

NMIN Capacity-Building Webinar

# Navigating Intellectual Property (IP) Risk



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# Navigating Intellectual Property (IP) Risk

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# What is IP Risk?

Examples:

- Patent and trademark litigation
- Inability to sell a product because of blocking patents
- Inability to partner if assumed risk too great
- Inability to use your brand because of the same or confusing trademarks owned by others



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# Consequences

## Immediate risk:

- Inability to secure financing if blocking IP

## Future risk:

- Injunction – delivery up of infringing products
- Damages – lost profits in worst case scenario or reasonable royalty
- Law suit can cause bankruptcy





# Can a start-up manage IP risk?

- **The answer is “yes”** with some education and knowledge of tools and resources available
- **In-house:**
  - Freedom-to-operate patent searching
  - Initial analysis of potentially blocking patents
- **Outside counsel:**
  - Checking status of IP rights
  - Legal opinions
  - Licensing negotiations





# Freedom-to-operate assessment

## Three step approach:

- **Define the topic** – can be simple or complex
- **Conduct the search** – use free on-line database tools
- **Analyze the results** – do a first cut in-house



# Define the topic

## This may or may not be required:

- Sometimes simple – determining if a drug is off patent
- Often complex – multiple aspects of a product or process may be covered by multiple patents

## Examples:

- **Simple:** I want to formulate ciprofloxacin but don't yet have details of the formulation
  - Drug and broad formulation patents
- **Complex:** Product development has advanced to the point that I've identified a unique liposomal formulation with targeting ligands to formulate ciprofloxacin using a unique loading process
  - Lipids, loading methods, drug itself, broad formulation, specific formulation characteristics, targeting agent alone or formulated....





# Define the topic

**In an ideal world, search every aspect of the invention**

**Reality check:** prioritize search to those features of invention that are enabling and prioritize search based on enabling features

**Example:** unique liposomal formulation with targeting ligands to formulate ciprofloxacin using a unique loading process

**What is the most enabling?** Make a list of features you cannot live without:

- Drug? Perhaps you cannot change the drug...then prioritize drug
- Loading process? Perhaps you can only use the new loading process...then prioritize loading process





# Conduct the search: free on-line tools

## Google patents <https://patents.google.com/>

- Easy to use and links to European Patent Office website
- PDF downloads

## Espacenet <https://worldwide.espacenet.com/patent/>

- Worldwide collection and relatively easy to use
- PDF downloads and translations

## USPTO

- Not easy to use, does not list results by order of relevance
- Use as a backup search





# Carrying out the search

## Kinds of searches:

- **Keywords** – easy to conduct, but retrieves non-relevant hits
- **Classification codes** – results in few non-relevant hits, but classification by Patent Office is imperfect

**Consider data extraction to an excel worksheet to help screen results**





# Analyzing the results

Carry out first cut yourself

- Compile list of potentially relevant patents/applications
- Review “claims” – single sentences at end of patent defining scope of monopoly
- Compare product/process to **independent** claims



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# Example of a claim

12. A liposome composition for use in treating a subject with an affinity moiety capable of inhibiting binding of a first binding member, which is a pathogen or cell in the bloodstream, to a second binding member, which is a target cell or cell matrix, comprising

liposomes having outer surfaces that contain (i) a hydrophilic polymer coating composed of polyethylene glycol chains that are covalently linked to surface lipid components in the liposomes through releasable linkages, and (ii) said affinity moiety bound to the outer surfaces of said liposomes, such that the affinity moiety is shielded by said hydrophilic polymer coating from interaction with such binding members and is exposed for interaction with such binding members when at least a portion of the hydrophilic polymer coating is released.



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# Example comparison

no infringement since missing a feature

Claim 1	Product
Liposome formulation comprising:	<b>Yes</b> - liposome
targeting ligand; and	<b>No</b> – absence targeting ligand
encapsulated ciprofloxacin.	<b>Yes</b> - encapsulated ciprofloxacin





# Example comparison

infringement since all claim features present

Claim 1	Product
Liposome formulation comprising:	<b>Yes</b> - liposome
targeting ligand; and	<b>Yes</b> – targeting ligand
encapsulated ciprofloxacin.	<b>Yes</b> - encapsulated ciprofloxacin





# What is the status of the patent or application?

Many patents/applications are allowed to lapse by owners and so are not enforceable

- **Check on-line records** at espace-net (global dossier) and confirm status with outside counsel
- **Check country filings** – there may be no patent rights where you intend to commercialize or a world-wide application failed to nationalize.



