UNeMed: Commercializing Intellectual Property in Research and Medicine

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Background

Experience:

UNMC / UNeMed (Omaha, NE) – Director of Intellectual Property
University Tech Transfer: Manage patent portfolio and IP contract matters

Foresight Science and Technology (Boston, MA) – Senior Consultant
Consulting Firm: Analyze new technologies for university and startup clients

International Intellectual Property Institute (Washington, DC) – Consultant
NGO and Think tank: Teach IP to government and universities in the Philippines


Chicago Law Firm: Draft patent applications, assist patent litigation

Education:

Chicago-Kent College of Law, Illinois Institute of Technology, Chicago, IL
LL.M. in International Intellectual Property Law

Creighton University School of Law, Omaha, NE
J.D. in law

Creighton University, Omaha, NE
B.S. in Biology
Outline

1) Overview of Intellectual Property
   Types of IP and Overlap
   Commercial Uses of IP

2) UNeMed’s role in the University
   Commercialization Process
   UNMC Policies on Intellectual Property
What is Intellectual Property?

“Products of the human mind and creativity that are protected by law”

- Intangible – lacks physical substance
- Transferrable – can be bought and sold (or licensed)
- Valuable (?) – may have significant worth
- Limited – by time and public access/use
What is Intellectual Property?

- **Intellectual Capital**: What the employees thought up (concepts, ideas, plans, creativity)
- **Intellectual Assets**: What the employees wrote down (lab notebooks, procedures, drafts)
- **Intellectual Property**: What the business protected under law (patents, copyrights, trademarks, trade secrets)
Types of Intellectual Property

World Trade Organization (WTO) recognizes 14 types:

1. Copyright
2. Moral rights
3. Industrial design rights
4. IP cores used in electronic design
5. Patent
6. Plant breeders' rights
7. Plant variety protection
8. Personality rights
9. Trade dress
10. Trademark
11. Geographical indication
12. Domain Name
13. Trade secret
14. Traditional knowledge

(The “Main Four”)
Copyright

Original works of expression having at least a modicum of creativity fixed to a tangible medium for 95/120 years (or life +70 for author-owned)

Examples: Literary works (includes software code), music, dramatic, choreographic, pictorial, graphic, sculptural, audiovisual, architectural (17 USC Section 102)

Rights: Reproduction, derivatives, distribution, perform, display (17 USC Section 106)

Note: Common-law rights upon fixation to tangible medium
Register for added damages/benefits with Copyright Office

Benefit to society: Incentivize creativity
Copyright Infringement

Infringement - the unauthorized or prohibited use of works under copyright, infringing the copyright holder's "exclusive rights".

Fair Use Defense to Copyright Infringement Factors:

1. The purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
2. The nature of the copyrighted work;
3. The amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
4. The effect of the use upon the potential market for or value of the copyrighted work.

Example: Kim Dotcom
Trademark / Service mark

A word, phrase, symbol, image, color, sound, or certain other indicator that conveys source identity for as long as functions as such.

Rights: Lanham Act 15 U.S. C. 1125 provides right to owner to protect the goodwill of the producer or service provider by protecting the mark designating origin of a product / service.

Note: Use TM (or SM) if not registered with the USPTO and ® once registered.

Benefit to society: Known quality expectations = faster decisions
TM / SM Infringement

Is there a "likelihood of confusion" to the consumers as to the source and therefore the expectations? Tarnish or Blur well-known mark?
Trade Secret

Protects confidential information that gives the business and economic advantage, such as formulas, practices, designs, recipes, for as long as maintained.

Rights: Defend Trade Secrets Act of 2016 created a federal right to assert against trade secret misappropriation which is in addition to state law causes of action.

Note: Use confidentiality agreements and security measures to protect rights.

Benefit to society: Incentivize business investment
Trade Secret Misappropriation

Tony Levandowski of Google → Uber

Former Google/Waymo employee secretly downloaded 14,000 files of “highly confidential data” from Google’s hardware systems before resigning a month later and launching a self-driving truck startup called Otto. Uber acquired Otto and put him in charge of its self-driving efforts. The data revolves around a key piece of technology called LiDAR ("Light Detection and Ranging"), which uses pulsing lasers to measure distances between one or more sensors and external objects to build a detailed map of the environment around the car. Waymo has invested millions in its own LiDAR hardware and alleges that Levandowski misappropriated this data in developing Otto and working for Uber. Waymo accepted $245 million settlement.

Biswaomohan Pani of Intel → AMD

Former Intel employee sentenced to prison for stealing valuable computer chip manufacturing and design documents.

