EXHIBIT A

AMGEN'S OBJECTIONS AND RESPONSES TO ROCHE'S OFFER OF PROOF FOR MR. SOFOCLEOUS

I. GENERAL NATURE OF MR. SOFOCLEOUS'S TESTIMONY

ROCHE'S PROFFER (¶ 1):

With respect to Roche's invalidity case,[1] Michael Sofocleous's testimony would have been a general discussion of the customs, habits, practices and procedure of the United States Patent and Trademark Office ("PTO" or "Patent Office"). As demonstrated herein, his testimony would have included a brief discussion of Patent Office practice, a general discussion of some terms and concepts that arise during patent prosecution and a discussion of the day-to-day real world practices and customs of the Patent Office, including the practice of examiners in the specific Art Unit responsible for examining the patents-in-suit. Mr. Sofocleous's testimony would not have been directed at disparaging or denigrating the competence of the Patent Office and its examiners. Rather, his testimony would have been intended to portray a proper framework for the jury to understand and evaluate the presumption of validity afforded to the patents-in-suit.

AMGEN'S RESPONSE (¶ 1) :

Amgen would have objected to any proposed testimony by Mr. Sofocleous concerning the examining group (referred to in his proffer as an "Art Unit") responsible for examining the patents-in-suit as lacking foundation. Mr. Sofocleous never worked in that examining group; moreover, it was not even created until a number of years after he left the examining division of the PTO and began working in the interference division. Amgen further objects to Roche's

[1] Roche understands that the Court has not precluded Mr. Sofocleous from testifying during the inequitable conduct phase of the trial. (Trial Tr. at 11:16-17). Therefore, this offer of proof addresses only those issue to which Mr. Sofocleous would have testified during the invalidity phase of trial.

characterization of Mr. Sofocleous's proposed testimony as not disparaging or denigrating the competence of the Patent Office and its examiners. As is set forth in greater detail below, Mr. Sofocleous's proffered testimony proposes to do just that, and such testimony should be precluded according to this Court's pretrial rulings.

II. MR. SOFOCLEOUS'S BACKGROUND AND EXPERIENCE

ROCHE'S PROFFER (¶ 2):

Mr. Sofocleous would have testified that he is personally familiar with all facets of Patent Office practice and procedure. In particular, he has thirty-eight years of experience with the practices and procedures of the Patent Office and related litigation. His experience includes examining, counseling and interferences. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).[2]

AMGEN'S RESPONSE (¶ 2):

On cross examination, Amgen would have questioned Mr. Sofocleous about the details of his claim to have "thirty-eight years of experience with the practices and procedures of the Patent Office and related litigation." In particular, Amgen would have used Mr. Sofocleous's own curriculum vitae to demonstrate that Mr. Sofocleous has not worked in the examining division since 1975, and never held the positions of examining group director, senior examiner, or any other supervisorial or managerial post higher than primary examiner. On cross examination, Amgen would further have established that the majority of Mr. Sofocleous's career was spent working on interferences in the Board of Patent Appeals and Interferences, and that the basis for his claimed expertise is largely derived from his interference-related experience.

ROCHE'S PROFFER (¶ 3):

Mr. Sofocleous would have testified that he received his Bachelor of Science degree in

[2] "R. Ex. " refers to the Declaration of Krista M. Rycroft in Support of Defendants' Offer of Proof Regarding the Testimony of Michael Sofocleous, filed concurrently.

Chemistry from Renssalaer Polytechnic Institute in 1965, which was followed by his Juris Doctorate degree in 1973 from The National Law Center at George Washington University. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 3):

General objections apply.

ROCHE'S PROFFER (¶ 4):

Mr. Sofocleous would have testified that he has been actively involved in the practice of patent law since 1966, with a three year break for military service. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 4):

General objections apply.

ROCHE'S PROFFER (¶ 5):

Mr. Sofocleous would have testified that prior to entering law school, he began working as a patent examiner at the PTO in 1966, and his duties included the examination of patent applications in Class 117 (now known as Class 427) (Coating Processes), primarily in the area of electrophotography, including processes and related apparatus. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 5):

General objections apply.

ROCHE'S PROFFER (¶ 6):

Mr. Sofocleous would have testified that in 1974, he was promoted to Primary Examiner, a position which he held until 1975. Mr. Sofocleous would have explained that the difference between an examiner and a primary examiner is that a primary examiner has signatory authority

and will review the work of examiners. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 6):

On cross examination, Amgen would have emphasized the fact that Mr. Sofocleous last held the position of examiner in the examining division of the Patent Office in 1975, more than 30 years ago.

ROCHE'S PROFFER (¶ 7):

Mr. Sofocleous would have testified that in 1975, he was promoted to Patent Interference Examiner, a position at the Board of Patent Interferences. In 1976, he became an acting member of the Board of Patent Interferences. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 7):

General objections apply.

ROCHE'S PROFFER (¶ 8):

Mr. Sofocleous would have testified that as a Patent Interference Examiner (Interlocutory), he was responsible for managing over 1,000 interferences from date of declaration until the final hearing, and authored countless interlocutory board decisions and approximately 20 final decisions on priority which constituted final agency actions. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 8):

General objections apply.

ROCHE'S PROFFER (¶ 9):

Mr. Sofocleous would have testified that in 1985, he was promoted to Administrative Patent Judge (Examiner-in-Chief) of the Board of Patent Appeals and Interferences, a position which he held until 1999. Mr. Sofocleous would have explained that the Board of Patent

Appeals and Interferences is an administrative tribunal that reviews priority contests between competing patent applicants as well as patentability issues, and also reviews final rejections by an examiner if appealed. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 9):

General objections apply.

ROCHE'S PROFFER (¶ 10):

Mr. Sofocleous would have explained that during his time as an Administrative Patent Judge, he managed an annual docket of approximately 50 to 60 interferences from date of declaration until the final hearing, authored countless decisions on preliminary motions and interlocutory matters, participated in approximately 300 three-member final hearing panels, authored approximately 100 final decisions on priority and patentability which constituted final agency actions, reviewed adverse decisions of examiners, participated in approximately 360 panels reviewing adverse decisions of examiners and authored approximately 120 decisions on appeals from such adverse decisions, which constituted final agency actions. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 10):

General objections apply.

ROCHE'S PROFFER (¶ 11):

Mr. Sofocleous would have testified that in 1999, he entered private practice as an attorney with the law firm of Greenblum & Bernstein, PLC, where he remained until 2002, when he became a partner with the law firm of Roberts, Mlotkowski & Hobbes, PC. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 11):

General objections apply.

ROCHE'S PROFFER (¶ 12):

Mr. Sofocleous would have testified that in 2004, he started his own practice, the Law Office of Michael Sofocleous, where he practices today. In his current practice, Mr. Sofocleous engages primarily in consulting on all aspects of Patent Office Practice and Procedure. (R. Ex. 1, Trial Ex. PIP, Sofocleous CV).

AMGEN'S RESPONSE (¶ 12):

General objections apply.

III. PATENT EXAMINING PROCEDURE

ROCHE'S PROFFER (¶ 13):

Mr. Sofocleous would have testified that the overall patent examination process concerns whether certain statutory criteria are met. The main criteria considered during the examination process include those set forth in §101 (utility/patentability), §102 (anticipation), §103 (obviousness) and §112 (including, for example, written description, enablement, best mode and definiteness) of Title 35 of the U.S. Code, the Manual of Patent Examining Procedure ("MPEP"), as well as relevant interpretations of these criteria by the Board of Patent Appeals and Interferences and the federal courts. He would have also testified that a number of patent examination rules appear in Title 37 of the Code of Federal Regulations.

AMGEN'S RESPONSE (¶ 13):

Amgen would have objected to such testimony on the basis that it pertains to purely legal issues, as to which this Court has previously indicated it would not permit witness testimony. Amgen would further have objected to any suggestion that the Manual of Patent Examining Procedure ("MPEP") is a source of generally-applicable legal authority, and on cross examination would have confronted Mr. Sofocleous with the foreword to the MPEP and Mr.

Sofocleous's prior deposition testimony, which clearly indicate the contrary.

ROCHE'S PROFFER (¶ 14):

Mr. Sofocleous would have testified that the MPEP is put together by the Patent Office and is updated frequently (approximately once a year) to reflect changes in case law and Patent Office practice and procedure. Such updates tend to affect only limited sections and the Patent Office does not normally rewrite large portions of the MPEP. Roche would have introduced Trial Exhibit PKB (MPEP (5th ed. Rev. 13, Nov. 1989)) (R. Ex. 2) to give the jury an example of what the MPEP looked like at one point during the examination of the patents-in-suit.

AMGEN'S RESPONSE (¶ 14):

Amgen would have objected to this testimony as pertaining to pure issues of law, and would further have objected on the basis of relevance. Amgen would further have objected to any suggestion that the Manual of Patent Examining Procedure ("MPEP") is a source of generally-applicable legal authority, and on cross examination would have confronted Mr. Sofocleous with the foreword to the MPEP and Mr. Sofocleous's prior deposition testimony, which clearly indicate the contrary.

ROCHE'S PROFFER (¶ 15):

Mr. Sofocleous would have testified that the examination process is an *ex parte* administrative proceeding. Accordingly, Mr. Sofocleous would have testified that third parties, including competitors and other adverse parties, generally do not have an opportunity to present arguments and evidence adverse to patentability including relevant prior art. (R. Ex. 2, Trial Ex. PKB, MPEP § 101 (5th ed. Rev. 9, Sept. 1988), at 100-1; R. Ex. 3, Trial Ex. PKD, MPEP § 101 (8th ed. Rev. 5, Aug. 2006) at 100-1).

