WIGGIN AND DANA

Counsellors at Law

BioInsights

BIOTECHNOLOGY & LIFE SCIENCES PRACTICE GROUP | FALL 2008

Wiggin and Dana and Its Clients in the News

From 2007 through 2008 to date, Wiggin and Dana LLP has represented its pharmaceutical, biotechnology and life sciences clients in corporate partnering transactions totalling in aggregate approximately $3 Billion and in merger and acquisition transactions totalling in aggregate approximately $2 Billion.

- BioInvent International AB's (OMX) and ThromboGenics NV's (EuroNext Brussels) outlicensed to Roche (SWX) their anti-cancer agent TB-403, a novel monoclonal antibody that blocks Placental Growth Factor (PIGF). Under the agreement, ThromboGenics and BioInvent received an upfront payment of €50 million and have the potential to receive up to €450 million in milestone payments for multiple indications, as well as double digit royalties on product sales. ThromboGenics, which discovered TB-403, will receive 60% and BioInvent will receive 40% of the revenue from the deal. While Roche has a worldwide, exclusive license to develop and commercialize TB-403, ThromboGenics and BioInvent retained co-promotion rights in the Benelux, Baltic and Nordic regions.
- Pfizer, Inc. (NYSE) spun-off its research and development facilities in Nagoya, Japan. The new entity, RaQualia Pharma, Inc., raised ¥11.1 billion from a consortium of investors, including Pfizer, NIF SMBC Ventures Co. of Japan and Coller Capital of the United Kingdom.
- Pfizer, Inc. (NYSE) sold its subsidiary Esperion Therapeutics. The transaction involved Pfizer receiving an interest in a new entity financed by a consortium of venture capital investors led by Aisling Capital and Alta Partners.

Quanta Computer, Inc. v. LG Electronics, Inc.: Supreme Court Clarifies that Patent Exhaustion Applies to Method Patents

On June 9, 2008, the United States Supreme Court ruled in Quanta Computer, Inc. v. LG Electronics, Inc. that the doctrine of patent exhaustion applies to method patents as well as product and composition of matter patents. Patent exhaustion provides that an authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control post-sale use of the article. This decision will likely have significant implications for biotechnology patent law since it will now be more difficult for patent holders to maintain a claim for infringement down the distribution chain of a product.

LG Electronics, Inc. ("LG") licensed several product and process patents to Intel Corporation ("Intel") in an agreement that authorized Intel to manufacture and sell microprocessors using the LG patents. A separate agreement required Intel to give its customers written notice that the license does not extend to a product made by combining an Intel Product with a non-Intel product, and provided that a breach of the agreement would not affect the license agreement. Quanta purchased microprocessors from Intel, which it used to manufacture a product using Intel parts in combination with non-Intel parts. LG sued, asserting that this combination infringed the LG patents.

The District Court held that because each of the LG patents include method claims, the doctrine of patent exhaustion did not apply because patent exhaustion applies only to apparatus or composition of matter claims. The Court of Appeals for the Federal Circuit (CAFC) agreed with the District Court that patent exhaustion did not apply to method patents and concluded that exhaustion did not apply because LG did not license Intel the right to sell the Intel product to Quanta to combine with non-Intel products. Quanta appealed.

Patent Exhaustion Applies to Method Patents

The Supreme Court, in a unanimous opinion written by Justice Thomas, held that the Patent Exhaustion Doctrine (also known as the First Sale Doctrine) applies to method patents as well as product and composition of matter patents.

Published periodically by Wiggin and Dana, a 140 attorney law firm with offices in New Haven, Stamford, New York, Hartford and Philadelphia (USA). Wiggin and Dana Biotechnology & Life Sciences expertise includes M&A, licensing and other transactions, public and private financing and intellectual property assistance.

The Court noted "[i]t is true that a patented method may not be sold in the same way as an article or device, but methods nonetheless may be 'embodied' in a product, the sale of which exhausts patent rights", and that the Court has repeatedly held that method patent rights are exhausted by the sale of "an item that embodied the method." As the Court pointed out, if patent exhaustion did not apply to method patents, patent owners could avoid patent exhaustion entirely by simply including at least some method claims in each patent.

Exhaustion is Triggered when the Product Sold Substantially Embodies the Patent

According to the Court, the holding of United States v. Univis Lens Co. (1942) controlled the facts of the case. In Univis, a patentee's rights in finished eyeglass lenses did not survive a licensee-purchaser's sale of lens blanks to downstream wholesalers and retailers who ground the lenses into finished products. The Court concluded in Univis that the patentee's rights were exhausted because the lens blanks sufficiently embodied the patented lenses such that their only and intended use was to be a finished product. In applying Univis to this case, the Court concluded that the microprocessors Intel sold to Quanta embodied the essential features of LG's method patents. The Intel products "constitute a material part of the patented invention and all but completely practice the patent", and LG did not offer any reason to doubt the conclusion that the only "reasonable use" for the Intel products was to practice LG's patents.

Exhaustion Applies If an Authorized Sale Takes Place

In order for the Patent Exhaustion Doctrine to apply, a sale authorized by the patent holder must occur. Based on the structure of the agreements between LG and Intel, the Court found authorized sales had occurred.