Boston Division

Former Intel Employee Sentenced to Prison for Stealing Valuable Computer Chip Manufacturing and Design Documents

U.S. Attorney’s Office
August 08, 2012

District of Massachusetts
(617) 748-2100

BOSTON - A Chelmsford man was sentenced today in federal court to three years in prison for stealing computer chip manufacturing and design documents.

Biswaomohan Pani, 36, was sentenced by U.S. District Judge P. Denis Seklir, IV to three years in prison, to be followed by two years of supervised release, and ordered to pay a fine of $175,000. In April 2013, Pani pleaded guilty to five counts of wire fraud.

In 2008, Pani was working in Hudson, Massachusetts, for Intel Corporation, a designer and manufacturer of computer chips. From February through April 2008, Pani was looking for a job at another computer chip manufacturer and ultimately obtained a job at Advanced Micro Devices, Inc. (AMD), an Intel competitor. Pani kept his job search secret from Intel. When he announced his departure on May 29, 2008, he told the company that he might work for a hedge fund. Pani told Intel that he wanted to take the rest of the summer off, but never returned to work on June 11, 2008.

Unbeknownst to Intel, Pani had started downloading from Intel numerous secret documents about Intel’s computer chip manufacturing and design of computer chips. The extensive downloads began on May 28, just before he announced his departure, and continued on May 29. Also unknown to Intel, Pani started working at AMD on June 2, while he was still on Intel’s payroll and still had access to Intel’s computer systems. On June 8 and June 10, Pani remotely accessed Intel’s computer system numerous times and downloaded 15 of Intel’s most valuable documents, along with other confidential and proprietary information, and a document containing how encrypted documents could be reviewed when not connected to Intel’s computer system. Pani also backed up the downloaded files to an external hard drive for access after he left Intel.

On June 11, 2008, Pani reported to Intel, for his exit interview, and falsely stated that he had not retained any of Intel’s property, when, in fact, he had kept the electronic equivalent of boxes full of downloaded documents and some printed Intel documents at his apartment. They were found a month later when the FBI searched his home. Intel has valued those documents as worth $200-400 million, at minimum.

The FBI was able to recover these documents quickly, before Pani could use them to Intel’s disadvantage, largely because Intel reported the theft quickly and assisted the investigation. AMD also cooperated with the investigation, and there was no evidence that AMD or its employees had asked Pani to take these documents or even knew that he had them. Pani nevertheless told Intel’s documents to advance his career at AMD or elsewhere by drawing on the documents when the opportunity arose, with his employees’ knowledge or not.
Patent

Utility patent – protect novel and nonobvious device, system, method, and/or use for ~20 years from filing

Design patent – for protecting the novel ornamental features for 14 years from issuance of design patent

Plant patent – for protecting asexually reproduced plants for 20 years from filing

Rights: 35 U.S.C. 271 (territorial negative right)

“the right to exclude others from making, using, offering for sale, or selling” the invention in the United States or “importing” the invention into the United States.

Benefit to society: Incentivize industrial applicability of creativity
Patent Requirements

35 U.S.C. 101 – Utility
- Useful
- Proper subject matter

35 U.S.C. 102 – Novelty
- Not previously disclosed
- (If by inventor, then less than 1yr for U.S. but no grace for most foreign)
- Invented by the inventor

35 U.S.C. 103 – Nonobviousness
- Not obvious to one having ordinary skill in the art at the time (inventive step)

- Written Description
- Enablement (and Best Mode?)
USPTO Guidelines

Claim is not directed to an abstract idea, and as a whole amounts to significantly more than the recited judicial exception (i.e. recites and inventive concept)
Proposed Legislation on 101

“The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.”

Results: Removes added subject matter restrictions imposed by the Supreme Court against technologies in fields of software (Alice cases) and products of nature (Myriad cases).
Patent Filing Strategy

“Just In Time”
1) Provisional US Patent Application (12 month “place-holder”)
2) PCT International Application (Patent Cooperation Treaty)
3) National Patent Applications (152 through PCT)
Patent Infringement

All Elements Test:

Each element of a claim must be present in the allegedly infringing device in order to establish literal infringement.

Doctrine of Equivalents:

If not every element is present, but the missing element* performs substantially the same function in substantially the same manner and obtains the same result then it is equivalent and infringes.

