TOWNSEND and TOWNSEND and CREW LLP

INTERNATIONAL CONGRESS OF NANOTECHNOLOGY

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PROTECTING RIGHTS TO INVENTIONS AND PATENTS IN JOINT RESEARCH OR DEVELOPMENT ACTIVITIES IN NANOTECHNOLOGY

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CHANGING WORLD

- The frequency of joint efforts to conduct research, development and/or commercialization of new products has been increasing over the years, as has the complexity of such programs
- Years ago - mainly arms-length arrangements - screening agreements, licenses
- A comparatively small number of joint research and/or development agreements - often narrowly focused
- Little technology transfer efforts by universities
- Little interest by most large companies in developments of individuals or small companies

- Today - starting with biotechnology, then nanotechnology - a different atmosphere -
- Significant new developments by individuals, nonprofit organizations, startups, etc. leading to more frequent joint arrangements with larger entities - alliances, partnering, etc.
- Major efforts by universities and other nonprofits to obtain funds via technology transfer
- Arrangements are much more collaborative, promise more benefits, but also are more complex
- More awareness of intellectual property

- But there is a high failure rate in pharmaceuticals/biotechnology partnering and alliances
- Small companies and nonprofits need to protect the technology they brought to the table as well as their rights in jointly developed technology generated during the partnership/alliance to maintain options to seek new partner should the agreement fail, and to preserve assets in general
- Large companies likewise need to protect their intellectual property, both as brought to the table and as developed during the arrangement, so that their competitors do not benefit if the agreement fails

MY VIEW

- In operating under a joint program, whether a joint r&d agreement or a partnering or alliance agreement,
- Personnel of both parties should expend the efforts necessary to help the project succeed
- While expending the efforts necessary to maximize proper ownership (sole or joint) of intellectual property in their own organizations

THE KEY FACTORS

- **SELECTION OF REAL ESTATE/PROPERTY:**
- **LOCATION, LOCATION, LOCATION**

THE KEY FACTORS (Cont.)

- PROTECTION OF INTELLECTUAL PROPERTY:
- DOCUMENTATION, DOCUMENTATION, DOCUMENTATION
- AND THINKING IN ADVANCE

SOME BASIC CONCEPTS ABOUT OWNERSHIP OF INTELLECTUAL PROPERTY UNDER U.S. LAW

- Ownership of patent rights flows from inventorship.
- Ownership of trade secrets/know-how similarly flows from inventorship
- Initially the named inventor(s) is/are the owner(s) of any patent rights in the invention. If the inventor is employed, there often is an agreement to assign rights in inventions to the employer -whether or not patented.
- If an invention is made jointly between employees of different organizations, the patent rights will normally be jointly owned by these organizations.

JOINT INVENTORSHIP

- "one of the muddiest concepts in the muddy metaphysics of the patent law" (1972 court decision)
- There must be some joint activity; some connection or collaboration
- The patent law (35 U.S.C. 116):

"When an invention is made by two or more persons jointly, they shall apply for patent jointly …. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time; (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent."

RIGHTS OF JOINT PATENT OWNERS

In the absence of an agreement providing otherwise:

Of a United States patent:

- each owns an undivided share in the patent rights
- each may separately and independently manufacture, use, sell, offer for sale or import the invention
- each may separately and independently license others to do any or all of the above

- each may do any of the above without being required to provide an accounting to other joint owners or to pay them royalties, including royalties received from licensees
- none has any fiduciary duty to the others
- However, all may be required to join in an infringement suit

For patents in other countries:

- patent law often requires joint owners to act jointly in exploiting, or licensing others to exploit, the invention

Licenses or collaborative agreements

- Generally have provisions that negate some or all of the independent rights in U.S. patents just mentioned in order that all parties obtain value from inventions and patents generated under the agreement
- Usually provide that inventions made by employees or consultants of one party to the agreement shall be owned by that party, and that inventions that are jointly made shall be owned jointly
- Usually provide for mechanisms for exploiting inventions and patents generated under the agreement, often irrespective of ownership

Licenses or collaborative agreements (Cont.)

