

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC.
Petitioner,

v.

UCB BIOPHARMA SPRL
Patent Owner.

U.S. Patent No. 8,633,194 to Fanara *et al.*
Case No.: IPR2019-00400

REPLY DECLARATION OF DR. PAUL A. LASKAR, PH.D.

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I, Paul A. Laskar, Ph.D., do hereby declare and state as follows:

1. I am the same Paul A. Laskar that provided the Declaration of Paul A. Laskar, Ph.D. in connection with this matter. EX1002. I provide this testimony below:

2. My Experience and Qualifications are provided in EX1002 and have not changed since.

3. I have been retained on behalf of the Petitioner for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$300 per hour for consulting; \$375 per hour for deposition and testimony, including preparation; and \$125 per hour for non-working travel time. My compensation does not depend in any way on the outcome of this IPR.

I. LIST OF MATERIALS CONSIDERED

4. In formulating my opinions provided in this Reply Declaration, I have relied on the materials referenced in this Reply Declaration.

II. LEGAL STANDARD

5. My understanding of the applicable legal standards are provided in Declaration of Paul A. Laskar, Ph.D. EX1002.

III. PERSON OF ORDINARY SKILL IN THE ART (“POSA”)

6. See the Declaration of Paul A. Laskar, Ph.D. in connection with this matter. EX1002. The opinions in this Reply Declaration are from the perspective of a POSA as previously defined and applying the same relevant priority date.

IV. REPLY OPINIONS

7. Although the PTAB gave some guidance on the claim term “substantially free of bacteria,” I have been informed that all other claims are governed by the plain and ordinary meaning as understood by a POSA as of the relevant priority date (i.e., July 14, 2004).

8. I have reviewed the Deposition transcript of Dr. Niazi. EX1043. During his deposition, Dr. Niazi offered the following testimony with respect to the challenged claims:

Q: So you're saying a syrup is excluded within the scope of the challenged claims, yes or no?

A: Just like you mentioned, you know, **“comprising” may mean that it can include sugar, and it does not limit as to how much sugar you can add, therefore, it can be a syrup, okay.** As long as the product meets the function of the specification given in Claim 1, okay, **it can include sugar also.**

EX1043, 39:16-40:2 (emphasis added); *see also* 44:17-24.

9. I agree with Dr. Niazi. All of the challenged claims (*i.e.*, 1-11), read under the plain and ordinary meaning as understood by a POSA, would include syrups.

10. I have reproduced the text of Claim 1 of the '194 patent below:

1. A liquid pharmaceutical composition **comprising** (i) levocetirizine or a pharmaceutically acceptable salt of levocetirizine, and (ii) a preservative mixture **consisting essentially of** a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight, said mixture being present in an amount of more than 0 and up to 0.75 mg/ml of the composition, wherein said composition is substantially free of bacteria.

11. Although I am not a lawyer, as explained in the Declaration of Paul A. Laskar, Ph.D. (EX1002), “comprising” is open ended, *i.e.*, it can include other components, elements, or steps. The term “consisting essentially of” also appears in the claim. It is my understanding that the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention. EX1002, ¶44.

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