IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

AMGEN, INC.,)	
Plaintiff,)	
V.)	Civil Action No. 05-12237 WGY
)	Civil Action 1vo. 05 12257 vv G I
F. HOFFMANN-LA ROCHE LTD., ROCHE)	
DIAGNOSTICS GmbH, HOFFMANN-LA)	
ROCHE INC.,)	
)	
Defendants)	

DECLARATION OF CULLEN N. PENDLETON IN SUPPORT OF AMGEN'S OPPOSITION TO ROCHE'S MOTION FOR SUMMARY JUDGMENT THAT CLAIM 7 OF THE '349 PATENT IS INVALID UNDER 35 U.S.C. § 112 AND IS NOT INFRINGED

- I, Cullen N. Pendleton, hereby declare under penalty of perjury that:
- 1. I am an attorney admitted to the Bar of the State of Illinois and am an associate in the law firm of Marshall, Gerstein & Borun LLP, counsel for Plaintiff Amgen, Inc. in the above captioned case.
- 2. I make this declaration in support of Amgen's Opposition to Roche's Motion for Summary Judgment that Claim 7 of the '349 Patent is invalid under 35 U.S.C. § 112 and is not infringed.
- 3. Exhibit 1 is a true and correct copy of excerpted pages from Plaintiff's Supplemental Responses to Defendants' First Set of Interrogatories (Nos. 1-12) (cited in Exhibit A to Declaration of Howard S. Suh (Docket No. 542) in support of Roche's motion.)
 - 4. Exhibit 2 is a true and correct copy of U.S. Patent No. 5,756,349.
- 5. Exhibit 3 is a true and correct copy of selected pages from the March 28, 2007 Deposition Transcript of Fu-Kuen Lin, Ph.D. and errata sheets thereto.
- 6. Exhibit 4 is a true and correct copy of excerpts from the May 31, 2007 Deposition Transcript of Eugene Goldwasser, Ph.D.
- 7. Exhibit 5 is a true and correct copy of excerpts from the May 11, 2007 Rebuttal Expert Statement of Ronald W. McLawhon, M.D., Ph.D.
- 8. Exhibit 6 is a true and correct copy of excerpts from the May 11, 2007 Rebuttal Expert Statement of Eugene Goldwasser, Ph.D.
- 9. Exhibit 7 is a true and correct copy of excerpts from the May 17, 2007 Deposition Transcript of Ronald W. McLawhon M.D., Ph.D.
- 10. Exhibit 8 is a true and correct copy of Goldwasser, E. & Sherwood, J.B. (1981) Brit. J. Haematol., 48:359–363.

- 11. Exhibit 9 is a true and correct copy of Goldwasser *et al.* (1991) *Endocrinology*, 128(1):440.
- 12. Exhibit 10 is a true and correct copy of Sherwood, J.B. & Goldwasser, E. (1979) *Blood*, 54(4):885–93.
- 13. Exhibit 11 is a true and correct copy of excerpts from the April 30, 2007 Expert Report of Ronald W. McLawhon, M.D., Ph.D.
- 14. Exhibit 12 is a true and correct copy of Annable, L. et al. (1972) Bull. Wld. Hlth. Org., 47(1):99–112.
 - 15. Exhibit 13 is a true and correct copy of AM-ITC 00558662.
 - 16. Exhibit 14 is a true and correct copy of UCH000005950–51.
 - 17. Exhibit 15 is a true and correct copy of AM-ITC 00550542–43.
 - 18. Exhibit 16 is a true and correct copy of AM-ITC 00558618–19.
- 19. Exhibit 17 is a true and correct copy of excerpts from the March 27, 2007Deposition Transcript of Joan C. Egrie, Ph.D.
- 20. Exhibit 18 is a true and correct copy of excerpts from the P. Veng-Pedersen Report (2006).
- 21. Exhibit 19 is a true and correct copy of excerpts from the February 14, 2007 Deposition Transcript of Eugene Goldwasser.
- 22. Exhibit 20 is a true and correct copy of excerpted pages from Defendants' Responses and Objections to Plaintiff Amgen Inc.'s First Set of Interrogatories to Defendants (Nos. 1-12).
- 23. Exhibit 21 is a true and correct copy of an excerpt from the EPO-Trac RIA kit manual.

