

TLO Toolbox: Hammer Out Successful License Agreements and Avoid Terminal Disclaimer Problems

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Intellectual Property Law

Presenters



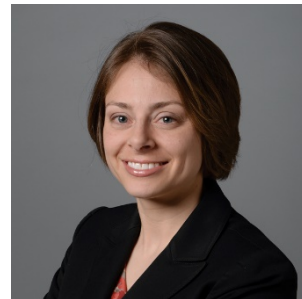
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Hamilton Brook Smith Reynolds

2
Offices



Boston

Seaport Innovation District



Concord

Route 128 Technology Corridor

1980
Year Founded

Broad Spectrum of Technology Specialties

- Artificial Intelligence
- Autonomous Vehicles
- Bioinformatics
- Biotechnology & Life Sciences
- Biologics & Immunotherapeutics
- Blockchain
- Chemical Engineering
- Pharmaceuticals
- Chemistry
- Material Sciences
- Clean Technology
- Medical Devices
- Medical Imaging
- Mechanical Engineering
- Electrical Engineering
- Semiconductors
- Optics
- Robotics
- Mobile
- Internet of Things
- Network Infrastructure
- Telecommunications
- Computer Hardware
- Computer Software
- Business Methods

35
Attorneys,
Patents Agents,
Technology Specialists

Numerous
Firm accolades since
2010, including:



Andy Curtin

Director of Intellectual Property, Northeastern University



- Over 20 years of intellectual property experience
- Served as Senior IP Counsel for the Enterprise and Imaging Divisions of Nuance Communications, Senior Patent Counsel at 3Com Corporation, and Patent Counsel at Mitsubishi Electric Research Labs

N Northeastern University Center for Research Innovation

The CRI team is agile and responsive – focused on the translation of University innovations into tangible solutions through licenses, spinouts and collaborations.

Our dedication to establishing ongoing dialogue with industry informs Northeastern’s progressive research, enabling a productive balance between exploration and implementation.

