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Protecting Patents for Personalized Medicine

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Personalized medicine companies should implement new strategies to deal with the challenges associated with protecting their inventions. Personalized medicine uses various types of diagnostic information to improve outcomes and reduce healthcare costs by determining in advance whether a patient is likely to respond to a proposed treatment.

The best-known and earliest success of the use of diagnostics in personalized medicine relates to measuring HER2/neu amplification in breast cancer patients. Only those patients whose tumors carry this amplification respond to Herceptin (trastuzumab), and the drug's use is indicated only in such patients. Current study results indicate that treatment for a year reduces risk of recurrence by half in these patients. The cost of Herceptin treatment is about $3,000 per month and is easily justified because of the benefits it provides.

New Challenges in Patent Protection

Getting patent protection for such diagnostics, however, recently became more difficult. The United States Patent and Trademark Office (USPTO) has made it difficult to obtain patent protection for certain types of personalized medicine technology. Unlike the test used for distinguishing Herceptin responders, which is a simple measurement of amplification of a single gene, other personalized medicine diagnostics require measuring gene or protein levels for a number of biomarkers. These measurements are used with sophisticated predictive modeling algorithms to generate a score associated with drug response or disease severity. One difficulty encountered in obtaining effective patent protection for this type of diagnostic arises from the ability to use various combinations of biomarkers to develop equivalent predictive models.

For example, while the expression of a handful of genes can be used in any particular predictive model, those genes can often be selected from a larger set of informative biomarkers. Consider a situation in which gene expression analysis identifies thirty genes whose expression significantly differs between identified groups of responsive and nonresponsive patients. Informative predictive models are generated using expression values for four or more genes. Consider further that many combinations of four genes out of the thirty provide good predictive power in the model. Ideally, a patent application would claim a method of determining the efficacy of the treatment by measuring the expression of four or more of the thirty genes and including those values in the predictive model. Such a patent claim encompasses 27,405 different combinations of genes. Because this is such a large number, a patent examiner may object that the large number of combinations creates an undue search burden for the examiner. Consequently, the examiner issues a "restriction requirement" that causes the applicant to choose one combination of, in this example, four or more genes whose expression values are used in the claimed method. Claims to other combinations would then need to be pursued in separate patent applications, raising the cost of protection to unaffordable levels.

This creates a difficult position for the patent applicant. If any combinations of four or more of the thirty genes are provided adequate predictive power, a patent for a single combination of four provides essentially useless patent protection. If restriction among each combination is required, the applicant is forced to choose which of the many combinations it developed and disclosed it will protect. The combinations that it cannot afford to protect can be used by competitors to develop essentially equivalent tests that are not protected by the applicant's patents.

Strategies to Solve the Claims Problem

One potential solution to this problem may be revealed by additional statistical analysis of the identified genes. Such analysis may show that the thirty identified genes are not all equally predictive. Faced with a choice among many combinations, an applicant can select a subset of combinations that provide the most informative predictions for protection. Those

combinations left unprotected, if carefully selected, would only allow competitors to produce inferior products unlikely to effectively compete in the marketplace with the patented tests.

Another potential solution relies on identifying subgroups of genes whose expression levels co-vary, making them natural substitutes for each other. Thus, the thirty genes may segregate into five subgroups—the members of which provide essentially equivalent information in the predictive model. Such analysis also may show that not all of the subgroups are equally predictive when input into the model. In such an instance, it may not be necessary to claim the product as testing any four of the thirty identified genes. Instead, the claim can be drafted in the form of a combination of genes selected from these subgroups, using a common claim form known as a Markush group. A claim can be drafted as choosing five genes, one from each of the five subgroups. Additional analysis may show that if a gene from the most predictive subgroup, A, is chosen, expression of only two other subgroup genes is necessary for the model to be informative. Thus claims would also be drafted to choosing one of the genes in A and then two others from the various combinations available from the remaining four subgroups. Further analysis may show that even lacking a gene from the most predictive subgroup, using three or four genes from the remaining subgroups, B–E, yields an informative result. Therefore, claims should be drafted to combinations that use only genes from B–E. Those claims protect against competitors working around the ideal product using the most predictive genes.

