

# FULL DISCLOSURE

## Patent Prosecution Update

July 2010

### **After *Bilski*: The USPTO Response and Claim Drafting**

The Supreme Court recently announced its greatly anticipated decision in *Bilski v. Kappos*, No. 08-964, 2010 WL 2555192 (June 28, 2010). In the decision, the Court held that the machine-or-transformation test is not the sole test for determining whether process claims are eligible for patent protection. Slip op. at 8. Instead, the Court found that the machine-or-transformation test remains “a useful and important clue . . . for determining whether some claimed inventions are processes under” 35 U.S.C. § 101. *Id.* [More](#)

### **The EPO Clarifies the “Methods of Treatment by Surgery” Exclusion**

Article 53(c) of the European Patent Convention (EPC) excludes from patenting all “methods for the treatment of the human or animal body by surgery.” Recently, an Enlarged Board of Appeals (Board) of the European Patent Office (EPO) was asked to evaluate the patentability of certain magnetic resonance imaging methods in view of this Article. *In re Medi-Physics*, G 0001/07 at 4-10 (EPO Enlarged Board of Appeals 2010). [More](#)

### **EPO Practice Tip**

As reported in the February 2010 edition of “Full Disclosure,” the European Patent Office (EPO) announced a number of changes to the European Patent Convention (EPC) effective April 1, 2010. The changes included amendments to Rule 161 EPC, which relate to responses to the Written Opinion or the International Preliminary Examination Report (IPER) of a PCT application. [More](#)

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*by Erika H. Arner, Charles T. Collins-Chase, and Justin R. Lowery*

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## After *Bilski*: The USPTO Response and Claim Drafting

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Moreover, the Court encouraged the “Federal Circuit’s development of other limiting criteria” consistent with the Patent Act and Supreme Court precedent. *Id.* at 16. The Court, however, was unable to find support in the Patent Act for a categorical exclusion of all business method inventions. *Id.* at 11.

Although the U.S. Patent and Trademark Office (USPTO) has indicated that it will be issuing more complete guidance soon, the USPTO has responded to the *Bilski* decision for now by instructing its examiners to continue applying the machine-or-transformation test to determine whether an invention is a process under Section 101. Memorandum from Robert W. Bahr, Acting Associate Commissioner for Patent Examination Policy, U.S. Patent & Trademark Office, to the Patent Examining Corps (June 28, 2010), available at [http://www.uspto.gov/patents/law/exam/bilski\\_guidance\\_28jun2010.pdf](http://www.uspto.gov/patents/law/exam/bilski_guidance_28jun2010.pdf). According to the USPTO’s guidance, if a claimed method satisfies the test, the method is likely patent eligible unless there is a clear indication that the claimed method is directed to an abstract idea. *Id.* If, however, the claimed method fails the machine-or-transformation test, examiners are instructed to reject the claimed method under Section 101 unless it is clear that the claimed method is not directed to an abstract idea. *Id.*

Despite the possibility of additional patent eligibility tests being created in the future, the USPTO currently intends to use the machine-or-transformation test as an initial gauge for the patent eligibility of processes. Accordingly, applicants should be sure to include a number of claims that clearly satisfy that test. To do so, applicants should ensure the claimed method is sufficiently tied to a machine or apparatus (e.g., computers or other devices) by including the machine or apparatus throughout the claim. A mere recitation of a machine or apparatus in a claim’s preamble or a field-of-use limitation may not be sufficient. Instead, applicants may include limitations drawn to how the machine or apparatus performs steps of the claimed method and/or interaction between multiple machines.

Alternatively, a claim may include one or more limitations drawn specifically to the transformative aspects of an invention. For example, a method claim may include a limitation claiming transformed data as a physical phenomena, such as, for example, a visual depiction. As another example, claims directed to diagnostic methods may include a step directed to administering a treatment to a patient or conducting a diagnostic test that transforms a test sample. Providing a claim with a number of transformative limitations makes clear to examiners that the claimed invention is not merely directed to an abstract idea or natural phenomenon. As a further alternative, applicants may include article-of-manufacture claims drawn to, for example, a computer program product including a computer usable medium having a computer readable program code embodied therein.