<https://www.northeastern.edu/cri/>



Technology Licensing Officer (TLO) Toolbox



Terminal Disclaimers

Exclusive Patent Licenses

Non-Exclusive Patent Licenses

Joint Research Agreements

Inter-Institutional Agreements

Patent Assignments

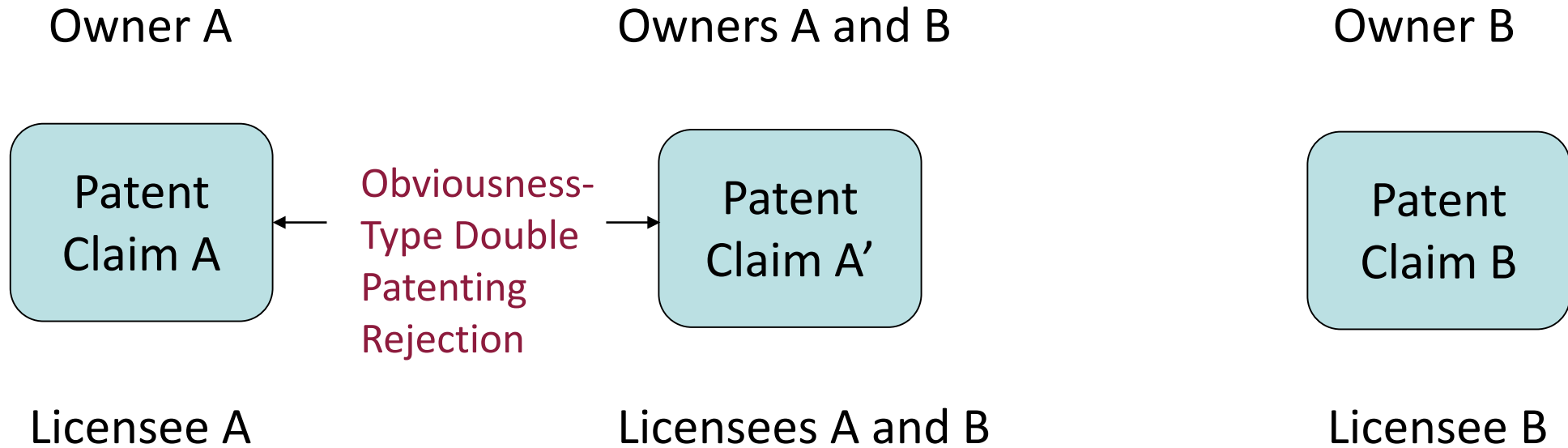
Deirdre Sanders

Principal, Hamilton Brook Smith Reynolds



- 25 years of law firm experience
- State Legislative experience
- University teaching experience
- Immediate Past President, Boston Patent Law Association
- Science expertise in monoclonal antibodies, immuno-oncology, genetics, therapeutic methods, diagnostic methods, biotherapeutics, vaccines, etc.
- Litigation experience: Federal District Court Trials, Federal Circuit Appeals

Risk of Impacting Rights



Rights of an Owner or a Licensee will be impacted.

Double Patenting Rejections

There are generally two types of double patenting rejections:

A "same invention" type double patenting rejection is based on 35 U.S.C. 101, which states in the singular that an inventor "may obtain a patent."

A "nonstatutory-type" double patenting rejection is based on a judicially created doctrine grounded in public policy and which is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent.

Options for Overcoming Double Patenting Rejections

- Terminal Disclaimers – common ownership required
- Arguments
- Claim Amendments
- Claim Cancellations
- Application Abandonment

Consider potential effect on co-owner or licensee

Input to Patent Counsel

Patent Manager Input

- Subject Matter
- Target Market
- Ownership
- License Commitments



Patent Counsel Recommendations

- Global Application Strategy
- Claim types
 - Serial or Parallel Filings
 - 1st Filing U.S. or PCT

