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BIOTECH LEGAL BULLETIN

SCIENCE • TECHNOLOGY
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IP NEWS

TiVo v. EchoStar: Parties Settle; Leave Behind New Infringement Contempt Standard

While the dispute over TiVo's patents for digital video-recording devices has finally settled for $500 million after seven years, the litigation generated an *en banc* Federal Circuit Court of Appeals decision that clarified the standards governing contempt proceedings in patent infringement cases. ***TiVo Inc. v. EchoStar Corp.*, No. 2009-1374 (Fed. Cir., decided April 20, 2011)**.

The litigation began in 2004, when TiVo sued EchoStar alleging infringement of hardware and software claims of TiVo's '389 patent. A jury awarded TiVo $74 million in lost profits and reasonable royalties, and when it entered judgment on the verdict, a district court also issued a permanent injunction against EchoStar, ordering the company to cease selling products that the jury found had infringed TiVo's patent. The Federal Circuit, affirming in part and reversing in part, upheld the determination that EchoStar infringed the software claims of the '389 patent. Thereafter, the injunction became effective on April 18, 2008.

TiVo then asked the district court to find EchoStar in contempt of the permanent injunction. The court evaluated the modifications EchoStar had made to its infringing devices and "found by clear and convincing evidence that the modified DVR software was not more than colorably different from the infringing software, and did continue to infringe the software claims." The court found EchoStar in contempt, imposed sanctions of nearly $90 million and awarded damages to TiVo for continuing infringement.

On appeal, EchoStar argued that "it was improper for the district court to decide issues relating to continuing infringement by EchoStar's modified software in a summary contempt proceeding, as opposed to a new trial on the merits, and to find EchoStar in contempt of the infringement portion of the injunction." The company also argued that it had engaged in a "Herculean"

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effort to redesign the DVR software and, "by obtaining opinions of counsel, it made a good faith effort to ensure that its devices would no longer infringe the software claims of TiVo's patent."

As to the latter issue, the court determined that, "a defendant's diligence and good faith efforts are not a defense to contempt," and thus, the district court here "was correct in rejecting EchoStar's good faith arguments in deciding whether a violation had occurred."

As to EchoStar's first issue, the Federal Circuit decided to overrule *KSM Fastening Systems, Inc. v. H.A. Jones Co.*, 776 F.2d 1522 (Fed. Cir. 1985), and its two-step inquiry in finding a defendant in contempt of an injunction in patent infringement cases. According to the court "*KSM* crafted a special rule for patent infringement cases, in that it required a threshold inquiry on the propriety of initiating a contempt proceeding. We recognize now that that inquiry confuses the merits of the contempt with the propriety of initiating contempt proceedings. . . . As a result, we will telescope the current two-fold *KSM* inquiry into one, eliminating the separate determination whether contempt proceedings were properly initiated. That question, we hold, is left to the broad discretion of the trial court to be answered based on the facts presented."

According to the court, "[w]hat is required for a district court to hold a contempt proceeding is a detailed accusation from the injured party setting forth the alleged facts constituting the contempt. As with appeals from findings of civil contempt in other areas of the law, we will only review whether the injunction at issue is both enforceable and violated, and whether the sanctions imposed were improper. Allegations that contempt proceedings were improper in the first instance do not state a defense to contempt. As to the question whether an injunction against patent infringement has been violated, courts should continue to employ a 'more than colorable differences' standard as discussed below." The Federal Circuit found that the district court did not abuse its discretion in deciding to hold contempt proceedings.

As to the "colorable differences" standard, the Federal Circuit rejected a test that "requires determining whether 'substantial open issues with respect to infringement to be tried' exist." Instead, the court states, "The contempt analysis must focus initially on the differences between the features relied upon to establish infringement and the modified features of the newly accused products. The primary question on contempt should be whether the newly accused product is so different from the product previously found to infringe that it raises 'a fair ground of doubt as to the wrongfulness of the defendant's conduct.'"

In other words, according to the Federal Circuit, "the court is required to evaluate the modified elements of the newly accused product against the asserted claim, on a limitation by limitation basis, to ensure that each limitation continues to be met. In making this infringement evaluation, out of fairness, the district court is bound by any prior claim construction that it had performed in the case. The patentee bears the burden of proving violation of the injunction by clear and convincing evidence, a burden that applies to both infringement and colorable differences."