AMGEN'S RESPONSE (¶ 15):

On cross examination, Mr. Sofocleous would have been asked to confirm (1) that interference practice is an *inter partes*, or adversarial, process; (2) that the adverse parties in interference proceedings are often competitors; (3) that in interference proceedings, the adverse parties do have opportunities to present arguments and evidence relating to patentability, including prior art; (4) that at the time of the interferences during the prosecution of the Lin patents, Genetics Institute (and its inventor Fritsch) was a competitor (or other adverse party) to Amgen (and its inventor Lin); and (5) that in the interferences during the prosecution of the Lin patents, Genetics Institute (Fritsch) did in fact present evidence relating to patentability, including prior art. In support of this cross examination, Amgen would have used documents from the interferences, including the final decisions from the Board of Patent Appeals and Interferences.

ROCHE'S PROFFER (¶ 16):

Mr. Sofocleous would have testified that a filed application, once accepted as complete, is assigned to an examiner for review to determine whether it meets all substantive and technical requirements for patentability set forth in the statutes, regulations and Patent Office guidelines. (R. Ex. 2, Trial Ex. PKB, MPEP §§ 702, 706 (5th ed. Rev. 6, Oct. 1987), at 700-2, 700-5-6; R. Ex. 3, Trial Ex. PKD, MPEP §§ 702, 706 (8th ed. Rev. 5, Aug. 2006) at 700-4-5, 700-19-21).

AMGEN'S RESPONSE (¶ 16):

Amgen would have objected to this testimony as purely legal and irrelevant.

ROCHE'S PROFFER (¶ 17):

Mr. Sofocleous would have testified that the examiner(s) assigned to the application is part of a Group Art Unit that specializes in the area of technology most relevant to the

invention. While patent examiners were placed into particular art units according to their technical background at the time the patents-in-suit were examined, they were typically generalists within their field.

AMGEN'S RESPONSE (¶ 17):

On cross examination, Mr. Sofocleous would have been asked to confirm (1) his lack of knowledge about the determination of examiners' technical qualifications for particular examining groups; (2) his lack of knowledge of the qualification requirements in the biotechnology examining group at the time Dr. Lin's patents were being examined; and (3) his lack of knowledge of the technical qualifications of the particular examiners responsible for examining Dr. Lin's patents, including in particular Examiner James Martinell, Ph.D., one of two Senior Level Examiners in the entire PTO examining corps at the time the patents-in-suit were being examined, who was also the examiner responsible for final approval of all of the patents-in-suit.

ROCHE'S PROFFER (¶ 18):

Mr. Sofocleous would have testified that an examiner receives on the job training to learn how to examine a patent, in addition to a couple of weeks of orientation.

AMGEN'S RESPONSE (¶ 18):

General objections apply.

ROCHE'S PROFFER (¶ 19):

Mr. Sofocleous would have testified that when an examiner receives an application, it typically consists of a specification, drawings, claims, an oath and information relating to priority or related applications. (R. Ex. 2, Trial Ex. PKB, MPEP § 601 (5th ed. Rev. 8, May 1988), at 600-1-3; R. Ex. 3, Trial Ex. PKD, MPEP § 601 (8th ed. Rev. 5, Aug. 2006) at 600-2-5). Mr.

Sofocleous would have testified that the oath requires the applicant to attest to inventorship, attest that he will abide by the rules of patent examining procedure, and that he understands the specification and claims. (R. Ex. 2, Trial Ex. PKB, MPEP § 602 (5th ed. Rev. 8, May 1988), at 600-11-13; R. Ex. 3, Trial Ex. PKD, MPEP § 602 (8th ed. Rev. 5, Aug. 2006) at 600-31-41). Roche would have introduced Trial Exhibit 2012.112 (R. Ex. 16), the Declaration for Patent Application submitted during prosecution of U.S. 5,441,868, to provide the jury with an example of an oath.

AMGEN'S RESPONSE (¶ 19):

To the extent Mr. Sofocleous would have testified about the contents of the MPEP as legal requirements, Amgen would have objected to the proffered testimony as pertaining to purely legal requirements. Amgen would further have objected to this proffered testimony as irrelevant under Rule 402.

ROCHE'S PROFFER (¶ 20):

Mr. Sofocleous would have testified that once an examiner receives an application, he reviews it to see if the application conforms with the criteria set forth in the relevant statutes of Title 35, administrative rules and the Manual of Patent Examining Procedures. (R. Ex. 2, Trial Ex. PKB, MPEP §§ 702, 706 (5th ed. Rev. 6, Oct. 1987), at 700-2, 700-5-6; R. Ex. 3, Trial Ex. PKD, MPEP §§ 702, 706 (8th ed. Rev. 5, Aug. 2006) at 700-4-5, 700-19-21). If the application does not meet the procedural and/or substantive requisites, the application is rejected pursuant to prescribed format. (R. Ex. 2, Trial Ex. PKB, MPEP §§ 706-706.03(z) (5th ed. Rev. 6, Oct. 1987), at 700-5-23; R. Ex. 3, Trial Ex. PKD, MPEP §§ 706-706.03(x) (8th ed. Rev. 5, Aug. 2006), at 700-19-80). Before the examiner issues an office action on the merits, an applicant may file a preliminary amendment. A preliminary amendment generally is used to make changes to the

application disclosure and/or claims, to present new claims to cover unclaimed embodiments or to cancel claims directed to, for example, non-elected inventions.

AMGEN'S RESPONSE (¶ 20):

Amgen would have objected to this proffered testimony as irrelevant under Rule 402.

ROCHE'S PROFFER (¶ 21):

Mr. Sofocleous would have testified that after reading the application, including the specification and claims, the examiner searches the prior art. (R. Ex. 2, Trial Ex. PKB, MPEP § 704 (5th ed. Rev. 6, Oct. 1987), at 700-3-4; R. Ex. 2, Trial Ex. PKB, MPEP § 904.02 (5th ed., Aug. 1983) at 900-36-37; R. Ex. 3, Trial Ex. PKD, MPEP § 704.01 (8th ed. Rev. 5, Aug. 2006), at 700-6; R. Ex. 3, Trial Ex. PKD, MPEP § 904 (8th ed. Rev. 5, Aug. 2006), at 900-47; R. Ex. 3, Trial Ex. PKD, MPEP §§ 904.01(c)-904.03 (8th ed. Rev. 5, Aug. 2006), at 900-48-52). Mr. Sofocleous would have testified that the examiner also generally looks for analogous art by searching the patent shoes in the Patent Office, which are classified according to subject matter. (R. Ex. 2, Trial Ex. PKB, MPEP § 904.01(c) (5th ed., Aug. 1983), at 900-36; R. Ex. 3, Trial Ex. PKD, MPEP §§ 904.01(c) (8th ed. Rev. 5, Aug. 2006), at 900-48). The examiner can also look at Chemical Abstracts, the APS system, a technical library and other databases.

AMGEN'S RESPONSE (¶ 21):

On cross examination, Amgen would have questioned Mr. Sofocleous about his knowledge concerning prior art search technologies introduced within the examining division after his departure from the examining division in 1975, and in particular about his knowledge concerning prior art search technologies available to and used by the biotechnology examining group at the time the patents-in-suit were being prosecuted. In particular, Mr. Sofocleous's proffered testimony appears not to include any computerized search technology, which may be

consistent with 1975-era prior art searching, but not necessarily with subsequently-introduced search technologies. Amgen would have further questioned Mr. Sofocleous concerning his knowledge whether examiners in a particular examining group develop familiarity over time with the literature pertinent to the technology of that examining group.

ROCHE'S PROFFER (¶ 22):

Mr. Sofocleous would have testified that while examiners conduct prior art searches to aid in their examination, the most relevant prior art was most often cited by the applicant, who has developed a particular knowledge of the technical field of invention, devoted substantial time and resources to study the field and was more likely to be familiar with the relevant publications and reference materials.

AMGEN'S RESPONSE (¶ 22):

Amgen would have objected to this testimony as lacking foundation as it relates to the field of technology and time period in which the patents-in-suit were prosecuted. On cross examination, Amgen would have questioned the empirical basis of Mr. Sofocleous's claim that "the most relevant prior art was most often cited by the applicant," including whether that assertion always holds true, whether it holds true in the biotechnology examining group, and whether it holds true with respect to the patents in suit, in view of the particular examiners involved and the particular prior art cited.

ROCHE'S PROFFER (¶ 23):

He also would have testified that at the time the patents-in-suit were pending third parties were not allowed to submit prior art due to the *ex parte*, confidential nature of patent prosecution.

AMGEN'S RESPONSE (¶ 23):

On cross examination, Amgen would have asked Mr. Sofocleous whether, in the interferences that occurred during the prosecution of the patents in suit, the adverse party, Dr. Fritsch (and by extension Genetics Institute), was allowed—and in fact did—submit prior art in connection with attacks upon the patentability of Dr. Lin's then-pending applications and the '008 patent.

