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In This Issue

Supreme Court Holds Patent Claims Unpatentable

The United States Supreme Court ruled in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (Case No. 10-1150), that claims for measuring patient drug levels and correlating those levels with a need to adjust dosage, is unpatentable subject matter tantamount to an attempt to patent a law of nature.

Claims from Prometheus's U.S. Patent No. 6,355,623, one of the patents-in-suit, required administering the drug to a subject, determining the blood level of the drug in the subject, and then establishing a correlation without actually requiring an adjustment to the dosage.

The district court had granted summary judgment of invalidity, holding that the Prometheus patents at-issue effectively claim natural laws or natural phenomena, and as such were not patentable. On appeal, the Federal Circuit reversed the district court, stating that the claimed processes specify the steps of: (1) "administering a [thiopurine] drug" to a patient; and (2) "determining the [resulting metabolite] level." The Federal Circuit explained that these steps involve the transformation of the human body or of blood taken from the body, thus, satisfying the "machine or transformation test," and therefore constituted patentable subject matter under §101.

The Supreme Court noted that the patent claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. However, the Supreme Court held that the process claims at-issue were not patentable because the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. The Supreme Court further noted that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."

Federal Circuit Affirms Order Compelling Arbitration

In *Promega Corp v. Life Tech* (Case No. 2011-1263), the Federal Circuit affirmed the district court's order compelling arbitration.

In 1996, Research Genetics entered into a license agreement with Promega. The Agreement required Promega to pay Research Genetics an initial fee and running royalties. Under the Agreement, Promega had the right to sublicense the licensed patents. The Agreement included an arbitration clause which provided that "[a]ll controversies or disputes arising out of or relating to this Agreement, or relating to the breach thereof, shall be resolved by arbitration."

Research Genetics through several mergers became Life Technologies. Life Technologies notified Promega that it had been paying less than it was required to pay under the Agreement. After negotiations between the parties failed to resolve the issue, Life Technologies sought arbitration. Rather than submit to arbitration, Promega filed suit, which the district court dismissed in view of the arbitration clause.

The Federal Circuit stated that the district court's determination that the parties have contractually bound themselves to arbitrate is reviewed *de novo*, and its factual findings for clear error. The Federal Circuit further noted that the Federal Arbitration Act ("FAA") mandates enforcement of valid, written arbitration provisions.

Promega raised several arguments as to why it should not be compelled to arbitrate: (1) the arbitration clause at-issue was permissive rather than mandatory; (2) the real party-in-interest was not a party; (3) the arbitration clause does not encompass the dispute over Promega's alleged failure to pay royalties because the parties intended arbitration to apply only to small disputes between non-competitors; (4) compelling arbitration would be unjust and unfair because the agreed upon arbitration procedures did not permit third-party discovery which would be needed to resolve the dispute; (5) arbitration is inappropriate because Promega's claims of patent infringement against Life Technologies and AB remain pending in the district court; and, (6) various equitable defenses to arbitration; namely, laches, waiver, unjust enrichment and estoppel.

The Federal Circuit found none of Promega's arguments convincing and noted that the FAA establishes that, as a matter of federal law, "any doubts concerning the scope of arbitrable issues should be resolved in favor of arbitration, whether the problem at hand is the construction of the contract language itself or an allegation of waiver, delay, or a like defense to arbitrability." Accordingly, the district court's order compelling arbitration was affirmed.

Federal Circuit Affirms Certain Means-Plus-Function Language Was Indefinite

In *Ergo Licensing v. Carefusion 303* (Case No. 2011-1229), the Federal Circuit affirmed the district court's determination that certain means-plus-function claim terms were indefinite.

The patent-in-suit described an infusion system used to meter and simultaneously delivers fluids from multiple fluid sources into a patient's body. The claims recited a "programmable control means" and a "control means." The only structure disclosed in the specification corresponding to these means was a "control device."

Ergo argued that "control device" is synonymous with computer, and that one skilled in the art would understand a control device to be a general-purpose computer. The Federal Circuit disagreed, stating that the specification fails to disclose a corresponding algorithm, and that computer-implemented means-plus-function terms are limited to the algorithms disclosed in the specification. The Federal Circuit stated that there was no algorithm described for the function of "controlling the adjusting means," and that the specification merely provides functional language and did not contain any step-by-step process for controlling the adjusting means. As a result, the Federal Circuit held that the district court correctly determined that the "control means" terms were indefinite for failure to disclose corresponding structure.

Federal Circuit Reverses And Remands Rejection To The PTO

In *In re Staats* (Case No. 2010-1443), the Federal Circuit reversed and remanded a rejection by the Board of Patent Appeals and Interferences ("Board"). The Board had rejected claims of a reissue application as being broadening beyond the two-year time limit set forth in 35 USC § 251.

Section 251 provides, in pertinent part, a two-year time limit to broaden the scope of claims in a reissue application:

> No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

Staats timely filed a first broadening reissue application relating to the first embodiment described in the specification. While the first broadening reissue

application was pending, Staats filed a second broadening reissue application as a continuation of the first broadening reissue application. This application, however, was filed outside the original two-year period. Similar to the first broadening reissue application, the second broadening reissue application only addressed errors related to the first embodiment.

Subsequently, while the second broadening reissue application was pending, and well outside of the two-year period, Staats filed a third broadening reissue as a continuation of the second broadening reissue application. During prosecution of the third broadening reissue application, Staat added broadened claims directed toward the second embodiment that was described in the specification, but which embodiment had not been previously claimed.

The patent examiner rejected the third reissue application under Section 251 finding that the new broadened claims were "not related in any way to what was covered in the original broadening reissue."

The Federal Circuit, following *In re Doll*, 419 F.2d 925 (C.C.P.A. 1970), stated that an applicant is "not barred from making further broadening changes" after the two-year period in the course of the prosecution of the reissue application, and that subsequently filed continuation applications relate back to a previously filed application under Section 120 if each successive continuation application was filed while its parent application was still pending. As such, the Federal Circuit held that the time limit for filing a broadening reissue application is satisfied provided the first broadening reissue application has been timely filed within the two-year statutory time period, so that the applicant can present new, broadened claims.

Greenblum & Bernstein Hosting Biosimilars Workshop

Greenblum & Bernstein is hosting a pre-conference workshop titled: Biosimilars In America: IP Strategy and Due Diligence at the 10th EGA International Symposium on Biosimilar Medicines that will take place April 19-20, 2012 in London.

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