The court vacated the district court' finding of contempt for violation of the infringement provision and remanded the case for the district court to make a factual determination under the guidance "we have provided today." The court also vacated the $110 million damages award for continuing infringement for recalculation, while upholding the court's finding of contempt for the disablement provision of its injunction and the sanctions imposed for this aspect of the case. So ruling, the court turned aside EchoStar's claims that the court's finding of contempt for violation of the disablement provision was based on an injunction that was unenforceable due to overbreadth and vagueness. Five judges disagreed with this part of the decision. *See The Wall Street Journal*, May 2, 2011.

NEW BIO BUSINESS VENTURES

Kadmon Pharmaceutics, Nano Terra Enter Licensing Deal

New York City-based Kadmon Pharmaceuticals and Nano Terra Inc., a Massachusetts-based research and development company, have announced a joint venture to license three of Nano Terra's clinical-stage product candidates. Called NT Life Sciences, the joint venture will give Kadmon rights to Nano Terra's drug-discovery platform and exclusive license to SLx-2119, SLx-4090, and SLx-2101, which are in early-to mid-stage clinical development for a variety of diseases, including metabolic syndrome, diabetes, cancer, autoimmune diseases, and spinal cord injury.

"Our development approach seeks to combine targeted drug candidates, acquired or internally developed, with innovative clinical strategies focused on sub-categories of disease, as determined by genetics, genomics, and other personalizing factors," Kadmon's CEO Samuel Waksal said. Nano Terra's CEO Myer Berlow added, "The ability to make intricate chemical changes which enable or increase the effectiveness of pharmaceutics in addressing diseases is one of the great promises of nanotechnology." Additional information about Waksal and Kadmon appear in **Issue 2** of this *Bulletin*. *See Kadmon/Nano Terra Press Release,* April 25, 2011.

Biotech Company Finds Partner for Skin Care Technology Venture

Canada-based biotech company ProtoKinetix and Massachusetts-based Imaginative Research Associates have announced a joint venture to formulate a topical anti-inflammation product for the skin care market. Imaginative Research has partnered with several large pharmaceutical dermatology and cosmetic companies and has "licensed out patents and know-how to launch many leading products in the skin care arena," according to ProtoKinetix.

Conditions such as dermatitis, psoriasis and eczema are often treated with corticosteroids or immune modulators, the company said, but these treatments may "carry inherent, long term health risks." According to ProtoKinetix, its AAGP ™ technology has anti-inflammatory properties "without toxic side effects. The formulation and development of this therapeutic product line will offer hope for an effective prescription and over-the-counter preparations to combat these chronic inflammation-causing diseases, while eliminating potential risks from many of the current front-line treatments." *See ProtoKinetix Press Release*, April 27, 2011.

Massachusetts, Seoul to Collaborate on Life Sciences Opportunities

A Massachusetts government official has reportedly **signed** a three-year memorandum of understanding (MOU) with a Seoul, South Korea, official designed to "identify opportunities for mutual growth and research and development in the burgeoning life sciences and technology sectors." South Korea has been actively engaged in the biotech sector, with the Korean American Society in Biotech and Pharmaceuticals recently establishing a local chapter in Boston. Boston-based Oxford Bioscience Partners reportedly handles the Seoul government's $100 million biotech fund.

Signed April 19, 2011, by Massachusetts' Secretary of Housing & Economic Development Greg Bialecki, the MOU reportedly states that "cooperative efforts will be focused on the life sciences sector within the fields of scientific, medical and industrial research, technological innovation and commercialization, training, public and private financing." It will also focus on increased trade and investment opportunities, establish contacts between research institutes and centers, and develop joint vocational training and education initiatives. *See Mass High Tech,* April 21, 2011.

UC Berkeley, Lawrence Berkeley Launch Synthetic Biology Institute

The University of California, Berkeley, (UC Berkeley) and the Lawrence Berkeley National Laboratory have announced the launch of a new institute designed to advance biological engineering research. Called the UC Berkeley Synthetic Biology Institute (SBI), the entity will work to "engineer cells and biological systems in ways that promise to transform technology in health

and medicine, energy, the environment, new materials, and a host of other critical arenas," according to SBI.