- For example, one party may have responsibility for licensing patents, including collecting and sharing royalties
- One party may have responsibility for prosecuting patent applications and maintaining patents
- If one party decides to discontinue work on a patent generated under the agreement, the other may have a right to receive ownership and/or take over this responsibility
- The agreement may provide acceptable terms of license or sublicense in advance, either in general or in detail, as by an attached form license

TO MAXIMIZE ONES' RIGHTS IN INTELLECTUAL PROPERTY UNDER A JOINT AGREEMENT, ONE MUST MAXIMIZE THE INVENTIVE CONTRIBUTIONS OF ONE'S PERSONNEL TO THE PROJECT

- That includes both making or contributing to inventions
- And being able to document your contribution
- To maximize making the inventions, think ahead of meetings with or disclosure to the other party. Discuss possible ideas in advance of the meeting
- Be proactive, not reactive
- Document the ideas before the meeting
- Document the ideas after the meeting
- File patent applications before disclosure if possible

Invention:

- Includes conception (mental part) and reduction to practice ("physical" part - carrying out the work or filing a patent application)
- By "the invention" is meant an invention as defined in a claim of a patent or patent application or a defined trade secret or piece of know-how

PATENTS

- For a complete conception of the invention, there must be a definitive and permanent idea in the mind of the inventor of the complete and operative invention as it is thereafter to be applied in practice
- This must include:

  - definition of what the invention is

  - knowledge of how to make it, without requiring undue experimentation

  - understanding, belief or expectation of its use
- Definite and permanent - when the inventor has a specific, settled idea, a particular solution in mind, not just a general goal or research plan he hopes to pursue

- The inventor does not need to fully understand the scientific aspects or basis of the work, and does not need to have competence to physically reduce it to practice
- Sometimes (but not necessarily as often as suggested) conception of the invention occurs simultaneously or contemporaneously with the actual reduction to practice.

  - for instance in an invention of a DNA sequence - may not know the actual sequence until it has been determined

  - or in cases in which the original conception proves, on testing, to have been incorrect or incomplete

WHO IS AN INVENTOR?

- Can be a complicated issue
- Tends to be fact-driven, especially as to whether joint inventorship may exist
- To be an inventor, one must participate in or make an original contribution to the conception of the invention that has significance
- Participation in reduction to practice may be irrelevant to inventorship
- Criteria are different from criteria for authorship of a paper
  - or from criteria for evaluating employee performance
  - or from politics

- It is inappropriate to name someone as an inventor because of criteria such as hard work, desire to reward, perceived need to accommodate or position in the organization

University of Denver Guidelines

(www.du.edu/osp/iptips)

"For legal and practical reasons, the status of co-inventor may not be conferred merely as a reward for hard work, friendship or even outstanding science. This means that colleagues, students, research assistants, technicians, machinists, or those who supervise them, even though they may gather essential data or construct a practical embodiment of the invention, are not inventors unless they have made an inventive contribution."

Why one must care about proper naming of inventors (besides the fact that ownership flows from inventorship)

- - US patent law requires that a patent application be filed in the name of the inventor or inventors.
- - Improper or incorrect naming of inventors can be the basis of a rejection of claims in the USPTO and can affect validity of a patent. Mechanisms exist for correction of inventorship.
- - However, if including or excluding an inventor is done with deceptive intent, it might not be possible to correct the patent; thus it could be invalid on that ground alone.
- - In some cases, e.g. university employees or employees of foreign companies, or where there has been no agreement to assign inventions the inventors may have rights of their own to share in proceeds of exploitation of the patent.

GAF v. AMCHEM (1981)

- Patent claiming use of 2-chloroethylphosphonic acid as a plant growth regulator (Ethrel®)
- Screening agreement for Amchem to test GAF compounds for use as herbicides and PGRs. GAF would send Amchem list of coded compounds; Amchem would select for screening. GAF used broad criteria for assembling list for submission to Amchem; had no express criteria for selecting compounds for this purpose. Amchem chose to screen most of the listed compounds (except those that were carcinogenic or certain toxics), without knowledge of their identity (revealed for compounds after Amchem had chosen what to screen).

