UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,

Petitioner,

v.

NOVARTIS PHARMA AG, NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,

Patent Owner.

Inter Partes Review No. IPR2021-00816
U.S. Patent No. 9,220,631 B2

PATENT OWNER'S NOTICE OF APPEAL

Pursuant to 35 U.S.C. §§ 141-144 and 319 and 37 C.F.R. §§ 90.2 and 90.3, notice is hereby given that Patent Owner Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceuticals Corporation hereby appeal to the United States Court of Appeals for the Federal Circuit from the Final Written Decision entered October 25, 2022 in IPR2021-00816 (Paper 113), and from all prior and interlocutory rulings related thereto or subsumed therein, to the extent they are adverse to Patent Owner. The Final Written Decision remains under seal, and the parties proposed redactions to the Board by email on November 18, 2022. *See* Paper 115. Because the Board has not yet approved or entered a redacted version, the Final Written Decision is not being attached to the electronically filed Notice of Appeal, but a paper copy is being served on the Director by mail.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Patent Owner further indicates that the issues on appeal include, but are not limited to:

(1) whether the Board erred in adopting Petitioner's definition of, and unique approach to identifying, a person of ordinary skill in the art, and whether the Board properly conducted the obviousness analysis from the perspective of the person of ordinary skill in the art it identified;

(2) whether the Board erred in concluding that Petitioner demonstrated by a preponderance of the evidence that independent claim 1 of U.S. Patent

No. 9,220,631 B2 would have been obvious to the person of ordinary skill in the art based on the combination of Sigg, Boulange, and USP789, including, but not limited to, whether the Board erred in concluding that:

(a) Boulange does not teach away from using Syringe C, and a skilled artisan would have been motivated to use Boulange Syringe C, in a pre-filled syringe for intravitreal administration of a VEGF antagonist;

(b) USP789 would have motivated a skilled artisan to design an ophthalmic solution with no more than 2 particles > 50 μm in diameter per mL;

(c) Boulange's pre-filled syringe would have been compatible with Sigg's terminal sterilization method, and a skilled artisan would have reasonably expected the combination to work;

(d) Sigg is enabled for the portions of its disclosure upon which Petitioner relied, and a skilled artisan would have been able to make and use the claimed invention without undue experimentation;

(e) Patent Owner did not establish that the Lucentis PFS is coextensive with the claims or that it embodies the claimed features;

(f) Patent Owner did not persuasively show that the commercial success of Lucentis PFS was due to a claimed feature that was not already known in the art prior to the '631 patent;

(g) the prior art would have taught a skilled artisan that the Macugen PFS was terminally sterilized;

(h) the Genentech license provides insufficient evidence of non-obviousness; and

(i) evidence of long-felt need, failure of others, and skepticism were outweighed by evidence of obviousness;

(3) whether the Board erred in concluding that Petitioner demonstrated by a preponderance of the evidence that dependent claim 14 of the '631 patent, including its additional limitations, would have been obvious to the person of ordinary skill in the art based on the combination of Sigg, Boulange, and USP789, including, but not limited to, whether the Board erred in concluding that Petitioner established by a preponderance of the evidence that it would have been a matter of routine optimization for a skilled artisan to achieve a slide force of "less than about 5N";

(4) whether the Board erred in concluding that Petitioner demonstrated by a preponderance of the evidence that dependent claim 17 of the '631 patent,

including its additional limitations would have been obvious to the person of ordinary skill in the art based on the combination of Sigg, Boulange, and USP789, including, but not limited to, whether the Board erred in concluding that Sigg would have provided motivation and a reasonable expectation of success with respect to "a blister pack comprising a pre-filled syringe according to claim 1, wherein the syringe has been sterilized using H_2O_2 or EtO";

(5) whether the Board erred in concluding that Petitioner demonstrated by a preponderance of the evidence that dependent claim 21 of the '631 patent, including its additional limitations would have been obvious to the person of ordinary skill in the art based on the combination of Sigg, Boulange, and USP789, including, but not limited to, whether the Board erred in concluding that the claimed "pre-filled syringe . . . wherein the syringe has been sterilized using EtO or H_2O_2 with a Sterility Assurance Level of at least 10^{-6}" would have been obvious, without addressing whether a person of ordinary skill in the art would have been motivated to achieve the claimed Sterility Assurance Level or had a reasonable expectation of success in doing so;

(6) whether the Board erred in concluding that Petitioner demonstrated by a preponderance of the evidence that dependent claim 22 of the '631 patent,

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