Life Sciences News

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LAW OF LIFE

BRADLEY ARANT BOULT CUMMINGS

Bradley Arant Boult Cummings Appellate Win Ranks No. 1 on "Drug and Device Law" Blog's Top 10 for 2009

The popular blog "Drug and Device Law," which reports on significant "topics that arise in the defense of pharmaceutical and medical device product liability litigation," has chosen the Alabama Supreme Court's decision in AstraZeneca LP v. State of Alabama, __ So. 3d ___, 2009 WL 3335904 (Ala. Oct. 16, 2009), as its most significant case of the year. In its decision the Court reversed fraud judgments totaling some $275 million against pharmaceutical manufacturers AstraZeneca, GlaxoSmithKline, and Novartis, and rendered judgment for all three defendants. Bradley Arant Boult Cummings lawyers Kevin Newsom, Marc James Ayers, and Andrew Brasher represented GlaxoSmithKline in the case, alongside lawyers from Covington & Burling, King & Spalding, and Dechert. For Drug and Device Law's full report, visit http://druganddevicelaw.blogspot.com/2009/12/top-ten-best-prescription-drugmedical.html.

Green Pilot Program

One of the greatest limitations of the current U.S. patenting system is the long period of time required for approval of a patent application. Current statistics show that the average time from the day an application is filed until a patent is finally issued is 32.2 months, with over 1.2 million patent applications still pending. As an applicant for a patent gains no protection for its invention until the applied-for patent actually issues, this time lag can have serious consequences for the commercial profitability of an invention.

The U.S. Patent and Trademark Office ("Patent Office") offers ways in which an applicant can expedite processing of its patent application. However, up until quite recently, requesting that an application be granted such "special status" required that the applicant provide an "examination support document" except in cases in which an inventor is over 65 years of age or is seriously ill. Because the examination support document is expensive and burdensome to provide, applicants rarely bother to submit them.

The Patent Office recently launched a pilot program to allow expedited processing of patent applications for certain global-warming abatement technologies without the requirement of the examination support document. Such technologies are defined as involving renewable energy sources, energy efficiency, or the reduction of greenhouse gas emissions. The program is currently limited to the first 3000 requests, and is only available for patent applications that were filed prior to Tuesday, December 8, 2009. The program will exist in this form for a year, at which point its value will be considered; at that time it may be cancelled, made permanent, or implemented in some modified form.

Anyone with a pending patent for any of the technologies mentioned above should consider taking advantage of this program. A modest publication fee must be paid ($300). The application must have a certain maximum number of claims (20 total and 3 independent claims); an applicant may amend its application to reduce the number of claims if necessary. The application must be made available for publication on an accelerated

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basis; if an applicant wishes that its application remain private, then this program might not be suitable. Only one "distinct invention" will be considered. For example, if patent application claims both a recycling process and the recycled product, then the applicant must choose one or the other for examination. The technology must involve at least one of the following: renewable energy sources, energy efficiency, or the reduction of greenhouse gas emissions.

The program involves other minor requirements. If you own a pending patent application that is directed to one of the listed technologies, we would be happy to discuss the value of participating in this pilot program for your particular case.

Qualifying Therapeutic Discovery Project Credit

The Senate "health care" bill may provide tax relief for "small" companies in the therapeutics. The Qualifying Therapeutic Discovery Project Credit is included in Section 9023 of the Senate's health reform legislation, the "Patient Protection and Affordable Care Act of 2009." The amendment, if approved, would set aside $1,000,000,000 for a credit that would allow qualifying companies (those with two hundred and fifty (250) employees or less) to claim fifty percent (50%) of investments made in 2009 and 2010 in certain qualified therapeutic discovery projects.

The proposed amendment would set up an approval process pursuant to which the Treasury Department would handle certification of a company's investments made in qualified therapeutic discovery projects. In determining qualifying projects under the program, investments must show reasonable potential to result in new therapies to treat areas of unmet medical need or to prevent, detect or treat acute diseases and conditions, reduce long-term health costs in the United States, and advance United States competitiveness in the fields of life, biological, and medical sciences and create and sustain high-quality, high-paying jobs in the United States. Please contact your local Representative or Senator if you have any questions or if you wish to support the Qualifying Therapeutic Discovery Project Credit.

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