- 24. Exhibit 22 is a true and correct copy of Garcia, J. F. (1977) "Assays for Erythropoietin" in KIDNEY HORMONES, Vol. II: Erythropoietin (J. W. Fisher, ed.; Academic Press)).
- 25. Exhibit 23 is a true and correct copy of Zaroulis, C. *et al.* (1981) *Am. J. Hematol.*, 11(1):85–92.
- 26. Exhibit 24 is a true and correct copy of Garcia, J.F. *et al.* (1979) *Blood Cells*, 5(3):405–419.
- 27. Exhibit 25 is a true and correct copy of Cotes, P. M. (1982) *Brit. J. Haematol.*, 50:427–438.
- 28. Exhibit 26 is a true and correct copy of Egrie, J. et al. (1987) J. Immunol. Meth., 99:235–241.
 - 29. Exhibit 27 is a true and correct copy of U.S. Patent No. 4,353,982.
- 30. Exhibit 28 is a true and correct copy of Rege, A. *et al.* (1982) *J. Lab. Clin. Med.*, 100(6):829–43.
- 31. Exhibit 29 is a true and correct copy of the February 7, 2007 letter from Patricia Carson, Esq. to Deborah Fishman, Esq.
- 32. Exhibit 30 is a true and correct copy of Koeffler, H.P. & Goldwasser, E. (1981) *Annals of Internal Med.*, 94:44–47.
- 33. Exhibit 31 is a true and correct copy of Thomas, R. et al. (1983) Brit. J. Obst. Gynec., 90:795–800.
- 34. Exhibit 32 is a true and correct copy of Garcia J.F. (1974) *Radioimmunoassay and Related Procedures in Medicine* Vol. I Vienna IAEA-SM -177, 275–287.

- 35. Exhibit 33 is a true and correct copy of Goldwasser, E. *et al.* (1975) *Endocrinology*, 97(2):315–323.
- 36. Exhibit 34 is a true and correct copy of Lange, R.D. *et al.* (1980) *Human Immunology*, 1:197–224.
- 37. Exhibit 35 is a true and correct copy of Lertora, J. *et al.* (1975) *J. Lab. Clin. Med.*, 86(1):140–151.
 - 38. Exhibit 36 is a true and correct copy of ITC-R-BLA-00005073.
 - 39. Exhibit 37 is a true and correct copy of ITC-R-BLA-00005581.
 - 40. Exhibit 38 is a true and correct copy of AM-ITC 00187104.
 - 41. Exhibit 39 is a true and correct copy of A 140563.
 - 42. Exhibit 40 is a true and correct copy of ITC-R-BLA-00002375–2378.
- 43. Exhibit 41 is a true and correct copy of excerpts from the June 6, 2007 Deposition Transcript of Dr. Charles Zaroulis.
- 44. Exhibit 42 is a true and correct copy of excerpts from the June 7, 2007 Deposition Transcript of Dr. Wayne Flintoff.
- 45. Exhibit 43 is a true and correct copy of excerpts from the June 21, 2007 Deposition Transcript of Dr. Thomas R. Kadesch.
- 46. Exhibit 44 is a true and correct copy of web pages showing search results for the terms "capable of" or "capable upon" in the claims of U.S. patents issued from 1976 to the present. Searches were performed in the USPTO Patent Full-Text and Image Database (available at http://patft.uspto.gov/netahtml/PTO/search-adv.htm, visited on July 2, 2007).
- 47. Exhibit 45 is a true and correct copy of excerpts from the April 6, 2007 Expert Report of Harvey F. Lodish, Ph.D. Regarding Infringement.

- 48. Exhibit 46 is a true and correct copy of R001402763–784.
- 49. Exhibit 47 is a true and correct copy of email correspondence from counsel for Roche dated March 20, 2007.
- 50. Exhibit 48 is a true and correct copy of R008886847–49, which was attached to the email correspondence provided as Exhibit 47.
- 51. Exhibit 49 is a true and correct copy of excerpts from the April 30, 2007 Expert Report of Richard D. Kolodner, Ph.D.
- 52. Exhibit 50 is a true and correct copy of laboratory notebook pages from Richard D. Kolodner, Ph.D., originally attached to the April 30, 2007 Expert Report of Richard D. Kolodner, Ph.D.
- 53. Exhibit 51 is a true and correct copy of the April 30, 2007 Addendum to Expert Report of Harvey F. Lodish, Ph.D. Regarding Infringement.
- 54. Exhibit 52 is a true and correct copy of excerpts from the June 4, 2007 Supplemental Expert Report of Harvey F. Lodish, Ph.D.
- 55. Exhibit 53 is a true and correct copy of correspondence from Roche to Dr. Richard D. Kolodner, dated March 19, 2007.

Dated: July 5, 2007 Respectfully submitted,

/s/ Cullen N. Pendleton
Cullen N. Pendleton

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 and paper copies will be sent to those indicated as non-registered participants.

/s/ Michael R. Gottfried

Michael R. Gottfried