The USPTO, however, has proposed new rules limiting the use of Markush groups. Under the new rules, 37 CFR 1.140 would be amended to require that all species encompassed by a claim that recites alternatives (*i.e.*,a Markush group claim) "meet at least one of the following two conditions: (i) share a substantial feature essential for a common utility, or (ii) are *prima facie* obvious over each other." Fed. Reg. 72(154):44997. The proposed method of diagnostics outlined above would meet even these new criteria. The grouping of claims would be done because they co-vary in response to a given criteria. As such they "share a substantial feature essential for a common utility." Also, because they co-vary, it could be argued that it is obvious to substitute one member of the group for the other.

Another option to address the undue search burden issue is for an applicant to request expedited examination from the USPTO. This route requires that the applicant provide a prior art search to the examiner. It allows for practitioners to develop search strategies for these new inventions and, by submitting those search results to the USPTO, to help the USPTO develop its search procedures for these inventions. The search strategy for such inventions can be divided into two broad categories—one in which the genes being tested have previously been associated with the disease or therapy for which the predictive model was developed, and another in which the genes have not been previously associated with that disease or therapy.

If the biomarkers have been previously associated with the disease or therapy, the most likely rejection from the USPTO would be that the invention is obvious. Obviousness rejections can be overcome by evidence of unexpected results. In the case of many predictive models, even if some or all of the biomarkers whose expression is being input into the model have been associated with that particular disease or therapy, the predictive model using multiple biomarkers is likely to be more powerful than predictions derived using any single biomarker. This gives a basis for arguing that the combination provides unexpected results, and therefore, is non-obvious.

In situations involving biomarkers that have not previously been associated with the disease or therapy, the search strategy is simpler. The search should be structured to determine whether any of the claimed biomarkers have been associated with the disease or therapy for which the predictive model has been developed. A favorable search result should permit the issuance of broad claims to predictive models using combinations of novel biomarkers for predictive modeling of the therapy or disease with which they have previously not been associated.

Although there certainly are challenges associated with protecting these types of personalized medicine inventions, experienced patent counsel can enhance the ability of personalized medicine companies to capture appropriate claim scope.

The Fallout From *Bilski*: Significant Change in What is Considered Patentable

BY ROBERT SACHS AND ROBERT HULSE

Bernard Bilski did not intend to be a poster child for business method inventions. He filed his patent application more than a year before the Federal Circuit decided *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), the case that inspired a blizzard of business method patent applications. Bilski claimed a method of hedging commodity transactions by performing "transactions" between commodity providers, commodity consumers, and market participants who have counter-risk positions to the consumers. Bilski's patent claims are directed to one class of "business methods," those pertaining to trading methods. The United States Patent and Trademark Office (USPTO) rejected Bilski's claims as part of a larger overall policy shift to limit the scope of patentable subject matter. It was therefore no surprise that Bilski appealed to the Federal Circuit. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), offered the Federal Circuit an opportunity to answer important questions about the scope of patentable subject matter. Superficially, the court did just that, setting

forth a so-called "machine-or-transformation" rule as the "definitive test" for deciding whether a "process" claim is patentable subject matter under 35 U.S.C. § 101. The court held that a process claim is patent eligible if either: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. Applying this test, the court held that Bilski's claim was not patentable subject matter because it did not transform "any article to a different state or thing." The court found that the claim "encompasses the exchange of only options, which are simply legal rights to purchase some commodity," and that " 'transactions' involving the exchange of these legal rights… do not involve the transformation of any physical object or substance, or an electronic signal representative of any physical object or substance." Because Bilski conceded that the claim was not tied to any particular machine, it failed the court's "machine-or-transformation" test. The court's decision leaves many significant questions unanswered, creates considerable uncertainty as to the validity of many existing patents, and may undermine the ability of inventors and businesses to protect advances in fields as diverse as database design, computer languages, cryptography, compression, financial engineering, signal processing, and potentially even medical and pharmaceutical research.