Furthermore, pre-*Bilski* guidance by the USPTO indicated that applicants should avoid limitations where a machine or transformation is only present in an insignificant extra-solution activity (i.e., an activity that is not central to the purpose of the invented method). For example, a mid-solution step of “entering bids in

the record” or a pre-solution step of “performing a plurality of clinical laboratory tests on an individual” may not be enough to pass the machine-or-transformation test. Stated differently, merely “reciting a specific machine or a particular transformation of a specific article in an insignificant step, such as data gathering or outputting, is not sufficient to pass the test.” Memorandum from John J. Love, Deputy Commissioner for Patent Examination Policy, U.S. Patent & Trademark Office, to Technology Center Directors and the Patent Examining Corps (Jan. 7, 2009), *available at* [http://www.uspto.gov/web/offices/pac/dapp/opa/documents/bilski\\_guidance\\_memo.pdf](http://www.uspto.gov/web/offices/pac/dapp/opa/documents/bilski_guidance_memo.pdf). Instead, applicants should ensure the use of a particular machine or the transformation of a particular article imposes a meaningful limit on the claim’s scope.

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## The EPO Clarifies the “Methods of Treatment by Surgery” Exclusion

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The Board’s conclusions offer insight on the interpretation of Article 53(c) EPC and set out new approaches for determining whether inventions are excluded from patentability as methods of surgery.

In the *In re Medi-Physics* case, the Board was asked to determine whether the claimed imaging method, which included a step of injecting a contrast agent into a patient’s heart, was eligible for patent protection. Based on the reasons discussed below, the Board held that the claimed method was excluded from patentability because it was a method for treatment by surgery within the meaning of Article 53(c) EPC.

In arriving at its decision, the Board refused to find that the exclusion of “treatment by surgery” is limited solely to purely therapeutic methods (i.e., directed to restoring or maintaining the health of the human or animal body). *Id.* at 47-48. Stated differently, the Board found that “surgery” may encompass traditionally nontherapeutic procedures, such as, for example, sex-change operations, sterilization, or the operative removal of wrinkles. *Id.* at 23. Similarly, the Board also refused to find that the exclusion applied broadly to any “non-insignificant intervention” performed on the structure of an organism. The Board found that such a broad exclusion is now unjustifiable due to advances in nonmedical technologies (e.g., cosmetic and hair-removal procedures, tattooing, and piercing) requiring contact with the human body. *Id.* at 58-59.

Having rejected the narrow and broad definitions, the Board then sought an appropriate definition that allowed the exclusion to be effective but not stifling. The Board reasoned that the exclusion was intended to “specifically [free] the medical profession from [the] constraints which would be imposed on them by patents granted on methods of surgical or therapeutic treatment.” *Id.* at 60. The Board concluded that “any definition of the term ‘treatment by surgery’ must cover the kind of interventions which represent the core of the medical profession’s activities, i.e., the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility.” *Id.* Thus, the Board held that methods involving “an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise [are] excluded from patentability.” *Id.* at 74. The Board, however, was unwilling to provide “an authoritative once and for all definition of what the term ‘treatment by surgery’ may comprise” because of the ever-changing nature of medical technology. *Id.* at 63.

Next, the Board confirmed that a multistep method may be ineligible for patent protection if the method contains a single step directed to “treatment by surgery,” as defined by the EPC. The Board, however, opined that exclusion under Article 53(c) EPC may be potentially avoided by specifically disclaiming any embodiments directed to “surgery” within the meaning of the EPC, provided the rest of the method claim complies with the requirements of the EPC. *Id.* at 68. The patentability of such inventions, however,

must necessarily be decided on a case-by-case basis. In addition, the Board announced that methods having diagnostic purposes should not be automatically excluded from patent protection merely because the method may be used during surgery. *Id.* at 74.

The *In re Medi-Physics* case makes it clear that most standard surgical methods (i.e., methods involving an invasive physical intervention of the body by a medical expert) are still ineligible for patent protection. Methods involving only a minor intervention or no substantial health risk, however, may be eligible for patentability. The EPO's treatment of such methods, however, has yet to be determined.

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## EPO Practice Tip

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In cases where the EPO acted as the International Searching Authority during the PCT stage, the amendments to Rule 161 EPC required a mandatory response to the Written Opinion or the IPER unless certain amendments were previously filed. If the required response was not filed within a one-month time period from the Rule 161 Communication, the applicant risked having its application lapse. A mandatory response is not required if amendments and/or comments were filed upon entry into the European national phase; amendments filed pursuant to Article 19 and/or 34 PCT were maintained on entry into the European national phase, provided these amendments were not considered in the issuance of an IPER; the Written Opinion or IPER was positive with respect to the claims; or a communication pursuant to Rule 161 had already issued before the rule changes became effective.

We now have the benefit of a few months of EPO practice under new Rule 161. For applications where any amended documents (e.g., claim amendments designed to reduce extra claims fees) are filed upon entry into the European national phase, the EPO typically invites the applicant to comment on the Written Opinion. A response is not mandatory and the application will not lapse if no response is submitted.

