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