Mr Clarke

I am writing to comment on the proposed changes discussed in the above Federal Register citations. These comments are my own and are not the comments of my firm. However, a number of my colleagues that I have talked to share my views. I will have to rely on them to file their own comments, should they have the time.

I started my practice in patent law in 1969 at Shell Oil Company as a patent agent in the chemical practice and attended night law school to get my J.D. In 1974, I joined Syntex Corporation, a pharmaceutical company, where I became Director of Patent Law for their U.S. pharmaceutical group. I “retired” in 1993 from Syntex and in 1994 joined the firm of Cooley Godward LLP, where I practiced until 2005. I left Cooley and joined my present firm of Foley & Lardner LLP. My practice has concentrated on life sciences, with a specialty in pharmaceuticals. Over my career, I have seen first hand the importance of patents to the life science practice and the importance of maximizing the value of a company’s (whether the company is large or small) patent portfolio to aid in the process of raising money, whether from public or private sources, to get a drug product to the market.

I have reviewed the proposed changes to the existing rules, as well as the numerous comments made by individuals and the AIPLA. I have also attended one of the PTO’s town meetings (2/28/06 at Berkeley, California) and reviewed the material presented and listened to the comments of practitioners at that meeting. In light of the comments and my own experience in over more than 30 years of practice, implementation of all of the proposed changes, in my opinion, would result in a system that would not best serve “progress in science and the useful arts” well, would not promote the goals of the Commerce Department, and would not aid life science companies in bringing products to the marketplace.

You are probably aware of the complexities of developing a new drug product. For small companies, funding the development of such a drug product often comes in stages of financing. A major asset that financiers (whether venture capitalists, angels, or partners) evaluate is the patent portfolio. Any opportunities to maximize the value of a company’s patent portfolio aids in the fund-raising process and, thus, the development of a new drug product. The proposed PTO changes appear to have the effect of reducing the opportunity to maximize the value of the patent portfolio and thus impeding “progress in science...”

Often when a patent is filed, neither the inventors nor the company’s development team fully recognize the value of a patent application. Having greater flexibility in claiming an invention under the present claiming and continuation procedures allows a company to maximize the value of a patent portfolio in light of changing commercial realities. The present patent publication procedures and other sources of information allow companies to regularly evaluate competitors’ present and future development programs. In light of that ongoing evaluation, the existing
claiming and continuation practice before the PTO aids in adjusting to the realities of the changing marketplace of ideas. The proposed changes would make it more difficult to adjust to those realities.

While I support improving the efficiency of the process for obtaining a patent and issuing high quality, enforceable patents, such efficiency and quality shouldn't decrease the overall value of a patent family to the owner. It seems that the proposed changes to the practice for the examination of claims and to the practice relating to continuing applications will decrease a patent owner's opportunities to positively affect the company's patent assets to aid in funding the development of a new drug product. In addition, the new procedures regarding pre-examination searches would add burdens and risks that would further adversely affect the value a patent portfolio. In my opinion, the present PTO procedures provide companies with better opportunities and greater flexibility in adding, or at least maintaining, value to their patent portfolio and, thus, funding projects to develop new products than the proposed procedures. In my view, the Commerce Department goals to promote economic development and technological advancement in the life sciences arena are better met with the present PTO procedures than the proposed procedures.

If the PTO representatives are feeling pressure to change, such change should reflect the concerns set forth by the majority of the practitioners who are faced with the day-to-day issues of patent practice in aiding their clients in maximizing the value of a patent portfolio so that products have an increased likelihood of getting to the market and helping people who need it. I recommend that the PTO carefully read and consider the comments submitted by seasoned practitioners (e.g. Sam Helfgott) and follow the collective wisdom of the members of the AIPLA in the letters of April 24, 2006. The likely problems that while accompany the proposed changes will probably make our situation worse, not better.

If you wish to discuss these issues further, please contact me. However, I think that Mr. Kirk has elegantly stated most of the details of my concerns.

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