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From: Maxwell, Beth Lynn [mailto:BMAXWELL@utsystem.edu]

Sent: Wednesday, May 03, 2006 5:30 PM

To: AB93Comments

Cc: Yudof, Mark; Barnhill, Robert; Burgdorf, Barry D.; Sanga, Arjuna; Shine, Kenneth; Sullivan, Terry; Malandra, Geri; Robert Hardy; michaels@mdanderson.org; Capelli, Chris - MD Anderson; Maxwell, Beth Lynn; Sampson, Margaret; Harper, Georgia

Subject: Comments to 71 Fed. Reg. 48 and 61

Dear Mr. Clarke,

Attached, please find a comment letter from The University of Texas System regarding the USPTO's proposed rule changes. We appreciate the opportunity to comment.

Sincerely,

BethLynn Maxwell

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May 3, 2006

Mr. Robert A. Clarke  
Mail Box - Comments  
Commissioner for Patents  
United States Patent and Trademark Office  
Alexandria, VA 22313

SENT BY E-MAIL – AB93Comments@uspto.gov

**RE: Comments to 71 Fed. Reg. 48 and 61**

Dear Mr. Clarke:

The University of Texas System is comprised of fifteen institutions: nine academic institutions, 6 health institutions and unlimited possibilities. According to the Patent and Trademark Office (PTO) data, the Board of Regents of the University of Texas System typically ranks either third or fourth in the United States in the number of patents issued to academic institutions per year.

The University of Texas System and its fifteen institutions thank the PTO for the opportunity to submit comments in response to the proposed rule changes in patent practice published in 71 Fed. Reg. 48 and 61.

The University of Texas System has serious concerns with the proposed rule changes, but for the sake of brevity, this letter only addresses two changes that would have a significant negative impact on it and all academic research institutions: (1) limiting continuations to one per patent application; and (2) limiting the number of initially examined claims to ten. The rule changes will also significantly front-load patent prosecution costs, further straining the already limited budgets of academic institutions.

**Limiting Continuations to One Per Patent Application<sup>1</sup>**

The PTO's stated goal for the proposed rule changes is to increase efficiency and reduce its backlog of pending patent applications. We are very concerned that the proposed changes will not only fail to accomplish these goals, but will have a disproportionately adverse affect on universities and their ability to license early-stage technologies to commercial partners, particularly in the pharmaceutical and biotechnology industries. Inventions conceived at universities comprise, by far, the largest share of technologies licensed by these industries. And given the nature of the technologies in these areas, patents that protect pharmaceutical and biotechnology inventions tend to have a high number of continuations and numerous, yet necessary, claims.

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<sup>1</sup> 71 Fed. Reg. 48 would require that any second or subsequent Continuation application, a Request for Continued Examination, or Continuation-in-Part application be supported by a showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted during the prosecution of the initial application or the first continuing application.

Several studies have shown that scientists at universities are significant drivers of technological innovations in the U.S. through the discovery of important and novel treatment modalities that offer hope to patients and humankind, in general. However, universities are not in a position to transform early-stage and significant discoveries into FDA approved drugs for the treatment of diseases. Universities rely heavily on the pharmaceutical and biotechnology industries to bring these discoveries to market by licensing such early-stage discoveries, providing their expertise, investing large sums of money, obtaining approval from the FDA and eventually marketing the drug to physicians, who, in turn, will prescribe the drug to their patients.

Thus, university inventions provide cutting edge technologies for which strong patent protection is required to attract the industry investments needed to further develop these early-stage technologies into commercial products. On average, it takes about 12 years and over \$800 million investment dollars to bring a single drug to market.<sup>2</sup> Without the ability to protect their extraordinary investments, pharmaceutical and biotechnology companies would not be willing to bear the risk of such ventures.

