

-----Original Message-----

From: Frank Nguyen [mailto:Frank.Nguyen@intusurg.com]

Sent: Monday, May 01, 2006 5:52 PM

To: AB93Comments

Subject: Intuitive Surgical Inc. Comments on Continuing Application Practice

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office
Mail Stop--Comments Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Attached please find the comments of Intuitive Surgical, Inc. on the proposed "Changes to Practice for Continuint Applications, RCE Practice, and Applications Containing Patentably Indistinct Claims."

We are grateful for the opportunity to provide our comments and would appreciate a confirmation of your receipt of our comments.

<<Intuitive Surgical AB93 Comments.pdf>>

Regards,

Frank Nguyen
Vice President of IP & Licensing
Intuitive Surgical Inc.
950 Kifer Road
Sunnyvale, CA 94086
Phone (408) 523-2129
Fax (408) 523-1390

VIA E-MAIL To AB93Comments@uspto.gov & FACSIMILE to 571-273-7735

May 1, 2006

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

RE: Notice of Proposed Rule Making Entitled "Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims" 71 Fed. Reg. 48-61

Dear Sir:

We at Intuitive Surgical, Inc. are writing to strongly oppose the Patent and Trademark Office's (PTO's) proposed rule changes on continuation practice. The proposed changes would provide unfair advantages to large companies in mature technological industries, while seriously curtailing the substantive rights of smaller companies at the forefront of innovation. In this letter, we clarify the reasons for our opposition, and propose alternative remedies which, in our opinion, better balance smaller companies' rights against the need to efficiently advance patent applications to issue.

I. Background of Intuitive Surgical, Inc.

Intuitive Surgical, Inc. is the leader in the field of robotic-assisted minimally invasive surgery. We serve customers throughout the United States and internationally, providing technological innovation across cardiac, urology, gynecologic, pediatric and general surgical disciplines. Our product, the da Vinci® Surgical System, enables surgeons to perform complex procedures such as cardio-thoracic surgery through 1-2 cm incisions in the human body, reducing patients' hospital stays from weeks to days. In addition, patients undergoing minimally invasive surgery tend to lose much less blood than in conventional surgery, and also experience an extremely low rate of complications. See, for example, "Robotic Arms Mend Robelot's Heart," available at <http://www.cbsnews.com/stories/2006/03/16/earlyshow/health/main1410430.shtml>, for a CBS news article on Jane Robelot (a.k.a. Jane Pauley, former co-anchor of *CBS This Morning*), who recently underwent successful heart surgery using minimally invasive techniques.

We control a patent portfolio disclosing and enabling many of the important advances in our field, such as telepresence, remote centering, robotic wrist manipulators, and surgical

end effector tools. Although we are a small company, we have invested literally hundreds of millions of dollars to develop, acquire, and license these technologies, many of which are still in their early stages of development. Without the chance to fully prosecute and obtain strong patents, the cost of developing and bringing these exciting and beneficial technologies to market simply cannot be justified. Moreover, every time one of our patent applications is published, key technical know-how is revealed to our competitors that would otherwise diminish our competitive advantage.

II. Concrete purposes of continuations / RCE's

The proposed rule changes unduly burden our ability to prosecute claims that adequately cover our inventions. First, by requiring second or subsequent continuations or requests for continued examination (RCE) filings to be supported by a showing as to why an amendment, argument, or evidence presented could not have been previously submitted, we will be forced to spend time and resources on 1) preparing such showings, 2) convincing the PTO why such showings should be deemed adequate, and 3) appealing any adverse decisions. Second, by requiring all patentably indistinct claims to be submitted in a single patent application, we will not be able to obtain the claims to which we are legally entitled. This is because many of our company's technologies are still in the development stage, making it difficult if not impossible to precisely define the scope of our inventions over the prior art at the time an application is initially filed.

A. Not all patents are created equal

Our concerns stem from a simple fact: not all patents are created equal. While patent applications in more mature fields such as semiconductor processing or information technology may disclose only incremental changes over the prior art, requiring only minimal prosecution to dispose of, other applications may disclose truly revolutionary advances, disclosing complex and intricate details that take time to prosecute fully and correctly. Extensive disclosures are often mandated by the need to satisfy the enablement and best mode requirements under 35 U.S.C. 112. Our inventions often require such extensive disclosures, covering, for example, multiple technical aspects of a complex robotic surgical system in one application. In fact, in the field of surgical robotics, a few key patents may disclose enough know-how to launch an entire industry.

