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From: patent attorney [mailto:uspatentno1@yahoo.com]

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To: AB93Comments

Subject: comments re rule change proposals

The comments represent the opinion of an experienced U.S. patent attorney with patent prosecution clients in the biotechnology arts.

Changes to the rules governing patent acquisition should, above all, promote progress of science. The ideal patent system would promptly award a patent to an applicant for an invention that satisfies patentability criteria (e.g., 35 USC Sections 101, 102, 103, 112). The claims of the patent would protect the full scope of the invention, nothing more, nothing less. The cost of the system would be low, so as not to pose a barrier to entry to applicants.

The Patent Office's current proposals fail at these goals. The apparent purpose of the new rules is to reduce the Patent Office's own workload, although, for reasons set forth below, the new rules will be largely ineffective at this. Most workload reduction will be attributable to increased burden/costs on applicants and/or strangling the applicant's ability to obtain full protection for their invention. The new rules are a sledgehammer taken to the heads of all patent applicants, for the purpose of addressing abuses that are, by the PTO's own admissions, practiced by a small minority of applicants.

One set of Patent Office proposed rule changes constitutes a practical limit on the number of claims that a patent applicant may pursue. The second set of rule changes constitutes a practical limit on continuation practice. Each set of rule changes contravenes the goal of granting patents that protect the full scope of an invention. Together, the rule changes represent the proverbial "rock" and "hard place", squeezing the patent applicant.

For many PTO customers, it is absolutely critical to issue patent claims early, e.g., as a validation for raising capital financing and/or for purposes of licensing, partnering, and deal-making. Currently, patent applicants are permitted to issue narrow claims as soon as they are allowed, and pursue broader coverage more commensurate with the scope of their invention in continuation applications. The proposed rules that limit continuation practice effectively nullify this strategy, to the detriment of progress of science.

At least some percentage of applications that receive multiple office actions and/or multiple continuations are eventually allowed. The PTO has done little to demonstrate that such protracted prosecution is due to applicant abuse. Multiple office actions also are attributable to examiner inexperience, examiner difficulty with the English language, an examination system that rewards examiners when continuations or RCE's are filed, and other internal PTO causes. Also, the onerous prosecution estoppel rules applied by the federal courts dictate that a prudent applicant should prosecute cautiously, e.g., by making the minimum number of amendments, arguments, and evidentiary submissions that are required to satisfy a patent examiner. The sledgehammer approach of the proposed new rules will have dastardly effects on applicants that prosecute the applications in these legitimate manners, because the rules fail to distinguish protracted prosecution that is abusive from protracted prosecution due to PTO imperfection and prudent applicant practice.

Out of fear of the finality imposed by the proposed rules, Applicants (that can afford to do so) will be forced to front-load responses to every office action with interviews and with declarations and other evidence, when attorney argument alone might have sufficed. Thus, the new rules will add prosecution costs for the applicants and possibly increase the examiner's workload (reviewing such larger submissions) beyond what experienced attorneys believe would be necessary to obtain an allowance.

Likewise, applicants (that can afford to do so) will unquestionably file more appeals and file petitions to establish reasons why they should be permitted to file further continuation applications. In these respects, PTO workload is not decreased, but rather, shifted from examination to administration (deciding petitions, deciding appeals). It is undoubtedly more efficient to permit an additional continuation application that will be further examined by an examiner familiar with a case, than to encourage appeals that require more rigorous briefing and require the attention of at least three additional examination-skilled board of appeals personnel that start unfamiliar with a case.

Only the Patent Office's richest (i.e., biggest) customers would be able to afford the effective surcharges (e.g., in attorney time) imposed by the Examination Support Document rules. Numerous studies demonstrate that a large percentage of innovation is attributable to smaller companies that would be more heavily impacted by the rule changes. And these rules are onerous and fraught with dangers in the form of prosecution estoppel, inequitable conduct allegations (if an ESD is imperfect or incomplete), and malpractice (if the attorney wrongly characterizes art in advance of examination).

The PTO's own statistics suggest that the proposed rule changes affect only a small percentage of applications. Thus, on an absolute scale, the PTO cannot expect the rule changes to drastically reduce its workload. However, the PTO did not (and cannot) perform an analysis as to what percentage of applications with large claim sets, or strings of continuations, are meritorious versus abusive. Accordingly, the PTO did not (and cannot) evaluate whether its rule changes are working to eliminate abuses, or curtail meritorious applications on complex technologies.

The proposed rule that requires all divisionals be filed based on a first application(1.78(d)(1)(ii)) can

be expected to have the effect if increasing the number of applications filed. Applicants that are permitted to defer divisionals frequently determine (with time) that such divisionals are unnecessary or not commercially warranted. However, the PTO eliminates this reality with the proposed new rule, and encourages defensive divisional filings, for those applicants that can afford them.

The divisional rule is particularly onerous in the biochemical arts, where the PTO is still routinely issuing restriction requirements that are effectively hundreds or thousands of allegedly independent and distinct inventions (e.g., through abusive restriction of individual species).

The proposed limitations on continuation practice are contrary to the plain language of the patent statute (35 USC 120) and will undoubtedly face challenges.

The PTO's apparent intent of burden-shifting to applicants (rebuttable presumptions of unpatentability) are contrary to decisional law in most other areas (obviousness, enablement, etc.), and also are likely to face challenges.

There are changes that would be more effective at reducing the PTO workload without increasing the burden on applicants.

**MORE TIME.** Congress has only recently increased patent fees, and the PTO is trying to hire new examiners. It is premature to assert that these efforts will be ineffective at reducing backlog.

**DEFERRED EXAMINATION.** If the PTO adopts a deferred examination procedure that is used in other countries, it could expect that some proportion of patent applications would be permitted to lapse without ever seeing examination. Some applications would lose commercial importance to their owners. Others would be permitted to lapse because previously secret prior art would have been published. With the publication of patent applications at 18 months, a voluntary system

of deferred examination would lessen workload, and lessen pendency of cases for which examination is desired, with little negative impact on the PTO, applicants, or industry.

**INCREASED PAY AND OTHER INCENTIVES.** Patent examiners must be technically proficient (which often means a Ph.D. in certain art units) and have an aptitude for patent law. These skills invite job mobility, and the PTO needs a vehicle to retain examiners in the face of competition from the private sector. Lobbying Congress for permission to provide a more competitive salary structure would be appropriate. The PTO also should explore satellite offices and flexible work schedules to make a PTO examiner's job available to more of the country and to part-time workers.

**DUTY OF CANDOR/DISCLOSURE.** The PTO should revise Rule 56 to provide an incentive to file an IDS of limited scope of potentially highly pertinent references. Due to fear of inequitable conduct charges, the current rule operates as an incentive to file large IDS's, placing a time burden on examiners.

**MULTIPLE DEPENDENT CLAIMS.** In this practitioner's experience, the use of multiple-multiple dependent claims permits an applicant to claim an invention more concisely (fewer total claims) in foreign jurisdictions than in the U.S. Such claims should be encouraged in the U.S. by changing claim fee structures and eliminating prohibition.