> Nothing in the License Agreement restricts Intel's right to sell its microprocessors and chipsets to purchasers who intend to combine them with non-Intel parts. It broadly permits Intel to "'make, use, [or] sell'" products free of LG's patent claims.

The Court found that Intel's sale to Quanta was within the scope of the license from LG, notwithstanding the apparent restriction in both the agreement between Intel and LG as well as the notice about the limitations on the license provided by Intel to Quanta. The Court concluded that LG's patent rights were exhausted by this sale, and LG could not pursue its patent infringement claims against LG.

Wiggin and Dana and Its Clients in the News

- Meda AB (OMX) acquired MedPointe, a US-based specialty pharmaceutical company focused on pain and allergy/respiratory drugs, for SEK 5.2 billion, including US $520 million in cash and 17.5 million in newly issued Meda shares. New shareholders in Meda included The Carlyle Group, The Cypress Group LLC and other US investors, with a combined shareholding in Meda of approximately 7%.
- Nuevolution A/S entered into a collaboration with Lexicon Pharmaceuticals, Inc. (Nasdaq) to use Nuevolution's proprietary Chemetics® drug discovery technology and libraries to screen, identify and optimize small molecule drug candidates against targets validated by Lexicon. Nuevolution is entitled to receive upfront fees, research funding and milestone payments, in addition to royalties on product sales. Nuevolution may have the option to expand its involvement in certain programs under a cost and profit sharing arrangement.
- Nuevolution A/S entered into a collaboration with Merck & Co. Inc. (NYSE) to use Nuevolution's proprietary Chemetics® drug discovery technology and libraries to screen, identify and optimize small molecule drug candidates. Nuevolution is entitled to receive upfront fees, research funding and milestone payments, in addition to royalties on product sales.
- Medivir AB entered into a collaboration with Ortho Biotech Products L.P. (a wholly owned subsidiary of Johnson & Johnson) and Tibotec BVBA for the discovery, development and marketing of orally active inhibitors of the HCV polymerase NS5B. Medivir is entitled to up to €278 million in upfront fees, research funding and development and regulatory milestones, in addition to royalties on product sales.

Conclusions

Although Quanta v. LG did not center around biotechnology, the decision will likely have significant implications for biotechnology patent law. For example, many inventions in biotechnology are analogous to "products" described in the decision. Key ingredients such as nucleic acids, proteins, and other biomolecules are often purchased and combined with additional substances such as solvents, carriers, or vectors in order to produce a product for sale. Unless the products for sale themselves are the subject of patent claims, it will now be more difficult to control the key ingredients through licensing arrangements due to exhaustion of patent rights. Although attempts will likely be made to license around patent exhaustion, licensors should be careful to avoid allegations of patent misuse. Since the patent exhaustion doctrine effectively prevents multiple royalties on products sold, licensors may also attempt to negotiate higher royalties for key ingredients covered by patent claims in order to compensate for loss of post-sale revenue. Finally, since the Court made clear that patent exhaustion applies to method claims (which are often present in biotechnology patents in the form of process and product-by-process claims), it may also be more difficult to limit exhaustion of patent rights through the use of claimed methods, particularly if a product that is sold embodies such methods.

Wiggin and Dana and Its Clients in the News

- BioInvent International AB entered into a license agreement with Bayer HealthCare for a non-exclusive research license for the use of BioInvent's proprietary n-CoDeR® library for the discovery of human monoclonal antibodies.
- Karo Bio AB entered into a research collaboration agreement with Cadila Healthcare Ltd. (Zydus Cadila) for the discovery and development of novel, selective glucocorticoid receptor modulators for the treatment of inflammatory diseases.
- Santaris Pharma A/S entered into a collaboration with GlaxoSmithKline (GSK) for the discovery, development and commercialization of RNA antagonists against viral targets. Under the agreement, GSK has exclusive options to license drug candidates developed through clinical proof of concept by Santaris Pharma and to in-license Santaris Pharma's existing preclinical candidate against Hepatitis C. If GSK exercises its options, the collaboration may have a combined potential return for Santaris Pharma in excess of $700 million in upfront fees and milestones, in addition to high single to double-digit royalties on product sales.
- Nerviano Medical Sciences S.r.l. (NMS) entered into a collaboration agreement with Genentech, Inc. for the discovery of small molecule inhibitors against oncology targets. Under the agreement, Genentech has the exclusive option to fully develop and commercialize clinical candidates screened by NMS. If Genentech exercises its options, the initial two research programs may have a combined potential return for NMS of up to $310 million in development and regulatory milestones, in addition to royalty payments for each collaboration compound commercialized.

Biotechnology & Life Sciences Lead Practice Group Partners

JIM FARRINGTON, *Chair*
203.363.7614
jfarrington@wiggin.com

TODD GARABEDIAN, PH.D
860.297.3716
tgarabedian@wiggin.com

MERT GOLLAHER
203.498.4362
mgollaher@wiggin.com

PATTI MELICK
203.363.7615
pmelick@wiggin.com