To arrive at its "machine-or-transformation" test, the court focused on the Supreme Court's decisions in *Gottschalk v. Benson*, 409 U.S. 63 (1972), *Diamond v. Diehr*, 450 U.S. 175, (1981), and *Parker v. Flook*, 437 U.S. 584 (1978). In *Gottschalk*, the Court summarized several earlier holdings by stating that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." The Court then expressly cautioned that a process claim "must operate to change articles or materials to a 'different state or thing.'" Nonetheless, the Federal Circuit latched onto the use of "the" and turned "the clue" to patent eligibility into a "definitive test" for it. But having sanctified the "machine-or-transformation" test as the sole inquiry, the court then left unanswered under what conditions would computer-implemented processes meet the "machine" prong of that test: "We leave to future cases the elaboration of the precise contours of machine implementation, as well as the answers to particular questions, such as whether or when recitation of a computer suffices to tie a process claim to a particular machine." Specifically, the court touched on, but did not resolve, whether the recitation of a "general purpose computer" would meet the "machine" prong of the test. The court similarly provided little guidance for the "transformation" branch of the test, on which its holding turned. The court stated that a transformation must be "central to the purpose of the claimed process" and that the "transformation must not constitute 'mere post-solution activity.'" But the court did not provide any test to determine whether a transformation was "central" or a "mere" post-solution activity, instead offering only inconsistent examples. On the one hand, the court suggested "that the electronic transformation of the data itself into a visual depiction" was sufficient. On the other hand, the court stated that storing data in a computer memory is not sufficient: "relying on *Flook*, we held that this step [recording bids] constituted insignificant extra-solution activity." To computer scientists, this is a distinction without a difference. The vast majority of innovative computer processes produce a result that may be displayed or stored for later use. An arbitrary distinction between these two alternative "post-solution activities" is not a technologically sound basis to define patentable subject matter.

The court's failure to address critical issues in the scope and application of the "machine-or-transformation" test, and its inconsistent treatment of equivalent situations, can only serve to disrupt settled expectations among patent holders, inventors, and the business community as a whole. Ostensibly, the court declined to exclude business methods *per se* from patentability. But, in a sweeping statement pregnant with unintended consequences, the court potentially crippled any attempts to protect business innovations by stating: "Purported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the test because they are not physical objects or substances, and they are not representative of physical objects or substances." The USPTO will likely treat this statement as a *per se* exclusion of business method claims. The Federal Circuit's statement that business risks cannot meet the transformation test may wipe out thousands of patents and applications pertaining to accounting, banking, credit management, and securities trading. Risk management is at the core of a wide range of patents dealing with credit card and telecommunications fraud, bankruptcy risk, currency exchange risk, loan default, and so forth. In addition, the court's "or other such abstractions" language is ambiguous enough to prompt the USPTO—or anyone seeking to invalidate a "software patent"—to characterize many software-implemented inventions as unpatentable. The court held that Bilski's claim did not "involve the transformation of any physical object or substance, or an electronic signal representative of any physical object or substance." Coupled together, these statements could be argued to exclude entire fields of computer science that focus on the design of algorithms independent of their application to specific data, such as cryptography, computer languages, compression, and database design, just to name a few. Finally, the exclusion of "public and private legal obligations" seems particularly shortsighted. All financial transactions and their constituent elements—price, asset value, bid, offer, exercise price, etc.—rest upon a framework that makes the transactions enforceable legal obligations. The court's statement here unnecessarily jeopardizes protection of legitimate innovation in fields such as ecommerce, financial engineering, and computational finance.

