Cooley

IP Protection for Start-Ups

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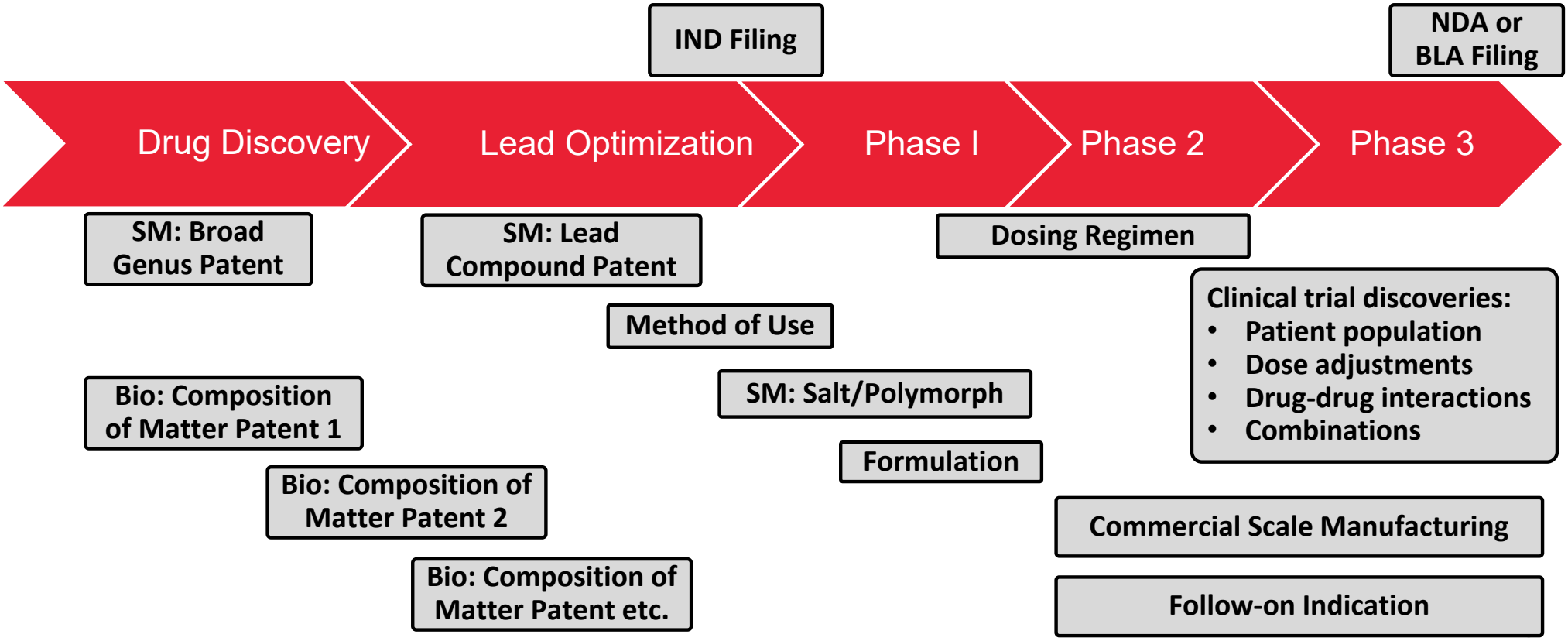
Overview

- R&D and Patent Timeline
- Drug Discovery:
  - What is a patent?
  - What is your patent strategy?
  - Ownership and Inventorship
  - Public Disclosures and Confidential Information
- Lead optimization:
  - Freedom to operate vs. Patentability
- Clinical stage:
  - Patent life cycle management
- Attracting early-stage investment
  - What do you need? What's not expected?