ROCHE'S PROFFER (¶ 24):

Mr. Sofocleous would have testified that references cited by the examiner during prosecution are listed on a PTO-892 Form. Similarly, references cited by the applicant for consideration by the examiner are generally submitted in an Information Disclosure Statement ("IDS") on a PTO-1449 form. (R. Ex. 2, Trial Ex. PKB, MPEP § 609 (5th ed. Rev. 8, May 1988), at 600-65-69; R. Ex. 3, Trial Ex. PKD, MPEP § 609 (8th ed. Rev. 5, Aug. 2006), at 600-139-146). Roche would have introduced Trial Exhibit 2012.951-977 (R. Ex. 4), a January 3, 1994 IDS from the file history for the '868 patent, to provide the jury with an example of an IDS. He also would have explained that references submitted to the examiner are subsequently printed on the face of the issued patent.

AMGEN'S RESPONSE (¶ 24):

Amgen would have objected to the bulk of this proffered testimony as offering purely legal testimony. Amgen would have objected to the last sentence of this proffered paragraph insofar as it is not true as a categorical statement; in the alternative, Amgen would have cross examined Mr. Sofocleous on the factual error of this statement. *See* MPEP § 609(D).

ROCHE'S PROFFER (¶ 25):

Mr. Sofocleous would have testified that examiners are only responsible for cursorily reviewing references cited by an applicant in an IDS. (R. Ex. 5, Trial Ex. PKC, MPEP §609 (8th

ed. Aug. 2001), at 600-118). Roche would have introduced Trial Exhibit PZG, 1223 OG 124 (1999) (R. Ex. 6), to corroborate Mr. Sofocleous's personal knowledge regarding these requirements. Mr. Sofocleous would have explained that a typical IDS consists of 10-15 references and that an IDS with many more references creates a burden on the examiner and makes it difficult, if not impossible, for the examiner to thoroughly consider the teachings of the cited art.

AMGEN'S RESPONSE (¶ 25):

Amgen would have objected to this proffered testimony as purely legal, lacking foundation and irrelevant. On cross examination, Amgen would have confronted Mr. Sofocleous with MPEP § 609, which sets forth the procedures and requirements for an examiner's consideration of references cited to the examiner. Roche would further have objected to Exhibit PZG on the ground that it is a purely legal document, is irrelevant, and that Mr. Sofocleous has no independent personal knowledge of the propositions set forth therein. Amgen would have cross examined Mr. Sofocleous concerning his assertion that "a typical IDS consists of 10-15 references," and in particular whether he means to assert that, within the biotechnology examining group at the time the patents in suit were prosecuted, this statistic holds true, and if so, the basis (or lack thereof) for his assertion. Amgen would have further cross examined Mr. Sofocleous concerning his level of knowledge about the ability of examiners to secure approved non-examining time to review voluminous references in connection with the examination of patent applications, as well as their ability to quickly review familiar references in a familiar field of technology.

ROCHE'S PROFFER (¶ 26):

Mr. Sofocleous would have testified that an examiner is responsible for dating each page

of a PTO-1449 form to show which date he reviewed the references cited on that page. (R. Ex. 7, Trial Ex. PLX, MPEP § 609 (5th ed. Rev. 14, Nov. 1992), at 609-72-73). Roche would have used Trial Exhibit 2012.951-977 (R. Ex. 4) to provide the jury with an example of an examiner's dating of pages in an IDS.

AMGEN'S RESPONSE (¶ 26):

Amgen would have objected to this testimony as irrelevant and purely legal. Amgen would have further objected and/or cross examined Mr. Sofocleous as to whether the date on a PTO-1449 in fact discloses how long the Examiner took to review the reference.

ROCHE'S PROFFER (¶ 27):

Mr. Sofocleous would have testified that once the examiner evaluates the specification and claims in relation to the requirements of patentability, and in light of any prior art found or brought to his attention by the applicant, the examiner will issue an office action with his findings. (R. Ex. 2, Trial Ex. PKB, MPEP § 707 *et seq.* (5th ed. Rev. 6, Oct. 1987), at 700-27-38). He would have explained that in the office action, the examiner can allow all claims, allow some claims, reject all claims and/or object to parts of the specification. He can also issue a restriction requirement if he deems there to be more than one invention in the application.

AMGEN'S RESPONSE (¶ 27):

General objections apply.

ROCHE'S PROFFER (¶ 28):

Mr. Sofocleous would have testified that if the examiner rejects claims in the office action, he will include an explanation of his rejection and an explanation of pertinent prior art. (R. Ex. 2, Trial Ex. PKB, MPEP § 707 *et seq.* (5th ed. Rev. 6, Oct. 1987), at 700-27-38; R. Ex. 3, Trial Ex. PKD, MPEP § 707 *et seq.* (8th ed. Rev. 5, Aug. 2006), at 700-111-132). Mr.

Sofocleous would have explained that the Patent Office requires these findings to be in writing to create a record of what transpired during prosecution and that all interactions between the applicant and examiner need be in writing to be given effect by the PTO. 37 CFR § 1.2.

AMGEN'S RESPONSE (¶ 28):

Amgen would have objected to this proffered testimony as purely legal in nature. Amgen would further have objected to and/or cross-examined Mr. Sofocleous concerning his erroneous assertion that prosecution-related actions are *required* to be in writing. *See* 37 C.F.R. § 1.2.

ROCHE'S PROFFER (¶ 29):

Mr. Sofocleous would have testified that once an applicant receives a rejection, he has a number of options, including (1) acquiescing and canceling claims, (2) abandoning the application, (3) amending the claims to try and overcome the rejection, (4) adding new claims to try and overcome the rejection and (5) traversing the rejection to try and argue that the examiner's rejection was improper. He would have explained that to traverse a rejection, the applicant will normally have to submit his arguments in writing and include additional affidavits or evidence to explain its view that the examiner erred.

AMGEN'S RESPONSE (¶ 29):

General objections apply.

ROCHE'S PROFFER (¶ 30):

Mr. Sofocleous would have testified that if an applicant submits affidavits or evidence to overcome a rejection, the examiner must consider the applicant's submissions. However, Mr. Sofocleous would have explained, the examiner generally can not independently verify the veracity of an affidavit's contents and generally needs to accept the information provided unless facially incorrect.

AMGEN'S RESPONSE (¶ 30):

Amgen would have objected to this proffered testimony as irrelevant and vague and ambiguous, insofar as it fails to differentiate among different kinds of arguments and evidence submitted to overcome an examiner's rejection. For example, without limitation, it fails to differentiate among legal arguments, arguments concerning the interpretation of references already before the examiner, the submission of additional references, and factual assertions concerning experiments that had been conducted. Amgen further objects to this testimony as legally erroneous. *See* MPEP § 716 ("It is the responsibility of the primary examiner to personally review and decide whether affidavits or declarations submitted under 37 CFR 1.132 for the purpose of traversing grounds of rejection are responsive to the rejection and present sufficient facts to overcome the rejection."). In the alternative, Amgen would have cross examined Mr. Sofocleous concerning the application of his general assertions to various kinds of arguments and evidence that can be submitted in response to an examiner's rejection.

ROCHE'S PROFFER (¶ 31):

Mr. Sofocleous also would have testified that if an examiner wanted to verify the accuracy of experimental data submitted by an applicant, he could not have done so because the Patent Office does not have laboratory testing facilities.

AMGEN'S RESPONSE (¶ 31):

Amgen would have objected to this testimony as irrelevant and legally erroneous. *See* MPEP § 716.

ROCHE'S PROFFER (¶ 32):

Mr. Sofocleous would have testified that if an applicant decides to amend claims in response to a rejection, the examiner has to look at the prior art again, possibly conduct new

prior art searches depending on the scope of the new claims and conduct an analysis to determine whether the new claims meet the requirements for patentability.

AMGEN'S RESPONSE (¶ 32):

Amgen would have objected to this proposed testimony as vague and ambiguous, overbroad, lacking foundation, and inadmissible under Rule 403 because it is likely to confuse the jury.

ROCHE'S PROFFER (¶ 33):

Mr. Sofocleous would have testified that following an applicant's amendment or remarks, the examiner will issue another office action.

AMGEN'S RESPONSE (¶ 33):

General objections apply.

ROCHE'S PROFFER (¶ 34):

Mr. Sofocleous would have testified that the back-and-forth between office actions and amendments and remarks does not end until claims are allowed or the examiner issues a final rejection.

AMGEN'S RESPONSE (¶ 34):

General objections apply.

ROCHE'S PROFFER (¶ 35):

Mr. Sofocleous would have testified that following a final rejection, the applicant's options include (1) submitting a response to try and overcome a final rejection, (2) filing an appeal to the Board of Patent Appeals and Interferences, (3) refiling the application as a continuation application and starting the examination process anew or (4) abandoning the application. (R. Ex. 2, Trial Ex. PKB, MPEP § 706.07 *et seq.* (5th ed. Rev. 6, Oct. 1987), at 700-

23-29; R. Ex. 3, Trial Ex. PKD, MPEP § 706.07 *et seq.* (8th ed. Rev. 5, Aug. 2006), at 70081-110).

AMGEN'S RESPONSE (¶ 35):

General objections apply.

ROCHE'S PROFFER (¶ 36):

Mr. Sofocleous would have testified that, in his experience, it is not uncommon for more than one examiner to be charged with examining an application over its pendency, especially if an application is pending in the PTO for a prolonged period of time.

AMGEN'S RESPONSE (¶ 36):

General objections apply.

