IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC., Plaintiff, v. F. HOFFMANN-LA ROCHE, LTD., ROCHE DIAGNOSTICS GMBH, and HOFFMANN-LA ROCHE, INC. Defendants.	Civil Action No. 05-CV-12237 WGY

ROCHE'S OPPOSITION TO AMGEN'S BENCH MEMORANDUM REQUESTING A JURY INSTRUCTION REGARDING THE HEIGHTENED PRESUMPTION OF VALIDITY WHEN ROCHE DID NOT PRESENT ANY ART THAT WAS NOT CONSIDERED BY THE PTO

Amgen improperly asks this Court to provide a jury instruction, despite clear law to the contrary, that the presumption of validity afforded to issued patents is heightened, insurmountable and unrebuttable. In particular, Amgen argues, as it has in the past, that because the references relied upon by Roche were, according to Amgen, submitted to the PTO examiner, Roche has a heightened burden to overcome the presumption of validity. Amgen misrepresents the facts in this case and skews the relevant law:

- Testimony and documentary evidence show that the PTO examiners were not provided with all the prior art references and information that Dr. Lowe, Dr. Bertozzi, Dr. Spinowitz and other Roche experts relied upon to reach their conclusions that the claims-in-suit would have been obvious to one of ordinary skill in the art.
- The law provides that, in evaluating the validity of an asserted patent, there is no change to a challenger's burden in overcoming the statutory presumption of validity. However, in *KSR*, the Court held, as here, where relevant art is not considered, it is questionable whether the presumption of validity even applies.
- While examiners are presumed to do have done their job properly, the PTO -- and its published procedures -- acknowledge that an examiner's job requires only cursory

> review of cited references, whereas the hypothetical person of skill in the art is charged, as a matter of law, with knowledge of all pertinent art.

Contrary to Amgen's assertion, the law does not support a "heightened presumption of validity" in any context, let alone when, according to Amgen, the asserted prior art references were submitted to the PTO examiner. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007) ("presumption [of validity] remains intact and [the burden of proof remains] on the challenger throughout the litigation, *and the clear and convincing standard does not change*") (emphasis added). Amgen relies on *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (Fed. Cir. 1984), but that case plainly states that "[a]ll evidence bearing on the validity issue, *whether considered by the PTO or not*, is to be taken into account by the tribunal in which validity is attacked." *Id.* at 1360 (emphasis added); *see also A.K. Steel Corp. v. Sollac*, 344 F.3d 1234, 1245 (Fed. Cir. 2003) ("the presumption is far from determinative"); *Neutrino Development Corp. v. Sonosite, Inc.*, 410 F. Supp. 2d 529, 544 (S.D. Tex 2006) ("the fact that invalidity defenses are permitted indicates that the presumption of validity is a rebuttable presumption"). Moreover, in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1745 (2007), the Court noted that where certain prior art references were not submitted to the examiner -- as is the case here, as explained below -- it is questionable whether the presumption of validity even applies. Accordingly, the applicable law plainly does not support Amgen's proposed jury instruction.

Even if there could be a "heightened presumption" where all references relied upon were submitted to the PTO examiner, Amgen is wrong, as an unassailable fact, when it suggests that Roche did not present any art that was not considered by the PTO. On cross-examination by Amgen's counsel, and also on re-direct, Dr. Lowe made clear that, despite Amgen's contention, numerous sections from the Maniatis Manual (TRX 10) upon which he relied in forming his

opinions were *not* cited to the examiners. (Lowe 462:21-464:10; TRX 2009.580). Each file history of the patents-in-suit plainly shows that examiners had only 18 pages of the Maniatis Manual and did not have or consider the remaining 505 pages of this highly relevant reference in determining patentability of the asserted claims over the prior art. (Lowe 383:1-8; TRX 2007.146, 2007.194, 2011.485, 2011.529, 2012.939, 2012.966, 2017.155, 2017.221, 2017.256; *see also* TRXs 1-5 (References Cited: each listing excerpts from Maniatis et al., "Molecular Cloning, a Laboratory Manual", pp. 197-199, 392-393, 479-487, 493-503, Cold Spring Harbor, N.Y. (1982)).[1] Moreover, additional documents relied upon by Roche in support of its obviousness defenses, including the INDs and data pertaining to the Baron-Goldwasser clinical study were not considered by the examiners of the patents-in-suit. (*See* TRX 2007.132-157, 2007.177-206, 2011.469-496, 2011.515-540, 2009.558-595, 2012.924-950, 2012.951-977, 2017.141-166, 2017.204-233, 2017.240-268; *see also Amgen v. TKT*, 126 F. Supp. 2d 69, 140 (D. Mass. 2000) ("Admittedly, Amgen neither submitted the actual scientific data relating to the study nor extensively described the Goldwasser study in any of its submission"). Accordingly, even if the submission of all references to an examiner somehow creates a heightened burden for a patent challenger -- which it does not -- no such heightened burden applies here.

Furthermore, even if all references were submitted to the PTO, if there is "evidence that there actually were defects in the particular application process at issue in this case, thus suggesting that deference to the PTO's determination may not be appropriate," such evidence may be relevant to overcoming the presumption of validity. *See Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 255 (W.D.N.Y. 2000). With respect to the references relied upon by Roche that were submitted to the examiners of the patents-in-suit, the examiners could

[1] In accordance with Patent Office Procedure, references considered by the examiner -- whether submitted by the applicant or independently discovered by the examiner -- are printed on the face of the patent. M.P.E.P. § 609(D) (8th ed. Aug. 2001), at 600-132-33 (references considered by the examiner will be printed on the patent).

not have understood the import of these references from the standpoint of one of ordinary skill in the art because other highly relevant references were not considered by the examiner. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 962 (Fed. Cir. 1986) (hypothetical person of skill in the art "is presumed to be aware of all the pertinent prior art"). Similarly, the file histories also provide clear documentary evidence that the examiners did not evaluate the available references with the same consideration that would have been employed by one of skill in the art motivated to make the claimed inventions. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007). The file histories demonstrate that in every instance the examiner reviewing the IDS reviewed *hundreds* of references in one or two days, unlike the hypothetical person of skill in the art. (*See, e.g.*, TRX 2009.558-595 (reviewing 436 references in 1 day), 2012.951-977 (reviewing 372 references in 1 day), 2007.177-206 (reviewing 437 references over 2 days), 2011.515-540 (reviewing 390 references over 2 days), 2017.240-268 (reviewing 437 references over 2 days); *see also* M.P.E.P. § 609.05(b) (8th ed. Aug. 2001) ("[t]he examiner must also fill in his or her name and the date the information was considered")). This is not surprising given that, pursuant to PTO regulations, an examiner is charged with only a cursory review of all references cited and is presumed to have performed only that level of review unless the particular reference subsequently is discussed by the examiner in an office action. M.P.E.P. § 609 (8th ed. Aug. 2001) at 600-118 ("Consideration by the examiner of the information submitted in an IDS means nothing more than considering the documents in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art").

Accordingly, the facts in evidence including the references relied upon by Roche, in conjunction with the applicable principles of law, preclude a jury instruction on a "heightened presumption of validity." Any such instruction would not only run contrary to established law,

but would also unduly prejudice Roche and confuse the jury by leading it to believe, contrary to the evidence, that all references relied upon by Roche were in fact submitted to the PTO. Therefore, the Court should deny Amgen's request.

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CERTIFICATE OF SERVICE

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