We believe the suggestion that seminal advances require more extensive descriptions should come as no surprise, for they often involve tremendous investments of money, time, effort, and ingenuity. For companies such as ours, whose competitiveness depends on getting a fair return on such investments, it is imperative that the novelties disclosed in patent applications be entitled to the maximum protection affordable under the law. To curtail this protection is to risk chilling innovation by forcing companies to keep technologies confidential as trade secrets, and worse yet, by foreclosing R&D investment in entire areas for which technologies are readily reverse-engineered.

B. Important function of continuations and RCE's

Continuations and RCE's serve the important function of allowing applicants to claim the possibly multiple and nuanced novelties disclosed in a patent application. The legitimacy of this purpose has been acknowledged by the Federal Circuit in Johnson & Johnston v. R.E. Service: "A patentee who inadvertently fails to claim disclosed subject matter, however, is not left without remedy... a patentee can file a separate application claiming the disclosed subject matter under 35 U.S.C. 120 (2000) (allowing filing as a continuation application if filed before all applications in the chain issue)." 62 U.S.P.Q.2d 1225, 1231 (Fed. Cir. 2002) (en banc). Indeed, Lemley and Moore, in their article Ending Abuse of Patent Continuations, referred to the act of frustrating this purpose as the "most serious problem prosecutors would face if continuations were abolished." 84 B.U. L. Rev. 63, 99 (2004). Yet while Lemley and Moore suggest that this would simply lead patent prosecutors to work harder on "getting claims drafting just right... at the outset," 84 B.U.L. Rev at 100, we believe that this is an unreasonable burden to place on patent prosecutors and the inventors they represent.

This is because while prosecutors should draft claims to the best of their ability from the outset, they cannot and should not be charged with knowing what and how prior art will be cited against them during prosecution. As the PTO is well aware, patent prosecution is a give-and-take educational process, involving the diligence and patience of both examiners and inventors. Just as inventors require the resourcefulness of examiners to point out prior art that may possibly invalidate a patent in court, examiners require the insight of inventors to point out the patentable features of an invention. The process is not perfect, and miscommunication does occur. Often several exchanges between the examiner and the inventor are needed for both sides to agree on allowable subject matter, especially for high-stakes innovations in which a company has invested tremendous resources. It is important for the PTO to realize that such prolonged exchanges are not necessarily the result of bad faith, or a desire to ambush the marketplace and deter innovation. Rather than abridging the right to pursue continuations and RCE's, thereby placing the burden to get it "just right" solely on inventors, we believe the PTO must work together with applicants to arrive at more mutually beneficial solutions to any perceived problems.

III. Under the current system, are continuations really a problem?

Several concerns have been raised over the increasing volume of applications that are filed with the PTO each year. We invite the PTO to reconsider the logic of attributing these problems to applicants' purported abuse of continuation applications.

A. Backlog of patent applications

First, the PTO has stated that the number of continuation applications relative to the total number of applications filed has been rising. According to the PTO, this "backlog"

prevents the examination of applications on new inventions. 71 Fed. Reg. 48, 48 (Jan. 3, 2006). We agree that it would be desirable for old applications to be disposed of quickly, and new applications to be taken up promptly for examination. However, we cannot endorse the suggestion that the PTO should artificially “dispose” of old applications by restricting their continuing prosecution, if the job simply has not been done with respect to those applications, and done well.

As we have noted, continuation applications are an important vehicle for ensuring the issuance of high quality claims, particularly for complex inventions with extensive disclosures. Issued claims serve as a baseline indication to the public of whether claims read on prior art, and whether they would be enforceable in court. They also serve to define the exclusive rights to which inventors are entitled under the Constitution. The proposed rule changes will cut prosecution short for the complex inventions that need it the most, resulting in a sacrifice of quality for quantity. Surely such a result would not be worthy of the PTO’s stated goal of maintaining the best patent system in the world.

Moreover, the current policies stated in the Manual of Patent Examining Procedure (MPEP) clearly conflict with the proposed rule change. “Before final rejection is in order a clear issue should be developed between the examiner and applicant... present practice does not sanction hasty and ill-considered final rejections. The applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in the prosecution of his or her application.” MPEP Sections 706.07(b), 706.07. If the proposed rule changes are instituted, then every application beyond a first continuation or RCE will face a burden even harsher than a final rejection. For one thing, an applicant must make a showing of necessity in a second or later continuation application, a showing that is subject to prosecution history estoppel, even if at that point there is no clearly developed issue between the examiner and applicant. Furthermore, in contrast to the appeals process, there is no developed procedural recourse for the applicant in the event the required showing is deemed inadequate. In this case, an applicant may be left with no avenue for continuing prosecution save for the reissue process, which requires a showing of error, and further limits the submission of broadening amendments to within two years. Such a drastic departure from current practice is unjustified.