ROCHE'S PROFFER (¶ 37):

Mr. Sofocleous would have testified that when a new examiner takes over prosecution of an application, he will give full faith and credit to the actions of the prior examiner. (R. Ex. 2, Trial Ex. PKB, MPEP § 706.04 (5th ed. Rev. 6, Oct. 1987), at 700-23; R. Ex. 3, Trial Ex. PKD, MPEP § 706.04 (8th ed. Rev. 5, Aug. 2006), at 700-80). Mr. Sofocleous would have explained that while the new examiner will review the specification and then-pending claims, and may review portions of the prior art depending on if there are claim amendments, normal Patent Office procedure requires the subsequent examiner to not take an entirely new approach to the examination, not try to reorient the point of view of the prior examiner nor make a new search in the mere hope of finding something new in the prior art.

AMGEN'S RESPONSE (¶ 37):

Amgen objects to the proffered testimony on the grounds that it is both purely legal and legally erroneous. *See* 37 CFR 1.104 (on taking up an application for examination or a patent in

a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention).

IV. DIFFERENT TYPES OF PATENT APPLICATIONS

ROCHE'S PROFFER (¶ 38):

Mr. Sofocleous would have testified that there are generally three different types of applications that an applicant can file: a continuation application, a continuation-in-part application and a divisional application.

AMGEN'S RESPONSE (¶ 38):

On cross examination, Mr. Sofocleous would have been asked about his knowledge of continuing applications pursuant to Rule 60 (37 C.F.R. § 1.60) and Rule 62 (37 C.F.R. § 1.62). Just as he was asked to do during his deposition, Amgen would have asked Mr. Sofocleous to identify the document constituting the Rule 60 application or Rule 62 application, which he failed to do accurately during his deposition. Amgen would further have cross examined Mr. Sofocleous on the particular definitions of continuation and divisional applications as set forth in the MPEP.

ROCHE'S PROFFER (¶ 39):

Mr. Sofocleous would have testified that a continuation application is a second application for the same invention claimed in a prior application and filed before the prior application becomes abandoned or issues as a patent. (R. Ex. 2, Trial Ex. PKB, MPEP § 201.07 (5th ed. Rev. 11, Apr. 1989), at 200-13; R. Ex. 3, Trial Ex. PKD, MPEP § 201.07 (8th ed. Rev. 5, Aug. 2006) at 200-53). Mr. Sofocleous would have explained that the examiner knows an application is a continuation because the applicant is required to designate it as such when requesting the right to claim priority to the parent application.

AMGEN'S RESPONSE (¶ 39):

Amgen would have objected that this is a purely legal issue. On cross examination, Mr. Sofocleous would have been asked to confirm that it is his testimony that, rather than considering the substance of an application in relation to the substance of parent applications, the examiner would have considered just the check-box or other form of designation in determining how to categorize an application.

ROCHE'S PROFFER (¶ 40):

Mr. Sofocleous would have testified that a continuation-in-part application ("CIP") is an application filed during the lifetime of an earlier application by the same applicant, repeating a substantial portion or all of the prior application and adding matter not initially disclosed in the first application. (R. Ex. 2, Trial Ex. PKB, MPEP § 201.08 (5th ed. Rev. 11, Apr. 1989), at 200-13; R. Ex. 3, Trial Ex. PKD, MPEP § 201.08 (8th ed. Rev. 5, Aug. 2006) at 200-53-54). Mr. Sofocleous would have further testified that a continuation-in-part application can add additional inventors because a named inventor need only contribute to one claim. (*Id.*). Mr. Sofocleous would have explained that the examiner knows an application is a continuation-inpart because the applicant designates it as a CIP application, and the examiner will generally not review a CIP to determine what information was carried forward from the prior application or deleted from the specification.

AMGEN'S RESPONSE (¶ 40):

Amgen would have objected to this testimony on the grounds that it is purely legal testimony and irrelevant.

ROCHE'S PROFFER (¶ 41):

Mr. Sofocleous would have testified that a divisional application is an application filed

for a patentably distinct or independent invention, filed as a result of a restriction requirement that discloses and claims only subject matter disclosed in the earlier application and that should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application. (R. Ex. 2, Trial Ex. PKB, MPEP § 201.06 (5th ed. Rev. 11, Apr. 1989), at 200-6-7; R. Ex. 3, Trial Ex. PKD, MPEP § 201.06 (8th ed. Rev. 5, Aug. 2006), at 200-21). Mr. Sofocleous would have explained that the examiner normally knows an application is a divisional because the applicant designates it as such when requesting the right to claim priority to the parent application.

AMGEN'S RESPONSE (¶ 41):

On cross examination, Mr. Sofocleous would have been asked to confirm that it is his testimony that, rather than considering the substance of an application in relation to the substance of parent applications, the examiner would have considered just the check-box or other form of designation in determining how to categorize an application.

ROCHE'S PROFFER (¶ 42):

Mr. Sofocleous would have testified that an examiner may issue a restriction requirement when upon initial examination if more than one patentably distinct invention is claimed and the examiner wants to reduce his burden of examination. (R. Ex. 2, Trial Ex. PKB, MPEP § 803 (5th ed. Rev. 8, May 1988), at 800-3; R. Ex. 3, Trial Ex. PKD, MPEP § 803 (8th ed. Rev. 5, Aug. 2006) at 800-3-4).

AMGEN'S RESPONSE (¶ 42):

Amgen would have objected to the proposed testimony on the basis that it is purely legal and that to the extent it is relevant at all, it is relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

ROCHE'S PROFFER (¶ 43):

Mr. Sofocleous would have testified that once subject matter is cancelled due to a restriction requirement, the applicant can file a divisional application to prosecute the cancelled subject matter. (R. Ex. 2, Trial Ex. PKB, MPEP § 201.06 (5th ed. Rev. 11, Apr. 1989), at 200-6-7; R. Ex. 3, Trial Ex. PKD, MPEP § 201.06 (8th ed. Rev. 5, Aug. 2006), at 200-21).

AMGEN'S RESPONSE (¶ 43):

Amgen would have objected to the proposed testimony on the basis that it is purely legal and that to the extent it is relevant at all, it is relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

V. DOUBLE PATENTING

ROCHE'S PROFFER (¶ 44):

Mr. Sofocleous would have testified that the doctrine of double patenting seeks to prevent the unjustified extension of exclusivity beyond the term of a patent. Mr. Sofocleous would have testified that the Patent Office is required to grant a single patent for a single invention or obvious variation. He would have explained that the purpose of this requirement is to prevent an applicant from extending the right to exclusivity afforded by the patent grant by filing multiple applications (including continuation applications) on the same or similar inventions which issue at different times. He would have explained that if an examiner determines that an applicant's claimed invention is identical to ("same invention type double patenting") or obvious in view of subject matter claimed in an issued patent or another pending application ("obviousness-type double patenting"), the examiner should issue a double-patenting rejection. (R. Ex. 2, Trial Ex. PKB, MPEP §§ 804-804.03 (5th ed. Rev. 8, May 1988), at 800-4-9; R. Ex. 3, Trial Ex. PKD, MPEP §§ 804-804.03 (8th ed. Rev. 5, Aug. 2006), at 80011-41).

AMGEN'S RESPONSE (¶ 44):

Amgen would have objected to this testimony as purely legal, and relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

Amgen would have further objected to the portions of this testimony pertaining to the purposes of legal doctrines as lacking foundation, and outside the scope of testimony under Rule 406.

ROCHE'S PROFFER (¶ 45):

Mr. Sofocleous would have explained that in issuing an obviousness-type double patenting, the examiner looks to the claims of the reference patents as well as (1) the level of ordinary skill in the pertinent art; (2) the scope of prior art known to one of ordinary skill in the pertinent art and (3) any objective indicia of nonobviousness. (R. Ex. 3, Trial Ex. PKD, MPEP §804 (8th ed. Rev. 5, Aug. 2006), at 800-21)

AMGEN'S RESPONSE (¶ 45):

Amgen would have objected to this testimony as purely legal, and relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

ROCHE'S PROFFER (¶ 46):

Mr. Sofocleous would have testified that a rejection for double-patenting is available where the application and reference patent (or application) has a common inventor, assignee or owner. (R. Ex. 2, Trial Ex. PKB, MPEP § 804, § 804.03 (5th ed. Rev. 8, May 1988), at 800-4-9; R. Ex. 3, Trial Ex. PKD, MPEP § 804, § 804.03 (8th ed. Rev. 5, Aug. 2006) at 800-11-30, 800-34-41). He also would have testified that the Patent Office normally applies a "one-way" test in determining obviousness-type double patenting, rather than the rare "two-way" test reserved for instances where the PTO has caused a first-filed application to issue as a patent after a later filed application. (R. Ex. 3, Trial Ex. PKD, MPEP § 804 (8th ed. Rev. 5, Aug. 2006), at 800-22-26).

AMGEN'S RESPONSE (¶ 46):

Amgen would have objected to this testimony as purely legal, and relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

Amgen would have further objected to this testimony as legally incorrect and contrary to the rulings of this Court, which has ruled that the two-way test applies.

ROCHE'S PROFFER (¶ 47):

Mr. Sofocleous would have testified that, unlike same invention type double patenting, obviousness-type double patenting may be obviated by filing a terminal disclaimer, but that for such a disclaimer to be effective, it must be linked to the earliest patent to which the claimed invention is obvious. (R. Ex. 2, Trial Ex. PKB, MPEP § 804.02 (5th ed. Rev. 8, May 1988), at 800-7; R. Ex. 3, Trial Ex. PKD, MPEP § 804.02 (8th ed. Rev. 5, Aug. 2006) at 800-31-33).