R&D Milestones and Patenting Timeline



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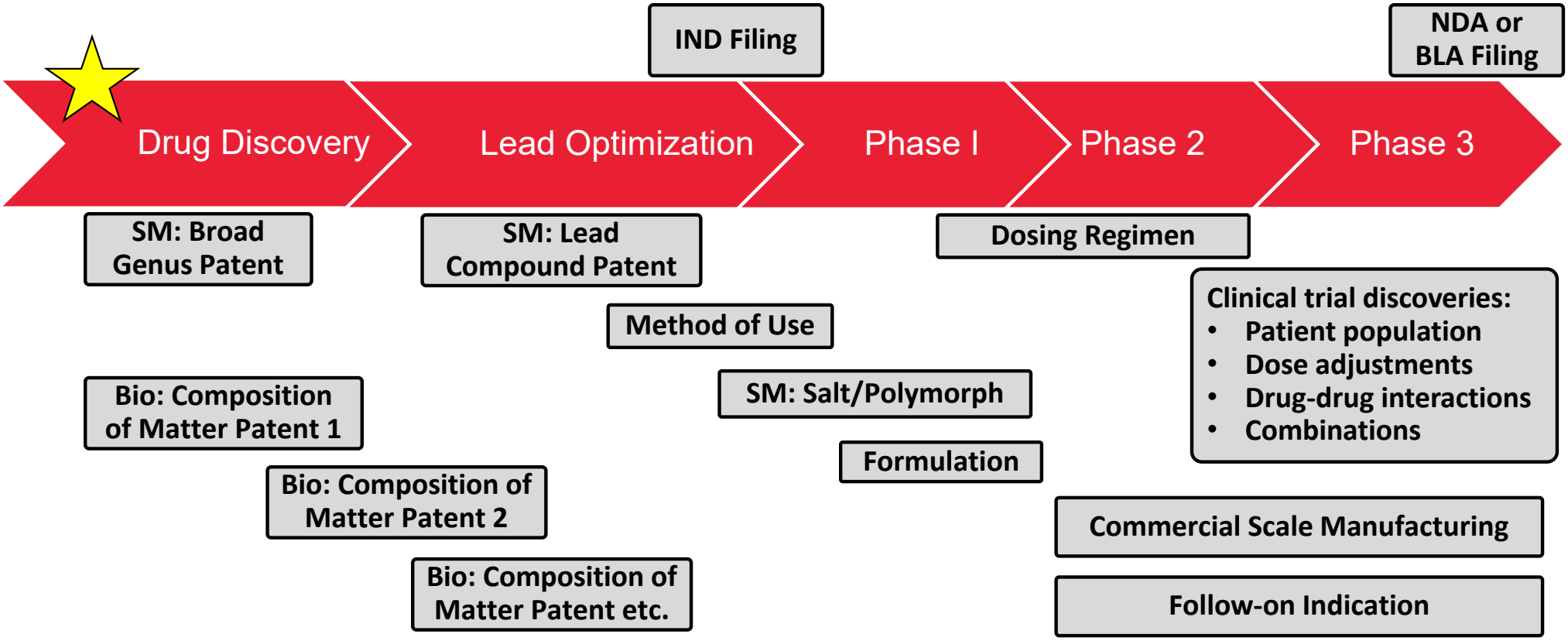


What is a patent?

- A patent is ***not*** a right to use, sell, etc. an invention.
- A patent is a right to exclude someone else making, using, selling, offering to sell & importing the invention.
- The right is granted for a limited period of time in exchange for sharing your technology
- Promotes innovation for the good of consumers, inventors, businesses, & the economy

What is your patent strategy?

- Consider what kind of company you are – are you developing a drug product? Are you providing a service? Are you selling a device or a kit for performing a test?
- Consider what kind of claims will cover what your company sells
  - Composition of matter – to cover your drug product or device
  - Method of manufacturing
  - Method of using
- Consider how your competitors might design around you
  - Build your patent wall with as many different types of bricks as possible
  - Enables for you to add claims that might be attractive to partners

When & where to file?