For example, a scientist at a university may identify a class of compounds that will treat a particular cancer, and file a patent application on that class. But years of additional research will be necessary to identify the exact compound that will provide the most effective treatment in humans while minimizing toxicity. The current continuation practice gives the university and its licensees the time to obtain appropriate patent protection of the commercially valuable compound, which given the costs of bringing the compound to market, is a necessary factor for pharmaceutical companies to invest in the technology. This fact is reflected by examining the patent protection of eight of the most currently used cancer drugs.<sup>3</sup> Only one drug, Epogen, is protected by patents having only one continuation, request for continued examination (RCE), or continuation-in-part (CIP) and containing ten or fewer claims. The remaining seven drugs are protected by patents that resulted from more than one continuation, RCE, or CIP and contained more than ten claims.<sup>4</sup> The remaining seven, Procrit/Epex, Eloxatin, Gleevec/Glivec, Gemzar, Lupron, Taxotere, and Herceptin, have helped countless numbers of patients and account for approximately 37% of the cancer market; while, Epogen accounts for approximately 13% of the cancer market.

If the PTO's proposed rule changes had been in effect at the time these most currently used cancer drugs were discovered, it is possible that only Epogen would have been brought to the commercial market, while Procrit/Epex, Eloxatin, Gleevec/Glivec,<sup>5</sup>

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<sup>2</sup> DiMasi, J.A., R.W. Hansen, and H.G. Grabowski. The Price of Innovation: New Estimates of Drug Development Costs. *J Health Economics*, 22: 151-185 (2003). According to the Pharmaceutical Research and Manufacturers of America, out of 10,000 potential compounds, only five ever succeed to the clinical trials and of these five, only one is approved by the FDA for patient use.

<sup>3</sup> They are: Epogen, Procrit/Epex, Eloxatin, Taxotere, Gleevec/Glivec, Lupron, Gemzar, and Herceptin.

<sup>4</sup> Lemley, M.A. and K.A. Moore. Ending Abuse of Patent Continuations. *Boston U. Law Review*, 84: 63-118 (2004). Of all technology centers, the highest percentage of continuations are filed in the Biotechnology and Chemical areas. See *Boston U. Law Review* at 85.

<sup>5</sup> Over 25,000 leukemia patients each year are given Glivec and experiencing significant survival rates.

Gemzar, Lupron, Taxotere, and Herceptin<sup>6</sup> may have never been developed because adequate patent protection to safeguard industry investment would not have been possible.

The PTO maintains that these rule changes will only affect a small percentage of applicants, e.g., those who file more than one continuation, RCE, or CIP during prosecution.

We disagree with the PTO in that **substantially more** than a small percentage of university applicants use the continuation and CIP practice. For the top 19 universities with the highest total number of issued patents<sup>7</sup>, approximately 32% of patents that they file are continuations or CIPs. These results were obtained by searching the USPTO patent database for the number of university patents that are continuations or CIPs. Please note that these data do not include RCEs. More specifically, for the University of Texas System, which ranks third for the total number of issued patents (~ 1679), approximately 38% of our patents were either continuations or CIPs.

Because the continuation and CIP practice is widely used throughout universities, the proposed rule changes would have a negative impact on universities.

We agree that the PTO is currently handling a high number of continuations, RCEs, and CIPs. But as stated above, we do not believe that the proposed rule changes will increase the PTO's efficiency, nor will it relieve the backlog of pending patent applications.

Furthermore, the PTO has not adequately addressed the effect that the proposed rule changes will have on the process it currently uses to evaluate patent examiner performance.<sup>8</sup> For each continuation or RCE, the examiner is awarded 2 points – one New point is awarded for the first office action on the merits and one Disposal point is awarded for the abandonment of the first patent application. If the applicant abandons the first application by filing a continuation or RCE, and the examiner allows the application on the first office action in the Continuation or RCE case, then the examiner is awarded 3 points. The net effect is that the examiner receives more points when the applicant files a continuation or RCE than for any other activity. To our knowledge, the PTO has not evaluated whether the Balanced Disposal System is at least a contributory

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<sup>6</sup> To date, over 230,000 patients have received Herceptin and nearly half of these patients had a reduced risk of death or cancer recurrence.