U.S. Application Claim Types Flexibility

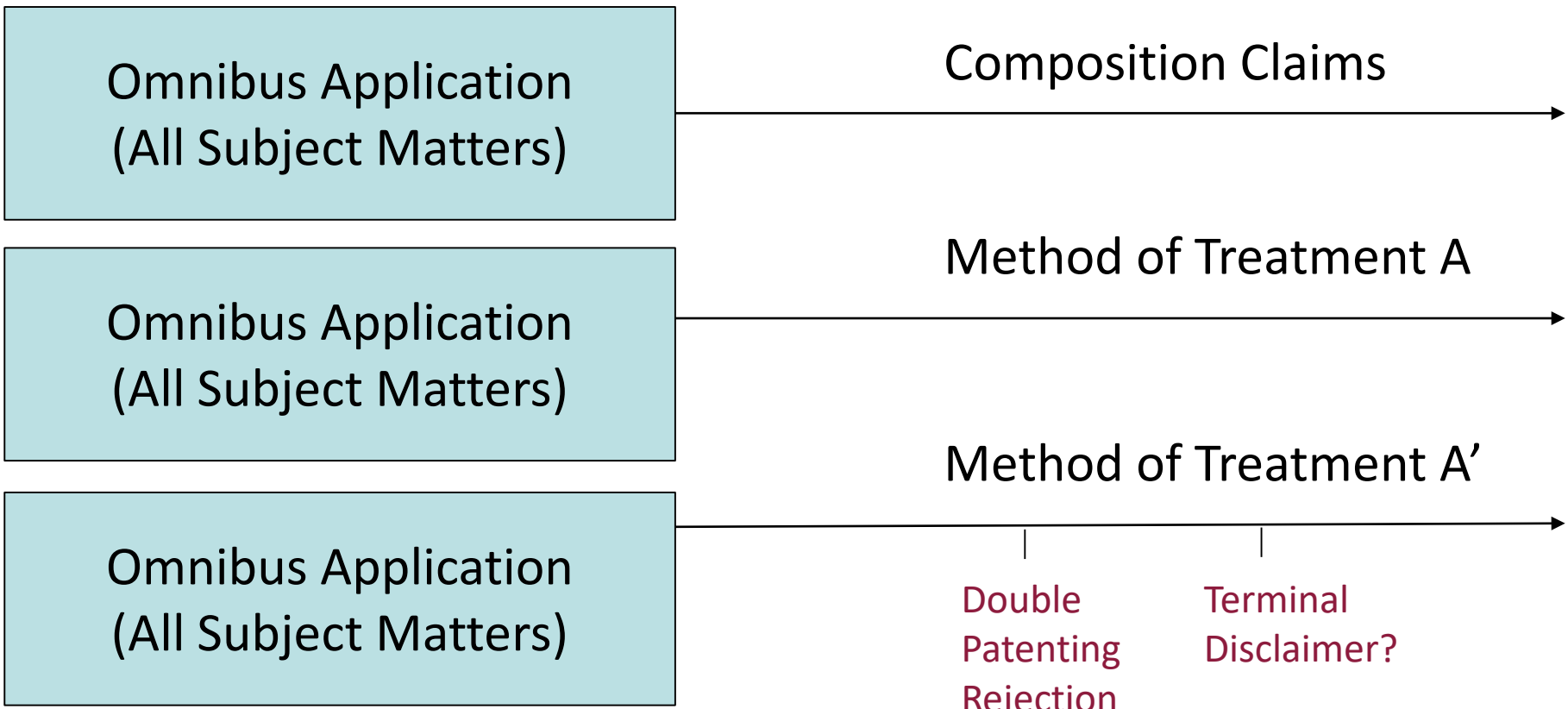
Life Sciences

- Compounds
- Compositions
- Methods of Treatment
- Methods of Diagnosis
- Methods of Detection
- Methods of Manufacture