- Consider need for further data vs. pressure of first to file
- Need a patent fast?
  - Consider filing a US utility at the same time you file a PCT
  - Consider Track I examination
  - Consider filing in the UK at the same time as the US/PCT
  - Address all issues at the non-final OA stage
- Early stage/still seeking funding?
  - Take full advantage of PCT process
  - Beware of risks to PTA by expediting examination

Inventorship

- Authorship on a journal article does not necessarily equate to inventorship for patent application
- Under US Patent law, an inventor is an individual who made a contribution to the **conception** of the subject matter of **at least one claim**
- A “pair of hands” is not an inventor
  - for example, a lab technician who merely follows direction of a supervisor
- But a lab technician may be an inventor when contributing more
  - for example, suggests further modifications or improvements
- Sole inventorship is easy, but joint inventorship can be challenging to get it right
- Why does this matter?
  - In the US, a patent can be invalidated for incorrect inventorship
  - Inventorship determines ownership

Joint inventorship

- When more than one person contributes to the **conception** of a non-obvious solution to the problem which constitutes the invention
- "[O]ne of the muddiest concepts in the muddy metaphysics of patent law".†
- One does not become a joint inventor by
  - suggesting a desired end or result, with no suggestion of how to reach that end
  - following instructions of the person who conceived of the solution
- Joint inventors work towards the same goal – but need not:
  - have worked together
  - worked at the same time
  - contributed the same type or amount of work
  - contributed to every claim
  - ****inventorship determinations are fact intensive and courts have found that some "quantum" of collaboration or connection between inventors is required****

†*Meuller Brass Co. v. Reading Industries, Inc.,* 352 F. Supp. 1357, 1372 (E.D. Pa. 1972)

Inventorship

- U.S. utility patent application must be filed in the name of the actual inventor(s)
  - Any mistakes can be corrected before issuance of patent
  - Inventorship update may be needed while claim scope change during prosecution
- A patent may be found invalid if the inventorship is incorrect (naming more or less than the true inventors)
  - Correction is possible, as long as there is no “deceptive intent”

Inventorship in the Age of AI

- U.S. utility patent application must be filed in the name of the actual inventor(s) – an AI model cannot be an inventor
  - Remember – Under US law, a patent may be found invalid if the inventorship is incorrect!
- Using an off-the shelf AI system to design a new compound ***does not*** amount to inventorship
- Inventing with AI
  - Develop an AI model to solve a specific problem
  - Modify the output of the AI system
  - Take a list of possible options from an AI system and follow-up with lab work to identify the options that work for your intended purposes

Inventorship Best Practices

- Discuss the contributions of individuals associated with the claimed subject matter
- Distinguish between conception and implementation
- Distinguish between authors and inventors
- Document each inventor's contribution – contemporaneous notes will help years later when issues come up
  - When working with AI – document the human contributions at each step (developing/training the system, prompt engineering, further lab work on AI-generated compounds)
- Determine inventorship and get necessary assignments executed as soon as possible

Patent Ownership

- Inventor(s) or a company/institution to which the inventor(s) assign their rights to (usually the latter)
- Important for all employment agreements, consulting agreements, or the like to have **present tense** IP assignment
  - I "hereby assign" = an assignment
  - I "will assign" or "agree to assign" ≠ an assignment, just a promise
- Public notice of ownership – recordation
  - Inventor assignments
  - Company name change
  - Company to company assignment (merger, acquisition, transfers, etc)
- Why does this matter?
  - One of the first questions an investor is going to ask during diligence is whether the company owns the IP
    → Having documentation for clear chain of title to your IP at the outset will save many headaches later

