

INTELLECTUAL PROPERTY BULLETIN

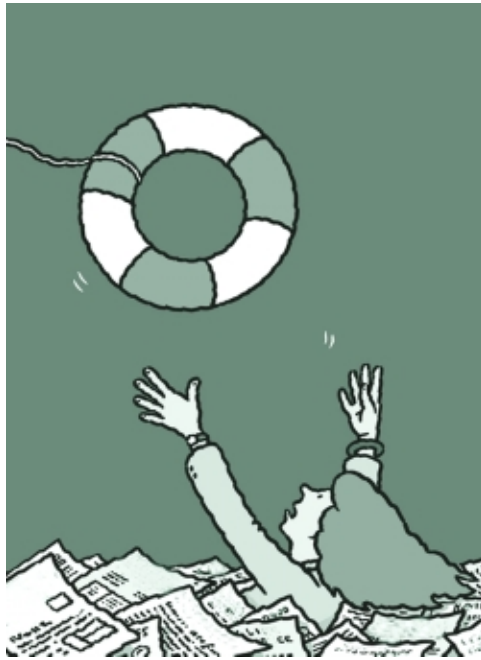
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Innovation in Biotechnology Drowning in a Safe Harbor?

by Dianne Rees, Ph. D.

As Judge Giles Rich noted in *In Re Bergy*, “an inventor must walk through three doors to obtain a patent, the doors of utility, enablement, and non-obviousness.” However, for inventors in the biotechnology industry, it often seems that there is another door to walk through, the door of politics. Particularly for those trying to obtain “gene patents,” seemingly stricter standards of enablement and utility, while not codified anywhere in the patent statutes, can delay patent issuance for years, making it difficult to bring commercially viable products to market. Nevertheless, important gene patents have issued, providing patent protection for diagnostic and therapeutic applications of genomic research in cancer, AIDS, and a variety of other previously intractable diseases.



Proposed Legislation

In March, the “Genomic Research and Diagnostic Accessibility Act of 2002” (H.R. 3967, hereafter referred to as ‘the bill’) was introduced in Congress. Starting from the premise that “patenting of human genes is both inhibiting important biomedical research and interfering with patient care,” the bill proposes a safe harbor for individuals who use patented genetic sequence information for “non-commercial research purposes.”

Under the proposed legislation, a researcher would compensate a patentee only when “commercially viable products” were produced. The bill further proposes an exemption from infringement remedies for genetic diagnostic testing, regardless of whether or not the testing is done for commercial purposes. Finally, the bill proposes making genetic sequence information public no later than thirty days after filing a

patent application. Unlike safe harbors already in place for medical treatment and research done to obtain FDA approval that rely on patented products, the bill as it stands is sweeping in its effects.

If passed, the legislation has the ability to prevent companies from licensing rights to genetic-based diagnostic assays and to decrease royalty rates from gene patents significantly. Furthermore, by forcing inventors to publish sequence data in advance of the eighteen-month grace period provided before publication of a patent application, the bill denies an inventor any significant grace period in which to determine whether the value of the invention could be better preserved as a trade secret.

Proponents vs. Opponents

The bill has polarized two groups, both of which vehemently disagree on the role patent protection plays in fostering inno-

vation in biotechnology. Proponents of the bill argue that gene patents prevent medical practitioners from implementing innovative and potentially life-saving tests through expensive royalty rates. Additionally, proponents fear that gene patents increase costs for biomedical research by necessitating multiple license agreements. Among examples that have been cited for the industry, are one company’s greater than \$2,500 diagnostic test for the detection of a breast cancer gene.

However, critics of the bill take the position that companies attempting to commercialize their products must have a way of recouping investment costs. This is particularly relevant for the biotechnology industry, which, like the pharmaceutical industry, spends millions of dollars to bring products to market. Thus, given the large development costs associated with research and development, critics of the bill point out that commercial, and even academic institutions, involved in biotechnology have to account for their bottom line. In this regard, although genetic research is done to advance science, it is in fact a business like any other. *(continued on page 3)*

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Patent Fees Gone Awry?