- Kits

Medical Devices/Engineering

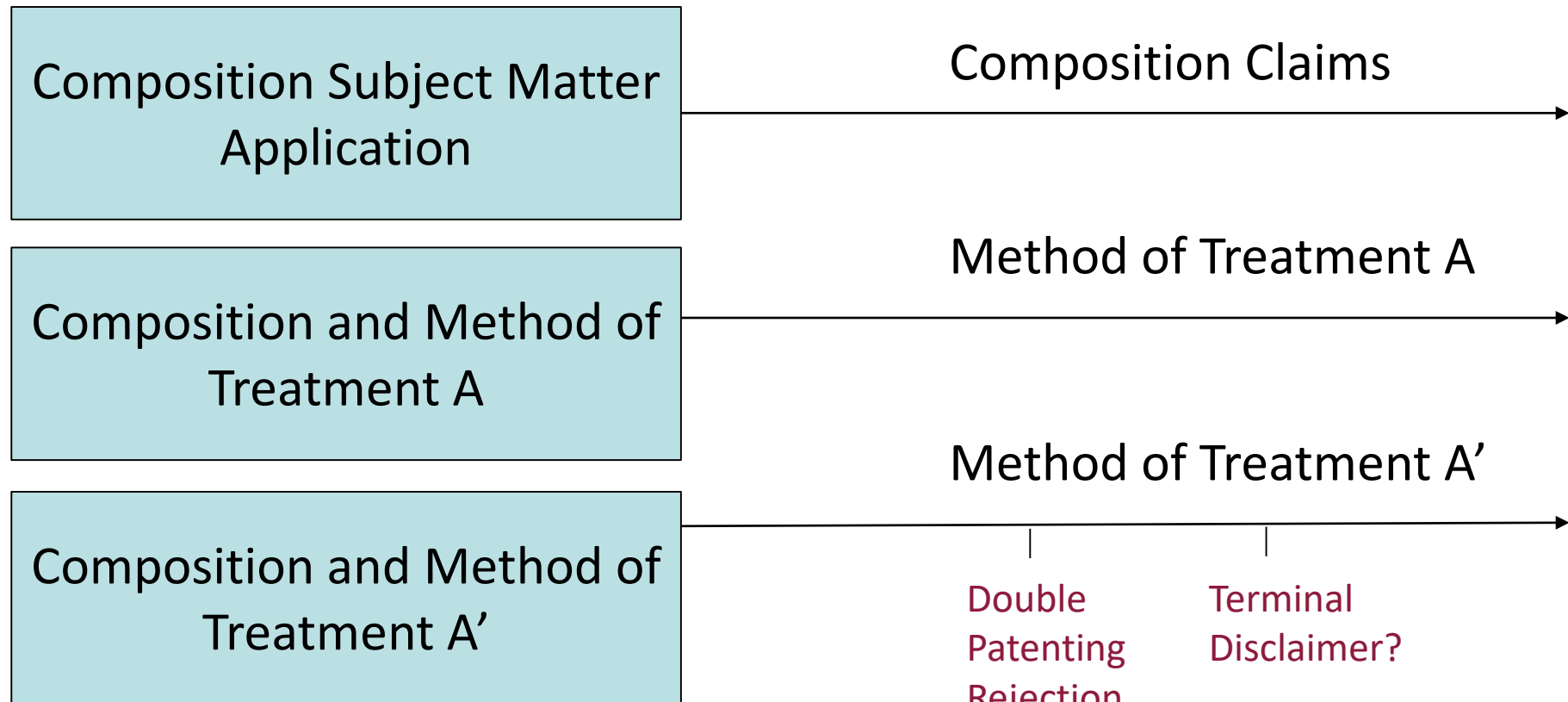
- Apparatus
- Means-plus-function
- Method of Use
- Method of Manufacture
- Computer Readable Medium
- Software as a Service (SaaS)
- Kits

