PRACTICAL ADVICE FOR PROTECTING AND INCREASING VALUE OF YOUR INTELLECTUAL PROPERTY IN NORTH AMERICA

Andréanne Auger, Ph. D.
Patent Agent

Skolkovo Patent School - October 2016

BCF AVOCATS D'AFFAIRES

A FEW WORDS ABOUT US

BCF LLP.
Business law
Montreal, Quebec,
Canada

Andreanne Auger, Ph.D.
Biotechnology, Pharmaceuticals & Chemistry
U.S. and Canadian Patent Agent

BCF BUSINESS LAW

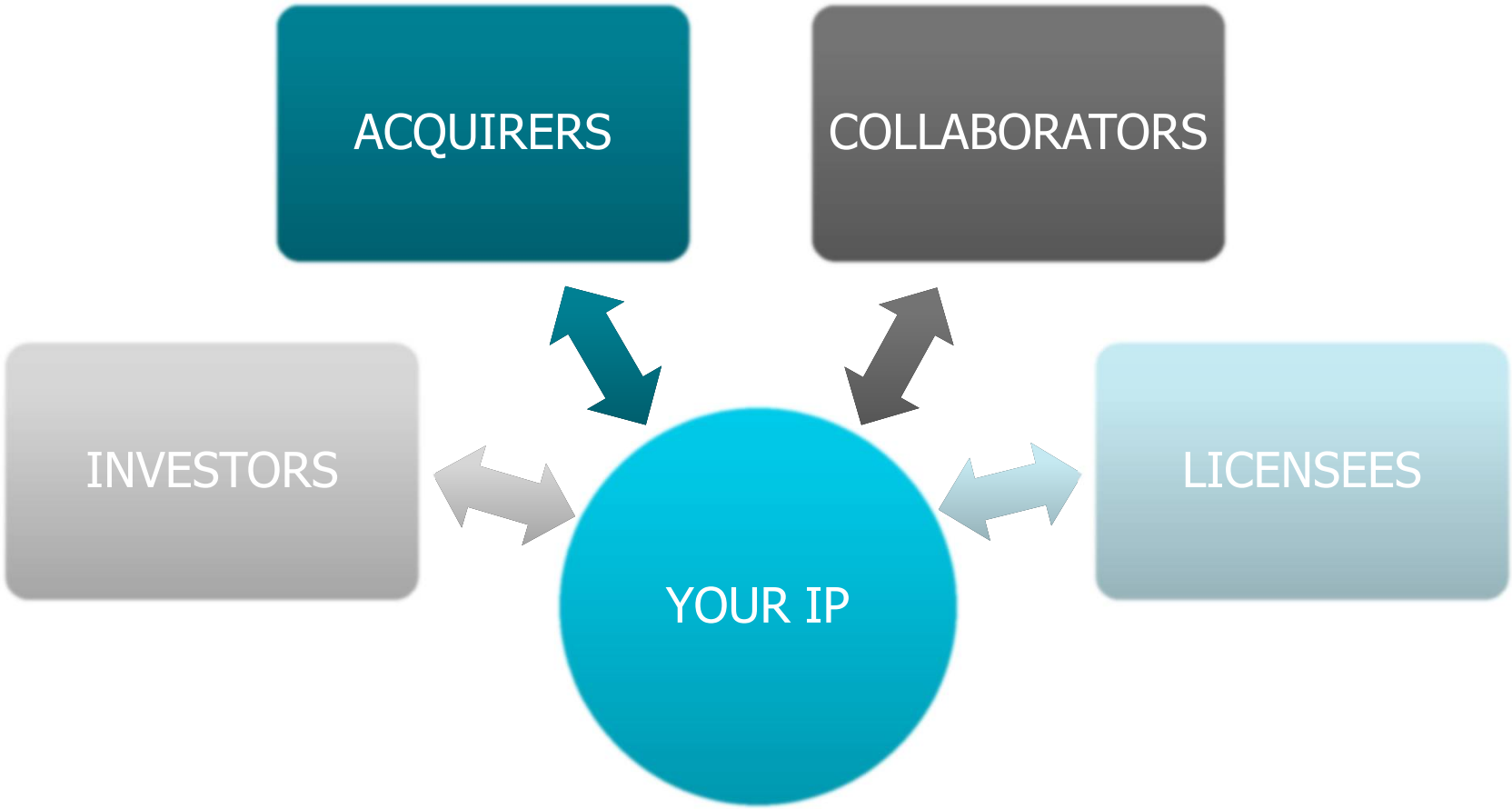
IP PROTECTION AS A BUSINESS TOOL IN NORTH AMERICA

ALIGNING IP PROTECTION TO PRODUCT LIFE CYCLE

Research	Product development	Clinical	Approval	Sales
Protect innovation	Freedom to Operate	Preparing for partnering	Alignment within regulatory framework	Second generation
Recording Know how	Capturing changes	Protecting additional features		Competitor/ Partner monitoring
Ownership issues	Ongoing alignment	Confidentiality		
IP infrastructure & management				