If, however, no amendments are filed upon national-phase entry, the EPO provides applicants with a one-month period to correct all deficiencies noted in the Written Opinion or IPER. If the applicant fails to comply, the application will lapse. An appropriate response may include amendments and/or arguments similar to those filed in response to an office action. Although the one-month period is not extendable, a request for further processing may be available with the payment of suitable fees.

The current EPO practice therefore typically treats applications filed with amended documents differently than those filed without any amendments. Although certain amendments, e.g., reducing claims or the inclusion of original claims at the end of a specification, may not address the deficiencies raised in a PCT Written Opinion, the EPO's practice appears to be based on an inability to efficiently determine whether amendments filed upon national-phase entry are responsive to the PCT objections. While it is possible that the EPO may change its practice in the future, applicants—for the time being at least—may eliminate the need to file a response to a Written Opinion or IPER by filing amended documents, e.g., amendments reducing the number of claims pending upon national-phase entry or making the claims consistent with those in another jurisdiction where prosecution has matured.

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### Rule Review

Rules 1.510 and 1.915 (collectively “the Rules”) set forth the requirements for a request for reexamination. Though the Rules relate to *ex parte* and *inter partes* reexamination respectively, they include many of the same substantive requirements. Thus, for the purposes of this article, the Rules are reviewed collectively. Compliance with the Rules will highlight information relevant to the examiner’s decision whether to grant reexamination.

In addition to several technical requirements, such as, e.g., including the required fee, identifying every claim for which reexamination is requested, and providing copies of the cited references, the Rules require (1) a statement pointing out each substantial new question (SNQ) of patentability based on the cited references, and (2) a detailed explanation of the pertinency and manner of applying those references to every claim for which reexamination is requested.

A statement pointing out an SNQ is a concise statement that identifies a new, noncumulative technical feature of a reference and explains why the feature is a new teaching that should have been considered. The new technological teaching may be presented by, e.g., discussing the subject matter of the cited reference that relates to at least one claim limitation and provides a teaching that was not considered in the prior examination. At least one reference cited in each proposed rejection must provide a new, noncumulative technological teaching. Furthermore, the request must state an SNQ for every claim for which reexamination is requested.

According to the USPTO, many defective requests do not distinguish the SNQ from the proposed rejections. To avoid a defective request, the SNQ should be limited to the new teaching in the cited reference, and should be distinct from the identification and explanation of the proposed rejections. The focus should be on the specific features of the reference, and requesters should refrain from adding extraneous material such as general recitations of the law.

The detailed explanation of how the cited references apply to the claims is a proposed rejection based on the new technological teaching. Each proposed rejection, e.g., anticipation, should have a *separate* explanation stating how the references apply to every claim limitation for each claim to which the proposed rejection is applied. The detailed explanation may be presented by either a claim chart or a narrative. The USPTO, however, cautions against including both because doing so may lengthen the request and introduce inconsistencies. According to the USPTO, “[p]roposed rejections that clearly and concisely identify and provide support for a *prima facie* case of unpatentability are more likely to be adopted by [an] examiner.” Best Practices and FAQs for filing requests for reexamination compliant with 37 CFR 1.510 and 1.915, at 17 (2010), [http://www.uspto.gov/patents/Best\\_Practices\\_and\\_FAQs\\_for\\_filing\\_reexaminations\\_5\\_10\\_10.pdf](http://www.uspto.gov/patents/Best_Practices_and_FAQs_for_filing_reexaminations_5_10_10.pdf). However, “[e]xplanations that are incomplete, unclear, or confusing may result in [an] examiner not adopting the proposed rejection or not understanding the requester’s position on how the references are applied to the claim limitations.” *Id.*

The USPTO finds many requests defective because they either “(1) do not explain how some of the references apply to the claim limitations or (2) group references or statutory bases of rejections in a way that does not clearly identify what rejections are proposed by the third party requesters, or what applications of the art are proposed by patent owner requesters.” *Id.* at 15. The USPTO suggests citing to only those references identified as a basis for a proposed rejection (or applied to the claims in the case of a patent owner’s request for reexamination). Further, obviousness and anticipation rejections should be proposed separately and not lumped together using “and/or” terminology. On the other hand, requesters may apply one ground of rejection to multiple claims grouped together.

Additional guidance for preparing requests for reexaminations that comply with the Rules may be found in the Best Practices and FAQs for filing requests for reexamination compliant with 37 CFR 1.510 and 1.915 (2010), [http://www.uspto.gov/patents/Best\\_Practices\\_and\\_FAQs\\_for\\_filing\\_reexaminations\\_5\\_10\\_10.pdf](http://www.uspto.gov/patents/Best_Practices_and_FAQs_for_filing_reexaminations_5_10_10.pdf).

