-----Original Message-----
From: Margaret Dunbar [mailto:mdunbar@burnham.org]
Sent: Wednesday, May 03, 2006 5:37 PM
To: AB93Comments
Subject: comments on proposed rule changes

May 3, 2006

BY ELECTRONIC MAIL TO AB93COMMENTS@USPTO.GOV

Mail Stop Comments – Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Robert W. Bahr

Comments to Notice of Proposed Rulemaking Entitled: *Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims*

Dear Mr. Bahr:

Burnham Institute for Medical Research welcomes the opportunity to comment on the proposed rule changes related to the examination of claims in patent applications published in the January 3, 2006 *Federal Register*.

Burnham Institute for Medical Research a 501c(3) non-profit corporation. Federal grants make up about 80% of our operating budget. Other important sources of funding include private foundations and philanthropy. The outstanding quality of our scientists allows them to compete for research funding from various government agencies, particularly the National Institutes of Health (NIH). These funds support the majority of the research. The Institute scientists currently contribute more than 300 scientific publications annually to the medical literature. The Institute has over 180 issued patents and 130 pending patent applications. The Institute has been ranked as one of the top 15 organizations worldwide in its field by the Institute for Scientific Information for the impact of its research. Discoveries by our Scientists have laid the foundation for multiple therapeutic agents and diagnostic tests currently in use or in clinical testing. It is the Institute's mission to conduct world-class, collaborative medical research to cure human disease, improve quality of life, and thus create a legacy for our employees, partners, donors, and community. More than 500 scientists, out of 725+ employees, work at the Institute. Currently the Institute has 69 faculty members, and each of these scientists runs a staffed research laboratory.

The Burnham Institute for Medical Research opposes the proposed rule changes for the reasons that the justification set forth by the Patent Office for the changes, i.e. decreased pendency, is not supported by objective evidence. The rules, as proposed, will disproportionately and negatively impact the biotechnology and pharmaceutical industries which have legitimate reasons for filing continuing applications. The changes would be particularly devastating for non-profit and academic research institutions and small businesses. The proposed rules are contrary to statute, case law, and international treaties to which the United States is a signatory; the proposed rules will inhibit innovation, create difficulties in licensing and will diminish the public disclosure function of patents; and the

proposed rules will not solve the current problems of patent quality but will simply re-create a backlog at the Board of Patent Appeals.

1. The Patent Office Has Presented No Objective Evidence That the Proposed Rules will Result in Decreased Pendency.

In its Notice of Proposed Rule Making, the Office states that the filing of continuing applications has had a "crippling effect on the Office's ability to examine 'new' applications" and that the new rules will allow it to "reduce the backlog of unexamined applications." These statements, however, are not supported by the Office's own statistics. The Office reports that of the 317,000 non-provisional applications, just under 10,000 or 3% were second or more requests for continued examination. It defies credulity to assume that a mere 3% of all pending applications are responsible for the Office's current backlog. If the backlog were in fact due to continuing applications there should be a correlation between the number of continuing applications filed and pendency in an art unit. No such correlation exists. In the 7 art units for which the Patent Office has made data available, the art unit with the highest percentage of continuing applications, 1600, does not have the longest pendency, but instead is 3rd out of 7. Conversely, Art Unit 2100, which has the longest pendency, shows only an average number of continuing applications. It is revealing that at least one official of the Patent Office has expressly and publicly admitted that the new rules will do nothing to decrease pendency. Instead, it appears that the Office's justification for the proposed rules is more akin to an artifice to move forward some internal agenda rather provide a solution to the problem it alleges to solve.

2. The Proposed Rules Would Disproportionately Have a Negative Effect on Biotechnology and Pharmaceutical Companies and In Particular Non-profit and Academic Research Institutions and Small Businesses.

Pharmaceutical and biotechnology companies differ from many industries in the cost to develop a product and the time from initial conception to commercialization. It is not unusual for a new chemical entity to take 10 years and a billion dollars in development costs before ever reaching the market. During that time, new data are obtained, and embodiments of the basic invention originally selected for commercial development are refined and evolve. It may become necessary to discarded some embodiments, while other fully described embodiments may be selected or show new properties or uses. Under the present rules, applicants can use continuing applications for the legitimate purposes of adding additional examples and supporting data, and for claiming the final commercial embodiments or additional indications. Under the proposed rules, companies would be forced to predict years in advance the commercial embodiment of their invention. Such constraints will frequently present an insurmountable financial hurdle for a non-profit or small business.