U.S. Patent Office Proposes Radical New Fee Structure

by Steven M. Jensen

In a significant departure from current practices, a new fee structure proposed by the United States Patent and Trademark Office (USPTO), if instituted, would result in sweeping changes to the manner in which patent fees are calculated. The result would be hefty fee increases to be borne by patent applicants. The fee proposals are set forth in proposed fee legislation included as part of “The 21st Century Strategic Plan” which was published on July 5, 2002 on the USPTO Web site, www.uspto.gov. The fee increases have been designed to generate fee income at a level sufficient to meet the President’s budget. Presently, the USPTO is not permitted to retain all of its fee income. A portion of that income is diverted to pay for other government programs.

Under current law, fee adjustments are governed by 35 U.S.C. 41(f), and most fees are adjusted annually to account for inflation. New fees typically include modest increases, e.g. in the basic filing fee and the issue fee. The purpose of these fees is to better approximate the USPTO’s costs in providing examination functions and to maintain the fees commensurate with inflation.

However, the USPTO has proposed a host of new fees and fee increases that far exceed the yearly inflation-based adjustment of patent fees. The American Intellectual Property Law Association (AIPLA) issued a statement on July 18, 2002 opposing the new fees (“AIPLA statement,” see www.aipla.org). It is the AIPLA’s position that these new fees are excessive because they have been arbitrarily set to amass a sum of \$1.527 billion, of which \$162 million is to be diverted to other government programs. The result constitutes a “stealth tax increase” on inventors, precluding some independent inventors and start-up companies from using the patent system and forcing many universities and corporations to reevaluate their patent portfolios.

The proposed fee changes include the

following: separate filing and examination fees, significant incremental increases for independent claims beyond the 3rd independent claim and for total claims beyond the 20th claim, a considerable increase in the cost of filing a brief in support of an appeal, and most notably, new surcharges for filing an application that contains one or more claims not patentably distinct from one or more claims in another pending application or patent.

The fee increases have been designed to generate fee income at a level sufficient to meet the President’s budget. Presently, the USPTO is not permitted to retain all of its fee income. A portion of that income is diverted to pay for other government programs.

According to the USPTO, separate filing and examination fees will enable applicants “to evaluate the commercial value of their invention” before paying a higher fee to cover the cost of patent examination. Unfortunately, while the proposed filing fee would be set at \$300, the proposed examination fee is \$1250 — approximately double the present cost of filing and examination — indeed forcing many applicants to reevaluate their inventions!

Proposed fees prescribing steeply escalating charges for independent claims beyond the 3rd independent claim and total claims beyond the 20th claim are aimed at discouraging applicants from needlessly filing large claim sets and lengthy specifications. Critics such as the AIPLA have proposed an alternative system employing charges for excess claims after the 7th in-

dependent claim and/or the 41st total claim, to avoid penalizing most applicants.

One of the most controversial proposed fee increases is the new “transitional” fees applicable if an application is filed or amended to contain one or more claims “that are not patentably distinct from [one] or more claims” of another pending application or patent. At the first occurrence of such an application, a fee of \$10,680 would be assessed. If two such pending application(s) or patent(s) exist, the fee would rise to \$13,350. As pointed out in the AIPLA statement, such measures would create enormous burdens on high volume patent filers, and may adversely impact many applicants who are not actually trying to abuse the system.

Other proposed fee increases include a more than five-fold increase in the cost of filing a brief in support of an appeal (over fee levels effective October 1, 2002), and a 25 percent increase in the patent issue fee.

Fortunately, at the present time, the USPTO’s fee proposals have not seen the light of day. As the government continues to raid USPTO coffers to support unrelated government activities, the new fee proposals nurture that practice and provide even fewer safeguards from future fee increases by removing the protective cap of inflation. It remains to be seen whether such proposals will be enacted in any form, but the inventive community should be wary of the government’s continued misuse of the USPTO for fundraising purposes. ■



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Innovation

(continued from page 1)

Balancing Patents and the "Public Good"

Safe harbors and compulsory licensing schemes are certainly within the purview of Congress to promote the progress of science and the useful arts since, ultimately, the purpose of the patent system is to protect the public good. Still, this is a balancing act that should be weighed very carefully by the legislature against the innovation-promoting effects of patents. Despite public outcry regarding the plun-

dering of genetic information by the private sector, broad patents reaching upstream development efforts do not *a priori* have to hamper downstream research and there is no evidence that collectively such patents do so. Perhaps the best example of a broad patent covering an upstream research tool is the one covering recombinant DNA, which represents one of the foundations of molecular biology. Through inexpensive, non-exclusive licenses, the tremendous volume of sales made the patent extremely profitable, demonstrating that a product of genetic research, which is itself a research tool, can be both profitable and accessible.