Parallel Filings



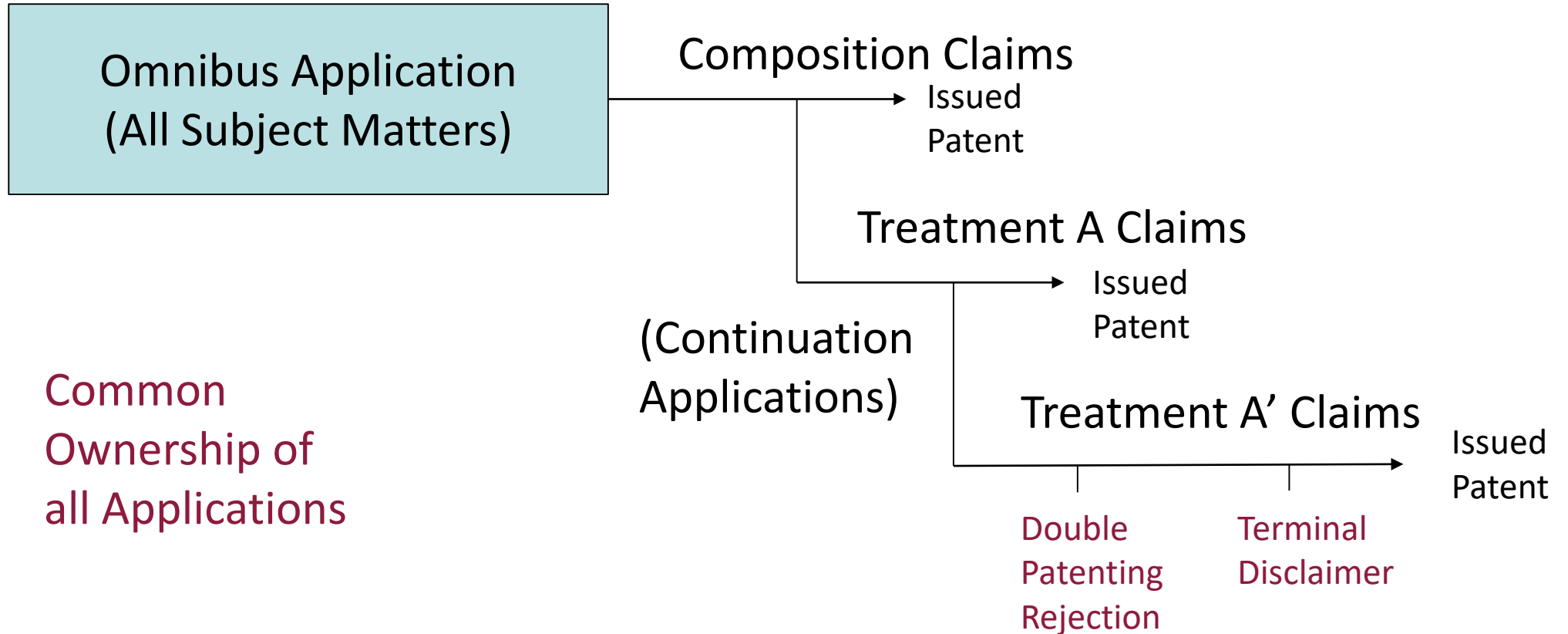
Ownership based on claims

Parallel Filings



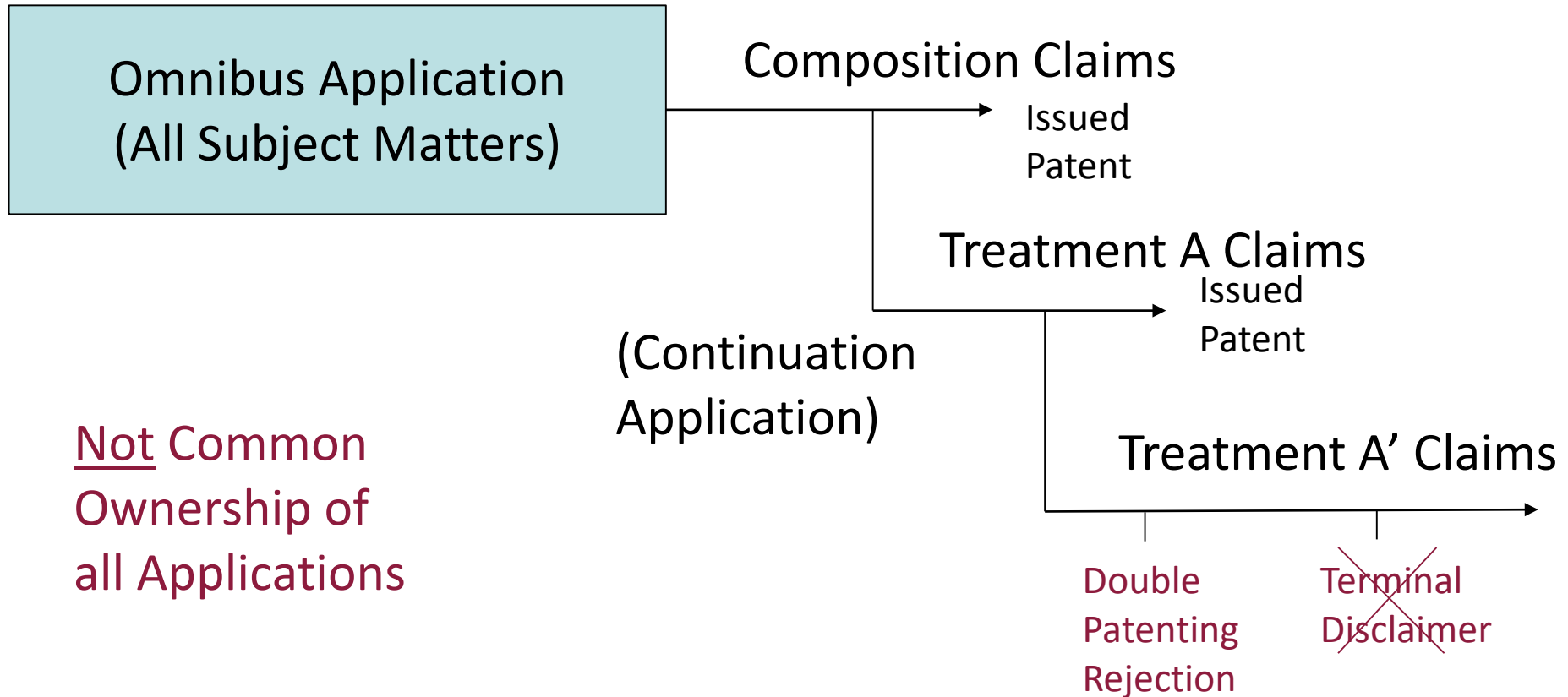
Ownership based on claims

Serial Filings – Continuation Applications

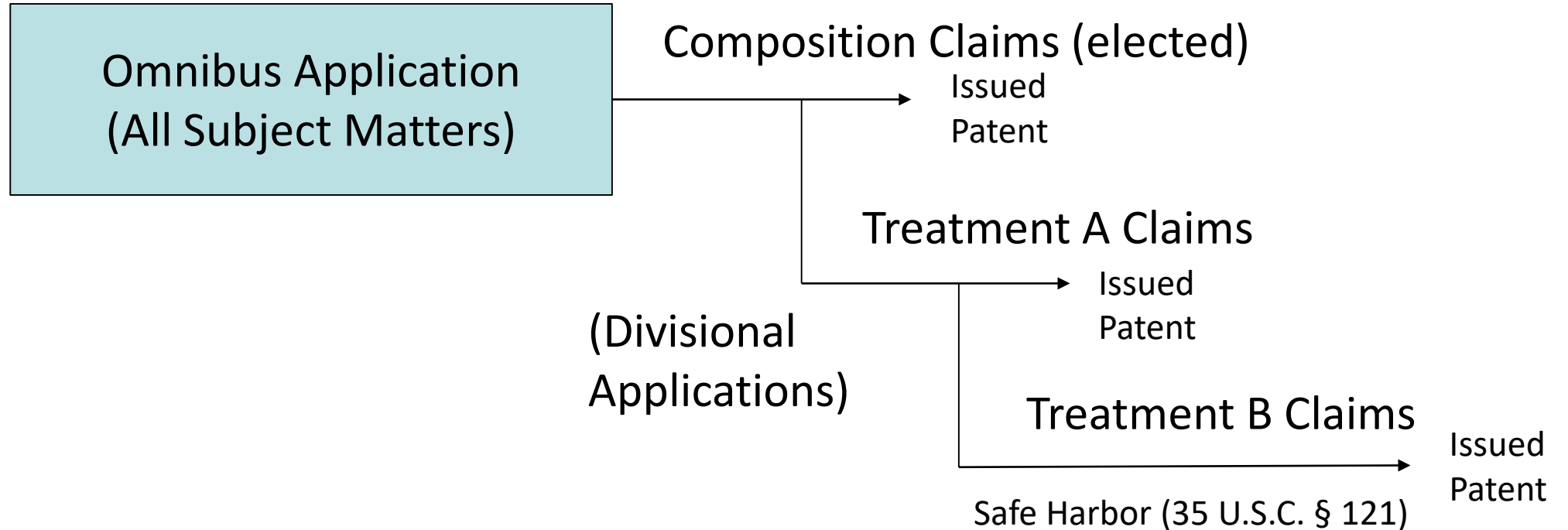


Common
Ownership of
all Applications

Serial Filings – Continuation Applications



Serial Filings – Divisional Applications



Restriction Requirement

Invention Group I (elected)

Inventor A

Owner A

Invention Group II (withdrawn/cancelled)