*This three-part assessment described in Graver Tank Mfg. v. Linde Air Products (1950) was limited to specific elements rather than the invention as a whole by Warner Jenkinson v. Hilton Davis Chemical (1997).
Patent Infringement

**7,654,321, Claim 1, as applied to Shady Mills Puppy Farm**

1. A fuzzy structure that fetches a ball, comprising:

<table>
<thead>
<tr>
<th>a tail;</th>
<th>Toward the back of the fuzzy structure depicted above is a tail.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) at least one wet nose; and</td>
<td>Below the eyes, above the mouth, is what appears to be one wet nose.</td>
</tr>
<tr>
<td>(b) a plurality of legs.</td>
<td>A plurality (four, in this case) of legs protrude below the body.</td>
</tr>
</tbody>
</table>
What is Claimed:

1. A compound having a structure of formula (I)

   \[
   \begin{array}{c}
   \text{R}^1 \quad \text{N} \quad \text{R}^2 \\
   \text{R}^3 \quad \text{N} \quad \text{L} \quad \text{R}^4 \\
   \end{array}
   \]

   \[\text{(I)}\]

   wherein

   each \( \text{R}^1 \) is independently heteroaryl, aryl, or alkyl;

   \( \text{L} \) is selected from \(-\text{NHC(O)NH-}, -\text{NH-SO}_2-, -\text{NHC(O)CH}_2-, -\text{NHC(S)NH-},\)

   \[
   \begin{array}{c}
   \text{N} \quad \text{N} \\
   \text{H} \quad \text{N} \\
   \end{array}
   \]

   and

   \[
   \begin{array}{c}
   \text{N} \quad \text{N} \\
   \text{N} \quad \text{H} \\
   \end{array}
   \]

   \( \text{X} \) is halo, alkyl, alkoxy, aryl, \( \text{CO}_2 \text{alkyl} \), \( \text{COalkyl} \), or haloalkyl;

   \( \text{R}^2 \) is \( \text{H}, \text{alkyl}, \text{alkoxy}, \text{CO}_2 \text{alkyl}, \text{COalkyl}, \) or haloalkyl; and

   \( \text{R}^3 \) is \( \text{H}, \text{alkyl}, \) or alkoxy;

   or a salt, hydrate, or solvate thereof.

2. The compound of claim 1, wherein each \( \text{R}^1 \) is independently selected from

   furanyl, thiophenyl, pyridinyl, and phenyl.
**Patent Infringement Ex.**

US Design Patent - $1 billion to Apple 2012... appealed to $539 million... settled for undisclosed amount 2018... other countries too

<table>
<thead>
<tr>
<th>Samsung Smartphones BEFORE iPhone</th>
<th>Apple’s iPhone (announced Jan. 2007)</th>
<th>Samsung Smartphones AFTER iPhone</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Samsung Smartphone Before iPhone" /></td>
<td><img src="image2" alt="Apple iPhone" /></td>
<td><img src="image3" alt="Samsung Smartphone After iPhone" /></td>
</tr>
</tbody>
</table>
Overlap of Intellectual Property

Multiple intellectual property rights may protect a single “product”

Example:

Patent: Design patent on shape of bottle
Trademark: COCA-COLA, COKE, bottle curves
Copyright: Advertising and Label
Trade Secret: The recipe / formula
IP in Research Contracts

Material Transfer Agreements – MTAs

- Provider transfers possession of materials to Recipient
- Limits on use and further distribution
- Possible reach-through to IP on inventions

Confidential Disclosure Agreements – CDAs (NDAs)

- Discloser shares confidential information with Recipient
- Limits on use and further distribution
- Possible reach-through to IP on inventions
UNeMed

Mission: “UNeMed improves healthcare by fostering innovation, advancing biomedical research and engaging entrepreneurs and industry to commercialize novel technologies.”

Annex 14 at 4460 Farnam Street
UNeMed Team

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UNeMed Process

Invention Disclosure
Process begins with a completed NIN form and meeting with the inventor

Protection
Patent applications; copyright or trademark; market as material

Commercialization
License to new company; exclusive; non-exclusive; option; sponsored research; build startup company

Evaluation
Examined for patentability & marketability; findings presented to committee; more data may be required before moving forward; committee recommendation discussed with inventor

Marketing
UNeMed.com; External websites; inventor contacts; UNeMed contacts; Finding potential investors, partners, collaborators
UNeMed Process – NIN Detail

Before you publish or share a new invention with others, contact UNeMed to discuss. Submit an invention (New Invention Notification) or just give a call to discuss next steps.
UNeMed Process – Triage Detail

Time and budget constraints require the “Triage” of inventions to prioritize those with most promise and impact for a serious need.

Is it feasible to fully develop and having solid data?
  Can we prove it really works?
  More data needed?

Is it marketable?
  Will someone buy it?
  Too expensive or too risky?
  Infringing others’ rights?