Patent licensors will likely be among the first casualties of *Bilski*. Many software patents, particularly those issued after *Alappat* and *State Street*, were written without paying homage to the court's talismanic "machine-or-transformation" test. Presumably, the claims of these patents

were crafted from the viewpoint of "one of ordinary skill in the art," who knows that software inventions are inherently executed by computers, that computer data is represented by electrical signals, and that the "transformation" of signals requires physical changes. Further, these inventors also know that any algorithm in software can be equivalently implemented in a "particular computer," and that when such form is used it is an engineering decision, not a philosophical one. Licensees may now take advantage of *Bilski* to renegotiate their licenses. Such a strategy was made possible by the Supreme Court's decision in *MedImmune, Inc. v. Genentech Inc.*, 549 U.S. 118 (2007), which allows a licensee to file a declaratory judgment action to challenge the validity of a licensed patent without breaching the license agreement. A less expensive option is reexamination. While invalidity under § 101 is not grounds for requesting reexamination, a licensee can request a reexamination on prior art grounds and then, if the reexamination is granted, the issued claims will almost certainly be reevaluated under the "machine-or-transformation" test. Either way, a licensee now has new leverage to obtain better terms from a licensor. Patent litigation defendants also benefit from *Bilski*. The majority of litigated software patents are not challenged under § 101 because historically the requirement was easily satisfied. Now that patents are subject to a rigid, formalistic test, invalidity under § 101 becomes a more powerful defense. With so little guidance from the court as to what constitutes a "particular computer," a district court judge could easily—and incorrectly—invalidate a patent claim for not reciting a "particular" type of computer by name, brand, or model number.

Patent applicants will undoubtedly experience difficulty as well. First, the USPTO is likely to use this test to reduce its backlog of pending applications. The USPTO currently rejects "computer program product" claims that do not include the magic words of "storage" or "tangible" to describe a computer-readable medium. Likewise, recent statements by the USPTO indicate that it will reject any computer-implemented process claim if the claim steps are not specifically recited as being performed by a computer. The easy solution for patent practitioners is simply to draft computer-implemented method claims with language limiting the operation of the method steps to a computer system. A more radical solution is to no longer use method claims for software inventions. Claims for "computer program products" can often be used instead and may avoid the "machine-or-transformation" test. Any activity that would infringe a software-implemented method claim would necessarily infringe a properly drafted computer-program claim. In the first decision applying *Bilski*, the Board of Patent Appeals and Interferences (BPAI), stated in *Ex parte Bo Li*, (Appeal No. 2008-1213), that such claims are "considered statutory at the USPTO." However, a downside to this strategy is a potential reduction in damages which an accused infringer might argue should be based on a reasonable royalty or lost profits from the sale of a computer program, rather than on the potentially more valuable methods implemented by the program. For business methods or other less clearly computer-based inventions, other strategies come into play. New claims that characterize the invention as a computer-based process will be necessary. Bilski's claims could have easily been drafted in this manner. *Bilski* appears to promote such an approach, even though it promotes form over substance. The primary stumbling block will be whether the patent specification describes the invention in this form, or only in terms of the more general business operations. If the latter is the case, then the claims must recite steps that transform some specific physical object, rather than a mere "legal obligation" or "business risk." Alternatively, where possible, the claims can be limited to operate on "signals" representative of "physical objects or substances." However, these strategies may still not be possible where the innovations concern financial transactions or affect legal obligations that do not have physical real world manifestations.