Led by UC Berkeley's College of Engineering and College of Chemistry, SBI will aim to develop inexpensive drugs for treating intractable diseases, methods for producing transportation biofuels from plants, microbes that target tumors and disease, water purification applications, agricultural advances, environmental remediation, and functional new materials.

As the institute's first industry partner, Agilent Technologies Inc. "is helping to initiate SBI research with a multi-year, multi-million dollar commitment," according to SBI. Agilent President and CEO William Sullivan asserted that synthetic biology can potentially have a profound impact in the 21st century. "To get there, we need to engineer biological solutions that are scalable, reliable and safe," he said. *See SBI Press Release,* April 19, 2011.

University of Michigan Receives $56 Million Targeted Mainly for Stem Cell Research

The University of Michigan (U-M) has announced that it has received a $56 million donation to be used primarily for stem cell research. A. Alfred Taubman's donation represents the latest portion of a $100 million pledge that the shopping mall mogul has made for medical research in heart disease, prostate cancer, Alzheimer's disease, and diabetes. In all, Taubman's gifts to the university have reached more than $142 million.

The A. Alfred Taubman Medical Research Institute houses the only laboratory producing embryonic stem cells lines in the state. In late March, the institute announced the creation of its first two embryonic stem cell lines carrying genes responsible for inherited diseases, according to U-M. Taubman said that he has "never been as excited about a donation's potential to have an impact on the lives and well-being of people in this nation and around the world." *See U-M Press Release, The Detroit News,* April 21, 2011.

Public-Private Partnership in Baltimore to Develop Stem Cell Therapies

The University of Maryland, Baltimore, (UMB) and Paragon Bioservices Inc., a contract research and manufacturing organization with headquarters at UMB's BioPark, have announced a public-private partnership to develop and manufacture stem cell therapies. UMB's Center for Stem Cell Biology and Regenerative Medicine and Paragon will establish a core facility to offer cell banking and "production of a variety of stem cell types" on a fee-for-service basis, according to UMB. "The main objective of the consortium is to accelerate the development of novel strategies for regenerative medicine,

including new treatments and preventatives derived from stem cell research," said an official from UMB's stem cell center. *See UMB Press Release,* April 28, 2011.

INVESTOR NEWS

Aduro BioTech Completes $19.25 Million Financing Round

California-based Aduro BioTech, a clinical-stage immunotherapy company, has announced the completion of its Series B equity financing by securing $19.25 million. The financing comes from current investors and Morningside Ventures, a diversified investment group focused on early-stage life sciences companies formed around new technologies.

"This new round of funding enables us to advance our lead cancer vaccine, CRS-207, into a Phase 2 clinical trial in pancreatic cancer," said Aduro BioTech's Stephen Isaacs. "In addition, these funds will support initial clinical development of CRS-207 or other indications and preclinical development of therapeutic vaccines for prostate cancer and melanoma as well as prophylactic vaccines for malaria and tularemia." *See Aduro BioTech Press Release,* April 20, 2011.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

USPTO Solicits Comments on Streamlining Reexamination Proceedings

The U.S. Patent & Trademark Office (USPTO) has **announced** a June 1, 2011, public meeting to address options under consideration to streamline its procedures for *ex parte* and *inter partes* reexamination proceedings. Those wishing to speak during the meeting must register by May 11; those wishing only to attend must register by May 25. Written comments are requested by June 29.

According to the agency, "These changes are intended to achieve faster, more efficient resolution of the substantial new question of patentability (SNQ) for which reexamination is ordered. The proposed changes are divided into three categories: changes to both *ex parte* and *inter partes* reexaminations, changes specific to *ex parte* reexamination, and changes specific to *inter partes* reexamination." The proposed changes would impose some requirements on reexamination requesters, narrow the matters under consideration in a reexamination proceeding and more clearly define petitions practice, among other matters. *See Federal Register*, April 25, 2011.