BCF BUSINESS LAW

ADAPTING YOUR IP PROTECTION TO YOUR NORTH AMERICAN BUSINESS GOALS



BCF BUSINESS LAW

ESTABLISHING OWNERSHIP

BCF BUSINESS LAW

ESTABLISHING OWNERSHIP

WHY

- A legal determination based on fact
- An inventor must contribute to the *conception* of the invention covered by *at least one claim*
- Under US law, wrong ownership is basis for invalidity (jurisprudence)
- Claims establish inventorship
- Will be investigated by US/CA parties in due diligence

BCF BUSINESS LAW

ESTABLISHING OWNERSHIP

WHAT TO DO

Get assignments from inventors or collaborators from the onset

Monitor evolution of claimed subject-matter vs. inventorship

Keep complete records of ownership and inventorship

BCF BUSINESS LAW

PATENTABLE SUBJECT-MATTER

BCF BUSINESS LAW

PATENTABLE SUBJECT-MATTER

FOR OVER 150 YEARS, U.S. SUPREME COURT HAS HELD PATENTABLE:

Diamond v. Chakrabarty, U.S. Supreme Court, 1980

- "*[A]nything under the sun that is made by man*."

U.S. Statute (35 U.S.C. § 101) authorizes:

- Machines
- Compositions of matter
- Articles of manufacture
- Processes

Similar statute in Canada (Section 2 of the Canadian *Patent Act*):

- *invention* means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

BCF BUSINESS LAW

PATENTABLE SUBJECT-MATTER

...AND UNPATENTABLE

Abstract ideas — *e.g.*, mathematical algorithms

e.g., a subject's reaction to a drug — **Natural phenomena**

Laws of nature — *e.g.*, Newton's law of gravity "F=ma"

You can't monopolize a fundamental principle

You can only patent a practical application of it

BCF BUSINESS LAW

PATENTABLE SUBJECT-MATTER

NATURAL PRODUCTS

(***Association for Molecular Pathology v. Myriad Genetics, Inc.*** **("Myriad"), 2013**)

UNPATENTABLE:	PATENTABLE:
- Naturally occurring nucleic acid segments or isolated DNA - Naturally occurring amino acid segments or isolated DNA - Naturally occurring microorganism (e.g., bacterium) - Naturally occurring antibodies	- cDNA (not naturally occurring) - Synthesized nucleic acid segments that are not found in nature (e.g., vectors, plasmids, primers) - Synthesized amino acid segments that are not found in nature (e.g., fragments of a naturally occurring protein) - Genetically modified microorganisms (e.g. bacterium) - Chimeric or humanized antibodies

BCF BUSINESS LAW

PATENTABLE SUBJECT-MATTER

DIAGNOSTIC METHODS

(Mayo Collaborative Services v. Prometheus Laboratories ("Mayo"), 2012)

Diagnostic methods are susceptible of relying on a natural correlation (unpatentable) or on a mental step (unpatentable).

Correlation found in nature:

Claim 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8 x 10^8 red blood cells **indicates a need to increase** the amount of said drug subsequently administered to said subject, and

wherein the level of 6-thioguanine greater than about 400 pmol per 8 x 10^8 red blood cells **indicates a need to decrease** the amount of said drug subsequently administered to said subject.

BCF BUSINESS LAW

PATENTABLE SUBJECT-MATTER

DIAGNOSTIC METHODS

(Mayo Collaborative Services v. Prometheus Laboratories ("Mayo"), 2012)

Conclusions from Mayo:

- When a fundamental principle is involved, must claim **"enough" additional subject matter** to amount to **"significantly more"** than the principle.
- Steps adding only well-known, routine or conventional subject matter unlikely to be "enough".
- Underlying concern: "pre-emption" of natural principles - too much patenting will prevent future innovation.