There is a companion bill, (H.R. 3966) that proposes to initiate a government study to obtain empirical evidence on the relationship between innovation and patent rights for the output of genetic research. While patent practitioners necessarily believe that patents promote the public good, all parties should agree that decisions made in the name of the public good should be informed ones. ■



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INTELLECTUAL PROPERTY PRACTICE GROUP HIGHLIGHTS

■ In July **Dave Conlin** presented a review of "Domestic and International Protection of Pharmaceutical and Biotechnology," in a course at the Massachusetts Continuing Legal Education, Inc. (MCLE).

■ In July **Howard Gitten** presented a lecture at the Florida Atlantic University entitled "Intellectual Property

Issues in eCommerce: Potholes on the Information Super Highway."

■ In August **Peter Corless** was an invited guest speaker at the American Chemical Society's 224th Annual Meeting. His topic was "Patent Protection for New Chemical Technologies." **Dianne Rees** and **Robert Buchanan** also attended the event.

■ In August **John Ottaviani** participated in a panel discussion titled, "Reality Bytes: E-Contracting in Today's Environment" at the American Bar Association's Annual Meeting in Washington, D.C. John discussed "Implied Assent to Terms in Electronic Form Agreements."

USPTO UPDATE

USPTO To Expedite Issuance Of Certain Certificates Of Correction

The USPTO has announced that it is now expediting the granting of Certificates of Correction where the request is accompanied by evidence that the error to be corrected was on the part of the USPTO.

The purpose of the change is to reduce the processing time for Certificates of Correction. Requests for Certificates of Correction will be expedited if the error was the fault of USPTO; the error is clearly disclosed in the records of the USPTO; and the requestor submits documentation that the error was on the part of the USPTO.

Issuance of Certificates of Correction continues to be discretionary. Minor typographical errors and other minor errors that are readily apparent may not warrant a Certificate of Correction. Such errors may be noted in a letter to the Patent Office. The letter will be included in the file so that the clarification or correction is part of the record without the USPTO's issuing an official Certificate of Correction.

"Hard Copy" Of Patent Official Gazette Discontinued

The USPTO will discontinue paper publication of the *Official Gazette of the United States Patent and Trademark Office - Patents* after the September 24, 2002 issue. The full patent *Official Gazette* is and will continue

to be available on CD-ROM from the USPTO for \$15/issue or \$30/year and may be ordered from the USPTO by calling (703) 308-4357. The most recent six issues may also be viewed at the USPTO Web site (www.uspto.gov).

USPTO Office of Congressional Relations Established

The USPTO has established a new Office of Congressional Relations, to be headed by Christopher Katopis.

The aim of the new office is to enable the USPTO to communicate effectively with Congress on informational and legislative matters related to intellectual property.

*Compiled by Brenda S. Campbell,
a Paralegal in our Boston office*

Treasure Trove in a File Cabinet?

by Howard M. Gitten

Your corporation is facing a cash crunch, or worse, is headed toward bankruptcy. There are many ways to raise cash such as selling company stock, selling hard assets such as the building or equipment, or borrowing cash. However, as a company faces bankruptcy, the value of its stock is greatly diminished, hard assets may be needed to reorganize, offers for assets may be at fire sale prices, and lenders loathe to lend to a financially distressed entity. However, there is one other source of income that most companies do not explore to the fullest potential: the intangible assets of intellectual property represented by the patent, trademark and copyright certificates locked away in filing cabinets.

Intellectual property can be utilized to unlock cash. Like real and personal property, intellectual property can be licensed, serve as collateral for loans or sold outright. The primary value of a distressed company may in fact be its intellectual property. Unlike hard assets, intellectual property retains more of its current value. Where there may be a glut of machinery or office space on the market, trademarks, copyrights and patents, by definition, represent unique assets.

