IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS II LLC,

Petitioner,

v.

NPS PHARMACEUTICALS, INC.

Patent Owner.

Cases IPR2015-00990 and IPR2015-01093
(Patent 7,056,886 B2)[1]

MOTION PRESENTING PATENT OWNER'S OBSERVATIONS REGARDING CROSS-EXAMINATION OF IVAN HOFMANN

[1] Pursuant to the Board's Scheduling Order in these IPRs, "the word-for-word identical paper is filed in each proceeding identified in the heading." *See, e.g.*, IPR2015-00990, Paper 29, footnote 1.

Pursuant to the USPTO Trial Practice Guide, 77 Fed. Reg. 157, 48767-68, 48769 (August 14, 2012) and the Scheduling Order in these IPRs, Patent Owner NPS Pharmaceuticals Inc. ("NPS") submits this motion to present observations regarding the May 6, 2016 cross-examination testimony of Ivan Hofmann. *See* Ex. 2170. Mr. Hofmann is a reply declarant of the Petitioner. *See* Ex. 1042.

OBSERVATIONS REGARDING TESTIMONY OF MR. HOFMANN

1. In Ex. 2170, at 9:8-10:2, Mr. Hofmann testified he has a bachelor's degree and "obtained continuing education," but he does not hold a masters, a Ph.D., or any university positions. *See also id.* 11:23-23-24 (alleging LES membership, available by paying dues, qualifies him to provide expert economic testimony). That testimony is relevant to whether Mr. Hofmann is qualified and credible as an economics expert on the subjects of long-felt need and commercial success, as presented in his declaration (Ex. 1042) and relied on in Petitioner's Reply (Reply[2] at 22-25). This testimony is also relevant because it establishes that Mr. Hofmann's qualifications do not rise to the level at which he should be considered a credible expert, such that his testimony should be afforded little weight.

[2] For convenience, citations to "Reply" encompass both IPRs, but refer specifically to Paper 42 in IPR2015-00990. Paper 40 in IPR2015-01093 is substantively identical, with different pagination.

2. In Ex. 2170, at 101:7-17, 117:4-118:21 and 144:8-15, Mr. Hofmann testified that alternatives to formulations claimed in the '886 patent are "possible" or "approvable", i.e., that "other things" in a formulation with teduglutide would make it stable, but when asked whether he could point to stabilizers that could be used, Mr. Hofmann admitted, "I don't have examples of others coming up with formulations," which he attempted to attribute to a lack of economic motivation to develop alternatives due to obstruction by "the compound patent [US 5,789,379] and other exclusivities.[3] That testimony is relevant to Mr. Hofmann's Declaration (Ex. 1042 at ¶¶ 34-35, 44-47, 63-65) and Petitioner's Reply (Reply at 23-25), which assert that commercial success of GATTEX® is not attributable to the '886 patent claims. This testimony is also relevant to whether or not there are known alternatives to the stabilizing formulation for teduglutide claimed in the '886 patent, such that the claimed formulation is necessary for Gattex to be a stable and commercially viable product, and thus enjoy its commercial success.

3. In Ex. 2170, at 37:22-38:20, when asked whether the involved patent claims encompass more than teduglutide, Mr. Hofmann testified, "[t]here may be other APIs [besides teduglutide] that could fall within [the scope of the '886

[3] "The '886 patent" is involved US Patent 7,056,886 (Ex. 1003); "the 379 patent" is the so-called "blocking" or "compound" patent, US 5,789,379 (Ex. 1029).

patent]." *See also*, *id.* at 63:12-83:19 (agreeing that each involved claim encompasses GLP-2 and/or GLP-2 analogs, *i.e.* not just teduglutide). That testimony is relevant to Mr. Hofmann's Declaration (Ex. 1042 at ¶¶ 28-30, 35) and Petitioner's Reply (Reply at 24-25), which allege that the long felt need addressed by Gattex was a result "of the '379 patent limit[ing] the possibilities for development of other GLP-2 products that could have satisfied any purported need for GLP-2 products now identified by PO" (Reply at 25). This testimony is relevant because, by admitting that other APIs could fall within the scope of the '886 patent, it addresses whether or not the '379 patent, by claiming teduglutide and not GLP-2 and many other GLP-2 analogs, precluded other GLP-2 products that could have satisfied the long felt need addressed by Gattex.

4. In Ex. 2170, at 90:3-94:10 and 96:17-23, Mr. Hofmann testified that alternative stable formulations of any GLP-analog could be developed without infringing the '379 patent, because "they're permitted" and "the safe harbor provisions do allow such research," and neither the '379 patent nor Gattex's orphan drug exclusivity precluded others from developing a stable formulation as claimed in the '886 patent (and licensing to NPS/Shire), to share in the profits of Gattex – a product with "hundreds of millions" in annual sales. That testimony is relevant to Mr. Hofmann's Declaration (Ex. 1042 at ¶¶ 28-30) and Petitioner's Reply (Reply at 24-25), which assert that "other companies did not have the economic incentive or

ability to commercialize a GLP-2 analog product as a result of the blocking nature of the '379 Patent that covers Gattex®." This testimony is also relevant because it addresses that a party was not precluded from developing a stable formulation of teduglutide and would have had an economic incentive to do so and license a resulting patent to NPS to share in the revenues of such a product.

5. In Ex. 2170, at 15:23-16:5, Mr. Hofmann testified that, "it's not atypical for the sponsor … to put some marketing effort behind a drug," which can "vary by degree;" and at 178:21-180:16 and 184:15-186:23, he testified that "it's typical that some level of marketing is put behind most branded drugs at some stage of their life cycle" and it "can generate demand," which "really varies" under the circumstances, although "I don't know" what sales representatives said" about Gattex and "promotional sensitivity" does not indicate whether or not sales were driven by the properties of Gattex. At 148:23-151:24, Mr. Hofmann testified that Gattex is marketed to physicians, "primarily gastroenterologists," who are "specialized" and have "higher levels of training and education." That testimony is relevant to Mr. Hofmann's Declaration (Ex. 1042 at ¶¶ 48-51) and Petitioner's Reply (Reply at 23), which assert that "the performance of Gattex® is driven by marketing" (Reply at 23). This testimony is relevant because it acknowledges that (1) Gattex marketing is not unlike marketing for all other marketed drugs and (2) the demand for a drug resulting from marketing efforts "really varies", yet Mr.

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