B. Need for public notice

Another problem cited by the PTO is a need for “finality” in prosecution, so that the public may be finally put on notice as to the metes and bounds of a particular invention. The concern is that as long as applications are pending, one might obtain unduly broad claims claiming priority to the filing date of an earlier application, thereby “ambushing” a public that has relied on already issued claims. However, we believe this fear is overstated, for under the written description requirement of 35 U.S.C. 112, what an

inventor is legally entitled to claim is a matter decided immediately upon the filing of the earliest application to which priority is claimed.

The written description requirement of Section 112 allows applicants to claim in later applications only subject matter that the applicant had possession of at the time of filing the original application, as discerned from the original text by one of ordinary skill in the art. See Space Systems/Loran v. Lockheed Martin, Docket No. 04-1501 (Fed. Cir. 2005); Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). This means an applicant cannot legally obtain claims that are broader than supported by an original application as filed. And since most applications are now published eighteen months after filing, the public can readily access the text of an original application as filed. By studying a published application, and checking whether applications claiming priority to that application are still pending, the public can readily determine what an inventor is or is not entitled to claim in any pending or future application. Thus there is little support for the suggestion that an unsuspecting public might be “ambushed” by claims issuing from continuing applications or RCE’s.

For all the criticism that some have directed toward a perceived “incoherency” in the courts’ written description doctrines (see e.g., Lemley and Moore, 84 B.U. L. Rev at 92), which may complicate the steps outlined above, we submit that it would decidedly be the province of Congress and the courts themselves to resolve any such incoherency. Any changes would necessarily affect the delicate balance between the rights of the public versus the rights of inventors, and must be addressed through the proper legal means, with checks and balances, as laid out in our Constitution.

C. Decreasing marginal value of continuations

Finally, as a further rationale for restricting continuation practice, the PTO asserts that “the marginal value vis-à-vis the patent examination process as a whole of exchanges between an applicant and the examiner during the examination process tends to decrease after the first continued examination filing.” 71 Fed. Reg. at 51. Again, we believe such an assertion overlooks the differences between seminal inventions and incremental ones. As already described, we believe that seminal inventions require more time to prosecute than other inventions, and hence the stage, if any, at which marginal value sharply decreases will vary greatly depending on each application.

Moreover, we do not see a problem for inventors in the observation that the marginal value of filing more continuations eventually decreases. As rational actors, we decide whether the marginal utility to us of filing a continuation application exceeds the filing fee and prosecution costs. However, we do see a serious problem for society in that PTO examiners perceive continuations to have decreasing marginal value to their work. According to Lemley and Moore, the incentive system currently in place at the PTO rewards examiners only for finally disposing of a case, i.e., allowing its claims. 84 B.U. L.

Rev. at 74. Continuations and RCE's allegedly "wear down" examiners, thereby pressuring them to give in to claims that may be of poor quality.

This is certainly a problem, for no one benefits from having patents issue with claims that are readily invalidated in court. We believe, however, that the solution to this problem does not lie in undercutting the efforts of applicants who tenaciously pursue their rights, but rather in realigning the incentives for examiners at the PTO. In our opinion, the focus of patent examiners should not be on allowing claims and disposing of inventions – rather, it should be on giving every claim for which an examination fee has been paid its proper consideration, regardless of whether the result is a rejection or an allowance. And if the examiners do not have the resources to do their job in this way, we believe the problem should at least be characterized as one of inadequate resources, rather than unfairly as one of unscrupulous inventors seeking to profit at the public's expense.

IV. Our proposals

A. Reform the incentive system

The last concern motivates our first proposal for addressing the cited problems: reform the incentive system at the PTO so that examiners are compensated for the valuable work that they actually perform, which comprises reviewing patent applications, searching for prior art, and making reasoned determinations as to the patentability of each individual claim. An examiner should not be penalized for continuing to reject claims that have no merit, for this is a vital part of their gatekeeper role within our patent system. Reforming the system in this way would eliminate the problem of examiners being "worn down" by repeated continuation filings, and allow them to address the merits of each case as each case deserves.