AMGEN'S RESPONSE (¶ 47):

Amgen would have objected to this testimony as purely legal, and relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

ROCHE'S PROFFER (¶ 48):

Mr. Sofocleous would have testified that double patenting may arise even if an application has been subject to a restriction requirement. Mr. Sofocleous would have explained that under 35 U.S.C. § 121, where the Patent Office requires restriction, the patent of either the parent or any divisional application thereof consonant with this requirement cannot be used as a reference against the other. (R. Ex. 2, Trial Ex. PKB, MPEP § 803 (5th ed. Rev. 8, May 1988), at 800-3).

AMGEN'S RESPONSE (¶ 48):

Amgen would have objected to this testimony as purely legal, and relevant only to the

issue of obviousness-type double patenting, which is not being tried to the jury.

ROCHE'S PROFFER (¶ 49):

Mr. Sofocleous further would have testified that the Patent Office does not apply protection under §121 to related applications in certain instances, including: (a) where the applicant voluntarily files two or more cases without requirement by the examiner, (b) if the claims of the different applications or patents are not consonant with the requirement made by the examiner or (c) the requirement for restriction was withdrawn or not reinstated by the examiner before the related patent issues. The requirement that consonance be maintained is violated, for example, when the later divisional application includes additional claims not consonant in scope to the original claims subject to the restriction or claims have been changed in material respects from the claims at the time the requirement was made. (R. Ex. 2, Trial Ex. PKB, MPEP § 804.01 (5th ed. Rev. 8, May 1988), at 800-6; R. Ex. 3, Trial. Ex. PKD, MPEP § 804.01 (8th ed. Rev. 5, Aug. 2006), at 800-30-31).

AMGEN'S RESPONSE (¶ 49):

Amgen would have objected to this testimony as purely legal, and relevant only to the issue of obviousness-type double patenting, which is not being tried to the jury.

Amgen would have objected to this testimony as legally incorrect and without foundation.

VI. STATE OF THE BIOTECHNOLOGY EXAMINING GROUP IN THE LATE 1980S AND EARLY 1990S

ROCHE'S PROFFER (¶ 50):

Mr. Sofocleous would have testified that the PTO examination system is run on a quota system in which examiners are required to review and dispose of a number of applications each year, depending on seniority and the complexity of the technology being examined in the group.

In 1988, PTO examiners in the biotechnology area had less than an average of 20 hours in total to devote to the examination of a single application. Roche would have introduced Trial Exhibit POZ, GAO/RCED-89-120BR, *Biotechnology: Backlog of Patent Applications* (April 1989) (R. Ex. 8), which would have corroborated Mr. Sofocleous's personal knowledge.

AMGEN'S RESPONSE (¶ 50):

Amgen would have objected to this testimony as irrelevant, lacking foundation, and precisely the testimony prohibited by the Court when it granted Amgen's Motion *in Limine* No. 16 (*see* 9/4/07 Trial Tr. at 11).

ROCHE'S PROFFER (¶ 51):

Mr. Sofocleous would have testified that the 20 hour statistic remained relatively consistent and constant during the time the patents-in-suit were pending. This means that a patent examiner has very limited time to read and consider each patent application. In these 20 hours, examiners were responsible for completing a number of tasks, including, but not limited to, (1) reading and reviewing the application, (2) obtaining an understanding of the specification and claims, (3) formulating prior art searches, (4) conducting prior art searches, (5) reviewing pertinent prior art, (6) issuing one or more office actions, (7) reviewing one or more applicant amendments and remarks, (8) reviewing one or more applicant IDS submissions, (9) conducting one or more examiner interviews and (10) issuing final rejections or notices of allowance.

AMGEN'S RESPONSE (¶ 51):

Amgen would have objected to this testimony as irrelevant, lacking foundation, and precisely the testimony prohibited by the Court when it granted Amgen's Motion *in Limine* No. 16 (*see* 9/4/07 Trial Tr. at 11).

ROCHE'S PROFFER (¶ 52):

Mr. Sofocleous would have testified that at the time the patents-in-suit were examined in the Patent Office, prior to the formation of the biotechnology examining group in March 1988, biotechnology applications were examined and processed by the chemical examining group, and that there were management issues in the chemical manufacturing group at that time. Mr. Sofocleous would have testified that his personal knowledge of this issue is corroborated by a government investigation memorialized in Trial Exhibit POZ (R. Ex. 8).

AMGEN'S RESPONSE (¶ 52):

Amgen would have objected to this testimony as irrelevant, lacking foundation, and precisely the testimony prohibited by the Court when it granted Amgen's Motion *in Limine* No. 16 (*see* 9/4/07 Trial Tr. at 11).

ROCHE'S PROFFER (¶ 53):

Mr. Sofocleous would have testified that at the time the patents-in-suit were examined in the Patent Office, examiners in the biotechnology examining group generally had a longer learning curve due to the complex nature of the underlying art. Mr. Sofocleous would have testified that his personal knowledge of this issue is corroborated by a government investigation memorialized in Trial Exhibit POZ (R. Ex. 8), which noted that new examiners in the biotechnology took approximately 20% more time to reach peak productivity than their peers in other examining groups so that it took about six years of experience in examining patents before reaching peak productivity.

AMGEN'S RESPONSE (¶ 53):

Amgen would have objected to this testimony as irrelevant, lacking foundation, and precisely the testimony prohibited by the Court when it granted Amgen's Motion *in Limine* No. 16 (*see* 9/4/07 Trial Tr. at 11). To the extent the Court treats the patent law experts' expert

reports as limiting the scope of their testimony notwithstanding the fact that they are offered as fact witnesses under Rule 406, Amgen would have further objected to this testimony as outside the scope of Mr. Sofocleous's expert reports.

Additionally, to the extent this testimony would have been permitted by the Court, Amgen would have cross examined Mr. Sofocleous concerning his knowledge of the qualifications and experience of the particular examiners responsible for examining the patents in suit, and in particular those of examiner James Martinell, PhD, whose involvement in examining the patents-in-suit spanned nearly 20 years, from the initial search report he performed to the issuance of the final patent.

ROCHE'S PROFFER (¶ 54):

Mr. Sofocleous would have testified that at the time the patents-in-suit were examined in the Patent Office, the biotechnology examining group could not hire as many examiners as it needed because of the lack of experienced senior staff to train them in this area. Mr. Sofocleous would have testified that his personal knowledge of this issue is corroborated by a government investigation memorialized in Trial Exhibit POZ (R. Ex. 8).

AMGEN'S RESPONSE (¶ 54):

Amgen would have objected to this testimony as irrelevant, lacking foundation, and precisely the testimony prohibited by the Court when it granted Amgen's Motion *in Limine* No. 16 (*see* 9/4/07 Trial Tr. at 11). To the extent the Court treats the patent law experts' expert reports as limiting the scope of their testimony notwithstanding the fact that they are offered as fact witnesses under Rule 406, Amgen would have further objected to this testimony as outside the scope of Mr. Sofocleous's expert reports.

ROCHE'S PROFFER (¶ 55):

Mr. Sofocleous would have testified that at the time the patents-in-suit were examined in the Patent Office, the biotechnology examining group had difficulty with retention of junior examiners with nearly 41% leaving the art unit within six years at the PTO. Mr. Sofocleous would have testified that his personal knowledge of this issue is corroborated by a government investigation memorialized in Trial Exhibit POZ (R. Ex. 8).

AMGEN'S RESPONSE (¶ 55):

Amgen would have objected to this testimony as irrelevant, lacking foundation, and precisely the testimony prohibited by the Court when it granted Amgen's Motion *in Limine* No. 16 (*see* 9/4/07 Trial Tr. at 11). To the extent the Court treats the patent law experts' expert reports as limiting the scope of their testimony notwithstanding the fact that they are offered as fact witnesses under Rule 406, Amgen would have further objected to this testimony as outside the scope of Mr. Sofocleous's expert reports.

Additionally, to the extent this testimony would have been permitted by the Court, Amgen would have cross examined Mr. Sofocleous concerning his knowledge of the qualifications and experience of the particular examiners responsible for examining the patents in suit, and in particular those of examiner James Martinell, PhD, whose involvement in examining the patents-in-suit spanned nearly 20 years, from the initial search report he performed to the issuance of the final patent.

VII. PETITIONS TO MAKE SPECIAL

ROCHE'S PROFFER (¶ 56):

Mr. Sofocleous would have testified that in the normal course of patent prosecution, applications are examined in the order in which they are received by the Patent Office. (R. Ex. 2, Trial Ex. PKB, MPEP § 708.02 (5th ed. Rev. 9, Sept. 1988), at 700-39-42; R. Ex. 3, Trial Ex. PKD, MPEP § 708.02 (8th ed. Rev. 5, Aug. 2006) at 700-134-139). However, there is a

procedural device in patent prosecution whereby an applicant can request that the Patent Office examine his application out of turn and move it to the front of the line for examination. (*Id.*)

AMGEN'S RESPONSE (¶ 56):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

ROCHE'S PROFFER (¶ 57):

Mr. Sofocleous would have testified that this procedural device is known as a Petition to Make Special. (*Id.*). Roche would have introduced Trial Exhibit 2012.179-180 (R. Ex. 9), a Petition to Make Special from the file history for the '868 patent, to provide the jury with an example.

