

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

_____	)	
AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	CIVIL ACTION No.: 05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD	)	
ROCHE DIAGNOSTICS GmbH	)	:
and HOFFMANN-LA ROCHE INC.	)	
	)	
Defendants.	)	
_____	)	

**DEFENDANTS’ OFFER OF PROOF REGARDING  
THE TESTIMONY OF MICHAEL SOFOCLEOUS**

In response to the Court’s partial grant of Amgen, Inc.’s Motion *In Limine* No. 16 to Exclude Sofocleous Testimony Regarding the Competence of the Examination Process in the U.S. Patent and Trademark Office, defendants, F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively “Roche”) make the following offer of proof:

**General Nature of Mr. Sofocleous’s Testimony**

With respect to Roche’s invalidity case,<sup>1</sup> 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

<sup>1</sup> 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.

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.

**Mr. Sofocleous's Background and Experience**

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).<sup>2</sup>

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

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).

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).

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<sup>2</sup> "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.

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).

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).

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).

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).

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).

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).

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).

### **Patent Examining Procedure**

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.

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 (5<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 100-1; R. Ex. 3, Trial Ex. PKD, MPEP § 101 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 100-1).

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-2, 700-5-6; R. Ex. 3, Trial Ex. PKD, MPEP §§ 702, 706 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 700-4-5, 700-19-21).

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.

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.

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 600-1-3; R. Ex. 3, Trial Ex. PKD, MPEP § 601 (8<sup>th</sup> 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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 600-11-13; R. Ex. 3, Trial Ex. PKD, MPEP § 602 (8<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-2, 700-5-6; R. Ex. 3, Trial Ex. PKD, MPEP §§ 702, 706 (8<sup>th</sup> 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) (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-5-23; R. Ex. 3, Trial Ex. PKD, MPEP §§ 706-706.03(x) (8<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-3-4; R. Ex. 2, Trial Ex. PKB, MPEP § 904.02 (5<sup>th</sup> ed., Aug. 1983) at 900-36-37; R. Ex. 3, Trial Ex. PKD, MPEP § 704.01 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 700-6; R. Ex. 3, Trial Ex. PKD, MPEP § 904 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 900-47; R. Ex. 3, Trial Ex. PKD, MPEP §§ 904.01(c)-904.03 (8<sup>th</sup> 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) (5<sup>th</sup> ed., Aug. 1983), at 900-36; R. Ex. 3, Trial Ex. PKD, MPEP §§ 904.01(c) (8<sup>th</sup> 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.

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.

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.

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 (5<sup>th</sup> ed. Rev. 8, May

1988), at 600-65-69; R. Ex. 3, Trial Ex. PKD, MPEP § 609 (8<sup>th</sup> 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.

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 (8<sup>th</sup> 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.

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 (5<sup>th</sup> 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.

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.* (5<sup>th</sup> 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.

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.* (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-27-38; R. Ex. 3, Trial Ex. PKD, MPEP § 707 *et seq.* (8<sup>th</sup> 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.

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.

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.

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.

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.

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

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.

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.* (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-23-29; R. Ex. 3, Trial Ex. PKD, MPEP § 706.07 *et seq.* (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 700-81-110).

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.

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-23; R. Ex. 3, Trial Ex. PKD, MPEP § 706.04 (8<sup>th</sup> 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.

#### **Different Types of Patent Applications**

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.

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 (5<sup>th</sup> ed. Rev. 11, Apr. 1989), at 200-13; R. Ex. 3, Trial Ex. PKD, MPEP § 201.07 (8<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 11, Apr. 1989), at 200-13; R. Ex. 3, Trial Ex. PKD, MPEP § 201.08 (8<sup>th</sup> 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-in-part 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.

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 (5<sup>th</sup> ed. Rev. 11, Apr. 1989), at 200-6-7; R. Ex. 3, Trial Ex. PKD, MPEP § 201.06 (8<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 800-3; R. Ex. 3, Trial Ex. PKD, MPEP § 803 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 800-3-4).