Many of the currently pending continuing applications in the biotechnology and phramacuetical arts are the result of the Office's current restriction practice. Under current practice, examiners have no set limits on the number of restriction groups that they can impose on an applicant. Often inventions that will require completely overlapping art searches are restricted out resulting in a duplication of searches and a self-imposed wasting of Office resources. The number of continuing applications filed could be significantly reduced by simply reforming restriction practice instead of the drastic rule changes proposed. In applications involving nucleic acids and proteins, it is now common for examiners to treat

each variant of the basic molecule as a separate invention. Thus, even moderate attempts to gain increased scope will result in an excessive number of restriction groups.

Instead of the present system in which the applicant can file divisional applications as different restriction groups are developed, under the proposed rules divisional applications must all be filed at once or rights will be lost. The result will be that the burden of the examining corps will be increased not decreased. The requirement to file all divisionals at once will create a devastating hardship on small entities such as start-up companies and non-profit research institutions. The massive costs and associated risks with preparing and filing multiple divisional applications early in development will simply mean that many important discoveries will never be commercialized. Non-profit and academic research institutions such as the Burnham Institute for Medical Research are the fertile ground of scientific advancement and innovation in the biotechnology and pharmaceutical arts. It should be noted that the Small Business Administration has notified the Patent Office that its opinion the proposed rule changes will have a significant impact on small businesses. Small Businesses have no means to expand their budget 10-fold or more to respond to the proposed changes in continuation practice.

Additionally continuing applications, especially Requests for Continued Examination (RCE), often result from the current practice of issuing a final rejection at the second Office action, even when the second office action contains a new ground for rejection. The applicant is forced to file an appeal with its associated delay and expense or file a continuing application to simply address the newly raised grounds for rejection. This problem is aggravated, with increasing frequency, in cases where examiners refuse to enter minor amendments or even discuss the case with the applicant following a final rejection. This, in turn, is likely due to the Office's current examiner evaluation process that rewards examiners for forcing applicants to file RCEs. Often, once the RCE has been filed and the amendment entered or the interview granted, a Notice of Allowance quickly follows. In these cases, contrary to the arguments put forth by the Office, few Office resources are consumed by the continuing application. In fact Office resources are saved since the need for a pre appeal conference and the preparation of an examiner's reply are avoided.

Continuing applications are also filed by applicants in order avoid the time and cost of filing an appeal when confronted with an examiner who simply does not understand or will not apply the proper legal standard in examination. This is shown in Board of Appeals statistics in which for every year between 2000 and 2005 the number of examiner reversals exceeded the number of decisions that are affirmed. This is especially true in the field of biotechnology where, for years, the number of reversals far exceeds the number of affirmances. This clearly demonstrates that the filing of continuing applications is not an attempt by applicants to in any way misuse the system, but is merely represents applicants' diligent attempt to obtain proper examination of their applications.

3. The Proposed Rules are Contrary to Current Statutes, Case Law and Treaties.

Under the proposed rules, an applicant would be limited to a single continuing application unless the applicant can satisfy the PTO why any amendment, argument or evidence submitted in the second application could not have been previously submitted. The proposed rules would effectively limit priority claims under 35 U.S.C. 120, 121 and 365(c) and limit the right to request continued examination under 35 U.S.C. 132(b). The language of these statutes is clear. Under 35 U.S.C. 120, 121 and 365(c) an applicant is entititled to

claim priority to an earlier filed application if certain conditions set forth in the statute are met. There plainly are not provisions in the statutes for additional restrictions by the PTO. Likewise, 35 U.S.C. 132(b) provides that the Office shall provide for continued examination at the request of the applicant. Although the statute provides for regulations to accomplish continued examination, the only limit on the applicant's ability to request continued examination provided for in the statute is the payment of fees.

The PTO acknowledges the existence of case law suggesting that it has no authority to place absolute limits on the number of continuations that can be filed from an original application. The Office contends that the proposed rules do not violate judicial precedent because the limits are not absolute. The rules, however, provide no guidance as to the granting of petitions to file a second continuing application. Notwithstanding the assertion by the Patent Office, judicial precedent strongly suggests that the PTO has no authority to prohibit the filing of a continuing application on its sole and unregulated discretion.