In the near term, *Bilski* may discourage some innovators in business operations and software from filing for patent protection, if only because the increased uncertainty as to whether they will obtain any protection makes the investment less attractive. Inventors with longer-term horizons and deeper pockets should continue to file for patent protection as they have been. While *Bilski* raises serious concerns for software and business innovators, overreaction would be a mistake. The case law may develop to interpret the "machine-or-transformation" test quite narrowly as simply a bar against pure mental-steps process claims. As long as a process claim is tied to a machine or transforms an article, it cannot be performed entirely in someone's head. This is a fair reading of *Bilski*, as the court itself stated that a process where all the claimed steps "may be performed entirely in the human mind is obviously not tied to any machine and does not transform any article into a different state or thing." If that is all the court means, then *Bilski* is a lengthy, but trivial decision. Moreover, the Supreme Court may ultimately overturn *Bilski*. Though the Court recently deemed it "improvident" to address the § 101 question in *Laboratory Corp. v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006), the issue is certainly ripe given the Federal Circuit's *en banc* opinion, with one concurring and three dissenting opinions. Indeed, the court itself seemed uncertain of its holding, suggesting that because of "future developments in technology and the sciences" the Supreme Court "may ultimately decide to alter or perhaps even set aside" the "machine-or-transformation" test. One can imagine the Supreme Court chastising the Federal Circuit for committing in *Bilski* the same sin in analyzing patentable subject matter as it did in analyzing obviousness in *Teleflex, Inc. v. KSR International Co.*, 119 Fed. Appx. 282 (Fed. Cir. 2005), *rev'd*, 550 U.S. 398 (2007).

Just as the Federal Circuit improperly applied a rigid test to determine obviousness in *KSR*, it now seeks to impose an inflexible "machine-or-transformation" test to determine whether a claim preempts the use of a fundamental principle. Nevertheless, in the short run, patent applications

for computer-based inventions may be more expensive particularly if the USPTO uses *Bilski* as an excuse to be aggressive in rejecting applications as being directed to unpatentable subject matter. Patent counsel may spend more time describing and claiming the invention as a "particular computer," characterizing the underlying data entities as "physical objects and substances," and focusing on the "transformation" of "signals" representing those entities. Patent applications for business innovations will also become more expensive. In addition to describing the invention using language familiar to those in the financial services industry, it will be necessary to provide a detailed description of a computer or other physical system with which the invention can be practiced. A proper description might require a description of appropriate algorithms, data structures and databases, programming interfaces, and other software engineering artifacts. A mere boilerplate recitation of a generic computer may no longer be sufficient.

It may take some time to determine whether *Bilski* has dramatically changed the contours of patentable subject matter, but early indications are that it has. If *Bilski* moved the pendulum too far in narrowing what is considered patentable subject matter, it may be years before that error is corrected.

Quick Updates

Ninth Circuit Applies Its Implied License Test to Software
In another case underscoring the undeniable wisdom of getting written contracts for the creation and use of intellectual property, the Ninth Circuit recently articulated the elements necessary to establish an implied license for computer software. *Asset Marketing Systems, Inc. v. Gagnon*, 542 F.3d 748 (9th Cir. 2008). In this case, the court affirmed the district court's holding—on summary judgment—that an independent contractor who developed custom software for his client granted an unlimited, nonexclusive, and irrevocable license to retain, use, and modify the software despite the absence of a written agreement to that effect.

Asset Marketing Systems (AMS) is a distributor of insurance products that provides sales and marketing support to insurance marketing entities. From May 1999 through September 2003, AMS retained Gagnon as an independent contractor to develop custom software and to provide certain IT services. Over the course of the relationship, AMS paid Gagnon roughly $250,000 to develop six custom-software programs.

The parties' Technical Services Agreement (TSA), which expired in 2001, specified Gagnon's fees and described Gagnon's contributions but was silent as to ownership and licensing. In June 2003, Gagnon offered AMS an Outside Vendor Agreement which would have granted AMS a nonexclusive license to the software. AMS never signed that agreement.

Given Gagnon's status as an independent contractor, and the lack of a written assignment of copyright ownership, there was no dispute that Gagnon continued to own the software. But did AMS have an implied license to use and modify the software? Under the Copyright Act, only exclusive licenses used to be in written form. 17 U.S.C. § 204. The Ninth Circuit had previously found implied licenses for movie footage and architectural drawings and reasoned that, regardless of the type of work involved, the relevant factors are the same. Citing its prior decisions and analogous cases from other circuits, the court set forth its three-element test: an author grants an implied license when (1) a person *requests* the creation of a work, (2) the author creates the requested work and *delivers* it to the requesting party, and (3) the author *intends* that the requesting party exercise certain rights in relation to the work.