# When blocking patents are uncovered

## Making the right business decisions

- **Can I design around easily?** Is it possible to alter your product/process so you can circumvent the patent?
- **If not, is patent invalid?** Can you find “prior art” that describes the subject matter of the claims?
- Analysis revolves around the claims
- Non-infringement and invalidity analyses should be conducted by outside counsel







# Example: design-around

Claim	Hypothetical product
Liposome formulation comprising:	Yes
targeting ligand; and	Yes but optional – remove to avoid claim
encapsulated ciprofloxacin	Yes





# Example: inability to design around



Claim	Hypothetical product
Liposome formulation comprising:	Yes
targeting ligand; and	Yes and cannot remove to avoid claim
encapsulated ciprofloxacin	Yes

# Assess validity if cannot design around

Is the claim novel and non-obvious?

- Example invalid claim:

Claim	Prior Art
Liposome formulation comprising:	Yes
targeting ligand; and	Yes
encapsulated ciprofloxacin	Yes





# Next steps if the patent is valid...

## Explore obtaining a license:

- **Universities** – often amenable to licensing their technology
- **Companies** – often less inclined to license, but consider cross-licensing:
  - if you have a patent application or patent in your portfolio that is key to the other company, then you might consider offering a license to them so you can use their patented technology (i.e., a license to use each others' patents)



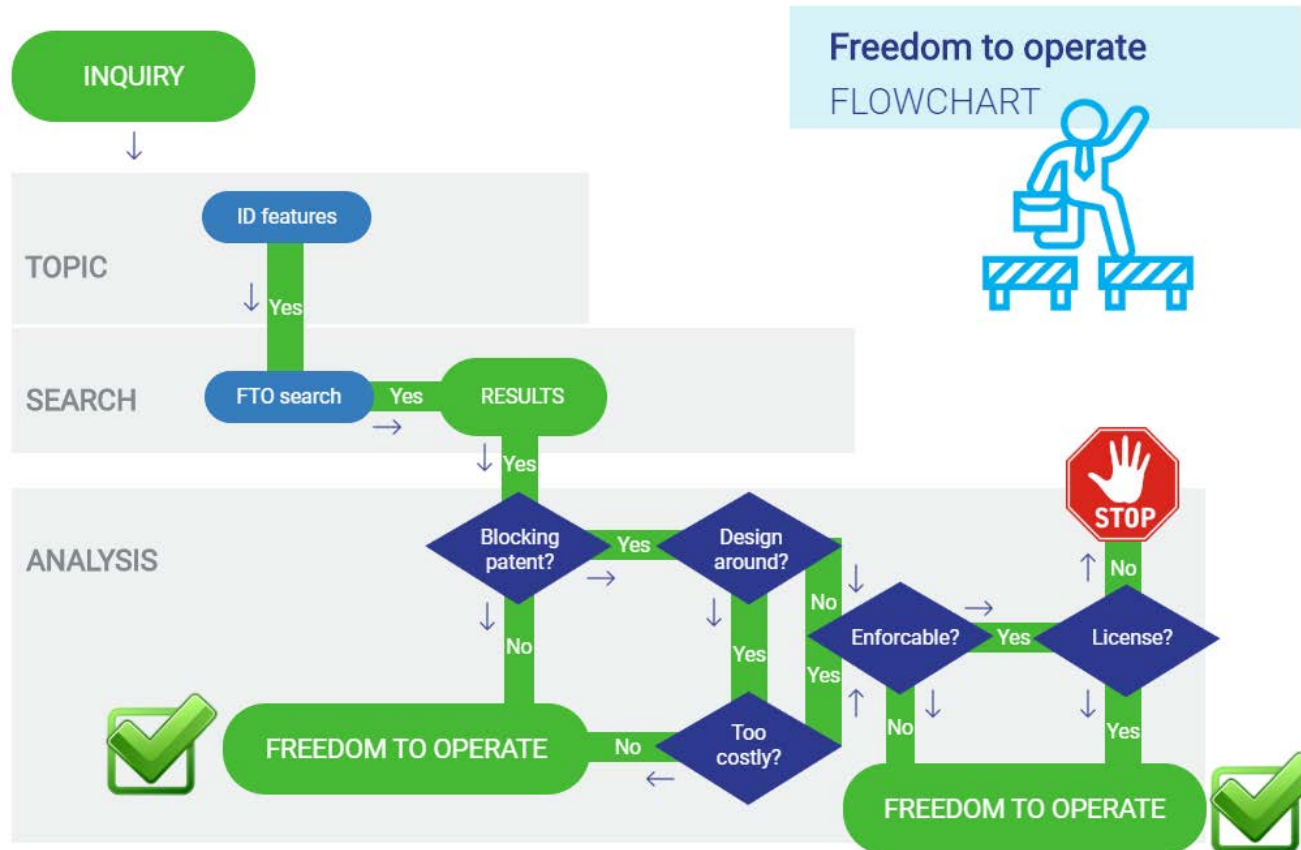


# What if blocking patent cannot be circumvented, is enforceable & you can't get a license?

- You will need to pull the plug on research/product development
- Underlines importance of doing your due diligence early on
- Also, ongoing FTO risk analysis is important throughout all stages of product development to uncover surprises early on in product development



