

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ALCON RESEARCH, LTD.

Plaintiff.

v.

WATSON LABORATORIES, INC.

Defendant

Civil Action No. 16-129 (LPS)(SRF)

**REPLY REPORT OF MAUREEN DONOVAN, Ph.D.**

## TABLE OF CONTENTS

<b>I.</b>	<b>Professional Background and Qualifications .....</b>	<b>3</b>
<b>II.</b>	<b>Materials Considered.....</b>	<b>4</b>
<b>III.</b>	<b>Legal Principles Relied Upon.....</b>	<b>5</b>
<b>IV.</b>	<b>Summary Of Opinions.....</b>	<b>6</b>
<b>V.</b>	<b>Bioavailability.....</b>	<b>7</b>
<b>VI.</b>	<b>'295 Patent .....</b>	<b>12</b>
	A. Ilevro® Does Not Embody the Claimed Inventions.....	12
	B. Unexpected results .....	13
<b>VII.</b>	<b>'337 Patent and '398 Patent .....</b>	<b>43</b>
	A. Ilevro® Does Not Embody the Claimed Inventions.....	43
	1. Particle Size .....	43
	2. “Guar” and “Native Guar” .....	46
	B. Unexpected Results.....	48
	1. Nepafenac Concentration.....	53
	2. Particle Size .....	67
	3. Sodium CMC .....	95
	4. Guar-Borate Gelling in Addition to Carbomer .....	107
	5. Conclusion .....	138
	C. Failure of Others .....	143
<b>VIII.</b>	<b>Commercial Success.....</b>	<b>147</b>
<b>IX.</b>	<b>Long-felt need.....</b>	<b>150</b>

I, Maureen Donovan, Ph.D., submit this Reply Expert Report on behalf of Defendant Watson Laboratories, Inc. (“Watson”) to set forth the basis for my opinion regarding the validity of the Asserted Claims of U.S. Patent No. 7,947,295 (“the ’295 patent”), U.S. Patent No. 8,921,337 (“the ’337 patent”), and U.S. Patent No. 9,662,398 (“the ’398 patent”). I understand that Alcon Research, Ltd. (“Alcon” or “Plaintiff”) asserts that the products for which Watson seeks approval for in ANDA No. 208816 (“the Watson ANDA products”) infringe the Asserted Claims of the ’295, ’337 and ’398 patents. This report responds to certain issues raised in the reports of Alcon’s experts, including the expert reports of Dr. Bellantone (referred to as Bellantone Opening, Supplemental and Rebuttal Reports), Dr. Fuller (referred to as the Fuller Report), and Dr. Majumdar (referred to as the Majumdar Report). This report, together with my Expert Report on Invalidity dated November 11, 2017 (referred to as my Opening Report) set forth the basis for my opinions. I understand that, since my Opening Report, Alcon has reduced the number of asserted claims in this matter, and now accuses Watson of infringing claims 13 and 19 of the ’295 patent, claims 1-13 and 15 of the ’337 patent, and claims 1-14 and 16-32 of the ’398 patent (“the Asserted Claims”).

## **I. PROFESSIONAL BACKGROUND AND QUALIFICATIONS<sup>1</sup>**

1. I am an expert in the field of drug delivery systems, including ophthalmic compositions. I have worked in the field of drug delivery system development since 1982. My background and qualifications are set forth in my Opening Expert and Exhibit A attached thereto.

---

<sup>1</sup> Headings are used in this Report for convenience and organizational purposes only; I reserve the right to rely on any part of this Report for any purpose notwithstanding any section headings.

## II. MATERIALS CONSIDERED

2. In reaching my conclusions and opinions set forth in this report, I have relied on my knowledge, education, training and experience, as well as the documents identified herein and the documents listed in **Exhibit A**. This Exhibit A is intended to supplement the Exhibit B listing materials considered and attached to my Opening Report. The documents that I cite to in this report comprise the information upon which I am specifically relying to support the opinions stated in this report. However, these documents are not the sole bases for my opinions, and I reserve the right to rely on additional documents and further information contained in **Exhibit A** as necessary. Further, citations to documents are exemplary; I reserve the right to rely on any portions of the documents cited in this Report, whether or not those portions are specifically cited.

3. I have considered what I understand to be the opinions of Drs. Flanagan, Amiji, Hofmann and Tanna, in reaching my conclusions. I have also considered the reports of Drs. Bellantone, Majumdar, and Fuller, as well as materials cited in these reports. I reserve the right to rely on any portion of these reports and their materials considered or cited, whether or not those materials or portions are cited in this Report.

4. My opinions are based on information currently known to me. Should additional information become available to me, I reserve the right to amend and/or supplement my opinions. To the extent I am provided additional documents or information, including any reports, expert opinions, testimony, or any ruling or order by the Court, I may offer further opinions. Examples of such additional information may include, for example: (i) any matters or information raised by Alcon or its experts; and (ii) documents presented by Alcon or its experts. Furthermore, I reserve the right to evaluate and testify about any issue raised by Alcon or its experts in submissions made after the date of this Report, or at trial. I also reserve the right to

supplement this Report in view of any further depositions taken in this case or document production, including any which occur at, about or after the time of filing of this Report.

### **III. LEGAL PRINCIPLES RELIED UPON**

5. As I explained in my Opening Report, I am not an expert in patent law. Counsel has informed me of the following legal standards, which I have applied in conducting my analysis and in reaching my conclusions. I understand that an issued patent is presumed to be valid, and a party challenging the validity of a patent claim must prove invalidity by clear and convincing evidence.

6. To the extent a claim construction has been ordered by the Court (Dkt. 147), recommended in the Report & Recommendation (Dkt. 150), or agreed to by the parties, I have applied that specific definition, instead of the ordinary and customary meaning, when performing my analysis. For terms that have not been interpreted and recommended to the Court, I have applied what I consider to be the understanding of the person having ordinary skill in the art (POSA) as of the appropriate time period. I provide in my Opening Report the definition of the POSA and the appropriate time period.

7. I have been informed by counsel that obviousness of a patent claim is determined by an objective standard considering:

- a) the scope and content of the prior art;
- b) the differences between the prior art and the claimed invention;
- c) the level of ordinary skill in the art; and
- d) any objective indicia of nonobviousness if present (including unexpected results, commercial success, long felt but unsolved needs, failure of others)

8. I have considered whether a person of skill in the art would have one must have a motivation to combine or modify the prior art accompanied by a reasonable expectation of

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.