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## The Federal Circuit Says

Patentees may violate the rule against recapture by claiming subject matter in a reissue patent that was surrendered during the prosecution of a related patent application. In *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, No. 2008-1288 (Fed. Cir. Apr. 12, 2010), the Federal Circuit found that certain claims of U.S. Reissue Patent No. 36,885 (the '885 reissue patent), owned by MBO Laboratories, Inc. (MBO), were invalid for recapturing previously surrendered subject matter.

The technology of the '885 reissue patent related to a design for a hypodermic safety syringe. The design protected against needle-stick injuries by slidably retracting a contaminated needle into a fixed protective guard after the needle is removed from a patient.

The '885 reissue patent is a reissue of U.S. Patent No. 5,755,699 (the '699 patent), which is part of a larger U.S. patent family. During prosecution of related family members, MBO made numerous assertions to overcome prior art rejections. In particular, the Court found that MBO overcame art rejections in one related patent by asserting that “[a] chief feature of [the] invention, inter alia, is . . . the *safe retraction* of the needle or cannula . . . into the tubular member . . . .” Slip op. at 4-5. The Court then found that MBO overcame prior art rejections during prosecution of another related patent by explaining that the applied reference disclosed a “needle . . . *fixed* to and extending from a conventional syringe barrel . . . . The needle is not *slidably received* in the barrel.” *Id.* at 5. The Court also found that MBO, in a parent application, once again distinguished the applied references by explaining that its needle is slidable into the disclosed guard body. Despite these assertions, MBO sought to reissue the '699 patent, alleging that it was entitled to claim a system having “any relative movement between the needle and the body,” not just a “system wherein the needle must be bodily moved toward the safety device.” *Id.* at 7.

On appeal, the Federal Circuit affirmed the lower court’s finding that certain claims of the '885 reissue patent violated the rule against recapture. The Court found that MBO was not entitled to claim all relative movement between the needle and guard body, as this subject matter was specifically surrendered during prosecution. Indeed, the Court noted that substantial evidence supported the lower court’s finding of MBO clearly surrendering the rights to claim a guard body that moved relative to a fixed needle.

To support its holding, the Federal Circuit reasoned that the rule against recapture only entitles a patentee to a reissue patent for broader claims when the patentee claimed less than he/she had a right to claim in the patent through error without any deceptive intent, not through deliberate amendments or arguments designed to procure allowance of claims. In the present case, the Court found that MBO had previously attempted to claim relative movement between a needle and an associated guard body in a related application. The Court also found that MBO had deliberately surrendered this subject matter in an effort to overcome prior art rejections. Thus, the Court concluded that deliberate surrender of subject matter is not an error of the kind that will justify the granting of a reissue patent drawn to the surrendered subject matter. *Id.* at 11.

Furthermore, the Federal Circuit clarified that “a patentee may violate the rule against recapture by

claiming subject matter in a reissue patent that the patentee surrendered while prosecuting a related application.” *Id.* at 16. Citing to similar policy goals governing the doctrine of prosecution history estoppel, the Court reasoned that equity requires a review of a patent family’s entire prosecution history in order to prevent patentees from encroaching back into territory previously dedicated to the public. *Id.* at 20.

To avoid inadvertently drafting claims that may be invalidated for violating the rule against recapture, applicants for reissue patents should review the prosecution histories of the entire patent family to ensure that the proposed reissue claims do not claim previously surrendered subject matter. Applicants should pay particular attention to the amendments and arguments submitted to overcome prior art rejections.

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## **Did You Know?**

In another effort to reduce backlog, the United States Patent and Trademark Office (USPTO) recently expanded the Application Exchange Program (Program) to include large entities. As originally implemented, the Program afforded small-entity applicants with more than one application, filed prior to the inception of the Program, an opportunity to seek expedited examination of one application in exchange for the withdrawal of an unexamined application. Recently, however, the USPTO expanded the Program to include large and small entities alike, and extended the duration of the Program to December 31, 2010. The USPTO further limited an entity's participation in the Program to fifteen (15) applications. Additional information on the recent expansion can be found at [http://www.uspto.gov/news/pr/2010/10\\_17.jsp](http://www.uspto.gov/news/pr/2010/10_17.jsp).

Applicants frustrated with the backlogs at the USPTO may find the expanded Program useful for expediting the prosecution of, for example, commercially significant applications.

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