# Sneak peek at interactive on-line tool:



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# Tips and Tricks

## managing the process

What to do in-house to save cost vs. outsourcing:

In-house	Outside Counsel (legal work)
Patent searching	Reviewing patents for relevance
Possibly initial identification of relevant patents	Non-infringement and invalidity opinion
Exploring licensing opportunities	Writing and negotiation of license





## Other practical tips

- Internal emails and other written communications are not privileged
- Keep such emails to a minimum and do not make negative statements regarding infringement or validity of a patent







# Conclusion - patents

- Managing patent infringement risk is a process
- Mitigating such risk at the start and throughout product development is manageable with some knowledge of tools available and an understanding of the analysis
- Good luck!





# Trademark Basics – What is a Trademark?



- Usually word or logo
- Under new legislation expansive approach to what is a tm
- Unique identifier that associates a product or service with its source
- Important- conceptualizes what your company/product/service is about and differentiates
- Identity + reputation
- Valuable



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# Trademark Test – Spot the Trademarks

HERSHEY'S KISSES ✓✓✓



- Silver ✓
- Brown ✓
- Blue ✓



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# Trademark Basics - Specific to Pharma



- Important to avoid confusion since health can be at stake
- Marks for medications etc. tend to be distinctive
- Marks tend to be well searched in advance of filing to ensure no overlap (clearance)
- Results in fewer tm contentious proceedings
- Companies invest in IP advice
- Less success with shape marks
- Colour applied to the surface of pill etc. not generally registrable
- Functionality prohibitions



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# Trademark Basics

## On Your Marks, Get Set, Go! How to Choose a Trademark



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- Distinctiveness is key
- Descriptive or generic = low or non-existent distinctiveness
- Suggestive
- Arbitrary
- Coined and arbitrary (fanciful)



# Trademark Basics – I Have Decided on a Trademark...Now What?

- Limited rights accrue through use
  - only where geographic sales
  - not prima facie presumption of rights versus others
  - entrenchment of rights as of first use (limited)
- Registration
  - Rights good across Canada
  - Presumption of valid rights
  - Advantageous to place on file as soon as possible, more expansive entrenchment of rights as of filing date
  - Enhanced value for secured financing etc.





# Trademark Basics

## Applying for Registration

- Easy process
- Difficult to ensure you are getting it right unless well versed in tm law
- Need:
  - Mark
    - Word, design, colour?
  - Owner
    - Must control character and quality of goods
  - G/S
    - Cost implications re classes but within class should describe expansively





# Trademark Basics – Where to Protect

- Filing strategies are exceptionally important to ensure you obtain the best possible protection at the lowest possible cost
- Madrid Protocol can be very useful tool over the national route
- Understanding the idiosyncrasies of major jurisdictions can save time and money and are important in your filing plan
- Budgeting is important







## Trademark Basics – Where to Protect

- Register in each country (or in the case of Europe and a few others, by region)
- File in Canada and then have a 6 month grace-period to file elsewhere claiming rights as of Canadian filing date (priority)
- Protect in countries where you have sales, manufacturing





# Trademark Basics – Tips for Success

- Choose a distinctive mark
- Invest in registration
- Use professional advice for filing strategies that meet your goals and your budget
- Ensure the way you use your mark preserves your rights
  - Set it apart
  - Use symbol
    - TM if unregistered
    - ® if registered
  - Refer to mark plus descriptor eg. Bandaid ® bandage
  - Do not use as verb –eg. Rollerblading is fun
  - Do not vary appearance of logo
  - Guard against becoming generic
- Protect by monitoring adoption and use of confusing marks by others



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# Q&A

CLICK to hear the questions & answers



What is the value of a trademark for a researcher with a patent?

What patenting/IP mistakes have you seen made by academics?

What is the difference between a patent application and a patent?

Is it worth paying for a patent search to get filewrappers?

How long does trademark registration last in Canada? Must you renew it?

Are there overarching patent classifications? Is there one that covers all lipid-based drug delivery systems?

Is there a database that records the termination date of patents or shows if they are still valid?



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# Q&A

CLICK to hear the questions & answers



What books would you recommend on these topics?

Are there best strategies to pursue when patenting or developing a patent portfolio?

Should you patent early even if you do not yet have scientific certainty?

Are there best strategies for securing trademarks?

How is a patent invalidated and how often does this occur?



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