AMGEN'S RESPONSE (¶ 57):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

Amgen would have objected to this testimony on the basis that it lacks foundation. Mr. Sofocleous has no personal knowledge concerning the prosecution of the patents in suit.

ROCHE'S PROFFER (¶ 58):

Mr. Sofocleous would have testified that, at the time the patents-in-suit were pending in

the Patent Office, there were a number of reasons why an application could be granted special status and examined out of turn, including (1) if another party is actually infringing on the applicant's prospective patent rights or (2) if the invention related to recombinant DNA. (R. Ex. 2, Trial Ex. PKB, MPEP § 708.02 (5th ed. Rev. 9, Sept. 1988), at 700-39-42; R. Ex. 3, Trial Ex. PKD, MPEP § 708.02 (8th ed. Rev. 5, Aug. 2006) at 700-134-139).

AMGEN'S RESPONSE (¶ 58):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

Amgen would have further objected to this testimony on the basis that it is either purely legal in nature or lacks foundation and is speculative.

ROCHE'S PROFFER (¶ 59):

Mr. Sofocleous would have testified that, in the normal course, to be granted special status, the applicant or his attorney must file a Petition to Make Special along with an accompanying declaration or oath. (*Id.*).

AMGEN'S RESPONSE (¶ 59):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

ROCHE'S PROFFER (¶ 60):

Mr. Sofocleous would have testified that the declaration accompanying a Petition to Make Special because of perceived infringement must set forth under oath, *inter alia*, (1) the applicant's basis for requesting special status, (2) that the applicant or his attorney has undertaken a careful search of the prior art, (3) that the applicant or his attorney has a good working knowledge of the pertinent prior art and (4) that the applicant or his attorney believes that all claims are allowable. (*Id.*). Roche would have introduced Trial Exhibit 2012.126-132 (R. Ex. 10), a Declaration Accompanying a Petition to Make Special in the file history for the '868 patent, to provide the jury with an example.

AMGEN'S RESPONSE (¶ 60):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

Amgen would have objected to this testimony on the basis that it lacks foundation. Mr. Sofocleous has no personal knowledge concerning the prosecution of the patents in suit.

ROCHE'S PROFFER (¶ 61):

Mr. Sofocleous would have testified that the purpose of requiring a declaration is that, in exchange for the Patent Office granting special status and examining the application out of turn, the applicant or his attorney is required to search for and provide all pertinent art to aid the examiner in completing his expedited examination.

AMGEN'S RESPONSE (¶ 61):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

Amgen would have further objected to this testimony concerning the purpose of PTO rules as lacking foundation, speculative, and outside the scope of Rule 406.

ROCHE'S PROFFER (¶ 62):

Mr. Sofocleous would have testified that after an applicant files a Petition to Make Special and an accompanying declaration, the Patent Office will examine the applicant's request and decide whether or not to grant it. (R. Ex. 2, Trial Ex. PKB, MPEP § 708.02 (5th ed. Rev. 9, Sept. 1988), at 700-39-42; R. Ex. 3, Trial Ex. PKD, MPEP § 708.02 (8th ed. Rev. 5, Aug. 2006) at 700-134-139).

AMGEN'S RESPONSE (¶ 62):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

ROCHE'S PROFFER (¶ 63):

Mr. Sofocleous would have testified that the Patent Office will normally memorialize its decision in written form to be placed in the application's file history. (*Id.*; 37 CFR § 1.2). Roche would have introduced Trial Exhibit 2012.169 (R. Ex. 11), a written decision on a Petition to

Make Special in the file history for the '868 patent, to provide the jury with an example.

AMGEN'S RESPONSE (¶ 63):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

Amgen would have objected to this testimony on the basis that it lacks foundation. Mr. Sofocleous has no personal knowledge concerning the prosecution of the patents in suit.

ROCHE'S PROFFER (¶ 64):

Mr. Sofocleous would have testified that the Patent Office may note in its decision that, in the event the application becomes involved in an appeal or an interference, the appeal or interference will also be conducted on an expedited basis. Roche would have used Trial Exhibit 2012.169 (R. Ex. 11) to provide the jury with an example of such a statement.

AMGEN'S RESPONSE (¶ 64):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial.

Amgen would have objected to this testimony on the basis that it lacks foundation. Mr. Sofocleous has no personal knowledge concerning the prosecution of the patents in suit.

ROCHE'S PROFFER (¶ 65):

Mr. Sofocleous would have testified that once an application is granted special status, the examiner expects the applicant or his attorney to bring pertinent information to his attention because the examiner is relying on the applicant and his attorney to aid him in the expedited examination.

AMGEN'S RESPONSE (¶ 65):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial. *See also* MPEP § 708.02 (no reference to examiner reliance).

Amgen would have further objected to this testimony as lacking foundation, speculative, outside the scope of Rule 406, and irrelevant.

VIII. PROTEST OF INVENTORSHIP

ROCHE'S PROFFER (¶ 66):

Mr. Sofocleous would have explained that although applications were normally filed and prosecuted confidentially during the time the patents-in-suit were pending, in limited circumstances, a third party may have become aware of the filing. Mr. Sofocleous would have testified that a Protest is a procedural device employed during patent prosecution when a member of the public attempts to contest the patentability of a pending application. 37 CFR § 1.291; (R. Ex. 2, Trial Ex. PKB, MPEP § 1901 (5th ed. Rev. 3, May 1986), at 1900-1-2; R. Ex. 3, Trial Ex. PKD, MPEP § 1901 (8th ed. Rev. 5, Aug. 2006) at 1900-1-3). In particular, he would have testified that a Protest of Inventorship is a device employed when a third party believes he should be named as an inventor of the pending application. Roche would have introduced Trial Exhibit 2012.796-801 (R. Ex. 12), a Protest of Inventorship by Por-Hsuing Lai in the file history of the

‘868 patent, to provide the jury with an example.

AMGEN’S RESPONSE (¶ 66):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche’s claims of inequitable conduct during the wrong phase of trial. In particular, insofar as there are no inventorship issues being litigated in this action, the sole apparent purpose for this proffered testimony is in support of Mr. Sofocleous’s speculative and unfounded theory that the review by Examiner Fitzgerald of the ‘334 Interference File in October through November 1993 was limited to issues pertaining to an inventorship protest asserted by Por Lai; Mr. Sofocleous apparently engages in this speculative exercise in an attempt to diverge in its inequitable conduct claim from this Court’s prior rulings in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 138-145 (D.Mass. 2001), that “the Examiner [Fitzgerald] reviewed and considered the Interference decision and record” and that “the evidence here is clear that the Examining Division reviewed and considered the Interference record and the Board’s decision.” *Id.* at 139.

Amgen would have further objected to this testimony on the bases that it falls outside the scope of Rule 406, and that it lacks foundation, as Mr. Sofocleous lacks personal knowledge of the prosecution of the patents in suit.

ROCHE’S PROFFER (¶ 67):

Mr. Sofocleous would have testified that to state a claim of co-inventorship, the protestor must file a writing with the Patent Office, identifying the application to which the protest is directed and the bases for his claim of inventorship. (R. Ex. 2, Trial Ex. PKB, MPEP § 1901.03

(5th ed. Rev. 3, May 1986), at 1900-3-4; R. Ex. 3, Trial Ex. PKD, MPEP § 1901.03 (8th ed. Rev. 5, Aug. 2006), at 1900-4-5). Roche would have used Trial Exhibit 2012.796-801 (R. Ex. 12) to provide the jury with an example.

AMGEN'S RESPONSE (¶ 67):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial. In particular, insofar as there are no inventorship issues being litigated in this action, the sole apparent purpose for this proffered testimony is in support of Mr. Sofocleous's speculative and unfounded theory that the review by Examiner Fitzgerald of the '334 Interference File in October through November 1993 was limited to issues pertaining to an inventorship protest asserted by Por Lai; Mr. Sofocleous apparently engages in this speculative exercise in an attempt to diverge in its inequitable conduct claim from this Court's prior rulings in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 138-145 (D.Mass. 2001), that "the Examiner [Fitzgerald] reviewed and considered the Interference decision and record" and that "the evidence here is clear that the Examining Division reviewed and considered the Interference record and the Board's decision." *Id.* at 139.

Amgen would have further objected to this testimony on the basis that it lacks foundation, as Mr. Sofocleous lacks personal knowledge of the prosecution of the patents in suit.

ROCHE'S PROFFER (¶ 68):

Mr. Sofocleous would have testified that the protestor can rely on and submit information in support of his claim of inventorship, and that, in the normal course, the protestor will submit

lab notebooks, memoranda and other evidence to support his claim that he should be a named inventor. (R. Ex. 2, Trial Ex. PKB, MPEP § 1901.02 (5th ed. Rev. 3, May 1986), at 1900-2-3; R. Ex. 3, Trial Ex. PKD, MPEP § 1901.02 (8th ed. Rev. 5, Aug. 2006) at 1900-3-4).

AMGEN'S RESPONSE (¶ 68):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial. In particular, insofar as there are no inventorship issues being litigated in this action, the sole apparent purpose for this proffered testimony is in support of Mr. Sofocleous's speculative and unfounded theory that the review by Examiner Fitzgerald of the '334 Interference File in October through November 1993 was limited to issues pertaining to an inventorship protest asserted by Por Lai; Mr. Sofocleous apparently engages in this speculative exercise in an attempt to diverge in its inequitable conduct claim from this Court's prior rulings in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 138-145 (D.Mass. 2001), that "the Examiner [Fitzgerald] reviewed and considered the Interference decision and record" and that "the evidence here is clear that the Examining Division reviewed and considered the Interference record and the Board's decision." *Id.* at 139.