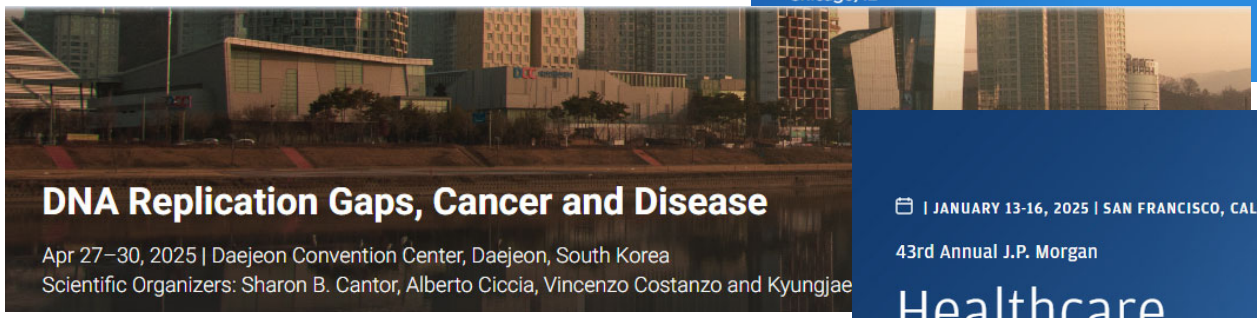
Government March-In Rights

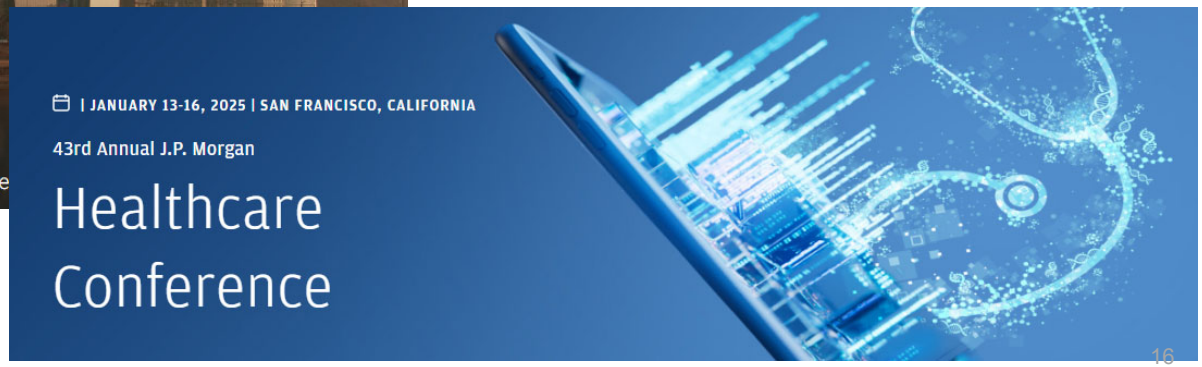
- If the invention was made under US Government support – Application is subject to provisions of the Bayh-Dole Act
- US Government has certain rights to the invention
  - March-in rights – allows a US agency to grant compulsory license to a third party if good-faith efforts aren't being made to commercialize invention
- Reporting obligation to those invention made with US Government support (iEdison)

Bayh-Dole Act – 2018 Update

- Bayh-Dole Act update took effect on May 14, 2018
- Applies to funding agreements **executed after May 14, 2018**, and may also apply to existing funding agreements **modified after May 14, 2018**
- New regulations requires to file any non-provisional patent application (whether a U.S. application, a PCT application, or a foreign application) **within 10 months**
- A request for extension of time is available, but should be requested early (by 8th month because there's a 60-day review period)
- Failure to convert within 10 months or obtain extension may jeopardize your ownership of the patent application and any associated rights

Let's talk about it!





Public Disclosures

- Patent protection is available to invention that are novel and nonobvious
  - Novel = no prior public disclosure, public use, public sale
- Examples of public disclosure
  - Publishing your invention in literature (abstract/paper submission)
  - Inclusion of your invention in a thesis or dissertation
  - Posting the details of your invention on the Internet (e.g., ClinicalTrials.gov disclosure, press release)
  - Oral or written disclosure of your invention at scientific meetings or lectures (e.g., oral/poster presentation)
  - Disclosing your invention to any visitors to the laboratory in a non-confidential manner, including posters
  - Nonconfidential disclosures to potential partners (e.g., pitch deck)

Before Public Disclosures…

- File a provisional patent application!
- Don’t assume what you intend to disclose is protected by prior application(s) – please consult your patent counsel

What if Public Disclosure was Made?

- US has one year grace period for inventor's own disclosures
- Many countries do not have such grace period so public disclosure can jeopardize patentability of your invention
- Duty-to-disclose to US Patent Office
  - Must notify patent office of all known prior disclosure and relevant art that are material to patentability
  - Withholding information = inequitable conduct = patent invalid

Confidential Information

- Obtain CDAs when possible
- Technical Information
  - File patent application prior to disclosure
  - Discuss without disclosure of specific compound structures if possible (wait to disclose)
- Don’t waive Attorney-Client privilege
  - For sensitive IP discussions, include your attorney in the email
  - Legal opinions etc.