PTO-sponsored presentations indicate that the limit on the ability to file continuing applications will apply to divisional applications filed in response to a restriction requirement. For example, if an applicant files a divisional application in response to a restriction requirement and the Office issues a subsequent requirement for restriction in the second application, the applicant would not be able to file the second divisional by right and would not be allowed to claim priority to the original application. This result is contradictory to the provisions of Article 4G(1) of the Paris Convention which states that when a application is found to contain more than one invention, the applicant may file a divisional application and maintain the applicant's claim to priority.

Also under the proposed rules, the PTO proposes to create a rebuttable presumption of patentably indistinct claims in two or more applications that are: (1) filed on the same date; (2) name at least one common inventor; (3) are owned by the same person; and (4) contain substantially overlapping disclosures. Again the PTO appears to have no authority to promulgate this rule, since under 35 U.S.C. 2(b)(2) the, PTO can implement regulations only if they are not inconsistent with law. 35 U.S.C. 131 requires that an examination shall be made of the application. In addition, courts have repeatedly held that burden of showing that claims are patentably indistinct rests with the Patent Office. See, *In re Kaplan*, 789 F.2d 1574 (Fed. Cir. 1986); *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985). The establishment of a rebuttal presumption is nothing less than an attempt by the Patent Office to impermissibly shift the burden from the Patent Office to the applicant.

4. The Proposed Rules Will Inhibit Innovation, Create Difficulties in Licensing, and Diminish Public Disclosure.

Instead of promoting innovation, the proposed rules will hamper it, especially in the areas of pharmaceuticals and biotechnology. As discussed above, innovations in these areas involve long development times and high initial costs. The long time lines and high development costs associated with the biotechnology and pharmaceutical industries require the flexibility that the present continuation practice allows. Currently applicants can file early on the broad inventive concept in order to attract investors and then, as development continues, use continuing applications to adapt claims to cover the eventual commercial embodiment and file new claims to cover additional embodiments that have been validated during development. Under the new rules, non-profit organizations, and companies would be forced to decide between filing early to attract licensees and/or funding and hope that they

correctly predicted what the eventual product will look like, or hold off filing, make funding more difficult. The Small Business Administration comments on the proposed rules point out that these proposed rules dramatically increase costs to prepare an application and hinder the patent prosecution process. Additionally, the retroactive nature of the rules, especially when combined with the proposed limitations on claim examination, may result in patentable subject matter disclosed in pending applications being dedicated to the public. The end result is that innovation will be stifled by the negative impact of these proposed rule changes. The patent system exists to promote the progress of science and the useful arts, the proposed rules act to cause an opposite outcome; participation becomes not just a hardship but financially impossible for a non-profit or small business.

The proposed limits on continuation practice will make licensing of inventions more difficult, thus limiting the commercialization of inventions and denying the public the benefit of these inventions. Non-profit research institutes, such as our Institute, and universities do not typically commercialize their inventions, but instead license them to third parties. In the situation where the patent holder has several licensees for different aspects of the basic invention, current practice allows for the filing of continuing applications having claims directed to each licensee. Under the proposed rules this would not be possible. Instead the patent owner would have to try and prosecute a single application to meet the needs of various licensees, who interests may not be aligned. The end result is that it will be more difficult to license patent. The increased difficulty in licensing will financially starve innovators of licensing income to fund further innovation and prevent the commercialization of all aspects of the invention, denying the public of potential benefits.

Additionally, the proposed rules will certainly have the effect on our Institute of defeating one of the major benefits of the patent system, namely the early disclosure of new innovations. Due to the limitations on continuation practice and the long time horizons associated with drug development, many innovators may opt to withhold filing until the ultimate commercial embodiment has been determine. This will deprive the public of information that can be used for further innovation.

5. The Proposed Rules will not Improve Patent Quality and will Simply Shift the Backlog to the Board of Appeals.

Many of the problems associated with patent quality can be associated with the lack of experience and training of many examiners. This, in turn, can be attributed to the high attrition rate among examiners, especially in the pharmaceutical and biotechnology arts. The proposed rules do nothing to address these problems and the Office has provided no objective evidence of any relationship between the number of continuing applications and patent quality.

