

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ASSOCIATION FOR MOLECULAR
PATHOLOGY, et al.,

Plaintiffs,

v.

UNITED STATES PATENT AND
TRADEMARK OFFICE, et al.,

Defendants.

09 Civ. 4515 (RWS)

ECF

**DECLARATION OF JENNIFER C.
TEMPESTA IN SUPPORT OF THE BRIEF
FOR AMICUS CURIAE BIOTECHNOLOGY
INDUSTRY ORGANIZATION IN SUPPORT
OF DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR SUMMARY
JUDGMENT**

I, Jennifer C. Tempesta declare as follows:

1. I am a member of the Bar of the State of New York, I am an associate at the law firm of Baker Botts L.L.P., Counsel to *Amicus Curiae* the Biotechnology Industry Organization. I make this declaration in support of *Amicus Curiae* the Biotechnology Industry Organization proposed *amicus curiae* brief. I have personal knowledge of the facts stated herein, and would testify to the same if called as a witness. Where possible, rather than burden the record of complete copies of materials already of record in this case, relevant excerpts have been attached as exhibits hereto.

2. The document attached as Exhibit 1 is a true and correct copy of select portions of U.S. Patent No. 5,747,282.

3. The document attached as Exhibit 2 is a true and correct copy of a figure available at: <http://www.accessexcellence.org/RC/VL/GG/chromosome.php> (last accessed December 30, 2009).

4. The document attached as Exhibit 3 is a true and correct copy of a select portion of *Molecular Biology of the Cell*, Alberts, Bruce et al. (4th ed. 2002), available at: <http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=mboc4&part=A592#A650> (last accessed December 30, 2009).

5. The document attached as Exhibit 4 is a true and correct copy of a select portion of *The Cell*, Cooper, Jeffrey M. (2000), available at: <http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=cooper&part=A601&rendertype=figure&iid=A604> (last accessed December 30, 2009).

6. The document attached as Exhibit 5 is a true and correct copy of a select portion of *Biochemistry*, W.H. Freeman and Co. (2002), available at: <http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=stryer&part=A3995&rendertype=figure&iid=A4013> (last accessed December 30, 2009).

7. The document attached as Exhibit 6 is a true and correct copy of Miao Lixia et al., *Alternative Splicing of Breast Cancer Associated Gene BRCA1 from Breast Cancer Cell Line*, J. Biochem. and Molecular Bio. 15-21 (2006).

8. The document attached as Exhibit 7 is a true and correct copy of Ivan Bieche et al., *Increased Level of Exon 12 Alternatively Spliced BRCA2 Transcripts in Tumor Breast Tissue Compared with Normal Tissue*, J. Cancer Research 2546-2550 (June 1, 1999).

9. The document attached as Exhibit 8 is a true and correct copy of a select portion of *Asking About Life*, Tobin et al. (2d ed. 2001).

10. The document attached as Exhibit 9 is a true and correct copy of a select portion of Ernst & Young, *Beyond Borders*, Global Biotechnology Report 2009.

11. The document attached as Exhibit 10 is a true and correct copy of Henry Grabowski, *Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, Nature Reviews Drug Discovery (May 12, 2008).

12. The document attached as Exhibit 11 is a true and correct copy of Henry Grabowski et al., *The Market for Follow-On Biologics: How Will It Evolve*, Health Affairs, 25(5): 1291-1301, 1299 (2006).

13. The document attached as Exhibit 12 is a true and correct copy of select portions of U.S. Patent No. 4,703,008.

14. The document attached as Exhibit 13 is a true and correct copy of Wolfgang Jelkmann, *Molecular Biology of Erythropoietin*, Internal Medicine, 43(8):649-659 (August 2004).

15. The document attached as Exhibit 14 is a true and correct copy of an Amgen Press Release entitled “FDA Clears Epogen For Treatment Of Anemia In Children On Dialysis” (Nov. 4, 1999).

16. The document attached as Exhibit 15 is a true and correct copy of a New York Times article entitled *Technology Briefing: Biotech; Amgen Shares Rise On Rulings* (Jan. 23, 2001).

17. The document attached as Exhibit 16 is a true and correct copy of Harvey J. Alter et al., *Hepatitis C Virus and Eliminating Post-Transfusion Hepatitis*, Nature Medicine, 6(1): 1084 (2000).

18. The document attached as Exhibit 17 is a true and correct copy of a select portion of a text entitled *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (2006).

19. The document attached as Exhibit 18 is a true and correct copy of John P. Walsh et. al., *Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions: Patents, Material Transfers and Access to Research Inputs in Biomedical Research* (Sept. 20, 2005).

20. The document attached as Exhibit 19 is a true and correct copy of CJ Murdoch et al., *Commercialization, Patenting and Genomics: Researcher Perspectives*, *Genome Medicine* 1:22 (2009) available at <http://genomemedicine.com/content/pdf/gm22.pdf> (last accessed December 29, 2009).

21. The document attached as Exhibit 20 is a true and correct copy of Christopher M. Holman, *Trends in Human Gene Patent Litigation*, *Science* 32, 198-200 (2008).

22. The document attached as Exhibit 21 is a true and correct copy of Ann E. Mills et al., *DNA-Based Patents: An Empirical Analysis*, *Nature Biotechnology* 26(9) 993-995 (2008).

23. The document attached as Exhibit 22 is a true and correct copy of Charles Auffray et al., *Systems Medicine: the Future of Medical Genomics and Healthcare*, *Genome Med.* 1(2) (2009).

24. The document attached as Exhibit 23 is a true and correct copy of Chandrasekharan et al., *Gene patents and personalized medicine - what lies ahead?*, *Genome Med.* 1:92 (2009).

25. The document attached as Exhibit 24 is a true and correct copy of Isabelle Huys et al., *Legal uncertainty in the area of genetic diagnostic testing*, *Nature Biotechnology*, 27(10): 903, 909 (2009).

26. The document attached as Exhibit 25 is a true and correct copy of Wei Hong et al., *For Money or Glory? Commercialization, Competition, and Secrecy in the Entrepreneurial University*, Sociological Quarterly, 50:145-171 (2009).

27. The document attached as Exhibit 26 is a true and correct copy of a select portion of SACGHS Public Consultation Draft Report for Public Comment from March 9 to May 15, 2009.

28. The document attached as Exhibit 27 is a true and correct copy of a select portion of U.S. Patent No. 7,341,750.

29. The document attached as Exhibit 28 is a true and correct copy of a select portion of U.S. Patent No. 7,307,057.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration was executed on December 30, 2009 at New York, New York.

By: /s/ Jennifer C. Tempesta
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