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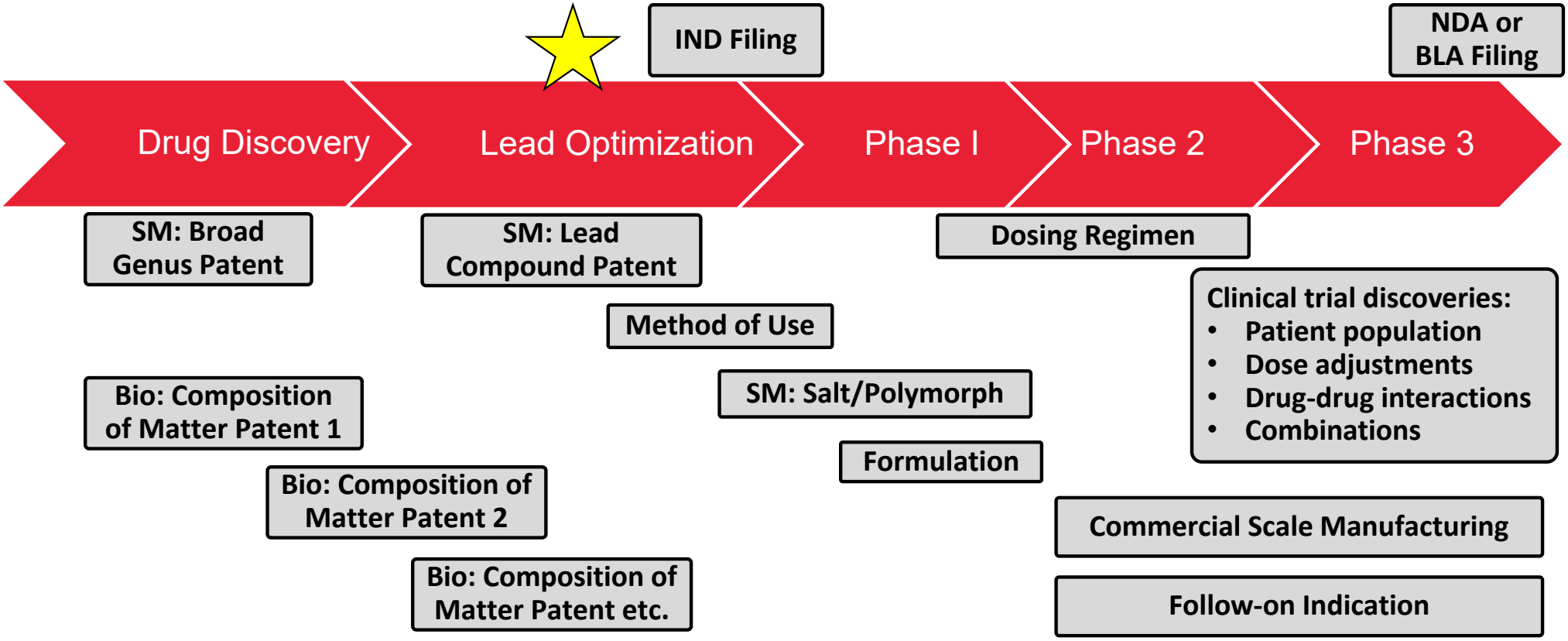
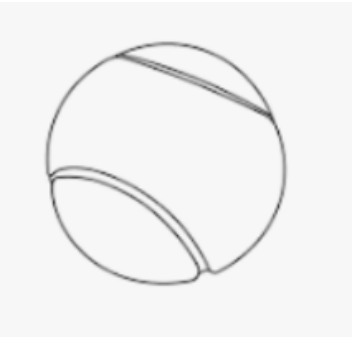


Freedom to Operate vs. Patentability

- A patent does not give you the right to practice your invention
  - Patents are issued with varying scope – there may be another entity with a claim that is broader than your patent claim that would prevent you from practicing your invention
- Patentabililty – Is your invention novel and nonobvious?
- Freedom to Operate (FTO) – To what extent are you infringing on patents by others?
  - Is your invention dominated by someone with a “generic” invention or claims to a “genus”?
  - Does your invention employ property that has been patented by someone else?