How intellectual property is utilized to unlock cash should be well thought out because each exploitation scheme and each type of intellectual property brings with it advantages as well as problems. For example, patents, trademarks and/or copyright certificates may serve as collateral for a loan. However, once collateralized, the intellectual property will be difficult to sell or even to license without the permission of the lender whose loan is secured by such collateral. Even licensing may backfire, in that the only willing licensee may be a competitor, and, although it provides a ready revenue stream, it may be coming from somebody who directly competes with your company. Outright sale of intellectual property suffers from the disadvantage that once sold, it usually cannot be regained at a later date, and therefore a valuable asset may be lost forever.

All Things Considered: Due Diligence

When business exigencies necessitate a transfer of intellectual property rights, the owner (transferor) and the buyer (transferee) each need to make an informed decision

about the transaction. Indeed, the transferor should conduct a due diligence inquiry to confirm that, in fact, it is the true owner of the intellectual property so that the transferor can so warrant. Such a due diligence inquiry can be accomplished by inspecting the chain of title to the intellectual property. A transferor's failure to perform appropriate due diligence may result in pecuniary liability for breach of warranty.



On the other hand, the transferee must ensure that it is getting the rights bargained for. Accordingly, prior to any transaction, the transferee should conduct a due diligence inquiry of its own to ascertain whether the party they are dealing with actually can transfer the rights they are offering to transfer; whether any existing license of the rights exists; and whether there are any liens against the intellectual property. Typically, this inquiry can be done by examining the internal documents of the transferor, and by searching United States Patent and Trademark Office, state, and county records.

Sum Of The Parts Greater Than The Whole

Trademarks are often registered across a number of classes of goods. Thus, a trademark is divisible and could be partitioned among different transferees for use of the mark in a specific respective class. For example, a brand name which is used for clothing and toys may have greater value if sold

to a clothing manufacturer for use with clothing and to a toy manufacturer for use with toys, than if sold to just one or the other. It may even be possible to transfer the use of the mark for specific goods within the same class such as the same mark used in connection with different toys sold by different sources. However, there is a caveat as some licensing or sales schemes like these can backfire and dilute or destroy the value of the mark. Accordingly, a mechanism such as a cross-license may be required to maintain the strength of the mark, and the actual licensing scheme should be well thought out to prevent any diminution in the mark's value.

Trademarks and patents also are territorial in nature, requiring separate filings in all nations of the world. For example, if one were selling goods in Europe and the United States, one would need both a European Union and a U.S. trademark or patent to protect the intellectual property in the respective countries. Therefore, these rights could be divided on a geographic basis to one or more distinct entities. Again, care must be given to make sure that such a geographic division does not lead to future conflict among the different parties, as any of the parties try to expand their territory. Therefore, the geographical areas should be divided with a view towards future expansion and competition between rights owners and/or licensees.

Copyrights also are divisible. For example, the book rights to a copyrighted work may be sold to a book publisher and the movie rights may be sold to a movie studio, thereby maximizing the value to the copyright owner.

In light of recent economic events, both intellectual property right holders and intellectual property right seekers have recognized that much of the untapped value of a company experiencing a cash shortage may lie in its intellectual property. Great care, however, should be taken when devising a scheme for exploiting the value of that intellectual property in order to avoid unnecessarily diminishing the value of the intellectual property. ■



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FEDERAL CIRCUIT UPDATE

by Kathleen B. Carr and
Renée M. Anckner

Reference To Public Deposits of Claimed Materials in Patent Specification Satisfies Written Description Requirement of 35 U.S.C. § 112

Enzo Biochem, Inc. v. Gen-Probe, Inc.,
63 U.S.P.Q. 2d 1609 (Fed. Cir. 2002).

Reversing its own panel decision, the Federal Circuit on reversing, decided that references in a plaintiff's patent specification to deposits of a nucleotide sequence adequately describes that sequence for purposes of 35 U.S.C. § 112's written description requirement. Referencing § 112's specific language, the Court considered that "any person skilled in the art" could read the accession numbers in the specification and obtain the claimed sequences from the public depository, and accordingly determined that references to the deposit of the sequence adequately described the sequence.

Inventor's Preferences in Carrying out Claimed Invention Need Not be Disclosed Absent Material Effect on Invention

Bayer AG v. Schein Pharmaceuticals, Inc.,
2002 WL 1830197 (Fed. Cir. 2002).