There was no dispute that AMS had requested the custom software from Gagnon and that Gagnon delivered it, along with its corresponding source code. Therefore, the only remaining question was whether Gagnon intended that AMS retain and be authorized to modify the software. According to the court, "[t]he relevant intent is the licensor's objective intent at the time of the creation and delivery of the software as manifested by the parties' conduct."

The court found evidence of such intent in both the executed TSA and the proposed draft agreements exchanged by the parties prior to the termination of the relationship. Furthermore, in the opinion of the court, "it defies logic" that AMS would have paid such large amounts for custom software if it would be required to pay additional license fees to use and modify that software. Finally, because Gagnon imposed no caveats or limitations on AMS's use of the software, Gagnon's proposed licensing terms and the nature of the arrangement militated in favor of an implied, nonexclusive, and unlimited license to retain, use, and modify the software. Because AMS paid Gagnon for his work, the court found the consideration needed for the license to be irrevocable.

This decision is not groundbreaking, as courts have routinely enforced implied contractual provisions in other contexts, and the *Gagnon* test embodies what appears to be a fair and logical result. But even an unmodified, vanilla "standard" consulting agreement from a transactional IP attorney would have saved the parties a great deal of cost and uncertainty.

One further possible implication was not expressly addressed in *Gagnon* but must also be kept in mind. If the commissioning party really intends an *exclusive* license, it could be sorely disappointed. Under the Copyright Act, a court should in that situation be limited to finding either an implied *nonexclusive* license outside of the parties' real intentions—or no valid implied license on the ground that the intended *exclusive* implied license was unenforceable because it was not in writing. This apparent issue was ignored in one of the cases that the Ninth Circuit relied on, *Effects Assocs., Inc. v. Cohen,* 908 F.2d 555, 558 (9th Cir. 1990), and the Ninth Circuit ignored it here, too.

***Minsky v. Linden Research Inc. – Tiffany v. eBay* Revisited**
As reported in the *Fall Bulletin*, a U.S. District Court in New York held that eBay's general knowledge of counterfeit products sold through its site did not subject eBay to liability for contributory trademark infringement. *Tiffany (NJ) Inc. v.*

eBay, Inc., 576 F. Supp. 2d 463 (S.D.N.Y. 2008). The standard for contributory trademark liability was not whether eBay had general knowledge of infringing activities on its site, or whether it could reasonably anticipate such activities, but whether eBay continued to allow users to use its site when it knew or had reason to know such users were selling infringing products. Absent evidence of such specific knowledge, eBay could not be held liable for its users' sale of counterfeit products on its site. This decision, currently on appeal to the Second Circuit, seemed to create a safe harbor, shielding service providers from contributory liability for infringing content posted by users, provided the service providers responded when presented with specific notice of infringing content on their site. A new case before the Northern District of New York, *Minsky v. Linden Research Inc.*, No. 08-819 (N.D.N.Y. filed July 29, 2008), tests this so-called safe harbor. Can service providers be held contributorily liable for infringing content posted by users if the service providers do not remove infringing content once specifically informed of such content?

In *Minsky*, Richard Minsky, a self-proclaimed leader in the art field, joined Linden's Second Life ("SL") virtual world, opening an art gallery to resell works that he acquired from other SL residents. Minsky also adopted the trademark SLART for a magazine detailing the art world in both the real and virtual worlds. After adopting SLART, Minsky applied for a federal trademark registration for the mark. The examiner reviewing the application initially refused to register SLART because she believed the term to be descriptive of Minsky's art publications as it is a term commonly used to describe art within the SL virtual world. In response, Minsky argued that the term "slart" is different from "SL art," the latter being the common term used to describe art in the SL virtual world. On the other hand, according to Minsky, "slart" is slang for something altogether different and not descriptive of art in the SL virtual world. The examiner accepted Minsky's arguments, approving his application for publication. No one opposed Minsky's application, and it subsequently registered on March 18, 2008.