Freedom to Operate vs. Patentability

- Example: invention is a species of a larger genus
  - Company A filed 1st and got claims to “A tennis ball” = genus
  - Company B filed 2nd and got claims to “A green tennis ball” = species
  - Both are patentable (as long as they are novel and nonobvious)
  - But only Company A (with claims to the genus) has FTO
    - Company B’s green tennis ball infringes Company A’s patent if used
- FTO analyses can be expensive – involve reviewing and analyzing large sets of search results; the more complicated your product, the more complicated the search
  - Be strategic in deciding when to engage in these searches – usually done before making decisions re: large investments in R&D
  - E.g., before finalizing any part of your product or process and/or at lead candidate selection
- Consider your timeline to market and safe harbor under 271(e) when evaluating FTO risks



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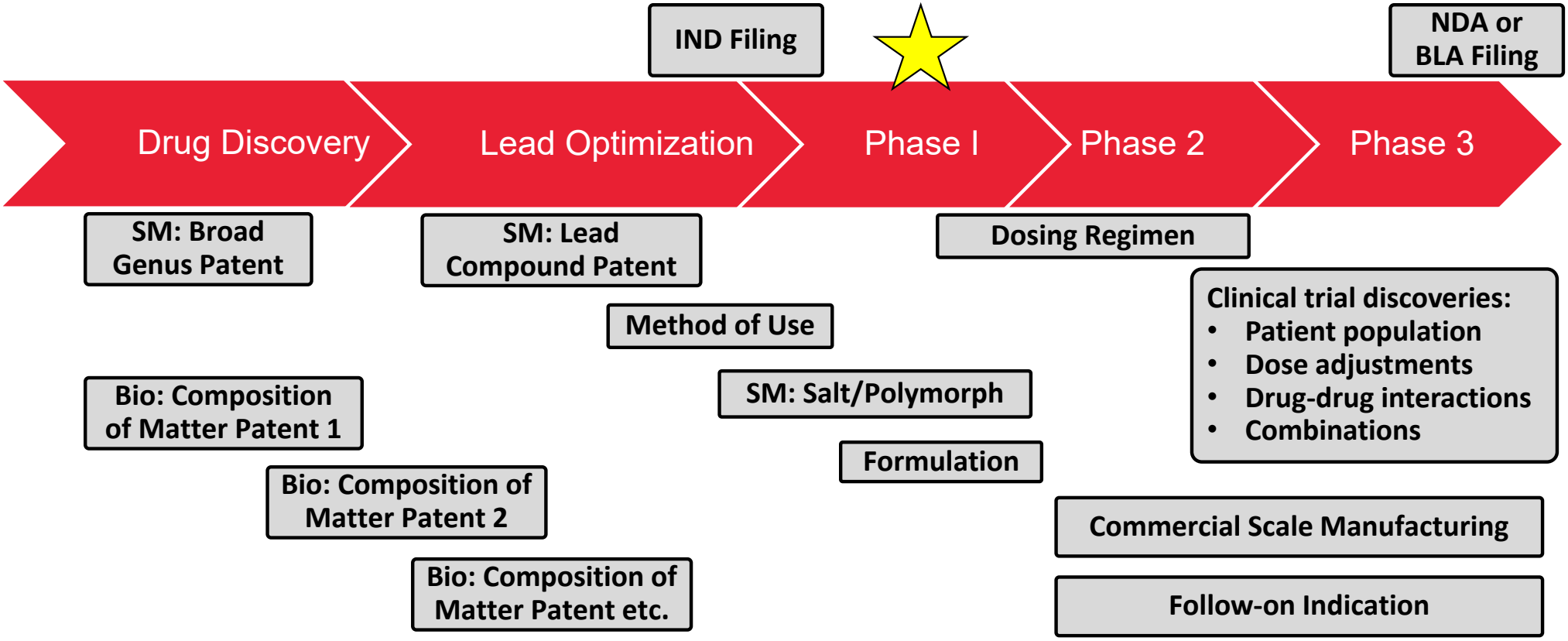