It is also likely that the proposed rule changes will not change overall pendency, but simply shift the delay from examination to the appeals process. The Patent Office has been denying that this will occur noting that the time to decision at the Board of Appeals declined to 4.8 months in fiscal year 2005. The 4.8 month time period, however, ignores the considerable amount of time and resources, both of the applicant and the PTO, that go into an appeal prior to its reaching the Board. Specifically not included is the time and resources devoted to the pre-brief appeal conference, preparation of appeal brief and preparation of an examiner's answer. Taken together, these add considerably to the 4.8 month time period and result in substantial costs to the applicants. Applicants that are committed to bringing their

innovations to the public in a business-viable form of patented-technology will be steward these applications through the appeals process.

RCE practice, which was instituted only 6 years ago, was promoted as a way that applicants could make additional arguments and amendments after final, thus avoiding the need to file appeals and lessening the backlog at the Board of Appeals. The RCE practice appears to have met its intended goal and the appeals backlog has lessened. Under the proposed rules, the number of appeals filed is very likely to increase, recreating the backlog problem that was recently solved. The backlog at the Board of Appeals will potentially be exacerbated by the introduction of a post grant opposition procedure. Under the proposed legislation, oppositions must be disposed of within a year. Appeals, with no statutory time limit, are likely to get pushed back, increasing the delay. An unintended consequence of this will be that patent term will be extended. Under the patent term adjustment rules, any time lost due to a successful appeal is credited to the applicant. Recent historical trends indicate that more than half of the appeals filed will be successful resulting in longer patent term.

Instead of the proposed rules, the Patent Office could do much to reduce the number of continuing applications filed, by improving examiner training, reforming restriction practice, and removing the current incentives for examiner's to force the filing of continuing applications. In terms of new initiatives, the Patent Office should consider reforming examination procedure so that an examiner does not issue a final Office action as long a prosecution is advancing, and in particular prohibiting the issuance of a final Office action when a new ground for rejection is raised. Additionally, the Office could provide for escalating filing fees for subsequent continuing examinations and could allow the applicant to control the timing of examination by allowing the applicant to request examination at any time during a set time period.

At least for the reasons stated above, Burnham Institute for Medical Research opposes the proposed Changes to Practice for the Examination of Claims in Patent Applications and urges the Patent and Trademark Office not to adopt them.

Respectfully submitted,

BURNHAM INSTITUTE *for* MEDICAL RESEARCH

By
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May 3, 2006

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Mail Stop Comments – Patents
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Burnham Institute for Medical Research a 501c(3) non-profit corporation. Federal grants make up about 80% of our operating budget. Other important sources of funding include private foundations and philanthropy. The outstanding quality of the Institute's scientists allows them to compete for research funding from various government agencies, particularly the National Institutes of Health (NIH). These funds support the majority of the research. The Institute scientists currently contribute more than 300 scientific publications annually to the medical literature. The Institute has over 180 issued patents and 130 pending patent applications. The Institute has been ranked as one of the top 19 organizations worldwide in its field by the Institute for Scientific Information for the impact of its research in the field of Molecular Biology and Genetics. Discoveries by our Scientists have laid the foundation for multiple therapeutic agents and diagnostic tests currently in use or in clinical testing. It is the Institute's mission to conduct world-class, collaborative medical research to cure human disease, improve quality of life, and thus create a legacy for our employees, partners, donors, and community. More than 500 scientists, out of 725+ employees, work at the Institute. Currently the Institute has 69 faculty members, and each of these scientists runs a staffed research laboratory.

The Burnham Institute for Medical Research opposes the proposed rule changes for the reasons that they disproportionately have a negative effect on biotechnology and pharmaceutical companies; are contrary to statute and case law; are contrary to international treaties to which the United States is a signatory; will create a substantial financial burden, especially on the biopharmaceutical industry and small entities; will create greater uncertainty and increased litigation; and will not substantially improve patent quality.

1. The Proposed Rule Disproportionately Effect Biotechnology and Pharmaceutical Companies and In Particular Non-profit and Academic Research Institutions and Small Businesses..