Also in March 2008, it came to Minsky's attention that another SL user, was using "SLART Garden" for an art gallery in the SL virtual world. Minsky, therefore, sent a demand letter to Linden requesting that it identify the user and remove such infringing material from the SL site. Linden, however, refused to identify the user and to remove any such material from its site. Linden also demanded that Minsky abandon his trademark registration for SLART because it contains Linden's "SL" mark in violation of its terms of use. As a result of Linden's refusal to act, Minsky sued Linden asserting that its failure to remove infringing content from its site after notification of such infringing materials amounts to contributory trademark infringement, among other things.

Shortly after filing its complaint, Minsky requested that the court grant a temporary restraining order (TRO) against Linden from enabling or condoning others to infringe his mark, hiding the identities of infringing users, harassing him, or claiming ownership of the mark. In granting the TRO on September 4, 2008, the court noted that Minsky's registered trademark for SLART is "sufficient to establish at least the existence of serious questions going to the merits of [his] claims" and that it is a comparatively minor hardship for Linden to remove the infringing uses from its site. Subsequently, the parties consented that the TRO be converted to a preliminary injunction.

Until a final decision issues on the merits of this case, service providers should consider removing infringing content after receiving a notice of infringement to shield themselves from potential contributory liability.

Consideration of Prior Art by Courts Does Not Bar Subsequent Consideration in Reexaminations

Recently, the Federal Circuit held that prior consideration of a reference during examination and a prior court judgment upholding the validity of a claim in view of the reference did not prevent a finding of a substantial new question of patentability for reexamination based upon the reference. *In re Swanson*, 540 F.3d 1368 (Fed. Cir. 2008).

Reexamination requests are granted by the United States Patent and Trademark Office (USPTO) upon a showing by a patentee or third party of "a substantial new question of patentability." 35 U.S.C. § 303. One rationale for this standard is to bar reconsideration of an argument already decided by the USPTO to prevent unjustified reexaminations and potential harassment of patentees. In *In re Portola Packaging*, 110 F.3d 786 (Fed. Cir. 1997), the court disallowed use of prior art during reexamination for a reference considered during prosecution, but in 2002 Congress amended the reexamination statute such that the existence of a substantial new question of patentability "is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office."

In re Swanson concerned U.S. Patent No. 5,073,484 ('484 patent), issued to Swanson, et al., which claims a method of quantitatively analyzing small amounts of biological fluids to detect presence of a particular substance. During prosecution, the USPTO initially rejected all claims as obvious under 35 U.S.C. § 103 in light of references including U.S. Patent No. 4,094,647 to Deutsch. The '484 patent ultimately was granted after claim amendments were made, and was assigned to Surmodics, Inc. who licensed it exclusively to Abbott Laboratories. On December 30, 1998, Abbott sued Syntron Bioresearch Inc. for infringement of the '484 patent, and Syntron countered that claims 22 and 23 were invalid in light of Deutsch. The jury upheld the validity of the '484 patent, and the Federal Circuit affirmed.

Syntron then filed a request for *ex parte* reexamination of the '484 patent. The USPTO granted the request and rejected claims 22-25 in view of references including Deutsch. Patentee Swanson appealed to the Board of Patent Appeals and Interferences (BPAI), arguing that the Deutsch reference, having been considered during examination of the '484 patent and again in litigation, could not raise a substantial new question of patentability. The BPAI found that previously

the Deutsch reference was considered only as a secondary reference in an obviousness rejection of a broader claim, and thus the question raised by the reexamination request had never been considered by the USPTO. The BPAI affirmed. Surmodics appealed to the Federal Circuit arguing that the consideration of Deutsch during the district court litigation precludes finding a new question of patentability for purposes of reexamination. The Federal Circuit disagreed.