ALZA's OROS DDS Patent Strategy

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GAF v. AMCHEM (1981) (Cont.)

- GAF sent the acid, the dichloride and the pyrocatechol ester to Amchem. Amchem observations showed growth regulating activity for the ester. Thereafter, Amchem found contradictory results as to which was active as a PGR - acid or ester but then resolved the issue in favor of the acid.
- GAF's patent dept. were of the opinion that in this situation GAF was not entitled to the patent.
- Amchem and GAF entered into negotiations for a supply agreement. GAF then contested validity, claiming that one of its scientists was at least a joint inventor of the patent. Its patent dept. reversed their earlier opinion.
- The court found for Amchem on the facts; **no contemporaneous GAF records showed that its scientist believed himself to be an inventor**; the court found **the concept was wholly within the Amchem scientists**; GAF's scientist only supplied more purified material for testing

BURROUGHS WELLCOME v. BARR LABS (1993-1994)

- Six patents variously claiming compositions and methods of use of AZT for treating patients infected with the HTLV-III virus. Patents named five Burroughs scientists as co-inventors.
- Burroughs had been investigating compounds for use against HIV, had found activity against murine retroviruses. Submitted AZT (coded) to the NIH, which could screen against live HIV.
- Burroughs filed an application with the FDA to register AZT. Barr obtained a license from NIH and filed an ANDA. Burroughs sued Barr for patent infringement, as well as Novopharm (which also filed an ANDA)
- Barr argued primarily that before the NIH screening Burroughs' inventors could not know that AZT would in fact be effective against HIV - would have no reasonable scientific basis for expecting it to work. Therefore the NIH scientists deserved to be named joint inventors.

BURROUGHS WELLCOME v. BARR LABS (1993-1994) (Cont.)

- The trial court held that **for a conception to be complete, it was not necessary that the inventors have an objectively reasonable basis for believing the invention would work**. (This result was also reached in older cases.). All that is necessary is having the complete concept. **Inventors must be able to disclose their invention to someone who can carry out the reduction to practice without fear that such person would (automatically) be named a joint inventor**.
- On appeal the decision was affirmed as to 5 patents, but returned to the trial court for further hearings on the 6th, which had claims to increasing the number of T-lymphocytes; evidence showed that this specific claim might not have been within the Burroughs concept.

ELI LILLY v. ARADIGM (2004)

- Lilly had patented "lispro", a modified form of insulin with greater bioavailability. Aradigm was working on drug delivery via inhalation of aerosols, including delivery of insulin.
- Lilly scientists met four times with Aradigm to discuss a possible collaboration using Lilly's knowledge of insulin compounds and Aradigm's knowledge of drug delivery. No collaboration ensued.
- Aradigm filed a patent application and obtained a patent claiming a method for improving bioavailability of insulin delivered via the lung that comprised aerosolizing a formulation of an insulin analog (and specifically lispro) that rapidly dissolved into monomeric form (a known property of lispro) and inhaling it into the lungs - and more specifically where the lispro dissolved so as to produce relative bioavailability more than twice greater than inhalation of a similar amount of recombinant insulin.

ELI LILLY v. ARADIGM (2004) (Cont.)

- Lilly sued to add two of its scientists to the patent, claiming that they had disclosed the concept of administering lispro via inhalation to Aradigm. At trial, one of Lilly's scientists testified that he remembered talking about insulin, and he always talked about lispro in such discussions, but he did not testify that he disclosed to Aradigm that bioavailability could be doubled by administration via inhalation.
- The court held Lilly to a high standard in seeking to correct inventorship of an issued patent, and ruled that Lilly had not met that standard - too much circumstantial evidence, not sufficient direct evidence of what was disclosed to Aradigm.

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