Patent Life Cycle Management

- The first filing (composition of matter, method of use) on your technology is not the only source of patentable material
- Consider the entire life cycle of your technology – when there is an inflection point in development, there is usually a patentable invention associated with this inflection point
  - Selection of leads – follow-on species filings for your selected leads, compound improvements
  - Entering the clinic – IND filings, dosing regimens, patient populations, formulations
  - Commercialization – consider methods necessary for commercial scale manufacturing
- Consider your drug label early!

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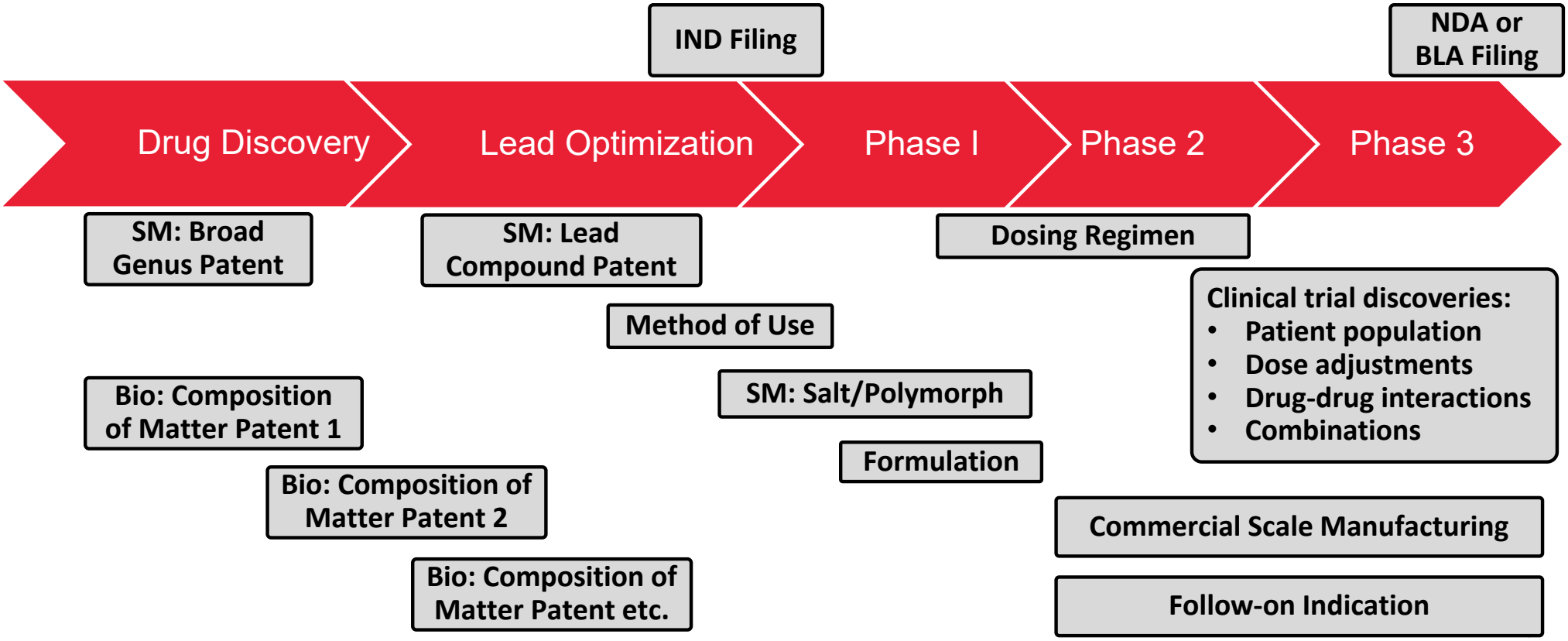

Questions?

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