Comments Sought on Extent of Appeal Board Involvement in Settlement Discussions

The U.S. Patent & Trademark Office has **published** a notice of inquiry seeking comments "about the extent to which the Trademark Trial and Appeal Board ('TTAB' or 'Board') should become more directly involved in settlement discussions of parties to *inter partes* proceedings, including oppositions, cancellations and concurrent use cases." Written comments are requested by June 21, 2011.

While TTAB recognizes that some two-thirds of all *inter partes* cases conclude without an answer being filed, due to, for example, withdrawal, default or settlement, the board suggests that this figure might be higher and that cases might settle more quickly, "if judges, attorneys or mediators were involved in settlement discussions early on." According to the notice, "anecdotal reports and observations," have suggested that "there are many cases in which settlement talks are most useful after the exchange of initial disclosures or after the exchange of discovery requests and responses." TTAB is thus also seeking comments on when in the settlement discussions Board personnel should become involved and what should trigger that involvement. *See Federal Register*, April 22, 2011.

FDA Seeks Comments on Adverse Experience Reporting for Licensed Biological Products

The Food and Drug Administration (FDA) is **seeking** public comment on the proposed collection of information concerning "requirements relating to FDA's adverse experience reporting (AER) for licensed biological products, and general records associated with the manufacture and distribution of biological products." FDA requests comments by June 20, 2011.

The primary purpose of the AER system is to "identify potentially serious safety problems with licensed biological products," according to FDA, which obtains AER reports from sources including manufacturers, patients, physicians, foreign regulatory agencies, and clinical investigators. Evaluating product safety issues allows FDA to take regulatory action, such as making changes to a product's labeling, coordinating with manufacturers to ensure corrective action is taken, and removing a biological product from the market if necessary.

FDA invites comments on (i) "whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility"; (ii) "the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity

of the methodology and assumptions used"; (iii) "ways to enhance the quality, utility, and clarity of the information to be collected"; and (iv) "ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology." *See Federal Register,* April 21, 2011.

Critics Question APHIS Pilot Project on Bio-Engineered Crops

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) recently **sought** participation in a pilot project that would allow those petitioning the agency for non-regulated status for genetically engineered (GE) crops to prepare the environmental reports on which the agency would base its environmental assessment or environmental impact statement under the National Environmental Policy Act (NEPA). A second option would allow the GE manufacturer/petitioner to pay a third-party contractor to prepare the required environmental report, with APHIS choosing and directing the contractor.

The biotech industry reportedly supports the initiative, which will, it is believed, reduce delays in agency approval for GE crops; insufficient APHIS resources are apparently responsible for protracted approval proceedings. And in recent years, biotech opponents have successfully challenged GE crop approvals in court claiming that APHIS violated NEPA by preparing inadequate environmental assessments.

Some critics are concerned that the pilot program could result in biased environmental reviews. Others, including a spokesperson for the Center for Food Safety (CFS), a GE-crop opponent, contends that the project will simply reinforce APHIS's role as an industry rubberstamp. CFS analyst Bill Freese was quoted as saying, "The underlying issue is—I don't say this lightly—APHIS doesn't really have the will to regulate genetically engineered crops. They're too tied to industry; a lot of their people come from the biotech industry." He suggested instead that APHIS rely on advisory panels to conduct investigations and analyses when dealing with issues over which the agency has little experience. *See Federal Register*, April 7, 2011; *Capital Press*, April 18, 2011.

Researchers Protest ECJ Advocate General's Position on Patenting Stem Cell Technologies

Viewing the issue as a matter of morality, the advocate general of the European Court of Justice (ECJ) recently delivered a non-binding ruling that would render unpatentable the cells removed from the human embryo at the blastocyst stage, because the removal involves the embryo's destruction. **Case C-34/10, *Brüstle v. Greenpeace eV*, Op. of Adv. Gen'l (Mar. 10, 2011)**.

The issue arose in a case involving Greenpeace's action to annul a German patent concerning "isolated and purified neural precursor cells, processes for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects." A German patent court declared the patent invalid, and the patent holder filed an appeal, which was stayed pending the resolution of questions referred to the ECJ.