ROCHE'S PROFFER (¶ 69):

Mr. Sofocleous would have testified that once a protestor submits the protest and supporting evidence, the examiner of the underlying application will review the materials and decide whether the protestor has provided clear and convincing evidence of co-inventorship. (R. Ex. 2, Trial Ex. PKB, MPEP § 1901.06 (5th ed. Rev. 3, May 1986), at 1900-5-8; R. Ex. 3, Trial

Ex. PKD, MPEP § 1901.06 (8th ed. Rev. 5, Aug. 2006) at 1900-8-11).

AMGEN'S RESPONSE (¶ 69):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial. In particular, insofar as there are no inventorship issues being litigated in this action, the sole apparent purpose for this proffered testimony is in support of Mr. Sofocleous's speculative and unfounded theory that the review by Examiner Fitzgerald of the '334 Interference File in October through November 1993 was limited to issues pertaining to an inventorship protest asserted by Por Lai; Mr. Sofocleous apparently engages in this speculative exercise in an attempt to diverge in its inequitable conduct claim from this Court's prior rulings in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 138-145 (D.Mass. 2001), that "the Examiner [Fitzgerald] reviewed and considered the Interference decision and record" and that "the evidence here is clear that the Examining Division reviewed and considered the Interference record and the Board's decision." *Id.* at 139.

ROCHE'S PROFFER (¶ 70):

Mr. Sofocleous would have testified that the examiner will normally memorialize his decision in an office action that is to be added to the application's file history, though the decision may or may not be sent to the protestor. Roche would have introduced Trial Exhibit 2012.907-918 (R. Ex. 13), an office action in the file history of the '868 patent, to provide the jury with an example of an examiner's decision on a Protest.

AMGEN'S RESPONSE (¶ 70):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of trial. In particular, insofar as there are no inventorship issues being litigated in this action, the sole apparent purpose for this proffered testimony is in support of Mr. Sofocleous's speculative and unfounded theory that the review by Examiner Fitzgerald of the '334 Interference File in October through November 1993 was limited to issues pertaining to an inventorship protest asserted by Por Lai; Mr. Sofocleous apparently engages in this speculative exercise in an attempt to diverge in its inequitable conduct claim from this Court's prior rulings in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 138-145 (D.Mass. 2001), that "the Examiner [Fitzgerald] reviewed and considered the Interference decision and record" and that "the evidence here is clear that the Examining Division reviewed and considered the Interference record and the Board's decision." *Id.* at 139.

ROCHE'S PROFFER (¶ 71):

Mr. Sofocleous would have testified that, in the normal course, the examiner will rely solely on the arguments and materials provided to him by the protestor and will not conduct an independent investigation to decide the merits of the Protest.

AMGEN'S RESPONSE (¶ 71):

Amgen would have objected to this testimony on the basis that it is irrelevant to issues of validity, and to the extent it relates to purely legal issues. Moreover, Amgen would have objected to this entire line of testimony being offered in the validity phase as an improper effort to offer evidence pertaining to Roche's claims of inequitable conduct during the wrong phase of

trial. In particular, insofar as there are no inventorship issues being litigated in this action, the sole apparent purpose for this proffered testimony is in support of Mr. Sofocleous's speculative and unfounded theory that the review by Examiner Fitzgerald of the '334 Interference File in October through November 1993 was limited to issues pertaining to an inventorship protest asserted by Por Lai; Mr. Sofocleous apparently engages in this speculative exercise in an attempt to diverge in its inequitable conduct claim from this Court's prior rulings in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 138-145 (D.Mass. 2001), that "the Examiner [Fitzgerald] reviewed and considered the Interference decision and record" and that "the evidence here is clear that the Examining Division reviewed and considered the Interference record and the Board's decision." *Id.* at 139.

IX. EXAMINER INTERVIEWS

ROCHE'S PROFFER (¶ 72):

Mr. Sofocleous would have testified that during the course of patent examination, a patent applicant or his attorney may request to meet with the examiner in person or via telephone to discuss matters pertaining to the examination of the underlying application. (R. Ex. 2, Trial Ex. PKB, MPEP §§ 713-713.05 (5th ed. Rev. 6, Oct. 1987), at 700-60-64; R. Ex. 3, Trial Ex. PKD, MPEP §§ 713-713.10 (8th ed. Rev. 5, Aug. 2006), at 700-224-234).

AMGEN'S RESPONSE (¶ 72):

General objections apply.

ROCHE'S PROFFER (¶ 73):

Mr. Sofocleous would have testified that Examiner Interviews are useful to develop and clarify specific issues relating to patentability to help advance the prosecution of the application. (R. Ex. 2, Trial Ex. PKB, MPEP § 713.01 (5th ed. Rev. 6, Oct. 1987), at 700-60-62; R. Ex. 3, Trial Ex. PKD, MPEP § 713.01 (8th ed. Rev. 5, Aug. 2006), at 700-224-228).

AMGEN'S RESPONSE (¶ 73):

Amgen would have objected to this testimony concerning the utility and purpose of Examiner Interviews on the basis that it falls outside the scope of Rule 406.

ROCHE'S PROFFER (¶ 74):

Mr. Sofocleous would have testified that Patent Office rules require that if an interview is held, the substance of that interview must be recorded in an Examiner Interview Summary Record because Federal Regulations require that the actions of the Patent Office be based exclusively on the written record in the Office. (R. Ex. 2, Trial Ex. PKB, MPEP § 713.04 (5th ed. Rev. 6, Oct. 1987), at 700-62-63; R. Ex. 3, Trial Ex. PKD, MPEP § 713.04 (8th ed. Rev. 5, Aug. 2006) at 700-229-232); 37 CFR §§ 1.2, 1.133. He would have explained that this cannot happen if the record is itself incomplete. Roche would have introduced Trial Exhibit 2012.449 (R. Ex. 14), an Examiner Interview Summary Record from the file history of the '868 patent, to provide the jury with an example.

AMGEN'S RESPONSE (¶ 74):

Amgen would have objected to this testimony as purely legal. Amgen would further have objected to this testimony as legally erroneous, insofar as it suggests a mandatory written record of prosecution where the MPEP makes only a normative recommendation that business should be conducted in writing. Amgen would have further objected to this testimony as lacking foundation, as Mr. Sofocleous has no personal knowledge concerning the prosecution of the patents in suit.

ROCHE'S PROFFER (¶ 75):

Mr. Sofocleous would have testified that if no record is completed for the interview, it is as if the interview never occurred, and if an issue discussed at the interview is not incorporated

into the summary record, it is as if that issue was not discussed.

AMGEN'S RESPONSE (¶ 75):

Amgen would have objected to this testimony as purely legal. Amgen would further have objected to this testimony as legally erroneous, insofar as it suggests a mandatory written record of prosecution where the MPEP makes only a normative recommendation that business should be conducted in writing. Amgen would have further objected to this testimony as lacking foundation.

X. INTERFERENCES

ROCHE'S PROFFER (¶ 76):

Mr. Sofocleous would have testified that the United States patent system mandates that a patent should be awarded to the first person to invent particular patentable subject matter, not necessarily the first person to file a patent application on that subject matter. He would have explained, however, that sometimes there is a dispute over who was the first to invent particular subject matter.

AMGEN'S RESPONSE (¶ 76):

Amgen would have objected to this testimony as purely legal, outside the scope of Rule 406, and irrelevant to validity issues.

ROCHE'S PROFFER (¶ 77):

Mr. Sofocleous would have testified that an Interference is an administrative proceeding to determine who in fact is the first to invent among two competing applicants and, thus, who is entitled to a patent. 35 U.S.C. § 135; (R. Ex. 2, Trial Ex. PKB, MPEP § 2300.01 (5th ed. Rev. 9, Sept. 1988), at 2300-1-3; R. Ex. 3, Trial Ex. PKD, MPEP § 2301 (8th ed. Rev. 5, Aug. 2006) at 2300-1).

AMGEN'S RESPONSE (¶ 77):

Amgen would have objected to this testimony as purely legal, outside the scope of Rule 406, and irrelevant to validity issues. Further, Amgen would have cross examined Mr. Sofocleous as to whether issues other than priority of inventorship may be addressed in interference proceedings.

ROCHE'S PROFFER (¶ 78):

Mr. Sofocleous would have testified that an Interference is overseen by and decided by the Board of Patent Appeals and Interferences, which is a separate and distinct branch of the Patent Office from the examination corps.

AMGEN'S RESPONSE (¶ 78):

On cross examination, Amgen would have emphasized this admission to establish that, since 1975, Mr. Sofocleous's experience in the PTO was in a "separate and distinct branch of the Patent Office from the examination corps," and on that basis he lacks foundation to testify concerning the habit, custom or routine practice of the examining corps after 1975. On cross examination, Amgen would have referred to MPEP § 2300 as well as MPEP § 1302.12 (in the first action after termination of an interference, the examiner should make of record in each application all references not already of record which were pertinent to any preliminary motions and which were discussed in the decision on motion).