B. First-action-final-rejection practice and laches

Second, we propose that any perceived "decreasing marginal utility" to society of claims filed in continuation applications should continue to be addressed under the first action final rejection (FAFR) practice outlined in MPEP Section 706.07(b). See In re Bogese, 22 U.S.P.Q.2d 1821 (Comm'r Pats, 1992). This section explicitly guards against the cases where all claims of the new application: (1) are drawn to the same invention claimed in the earlier application, and (2) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. MPEP 706.07(b). For those egregious cases where an applicant repeatedly files continuation applications without substantively advancing prosecution, the examiner has resort to the equitable doctrine of laches, with proper notice, as sanctioned by the court in In re Bogese II, 64 U.S.P.Q.2d 1448 (Fed. Cir. 2002).

C. Sliding fee scale for continuations and RCE's

Third, to address the resource issue, we propose that the filing fees of successive continuation applications be increased to offset any perceived additional cost to the PTO of dealing with further continuation applications. While we believe that continuation applications are in fact no different from any other type of patent application, we realize that our proposal to realign examiners' incentives may take time to implement. Thus a temporary solution such as a sliding fee schedule may be in order. According to such a scheme, the filing fee for a second continuation application may be higher than the first continuation, the third application higher than the second, and so on. To this end, it is incumbent on the PTO to quantify just how much more in resources is needed to deal with continuation applications than for any other applications. In this way, inventors and the PTO might work together to address the problems facing our patent system, until a better long-term solution can be reached.

V. Other considerations

A. Proposed changes are pre-empted by statutory and judicial prerogatives

Besides being unjust, we believe the proposed rule changes are also legally defective. First, as an administrative agency, the PTO must observe the delicate balance between inventors' and the public's rights that has been codified by Congress and interpreted by the courts. "A limit upon continuing applications is a matter of policy for the Congress, not for us." In re Hogan and Banks, 194 U.S.P.Q. 527, 536 (CCPA 1977); see also In re Henriksen, 158 U.S.P.Q. 224, 231 (CCPA 1968). This balance is manifested in the statutory provisions on the right to pursue continuations, 35 U.S.C. 120, the reissue provisions of the statute 35 U.S.C. 251-252 which do not contemplate the proposed abridgment of continuations, and the disclosure requirements of 35 U.S.C. 112. The Federal Circuit has held: "Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of an invention progresses... one may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive." Symbol Technologies v. Lemelson, Docket 04-1451 (Fed. Cir. 2005) at 12. We also believe that the proposed rule changes would be an unprecedented and legally untenable expansion of the PTO's authority under 35 U.S.C. 2.

B. Retroactive nature of proposed rule changes

From a Constitutional rights standpoint, we believe that the retroactive nature of the proposed rule changes violate inventors' rights to Due Process of Law, as the PTO is proposing to apply the proposed rule changes even to continuations claiming priority to applications that have already been filed. If a petition for filing a subsequent continuation application is denied, then important substantive aspects of disclosures already filed may never be claimed in future applications. The Supreme Court has held:

“a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms.” Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988). And while “the PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications,” In re Bogese II, 64 U.S.P.Q.2d 1448, 1453 (Fed. Cir. 2002), “an administrative agency cannot impose a penalty or forfeiture without providing notice.” 64 U.S.P.Q.2d at 1453. Proper notice would require that the rule be applied only to continuation applications claiming priority to future-filed original applications, allowing applicants *a priori* knowledge of the rules to decide what subject matter to disclose in a specification.

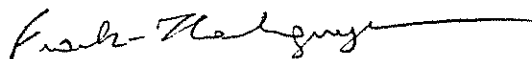
C. Ineffectiveness of proposed rule changes

Finally, we submit that even if the proposed rule changes are adopted, they will not be effective to achieve their intended purpose of streamlining patent prosecution. As we have repeatedly stated, companies such as ours do not file continuation applications simply to annoy the PTO – we do so as a matter of grave significance to protect the business investments we have made in our technologies. If the proposed rule changes are adopted, the resources that we have hereto expended in advocating the merits of our claims will instead be diverted to preparing extensive showings of why, in our opinion, any continuation application beyond the first should continue to be examined on the merits. Adverse rulings on this point will then be appealed, and eventually litigated in the courts. It thus seems unclear to us whether implementing the proposed rule changes would buy the system any efficiency at all.

VI. Conclusion

In conclusion, we strongly urge the PTO not to adopt the proposed rule changes in their current form, but to seriously consider and act on the suggestions we have put forth in this letter. We at Intuitive Surgical welcome continuing dialogue on the issue, and urge the PTO to refrain from abridging important substantive rights, and inadvertently stifling innovation in this country.

Sincerely,



Frank Nguyen
Vice President, Intellectual Property and Licensing
Intuitive Surgical, Inc.