The very nature of pharmaceutical and biotechnology inventions dictates a number of useful embodiments. For example, a pharmaceutical composition may be useful to treat several indications, be formulated for different modes of administration, have different dosing regimes, and alternative means of manufacture. Likewise, a biopharmaceutical innovation may encompass numerous variants each with its own set useful properties. In its Notice of Proposed Rule Making, the Patent Office provides data to support its allegation that the proposed rule changes will affect only a limited number of applications. The use of these numbers by the Patent Office is disingenuous. The Office reports that only 1.2 percent of applications contain more than 10 independent claims. This number would be meaningful if the proposed rules restricted examination to 10 independent claims, but the proposed rules are much more limiting. The proposed rules allow examination of not more than 10 independent claims, and that if fewer than 10 independent claims are present, the applicant may select additional dependent claims so that the total of all claims to be examined is 10. If the applicant wants more than 10 claims examined, the rules require the applicant to justify such examination. Thus, the appropriate statistic to measure the scope of applications affected is the number of applications having greater than 10 claims. A random sample of 50 U.S. patent applications related to pharmaceutical compositions and methods of treatment published on April 20, 2006, revealed that all but five had greater than 10 claims. Thus the proposed rule changes will affect that vast majority of biotechnology and pharmaceutical applications and be particularly devastating for non-profit and academic research institutions and small businesses. The Small Business Administration notes in its comments that the USPTO's estimates for cost for examination support documents are potentially underestimated by as much as $25,000 per application. And of critical importance is the fact that metrics used by the Patent Office to certify that small business will not be negatively impacted severely underestimates the number of non-profits and small business that will be affected. Every application that is successfully licensed to a large entity is no longer considered in the calculation which incorrectly factors in the most frequent scenario in which expenses are born by non-profits throughout the filing and prosecution of the applications before they are licensed. The comparison to the use of representative claims before the Board of Appeals is also misplaced. In the appeals process, the application has undergone examination so that the issues have often been narrowed to relatively few. In the present situation, no examination has taken place so there has been no narrowing of the issues. In addition, the Board of Appeals has no per se limit on the number of representative claims as do the present proposed rules.

2. The Proposed Rules are Contrary to Statute and Case Law.

The proposal to limit initial examination to representative claims is contrary to existing statutes. Under 35 U.S.C. 131, the "Director shall cause an examination to be made…of the alleged new invention." (emphasis added). It is axiomatic that the alleged new invention is defined by the claims and that the applicant is entitled to define the

alleged new invention as narrowly or as broadly as the applicant sees fit. There is no provision in the statute for the examination of a representative portion or embodiment of the alleged new invention or for the Director to impose additional burdens on the applicant who wishes the full extent of the alleged new invention to be examined. The Patent and Trademark Office has no "inherent authority" to do less than the statute commands it to do.

If an applicant wished more than 10 claims initially examined, the new rules require that the applicant, in the words of the Patent Office, "share the burden of examination by submitting an examination support document." In this examination support document, among other things, the applicant is required to explain how each of the claims is patentable over the prior art, the utility of the invention embodied by the claims, and to show that the claims are supported as required by 35 U.S.C. 112. The proposed rules are in direct conflict with well-established case law that the Patent Office has the initial burden of determining patentability and that the Patent Office may not shift this burden to the applicant. Section 102 states that "[a] person shall be entitled to a patent unless - …" (emphasis added). Courts have repeatedly interpreted this language as placing the initial burden of determining patentability over the prior art solely with the Patent Office. *See, e.g., In re Warner*, 379 F.2d 1011 (C.C.P.A. 1967); *In re Oetiker*, 977 F.2d 1443 (Fed. Cir. 1992). These same courts have held that the burden is also on the Patent Office regarding the patentabilty of the claims over the prior art under 35 U.S.C. 103. *Id.* Likewise, the initial burden of showing lack of utility or failure to meet the requirements of 35 U.S.C. 112 rests solely with the Patent Office. *See, e.g., In re Langer*, 503 F2d 1380 (C.C.P.A. 1974) (utility); *Ex parte Sorenson*, 3 U.S.P.Q. 2d 1462 (B.P.A.I. 1987) citing, *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976) (written description). The Patent Office simply has no authority, inherent or otherwise, to shift to applicants a burden placed upon it by statute and the courts.

3. The Proposed Rules are Contrary to International Treaties

Under Article 17 of the Patent Cooperation Treaty (PCT), the United States Patent Office as a Receiving Office is required to search all claims not excluded from searching by the treaty or its implementing regulations. Likewise under Article 31 PCT, the Patent Office must prepare a preliminary examination report on the searched claims when requested by the applicant. Upon entry into the national phase, the Patent Office cannot impose a limitation that is contrary to the provisions of the treaty. *See Caterpillar Tractor Co. v. Commissioner for Patents*, 650 F. Supp. 218 (E.D. Va. 1986). Thus, the result of the proposed rules may be that applicants will simply shift to entering the United States through national phase PCT filings rather than filing applications directly in the USPTO. In this case, under the proposed rules, the USPTO would be making the questionable argument that efficiency is increased by not examining claims that under the requirements of the PCT it would have already searched and issued a preliminary opinion on patentablity.

