WIGGIN AND DANA

Counsellors at Law

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The CREATE Act: Protecting Patentable Inventions that Arise from Collaborative Research

The Cooperative Research and Technology Enhancement ("CREATE") Act of 2004 was signed into law by President Bush on December 10, 2004. The Act amends 35 U.S.C. §103(c) of the U.S. Patent Laws to provide a safe harbor where research is carried out under a joint collaborative research agreement between individuals or entities. The CREATE Act responds to an earlier decision by the Court of Appeals for the Federal Circuit (CAFC), which held that while 35 U.S.C. §103(c) provides a safe harbor for inventions that are the product of collaboration involving coinventors within a single company or entity, a safe harbor is not provided for inventions made by researchers not employed by the same entity. *OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997). The practical implication of the *OddzOn* decision was that a patent application filed early in the collaboration could become disqualifying prior art against later-filed patent applications if different inventors are listed on the applications and are considered applications "of another" under the patent laws. The decision also created a situation where an otherwise patentable invention could be rendered unpatentable on the basis of confidential information routinely exchanged between research partners. This new legislation addresses these problems and should encourage greater cooperation among universities, public research institutions, and the private sector by allowing parties to freely share information among researchers that are working under a joint collaborative research agreement.

From a practical standpoint, the CREATE Act will treat a claimed invention as having a common owner for purposes of determining patentability if: (1) the claimed invention was made by or on behalf of parties to a written collaborative research agreement that was in effect on or before the date the claimed invention was made; (2) the claimed invention was made as a result of activities undertaken within the scope of the agreement; and (3) the patent application discloses the names of the parties to the agreement. In effect, the legislation will enable different parties in a collaboration to obtain and separately own patents that have claims that may not be patentably distinct. Thus, where a collaborative agreement is in place, and a patent application results from activities falling within the scope of the collaborative agreement, the claims of the patent application would no longer be "obvious" in view of a previous patent application that resulted from the same collaborative agreement. As a result, the Act permits separate ownership and validity of patents that have patentably indistinct claims. However, these separately owned patents must be subject to a disclaimer that will protect the public against separate enforcement actions from both the first-issued patent and any patents with claims that are not patentably distinct over the claims of the first-issued patent.

Practice Tips

To benefit from the new CREATE legislation, consider the following:

- Since a written joint research agreement must have existed prior to the creation of the claimed invention, execute the collaborative research agreement before any research is conducted. No specific form of agreement need be used to benefit from this new legislation, nor must the agreement be contained in a single document. However, the writing(s) must demonstrate that a qualifying collaboration existed. Governmental or private sector cooperative research agreements, development agreements, and other transaction agreements, including Government Cooperative Research and Development Agreements are specifically included in the legislation. Consider whether less-conventional collaborative arrangements (such as a material transfer agreement or an option agreement) might qualify for favorable treatment under the new law and if so, include a statement that makes it clear that the agreement is intended to qualify as a collaborative research agreement for purposes of 35 U.S.C. §103(c).

- Since the claimed invention must be within the scope of the agreement, the stated purpose or scope

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of the agreement should be sufficiently broad to encompass all the subject matter that may reasonably be expected to arise from the collaborative work. Amendments to existing agreements may be desirable in some circumstances where the scope of the research is too narrow. However, if the parties are agreeing to work exclusively with one another within the stated purpose or scope, consider a balanced scope or stated purpose.

• The claimed invention must be made by or on behalf of the parties to the collaborative research agreement. Therefore, if affiliates or consultants are conducting work under the collaboration, make it clear that they are doing so on behalf of the parties.

• Pending patent applications could claim the benefit of the CREATE Act if they meet the requirements of the Act. Therefore, it is desirable to review any pending patent applications that have arisen from a collaborative research agreement and amend those applications to include the names of the parties to the agreement. Certificates of Correction can incorporate the parties' names to issued patents that cover collaborative works. Broadening reissue applications should be considered if the claims of a collaborative issued patent were narrowed in response to prior art that the Act now exempts.

• A patentably indistinct patent must include a disclaimer that prevents the owner from separately enforcing that patent from the first-issued patent, and limits the term of the patent to that of the first-issued patent. Therefore, prior to entering into a collaborative agreement, consider whether your company is willing to potentially give up the opportunity to separately enforce its patent. In making this determination, consider where most research will be conducted (e.g., where most patent applications will come from), who is in better position to bring an infringement action, and whether you are willing to be tied to your collaborator in the event there is a need to pursue a patent infringement action.

Wiggin and Dana and its Clients in the News:

In August 2004, **Wiggin and Dana** was selected as one of nine "highly recommended firms" by *Global Counsel* for Corporate Partnering in the Life Sciences Industry.

Wiggin and Dana attorneys assisted clients in four of 2003's global top 25 corporate partnering transactions in the life sciences, including **Biovitrum AB's** $540 million alliance with **Amgen Inc**. to develop new treatments for diabetes; **Neurogen Corporation's** $118 million collaboration with **Merck** for novel small molecules that work by targeting VR1, a key integrator of pain signals in the nervous system; and **Medivir AB's** HIV licensing deals with **Boehringer Ingelheim GmbH** and **GlaxoSmithKline,** which together totaled $240 million.

Other recent highlights include:

Medivir AB's $92 million collaboration with **Tibotec Pharmaceuticals**, a subsidiary of **Johnson & Johnson**, for the discovery, development, and commercialization of orally active HCV inhibitors.

Doxa AB's development and licensing agreement with **Dentsply International** for the development and commercialization of dental products based on Doxa's proprietary bioactive ceramic technology.

Genaissance Pharmaceuticals' license from **Merck KGaA** to develop and commercialize the small molecule compound, vilazodone, currently in Phase II clinical trials for depression, and **Genaissance's** collaboration with **Sciona**, a nutritional genomics company.

Cellular Genomics' $34.9 million Series C Financing led by new investors **CDP Capital**, **RiverVest Venture Partners** and **Toucan Capital Corporation**, as well as previous investors **Coastview Capital** and **Connecticut Innovations**.

Protometrix's merger into a wholly-owned subsidiary of **Invitrogen Corporation**.

Active Biotech AB's collaboration with **Teva Pharmaceutical** to develop and commercialize Active Biotech's novel compound, laquinimod, for the treatment of multiple sclerosis.

VaxInnate Corporation's $23.1 million Series B Financing led by **HealthCare Ventures.**

Technology licenses and start-up venture capital financing for **Applied Spine Technologies** and **HistoRx**.

Wiggin and Dana is ranked among the top dozen firms nationwide in the number of investor-side PIPE transactions handled in 2003 according to *PrivateRaise.com's PIPEs Scorecard Industry Ranking.* Biotech PIPE transactions handled in 2004 include representing the lead investors in PIPE investments in **Access Pharmaceuticals, Inc., Bioenvision, Inc., AdventRx Pharmaceuticals, Inc., Spectrum Pharmaceuticals, Inc., Genetronics Biomedical Corporation,** and **NexMed, Inc.**

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