A "best mode" violation under 35 U.S.C. § 112 occurs only when the inventor has failed to disclose the preferred embodiment of his invention or when the inventor fails to disclose a preference that *materially* affects the aspects of either making or using the claimed invention. Recognizing that the best mode test is subjective, the Federal Circuit held that absolute disclosure of every preference is not necessary – as long as it is not material. Rather, as long as the inventor's preference in making the claimed material was unclaimed subject matter, the best mode requirement of § 112 was satisfied.

Prosecution History Estoppel Applies to All Patents Issuing from Same Application

Semitool, Inc. v. Novellus Sys., Inc.,
2002 W.L. 1628368 (Fed. Cir. 2002).

The prosecution history regarding a claim limitation in any issued patent applies with equal force to subsequently issued patents containing the same claim limitation, the Federal Circuit recently held. Thus, in interpreting claims, the prosecution history

will limit the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution of an antecedent patent application.

On-Sale Bar Analysis Requires Investigation of All of the Circumstances Regarding the Sales at Issue

Allen Eng'g Corp. v. Bartell Indus., Inc.,
249 F.3d 1336 (Fed. Cir. 2002).

A district court's conclusion that sales of a device did not trigger an on-sale bar to issuance of a patent was reversible error according to the Federal Circuit. The district court's decision was based on the fact that the device was an experimental prototype that never reached completion based on its findings that customers received a guarantee of repair or replacement and it was necessary to test the devices on jobsites. Although assessment of the commercial versus experimental significance was important, the Court found those findings insufficient to determine whether sale of the device qualified as a commercial offer for sale. The Federal Circuit remanded the case for further findings including an investigation of all of the circumstances regarding the sales in question to determine whether they were "commercial sales not incidental to the primary purpose of experimentation."

Means-Plus-Function Limitations Require Link Between Structure and Claimed Functions

Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 296 F.3d 1106 (Fed. Cir. 2002).

Where patent claim language contains "means-plus-function" limitations, corresponding structures in the specification must include all structure that actually performs the recited function. Cardiac Pacemaker's failure to disclose structure corresponding to the claimed function of its "third monitoring means" limitation caused the claim, and any other claims depending on it, to fail for indefiniteness. Though the means-plus-function limitation need not "include all things necessary to enable the claimed invention to work," the claimant must expressly establish the link between the claimed functions through the corresponding structure. According to the Federal Circuit, this is so despite presumptions of validity usually granted when a party complies generally with the definiteness requirements of 35 U.S.C. § 112, second paragraph.

Well-Pleaded Complaint Rule Prevents Federal Circuit from Hearing Patent Infringement Counterclaims

Telcom Technical Services, Inc. v. Siemens Alm. Commun. Inc.,
295 F.3d 1249 (Fed. Cir. 2002).

Raising the issue of subject matter jurisdiction *sua sponte* the Federal Circuit recently held that the Supreme Court's decision in *Holmes Group Inc. v. Vornado Air Circulation Sys. Inc.*, (122 S. CT 1889, (2002,)) prevented the Court from hearing the merits of the plaintiff's claim. The Federal Circuit quoted the *Holmes* Court's observation that the well-pleaded complaint rule "endures no necromancy," and determined that it has no jurisdiction over counterclaims for patent infringement in an anti-trust case. Citing the *Holmes* reasoning, the Federal Circuit stated that it would not vest the statutory phrase "arising under" with a meaning that encompasses appellate jurisdiction based on a patent infringement counterclaim.

Reduction to Practice Requires Proof of Successful Testing In Patent Interference Dispute

Manning v. Paradis,
63 U.S.P.Q. 2d 1681 (Fed. Cir. 2002).

When testing is required to show that an invention has actually been reduced to practice, only successful testing determines that it serves its intended purpose. In finding that the junior party's patent claim for "treating a subject in cardiac arrest" was not successful prior to the filing date of a senior party competing inventor, the Federal Circuit held that the junior party was not entitled to claim the subject matter. The Federal Circuit noted that reduction to practice must be shown by a preponderance of the evidence during interference disputes, and found that requirement unsatisfied because neither the junior party's published statements nor his affidavits stated that his invention delivered an effective amount of oxygen to treat cardiac arrests prior to filing.



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