Paper No. __

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MICRO LABS LIMITED AND MICRO LABS USA INC.
Petitioners,

v.

SANTEN PHARMACEUTICAL CO., LTD. AND ASAHI GLASS CO., LTD.
Patent Owners.

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Inter Partes Review No. IPR2017-01434
U.S. Patent No. 5,886,035

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PETITIONERS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE EVIDENCE

I. EXHIBIT 2027 SHOULD BE EXCLUDED

Patent Owners' arguments demonstrate exactly why the Board should grant Petitioners' motion to exclude the Canadian court decision (Ex. 2027). It is irrelevant and confuses the issues. The issue facing the Board is "what a POSA would have *chosen to select as a lead compound and modify* [in view of Kishi or any other prior art]… in December 1996." (Ex. 1031, ¶ 74) (emphasis added). But the issue before the Canadian court was: whether a POSA in August 1993, would have considered compound C as a therapeutic agent for *direct* "human testing" (and whether the compound would accordingly *anticipate* the claims of the Canadian patent at issue in that case). (*Id*. at ¶ 72; Ex. 2027 at ¶¶ 9–11, 337.) The Canadian decision has been ***taken out of context*** and Patent Owners' reliance on cherry-picked, paraphrased, and incomplete portions of Dr. deLong's alleged opinions from the Canadian case is unfairly prejudicial.

In any event, there is no contradiction between Dr. deLong's opinions in the Canadian case and his opinions in this case. A compound that causes moderate hyperemia may not be considered as having an acceptable therapeutic profile for *direct use as a therapeutic drug*, but it may be the *best candidate for a lead compound* if further modification is expected to reduce the side effects. (Ex. 1031, ¶¶ 73–74.) Dr. deLong, however, was not asked in the Canadian proceeding to consider what compound would be selected as a lead compound and what

modification to make to the compound in view of the prior art. Indeed, neither Kishi nor the '856 publication was ever referenced in the Canadian proceeding, nor was there any reason to because in the Canadian case the issue was *not* modification of compound C in view of any prior art reference, including Kishi, but direct human testing of compound C. Also, Dr. deLong's opinion regarding 16-phenoxy $PGF_{2\alpha}$ analogs in the Canadian case was based on "the prior art information available" in August 1993, which would have excluded Klimko.

The rule of completeness and fundamental fairness warrants exclusion of the Canadian opinion because it gives a "misleading impression created by taking matters out of context." FRE 106 Adv. Comm. note; *Echo Acceptance Corp. v. Household Retail Servs., Inc.*, 267 F.3d 1068, 1089 (10th Cir. 2001) ("The rule of completeness ... functions as a defensive shield against potentially misleading evidence proffered by an opposing party."). Patent Owners' assertion that they "do not rely on any analyses or conclusions in the Canadian court decision that implicate Canadian law" is misleading. (Opp. at 5). ***All*** of Dr. deLong's opinions submitted in the Canadian proceeding were provided based on his understanding of Canadian patent law and the issues in that proceeding. Patent Owners did not ever attempt to introduce a full copy of his purported testimony into the record. Patent Owners' assertion that Dr. deLong "had every opportunity to provide testimony on any pertinent aspects of his opinions in the Canadian proceeding" is simply wrong.

(Opp. at 9.) As Dr. deLong testified, he is not allowed to due to the obligations of his confidentiality agreement. (Ex. 2025 at 17:4-5; 11:1–4.) Patent Owners' intent is clear: To not afford Petitioners the opportunity to examine the different legal context at play in the Canadian case. (*Cf.*, *e.g.*, Ex. 1027, deLong Decl. at ¶¶ 19–28 (setting forth his understanding of the U.S. law of obviousness as a basis for his opinions in this IPR proceeding).)

Patent Owners erroneously assert that Dr. deLong has "had every opportunity to dispute whether he made those statements or the truth of those statements." (Opp. at 6). This is simply not true. Despite having taken two depositions, Patent Owners did ***not*** once seek to cross-examine Dr. deLong about the allegedly contradictory statements that he made in the Canadian court proceeding, and in fact did not introduce Ex. 2027 during his cross-examination. That Petitioners could have asked Dr. deLong questions to obtain evidence that is more reliable than the hearsay testimony currently being offered means that the residual exception is unavailing to Patent Owners. The Canadian court decision is simply ***not*** more probative of Dr. deLong's prior statement in the Canadian proceeding "than any other reasonably obtainable evidence." (Opp. at 7; FRE 807(a).)

Patent Owners' reliance on Ex. 2027 is also undisputedly ***double*** hearsay because the statements purportedly attributable to Dr. deLong come from a third

party, a foreign judge, in the form of an opinion allegedly written by that judge. Statements allegedly made by Dr. deLong reported in the opinion is what is ultimately being relied on by Patent Owners in this case. Because each level of hearsay must fall within an exception to hearsay to be considered "not hearsay," FRE 801(d)(1)(A), which provides for an exception for prior inconsistent statements, does not render the double hearsay *not* hearsay. FRE 805. None of the hearsay exception rules are applicable here. Indeed, Dr. deLong was never cross-examined on any of his prior testimony in the Canadian proceeding. Ex. 2027 should be excluded in its entirety.

II. PARAGRAPHS 8–26 OF EXHIBIT 2028 SHOULD BE EXCLUDED

Patent Owners do not dispute that Dr. Macdonald has **zero** publications or patents in the area of prostaglandin analogs. Nor do Patent Owners dispute that Dr. Macdonald lacks personal knowledge regarding the subject matter that he provides expert opinions on. Patent Owners also do not refute that his expertise is only "*generally applicable* to lipid signaling systems." (Opp. at 9) (emphasis added). There is no evidence that Dr. Macdonald's alleged consulting experience relates to use of prostaglandin analogs for the treatment of glaucoma and ocular hypertension. Patent Owners' only response to Dr. Macdonald's lack of expertise is that the Board should draw a negative inference regarding Petitioners' decision to not take his deposition. But Patent Owners submitted two declarations from Dr.

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