ROCHE'S PROFFER (¶ 79):

Mr. Sofocleous would have testified that, in the normal course, both parties to an Interference believe they have invented patentable subject matter and, therefore, direct the majority of their arguments and evidence to determining who was the first to conceive of and reduce to practice the claimed subject matter.

AMGEN'S RESPONSE (¶ 79):

On cross examination, Amgen would have questioned Mr. Sofocleous about the fact that issues other than priority of inventorship—including issues of validity—can be, and often are, litigated during interference proceedings, and would have used the decisions in the Lin interferences as exhibits.

ROCHE'S PROFFER (¶ 80):

Mr. Sofocleous would have testified that an Interference is declared when an examiner finds two applications or an application and a patent that he deems to have the same or similar subject matter. (R. Ex. 2, Trial Ex. PKB, MPEP § 2300.02 (5th ed. Rev. 9, Sept. 1988), at 2300-4-6).

AMGEN'S RESPONSE (¶ 80):

Amgen would have objected to this testimony as purely legal, vague and ambiguous, irrelevant, and legally incomplete.

ROCHE'S PROFFER (¶ 81):

Mr. Sofocleous would have testified that when an examiner decides to declare an Interference, he will define one or more "counts" of the Interference, which correspond to the overlapping subject matter. (R. Ex. 2, Trial Ex. PKB, MPEP § 2309.01 (5th ed. Rev. 9, Sept. 1988), at 2300-20-22; R. Ex. 3, Trial Ex. PKD, MPEP § 2304.02(b) (8th ed. Rev. 5, Aug. 2006) at 2300-13); 37 CFR § 41.201.

AMGEN'S RESPONSE (¶ 81):

Amgen would have objected to this testimony as purely legal, vague and ambiguous, irrelevant, and legally incomplete.

ROCHE'S PROFFER (¶ 82):

Mr. Sofocleous would have testified that *ex parte* prosecution of the underlying

application(s) will be suspended upon declaration of an Interference. He would have explained that this often means an examiner will not be involved with an application for years and will become less familiar with the file within that time. (R. Ex. 2, Trial Ex. PKB, MPEP § 2315 (5th ed. Rev. 9, Sept. 1988), at 2300-27-28; R. Ex. 3, Trial Ex. PKD, MPEP § 2307.03 (8th ed. Rev. 5, Aug. 2006), at 2300-21).

AMGEN'S RESPONSE (¶ 82):

Amgen would have objected to the second sentence of this testimony as irrelevant, lacking foundation, speculative and outside the scope of Rule 406. *See also* 37 CFR § 1.104.

ROCHE'S PROFFER (¶ 83):

Mr. Sofocleous would have testified that in the late 1980s and early 1990s, when the patents-in-suit were pending, it was common practice in the Patent Office for more than one Interference to be declared between the same parties. He would have explained that this would happen when the overlapping subject matter appeared in more than one application or patent co-owned by the same party. At the time, Patent Office procedure would not permit more than one application or patent owned by the same party to appear in the same Interference unless the party agreed to filing a terminal disclaimer prior to entering interference and, therefore, multiple Interferences had to be declared. Mr. Sofocleous would have explained, however, that when this occurred, there was no evidentiary determination that the counts of the two Interferences were patentably distinct because the declaration of separate Interferences was simply a function of the administrative procedures of the Patent Office. (*See* R. Ex. 2, Trial Ex. PKB, MPEP § 2300.02 (5th ed. Rev. 9, Sept. 1988), at 2300-4-6 ("[t]he Board .. has discretion to determine whether counts are patentably distinct")).

AMGEN'S RESPONSE (¶ 83):

Amgen would have objected to this testimony as purely legal and legally incorrect. On cross examination, Amgen would have inquired about the properly-construed requirements of the MPEP, and also would have inquired about the fact that in the interferences in this case, on February 9, 1990, the Patent Office determined the three counts to be patentably distinct. *See also* 37 CFR § 1.601 (each count is defined as a patentably distinct invention).

ROCHE'S PROFFER (¶ 84):

Mr. Sofocleous would have testified that in the late 1980s and early 1990s, if a party to an Interference felt that the examiner erred in declaring more than one Interference between the same parties, that party had no recourse because, at the time, there was no provision in the Patent Office rules for combining Interferences. Roche would have introduced Trial Exhibit BYJ (R. Ex. 15), a Decision on Motions from Interference No. 102,096, to corroborate Mr. Sofocleous's personal knowledge that there was no provision for combining interferences in the late 1980s and early 1990s.

AMGEN'S RESPONSE (¶ 84):

Amgen would have objected to this testimony as purely legal. Amgen would have further objected as lacking foundation, insofar as Mr. Sofocleous has no personal knowledge concerning the interferences that occurred during the prosecution of Dr. Lin's patents. On cross examination, Amgen would have inquired about the properly-construed requirements of the MPEP, and also would have inquired about the fact that in the interferences in this case, on February 9, 1990, the Patent Office determined the three counts to be patentably distinct. *See also* 37 CFR § 1.601 (each count is defined as a patentably distinct invention).

ROCHE'S PROFFER (¶ 85):

Mr. Sofocleous would have testified that in the normal course, once an Interference has

been declared, the parties will submit evidence to the Board of Patent Appeals and Interferences to support their claim of prior invention.

AMGEN'S RESPONSE (¶ 85):

General objections apply.

ROCHE'S PROFFER (¶ 86):

Mr. Sofocleous would have testified that in the normal course, the Board will retain this evidence in its own files that it sets up for the Interference. 37 CFR § 1.4(b), (c). He would have explained that once the Interference is decided and terminated, the Board will put all of the materials collected in the course of the Interference into files for storage.

AMGEN'S RESPONSE (¶ 86):

Amgen would have objected to this testimony as lacking foundation and irrelevant. On cross examination, Amgen would have inquired about MPEP § 2363 (5th ed., Rev. 13) (file goes to Examiner after interference).

ROCHE'S PROFFER (¶ 87):

Mr. Sofocleous would have testified that in the normal course, the Board will not send evidence collected during the Interference to the examiner of the underlying application for inclusion in the application's file history because Patent Office rules require that files for different branches of the Patent Office be maintained separately. (R. Ex. 2, Trial Ex. PKB, MPEP § 2363 (5th ed. Rev. 13, Nov. 1989), at 2300-49); 37 CFR § 1.4(b), (c). Instead, Mr. Sofocleous would have explained, the examiner normally will only get the first and last volumes of the Interference file, which contains the final decision but no exhibits or testimony, so that he can note the final decision, after which he will return those materials to the Service Branch of the

Interference Branch of the Patent Office. (*Id.*)

AMGEN'S RESPONSE (¶ 87):

Amgen would have objected to this testimony as lacking foundation and irrelevant. On cross examination, Amgen would have asked Mr. Sofocleous about whether examiners may request and obtain copies of the interference files. On cross examination, Amgen would also have asked Mr. Sofocleous about his lack of personal knowledge concerning what occurred during the prosecution of Dr. Lin's patents, and in particular his lack of personal knowledge about which files Examiner Fitzgerald reviewed in October through November of 1993. On cross examination, Amgen would also have inquired about MPEP § 2363 (5th ed., Rev. 13) (file goes to Examiner after interference, no mention of first and last volumes).

ROCHE'S PROFFER (¶ 88):

Mr. Sofocleous would have testified that once the Interference is terminated, the prevailing application (in the case of an application v. application Interference) will return to the examiner for *ex parte* prosecution. (R. Ex. 2, Trial Ex. PKB, MPEP § 2363 (5th ed. Rev. 13, Nov. 1989), at 2300-49; R. Ex. 3, Trial Ex. PKD, MPEP § 2308 (8th ed. Rev. 5, Aug. 2006), at 2300-21-22).

AMGEN'S RESPONSE (¶ 88):

General objections apply.

ROCHE'S PROFFER (¶ 89):

Mr. Sofocleous would have testified that after an examiner resumes *ex parte* prosecution, he or she generally does not review portions of the interference file other than the final decision. In some rare circumstances, Mr. Sofocleous would have explained, the Board of Patent Appeals and Interferences may specifically refer the examiner to certain motions or issues that were

raised in the interference that must be addressed during subsequent examination.

AMGEN'S RESPONSE (¶ 89):

Amgen would have objected to this testimony as speculative and lacking foundation. On cross examination, Amgen would have asked Mr. Sofocleous about his lack of knowledge concerning what in fact occurred following the termination of the interferences involving Dr. Lin's patents, including the search notes in the '933 patent file history. *See also* 37 CFR § 1.2.

ROCHE'S PROFFER (¶ 90):

Mr. Sofocleous would have testified that, in the normal course, an examiner would not sift through subsidiary papers in the Interference file such as declarations, exhibits or transcripts to find information that possibly may be relevant to the continued examination of the pending claims or new claims added after the interference has concluded. Indeed, he does not have the time to look for the proverbial "needle in the haystack" and it is extremely unlikely an examiner would be able to meet his "disposal" requirement if he did so.

AMGEN'S RESPONSE (¶ 90):

Amgen would have objected to this testimony as speculative and lacking foundation. Amgen would further have objected to this testimony under Rule 403 as prejudicial and likely to cause jury confusion. On cross examination, Amgen would have asked Mr. Sofocleous about his lack of knowledge concerning what in fact occurred following the termination of the interferences involving Dr. Lin's patents. On cross examination, Amgen would have further confronted Mr. Sofocleous with documents from the actual interference files and interference file indices. *See also* 37 CFR § 1.2.