Is it protectable?
  Can we transfer this advantage to a company?
  Patent / Copyright / Trade Secret / Trademark / Contract
UNeMed Commercialization

Analyze inventions and protect their IP rights typically with patents to then license those rights to companies for development of inventions into products which improve lives.
Example 1:

Surgical Robots (Drs. Shane Farritor and Dmitry Oleynikov)
Example 2:

Interventional Radiology Devices (Dr. Greg Gordon)
Example 3:

Tumor Ablation Probe (Drs. Robert LeVeen and Randy Fox)

Radiofrequency ablation (RFA) uses radiofrequency energy, which is an electrical current designed to ablate lesions. The electrical current is delivered to the lesion with a needle electrode. It generates heat that is designed to be high enough to ablate the lesion cells.
UNMC Policies on IP

Regents Bylaws 3.10
Regents Policy 4.4.1  (nonpatentable subject matter)
Regents Policy 4.4.2  (patentable subject matter)
UNMC Policy 7001

http://nebraska.edu/docs/board/bylaws.pdf
http://nebraska.edu/docs/board/RegentPolicies.pdf
http://wiki.unmc.edu/Royalty/Equity_Distribution
Ownership and Commercialization of Inventions and Discoveries

Every invention or discovery by members of the faculty and staff that results from the performance of duties within the scope of their University employment, or from the use of University personnel, property, facilities, or other resources, except where such use is minimal, shall be solely owned by the University provided that the inventor or inventors shall have a share of no less than one-third (1/3) of the net proceeds received by the University resulting from licensing or sale of University owned intellectual property rights associated with such invention or discovery. Further, .... it shall be a condition of employment at the University of Nebraska that any such rights shall be assigned to the University.

The Board shall adopt a formal Patent and Technology Transfer Policy which shall govern the disclosure of inventions and discoveries resulting from performance of duties by faculty or staff within the scope of their employment, or from the use of University personnel, property, facilities, or resources. ....

Amended, 64 BRUN 139 (17 Oct. 2003)
Regents Policy 4.4.1

RP-4.4.1 Ownership of Intellectual Property

Central to the University of Nebraska’s mission is the creation, preservation, and dissemination of knowledge.

The University of Nebraska is committed to providing an environment that supports the research, teaching, and service activities of its faculty, students, and staff. As a matter of principle and practice, the University encourages all members of the University community to publish their articles, books, and other forms of scholarly communication in order to share openly and fully their findings and knowledge with colleagues and the public. This Policy is intended to promote and encourage excellence and innovation in scholarly research and teaching by identifying and protecting the rights of the University, its faculty, staff, and students.

This Policy is included in the terms of employment of all University employees. Admission as a student at the University constitutes an agreement to abide by the terms of this Policy.
Classification of creative works

The ownership of Intellectual Property created by a University employee is determined by the nature of the activity resulting in the Intellectual Property. Under this Policy, Intellectual Property not governed by Section 3.b (Patent Policy) is classified as either:

1) an **Independent Work** governed by Section 4;
   -> Typically Employee Owns

2) a **University Supported Work** governed by Section 5;
   -> Typically Employee Owns unless Support is Substantial

3) an **Institutional Work** governed by Section 6; or
   -> Typically University Owns

4) a **Contractual Work** governed by Section 7.
   -> Typically University Owns
Regents Policy 4.4.2 - Invention

Each invention by a member or members of the faculty or staff of the University resulting from performance of duties within the scope of University employment or resulting from the use of University personnel, property, facilities, or other University resources, except were such use is minimal, shall be solely owned by the University.

Division of Net* Royalties and Proceeds:

One-third to the inventor or inventors; and

Two-thirds in accordance with a separate distribution policy to be established and implemented by each University campus.

(UNMC 7001)

*Net equals gross minus 10% tech transfer fee and sunk costs
UNMC Policy 7001

As per RP-4.4.2 Board of Regents Patent and Technology Transfer Policy, UNMC is responsible for allocating non-inventor technology transfer proceeds according to its individual campus policy. In order to best utilize non-inventor proceeds and to serve the objectives of the Regents Policy, UNMC shall allocate non-inventor proceeds on a case by case basis as determined by the Committee for Proceed Distribution (CFPD).

Members of the Committee for Proceed Distribution shall be the Vice Chancellor for Business and Finance, the Vice Chancellor for Research, the Vice Chancellor of Academic Affairs, the President of UNeMed, the Patent Administrator and one member at large to be selected annually by a majority vote of the other members.
Gross Proceeds:
  UNeMed retains 10% of gross proceeds to cover a portion of technology transfer expenses, and sunk costs recovered.

Net Proceeds:
  1/3 to the pool of inventors
  2/3 to the Committee For Proceed Distribution (CFPD) to support translational projects

For example, if a licensee paid $200,000 for a technology that has $30,000 in sunk expenses, the distribution would look like this for that revenue:
  $200,000 (Gross Proceeds)
  $20,000 (UNeMed 10%)
  $30,000 (sunk expenses)
  $150,000 (Net Proceeds)

  $50,000 (1/3 of Net Proceeds) would go to the inventor(s)
  $100,000 (2/3 of Net Proceeds) would be distributed by the CFPD