<sup>7</sup> In descending order: University of California System, MIT, University of Texas System, Cal Tech, University of Wisconsin, Cornell Research, University of Florida, University of Michigan, University of Minnesota, Iowa State, Columbia University, University of Pennsylvania, State University of NY, Harvard, Duke University, Michigan State University, University of Washington, North Carolina, Stanford.

<sup>8</sup> We are referring to the Balanced Disposal System, wherein the Examiner must earn a number of Balanced Disposals within a two-week period. A Balanced Disposal consists of a New point and a Disposal point. A New point is awarded only for a first office action on the merits; while a Disposal point is only awarded for each of the following three activities: the application is abandoned, the application is allowed, the application is appealed and the Examiner writes an Examiner's Answer in response to the Appeal Brief.

factor to the large numbers of continuations filed by applicants.<sup>9</sup> This Balanced Disposal System is not even referenced with respect to this rule change. The PTO must carefully and fully examine the impact of these rule changes, as well as alternative ways to achieve its desired goals, before implementing such dramatic changes to the patent system.

### **Limiting the Number of Initially Examined Claims to Ten<sup>10</sup>**

The proposed change to limit applicants to ten representative claims will also have a negative effect on universities, particularly in the pharmaceutical and biotechnology areas. For example, it is not uncommon for claims of such applications to be restricted twenty different ways, yet applicants are now limited to ten representative claims. Under the proposed rule changes, to have more than ten claims examined, the applicant must provide an Examination Support Document that covers all of the independent claims and the dependent claims designated for initial examination. The PTO characterizes this as a sharing of the burden by applicants that file large numbers of claims, but the PTO is shifting the burden too far to applicants. This Examination Support Document will be time consuming and expensive for universities to prepare and submit. And, this will ultimately slow the transfer of new lifesaving drugs from universities to patients.

The net effect of the rule changes on universities such as the University of Texas System, in conjunction with the proposed restrictions on continuation practice, would be to stifle innovation. These changes would also greatly increase patent prosecution costs, which would further negatively impact universities. The University of Texas System, along with other academic and research institutions, file continuations to more clearly refine their patent claims during the course of research and development. To protect these pioneering inventions, universities try to claim many aspects of the invention to ensure that one of these aspects will eventually encompass the commercial product. If this proposed rule change comes into effect, universities, such as the University of Texas System, would be forced to prosecute applications that are less likely to cover the actual commercial product. As a result, pharmaceutical and biotechnology companies would be reticent to invest their money and the time necessary to move university inventions into the commercial market if they are now less likely to recoup their investment because of inadequate patent protection.

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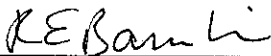
<sup>9</sup> Further, the USPTO's internal practice of evaluating Examiner performance does not provide an incentive to adequately review and understand complex and detailed specifications as are often the case in biomedical applications. Continued examination filings provide a counterbalance to this imperfect system by giving the Examiners additional opportunities to consider the entirety of the application's disclosure. And, this balancing is particularly important for complex, early-stage biomedical discoveries.

<sup>10</sup> **71 Fed. Reg. 61** proposes that if an application contains more than ten independent claims or if the applicant wishes to have initial examination of more than ten representative claims, then the applicant must provide an examination support document (a pre-examination search report, copies of the references deemed by the applicant to be most closely related to the subject matter encompassed by the claims, and a detailed discussion of the references and how the claimed subject matter is patentable over the references) that covers all of the independent claims and the dependent claims designated for initial examination.

Given these potentially serious negative effects, particularly for university inventions on which the U.S. depends for future economic innovations, we urge the PTO to withdraw these proposed rule changes and to commission a study to determine the best solution to solve its pendency problem or to further study and validate the assumptions on which the proposed changes are based.

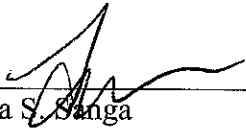
We appreciate the opportunity to comment.

Cordially,



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Robert E. Barnhill, PhD  
Vice Chancellor of Research and Technology Transfer  
The University of Texas System



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