The advocate general, whose rulings do not bind the ECJ but are considered influential, concluded that "an invention must be excluded from patentability, in accordance with that provision, where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos." The ruling also included in the "concept of a human embryo" an "unfertilised ova into which a cell nucleus from a mature human cell has been transplanted or whose division and further development have been stimulated by parthenogenesis . . . insofar as the use of such techniques would result in totipotent cells being obtained." The advocate general did not include "pluripotent embryonic stem cells" in the human embryo concept, because "they do not in themselves have the capacity to develop into a human being."

The ruling triggered a call by research scientists in an **open letter** published in *Nature* to urge the court to consider the "full implications before making a legally binding ruling." They contend that (i) stem-cell researchers need patent protection "to become active in Europe"; (ii) "[e]mbryonic stem cells are cell lines, not embryos. They are derived using surplus *in vitro* fertilized eggs donated after fertility treatment and can be maintained indefinitely. As more than 100 established lines are now supplied through national and international cell banks, concern about commercialization of the human embryo is misplaced"; (iii) no suitable alternatives exist to using the stem cells currently undergoing their first clinical trials; and (iv) "[t]he advocate-general's opinion . . . represents a blow to years of effort to derive biomedical applications from embryonic stem cells in areas such as drug development and cell-replacement therapy." *See Reuters*, April 27, 2011; *EuroStemCell.org Press Release*, April 28, 2011.

LITIGATION

D.C. Circuit Allows Stem Cell Research Funding to Continue

A divided D.C. Circuit Court of Appeals panel has determined that National Institutes of Health (NIH) guidelines allowing federal funding for research using embryonic stem cells are not clearly at odds with an ambiguous federal statute and thus that a district court abused its discretion in granting a preliminary injunction to two scientists who opposed the guidelines. ***Sherley***

v. Sebelius, No. 10-5287 (D.C. Cir., decided April 29, 2011). Additional information about the case appears in Issue 4 of this *Bulletin*.

The court majority distinguished research that involves the derivation of stem cells, which NIH cannot fund under the law, from projects using an embryonic stem cell that was previously derived. Because simply using embryonic stem cells in research does not itself destroy human embryos, which occurred in the past during the derivation phase, the court determined that the use-only projects can be funded under the Dickey-Wicker amendment, "an appropriations rider that bars federal funding for research in which a human embryo is destroyed." The dissenting judge characterized the court's effort to divide "research" into "temporal bits" as "linguistic jujitsu."

The D.C. Circuit previously determined that the researchers who brought the challenge had standing to pursue their claims because they use adult stem cells and thus compete with embryonic stem cell researchers for NIH funding. The only issue before the appeals court was the propriety of the preliminary injunction, which it had earlier stayed to allow the continuation of funding for ongoing projects. Because the court determined that the statute was ambiguous, it concluded that the plaintiffs had not shown they are likely to prevail on the merits. The district court is currently considering cross motions for summary judgment.

NEWS BYTES

The U.S. Patent & Trademark Office postpones the start date of the Track One fast-track patent processing examination program until further notice because of the reduced spending authority in the Full-Year Continuing Appropriations Act of 2011.

UPCOMING CONFERENCES AND SEMINARS

The American Intellectual Property Law Association has announced a spring meeting to discuss the latest issues and trends in intellectual property (IP) law. Agenda items for the May 12-14, 2011, meeting in San Francisco, California, include patent damages, new U.S. Patent & Trademark Office rules, inequitable conduct issues facing prosecutors, best practices for in-house trademark lawyers, infringement litigation, patent licensing strategies, global IP enforcement challenges, protecting trade secrets, IP assets and bankruptcy, and "the inside scoop from corporate in-house counsel."

The American National Standards Institute (ANSI) has scheduled a May 12, 2011, workshop to consider whether private standards-development organizations have created too many standards, what compels them to do so and how companies, organizations and government agencies can choose from

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among duplicative or conflicting standards to best meet their needs. Titled "Standards Wars: Myth or Reality?," this workshop will be held in Washington, D.C.; the registration deadline was April 27. ANSI coordinates the U.S. standards and conformity assessment system, accredits standards-development bodies and ensures that standards are created through an open process.

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