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 (5<sup>th</sup> ed. Rev. 11, Apr. 1989), at 200-6-7; R. Ex. 3, Trial Ex. PKD, MPEP § 201.06 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 200-21).

### **Double Patenting**

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 800-4-9; R. Ex. 3, Trial Ex. PKD, MPEP §§ 804-804.03 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 800-11-41).

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 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 800-21)

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 800-4-9; R. Ex. 3, Trial Ex. PKD, MPEP § 804, § 804.03 (8<sup>th</sup> 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 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 800-22-26).

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 800-7; R. Ex. 3, Trial Ex. PKD, MPEP § 804.02 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 800-31-33).

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 800-3).

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 (5<sup>th</sup> ed. Rev. 8, May 1988), at 800-6; R. Ex. 3, Trial. Ex. PKD, MPEP § 804.01 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 800-30-31).

### **State of the Biotechnology Examining Group in the Late 1980s and Early 1990s**

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.

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.

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).

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.

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).

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).

### **Petitions to Make Special**

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 700-39-42; R. Ex. 3, Trial Ex. PKD, MPEP § 708.02 (8<sup>th</sup> 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.*)

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.

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 700-39-42; R. Ex. 3, Trial Ex. PKD, MPEP § 708.02 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 700-134-139).

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.*).

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.

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.

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 700-39-42; R. Ex. 3, Trial Ex. PKD, MPEP § 708.02 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 700-134-139).

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.

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.

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.

### **Protest of Inventorship**

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 (5<sup>th</sup> ed. Rev. 3, May 1986), at 1900-1-2; R. Ex. 3, Trial Ex. PKD, MPEP § 1901 (8<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 3, May 1986), at 1900-3-4; R. Ex. 3, Trial Ex. PKD, MPEP § 1901.03 (8<sup>th</sup> 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.

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 (5<sup>th</sup> ed. Rev. 3, May 1986), at 1900-2-3; R. Ex. 3, Trial Ex. PKD, MPEP § 1901.02 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 1900-3-4).

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 (5<sup>th</sup> ed. Rev. 3, May 1986), at 1900-5-8; R. Ex. 3, Trial Ex. PKD, MPEP § 1901.06 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 1900-8-11).

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.

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.

### **Examiner Interviews**

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-60-64; R. Ex. 3, Trial Ex. PKD, MPEP §§ 713-713.10 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 700-224-234).

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-60-62; R. Ex. 3, Trial Ex. PKD, MPEP § 713.01 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 700-224-228).

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 (5<sup>th</sup> ed. Rev. 6, Oct. 1987), at 700-62-63; R. Ex. 3, Trial Ex. PKD, MPEP § 713.04 (8<sup>th</sup> 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.

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.

### **Interferences**

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.

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 2300-1-3; R. Ex. 3, Trial Ex. PKD, MPEP § 2301 (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 2300-1).

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.

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.

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 2300-4-6).

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 2300-20-22; R. Ex. 3, Trial Ex. PKD, MPEP § 2304.02(b) (8<sup>th</sup> ed. Rev. 5, Aug. 2006) at 2300-13); 37 CFR § 41.201.

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 2300-27-28; R. Ex. 3, Trial Ex. PKD, MPEP § 2307.03 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 2300-21).

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 (5<sup>th</sup> ed. Rev. 9, Sept. 1988), at 2300-4-6 (“[t]he Board .. has discretion to determine whether counts are patentably distinct”).

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.

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.

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.

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 (5<sup>th</sup> 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.*)

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 (5<sup>th</sup> ed. Rev. 13,



Nov. 1989), at 2300-49; R. Ex. 3, Trial Ex. PKD, MPEP § 2308 (8<sup>th</sup> ed. Rev. 5, Aug. 2006), at 2300-21-22).

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..

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.

Dated: September 14, 2007  
Boston, Massachusetts

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

/s/ Keith E. Toms

Keith E. Toms

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