BCF BUSINESS LAW

DESCRIBING YOUR INVENTION

BCF BUSINESS LAW

DESCRIBING YOUR INVENTION

KNOWING WHEN TO FILE IN VIEW OF OBTAINING PROTECTION IN US/CA

- Very difficult to get life science claim without any experimental data at filing
- Determination is fact specific; no general rule
- Human clinical data generally not required
- If similar known compounds have been shown to have therapeutic activity based on same data/structure, or if good link between data in application and therapeutic treatment, then likely enablement/utility
- If invention is based on improved efficacy, need strong data to support such efficacy
- If advantage is reduced side effects, may need clinical data comparing/showing same
- Novel compound claims generally easier than use claims

A balance between sufficiency of experimental data and need to establish early filing date in view of third parties' disclosures!

BCF BUSINESS LAW

DESCRIBING YOUR INVENTION

US WRITTEN DESCRIPTION AND UTILITY REQUIREMENTS

(35 U.S.C. § 112)

- Need support in the application as filed – ideally the first-filed (priority) application;
- Need both "literal" support and data
- Description must support the entire breadth of the claims
- Don't write too narrowly, or you will not be able to claim more
- Example:
  - "*The reaction is run at 60°C.*" *vs.*
  - *"The reaction can be run at a temperature in the range of about 50-about 70°C, for example at about 50, about 55, about 60, about 65, or at about 70°C."*
- Need many different embodiments in description to support broad claims;
- Best to include many different claims of varying scope
- Post-filing data may be helpful

BCF BUSINESS LAW

DESCRIBING YOUR INVENTION

CA WRITTEN DESCRIPTION AND UTILITY REQUIREMENT

(Section 2 and Subsection 27(3) of Canadian Patent Act)

- Utility can be demonstrated or soundly predictable
- Accountable to your promise of utility
- Post-filing data not admissible to demonstrate utility

BCF BUSINESS LAW

DESCRIBING YOUR INVENTION

LANGUAGE

- Be cautious with language which characterizes the invention, such as "effective", "advantageous", "improved", "outstanding", "human use", "chronic" vs. "acute" condition, mechanism of action
- Such promises may need to be supported by data
- Avoid declarative statements (the invention is useful for) and use speculative terms instead (the invention **may**…; the invention **can** provide…; **in some embodiments** the invention...)

EXAMPLES:

- "*Compounds of the invention are inhibitors of angiotensin converting enzyme (ACE), and in some embodiments, are useful for hypertension*." **YES**
- "*Compounds of the invention are improved inhibitors, have fewer side effects, and are specifically useful for treating chronic hypertension in humans*." **NO**
- "*In some embodiments, compounds of the invention may be improved inhibitors, may have fewer side effects*..." **YES**

BCF BUSINESS LAW

CLAIMING YOUR INVENTION

BCF BUSINESS LAW

CLAIMING YOUR INVENTION

WHAT TO BE MINDFUL OF IN US AND/OR CA

- Claims will be given the broadest interpretation
- Cover all claim types in the initial application
- Excess claim fees in US
- Antecedence basis (e.g., “an”, “a” / “the”)
- Mechanisms against Double patenting different between US and CA

Specific to Pharmaceutical Applications:

- Ensuring application comprises claims type that are suitable for listing
- Ensuring claims cover the medicinal ingredient to be sold
- Balancing advantages/disadvantages of listing patent

BCF BUSINESS LAW

OTHER CONSIDERATIONS

BCF BUSINESS LAW

OTHER CONSIDERATIONS

- Advantages in prosecuting US application before other countries (avoid file wrapper admissions)
- Protecting improvements / clinical trial results
- Keep records of know how associated with patented invention – valuable to North American parties
- Marketing / Regulatory affairs / Business development efforts in the US/CA

BCF BUSINESS LAW

FINAL COMMENTS

BCF BUSINESS LAW

FINAL COMMENTS

US/CA PATENTS

- A business tool and a source of revenue;
- A legal document rather than a technical one that needs to be analysed and valuated by lawyers in the context of a due diligence;
- Weaknesses in your US/CA patents can reduce its value or kill a deal;
- An early investment in a solid US/CA patent and protection strategy can pay dividends in the long run;
- Claimed subject matter should be revisited periodically throughout the patent application life cycle to ensure alignment with business objectives.

MANAGE YOUR US/CA ASSETS WISELY TO SUPPORT YOUR BUSINESS GOALS IN NORTH AMERICA!

BCF BUSINESS LAW

THANK YOU
СПАСИБО

Andréanne Auger, Ph. D.
Patent Agent

Andreanne.Auger@bcf.ca

BCF AVOCATS D'AFFAIRES