The court made sense of this disparity because the standard of proof differs between the USPTO and patents in litigation. In reexamination, the standard of proof is preponderance of the evidence, whereas in civil litigation the standard of proof is clear and convincing evidence to invalidate a patent. During litigation, the court presumes a patent to be valid, whereas there is no such presumption of validity by the USPTO. In addition, the USPTO examines claims in view of prior art, giving the claims their broadest reasonable interpretation consistent with the specification, whereas courts construe the claims based on the patent, its prosecution history, and possibly other evidence. Thus, the court noted that consideration of an issue by a court is not equivalent to USPTO consideration of the issue and thus is not dispositive for a similar issue raised in reexamination.

California Supreme Court Rejects the "Narrow Restraint" Exception to Noncompetition Agreements

California has a long-standing public policy of open competition and employee mobility, which is embodied in California Business & Professions Code § 16600. Section 16600 provides that "every contract by which anyone is restrained from engaging in a lawful profession, trade or business of any kind is to that extent void." The limited exceptions include sale or dissolution of corporations, partnerships, and limited liability companies. In the late 1980s, the Ninth Circuit also adopted the "narrow restraint" doctrine. Under this judicially created exception, a noncompetition agreement would pass muster if it only restrained a person from engaging in a "small or limited" part of the trade or profession. For example, federal courts have upheld noncompetition agreements that restrict employees from working for an employer's direct competitor for a limited period of time or restrict employees from working for particular customers. Courts have also been willing to uphold noncompetition agreements to the extent "necessary to protect trade secrets." On August 7, 2008, the California Supreme Court in *Edwards v. Arthur Andersen LLP*, 44 Cal.4th 937 (Cal. 2008) unanimously rejected the "narrow restraint" exception, holding that § 16600 prohibits employee noncompetition agreements unless the agreements fall within a statutory exception.

Upon employment by Arthur Andersen, Raymond Edwards II was required to sign a noncompetition agreement. In this agreement, Edwards agreed that, for eighteen months after his release or resignation, he would not perform professional services (of the type he provided while at the firm) for any Arthur Andersen client on which he worked during the eighteen months prior to release or resignation. Moreover, for a period of twelve months after leaving the firm, Edwards agreed to refrain from soliciting business (of the type he provided while at the firm) from any client of the Arthur Andersen offices to which he was assigned during the eighteen months preceding his release or resignation. Notwithstanding these limitations, Edwards was expressly not prohibited from accepting employment with a client. After the Enron investigation, Arthur Andersen sold a portion of its practice to HSBC. HSBC offered Edwards employment, on the condition that Edwards execute a "Termination of Non-compete Agreement." In exchange, Arthur Andersen would release Edwards from the noncompetition agreement. Edwards refused to sign the HSBC agreement because he believed that it would require him to give up his right to indemnification, which he felt was important due to the government's investigation of Arthur Andersen. As a result, Arthur Andersen terminated Edwards' employment and HSBC withdrew its offer.

Edwards filed a complaint for intentional interference with prospective economic advantage, alleging that the noncompetition agreement violated § 16600. The California Supreme Court rejected Arthur Andersen's argument that the noncompetition agreement was enforceable under California law, concluding that mere limitations on an employee's ability to practice his or her profession, even if reasonably based, are prohibited. The court also declined Arthur Andersen's contention to adopt a narrow-restraint exception, stating that "[c]ontrary to Andersen's belief, however, California courts have not embraced the Ninth Circuit's narrow-restraint exception … and we are of the view that California courts 'have been clear in their expression that § 16600 represents a strong public policy of the state which should not be diluted by judicial fiat.'" The court further reasoned that if the legislature intended the statute to allow for reasonable restraints, it could have included that language, and thus leaves it to the legislature to adopt any additional exceptions.

As a result of this decision, employers should reexamine any contracts containing noncompetition provisions, including employment and nondisclosure agreements, to ensure the provisions are covered by a statutory exception. While it is important to note that the court's ruling specifically does not address the judicially created trade-secret exception to § 16600 (something Edwards did not dispute), the court has nonetheless taken a strong stance against nonstatutory exceptions. As such, it is unclear whether noncompetition provisions will still be upheld to the extent "necessary to protect trade secrets."

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