4. The Proposed Rules Will Create a Substantial Financial Burden.

If put into effect, the retroactive nature of the rule changes will impose a substantial deadweight loss on the economy. This loss will be especially felt by the pharmaceutical/biotechnology industry and small entities. The retroactive nature of the

rules would require applicants to select 10 representative claims for each application that has not yet received an Office action or risk having important aspects of their invention go unexamined. This risk is exacerbated by the Patent Office's proposed limits on continuation practice. The Patent Office's statistics show over 600,000 applications awaiting action. Assuming only half of these contain more the 10 claims, that leaves 300,000 applications which applicants must review and select 10 representative claims. Conservatively, such an analysis of the file and filing of an amended claim set would take 2 hours at a cost of $300.00 per hour based on the current billing rates of patent attorneys. This would represent a loss of $180,000,000 to the economy. This value grossly underestimates the true cost, since it does not account for the substantial cost associated with the production of an examination support document should the applicant wish more than 10 claims examined. Again, the Small Business Administration has noted that a realistic estimate for the preparation of examination support documents to cost from $25,000 to $30,000 per application. As noted above, since the vast majority of applications in the pharmaceutical and biotechnology industries contain greater than 10 claims, these industries will be disproportionately affected. Small entities and non-profit research institutions, such as universities, with limited resources will find this financial burden to be an absolute barrier to entry, in most cases. These financial burdens would in many cases reduce the ability of a non-profit to produce commercially viable innovation by orders of magnitude. This cost shifting from the government to the private sector will only serve to limit resources available for innovation.

5. The Proposed Rules Will Create Greater Uncertainty and Increased Litigation.

One result of the proposed rules, especially when combined with the proposed limits on continuation practice, is that Applicants will file limited applications in order to avoid the potential problems associated with filing an examination report document discussed below. Such applications containing only 10 claims can be expected to contain a narrow disclosure to support only those claims. Thus, the new rules will serve to defeat one of the major benefits to the public of the patent system, namely the early disclosure of information. Under the current system, applicants can file an application covering the full scope of the invention. Upon publication, the application gives notice to the public of the full extent of the invention and the information provided can be used by the public to spur further improvements or new, competing products by way of design arounds. With the narrow disclosure that the proposed rules will encourage, uncertainty will be created about the full scope of the invention and the knowledge flow to the public will be diminished. Much of the difficulty associated with the examination of applications in the business methods and software arts can be attributed to the lack of public disclosure in these areas. This lack of disclosure can, in turn, be attributed to the past unavailability of patent protection in these areas which discouraged the disclosure of new innovations. The proposed rules will simply serve to spread the problems associated with non-disclosure in the business methods area across the patent system.

The proposed examination support document will provide fertile ground for future litigation. The requirement that the applicant opine as to the patentablilty of the claims over the prior art will provide an entirely new basis for attacking patents, thus increasing the already high cost of litigation. Many of the problems associated with this proposal

were pointed out in the public comments regarding the Patent Office's previous proposal to privatize searching. These identified problems have not disappeared in the interim and continue to argue against the proposed rule changes.

6. The Proposed Rules Will Not Substantially Improve Patent Quality.

Many of the problems associated with patent quality can be associated with the lack of experience and training of many examiners. This, in turn, can be attributed to the high attrition rate among examiners, especially in the pharmaceutical and biotechnology arts. The proposed rules do nothing to address these problems. Moreover, nowhere has the Patent Office shown any relationship between the number of claims and patent quality or lack thereof. The Patent Office and the nation as a whole would be better served by the Patent Office devoting more resources to the training and compensation of patent examiners, and by doing away with the current point system that mandates resolution of examination during a fixed and arbitrary time period regardless of the complexity of the invention; which engenders many of the issues raised by the Patent Office.

At least for the reasons stated above, the Burnham Institute for Medical Research opposes the proposed Changes to Practice for the Examination of Claims in Patent Applications and urges the Patent and Trademark Office not to adopt them.

Respectfully submitted,

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