Inventor B

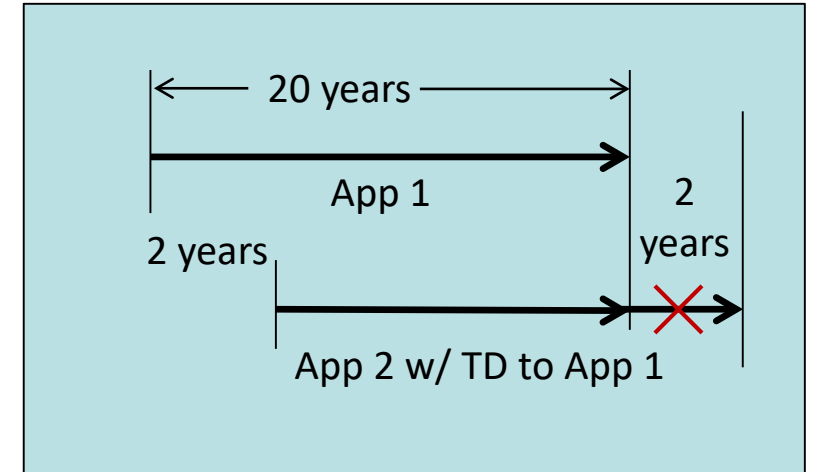
Owner B

Effect on Owner B

Effect on Licensee of Group II claims

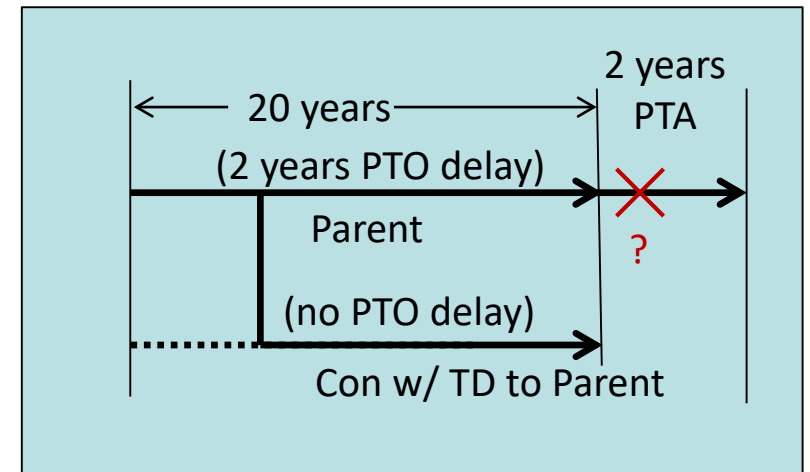
Terminal Disclaimers – Typical Considerations

- Terminal Disclaimers overcome an obviousness-type double patenting rejection in exchange for matching end of term with patent that formed the basis of rejection
- Applications must be **co-owned** throughout patent term



Terminal Disclaimers – Advanced Considerations

- Are earlier issued claims obvious over later issuing claims (*i.e.*, does double patenting apply)?
- Earlier issued patent is invalid until Terminal Disclaimer is filed, if Terminal Disclaimer is needed.
- Patent with Terminal Disclaimer ends at same time as other patent, even if term is lost in earlier issued patent. (*Gilead*)
- Terminal Disclaimers may affect the duration of a license -- patent owner cannot charge royalties after the patent expires (*Marvel*)



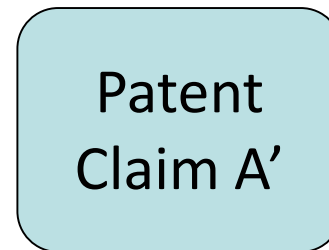
Strategic Agreements or Filings Reduce Risk of Impacting Rights

Owner A



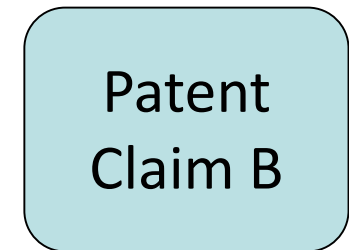
Licensee A

Owners A and B



Licensees A and B

Owner B



Licensee B

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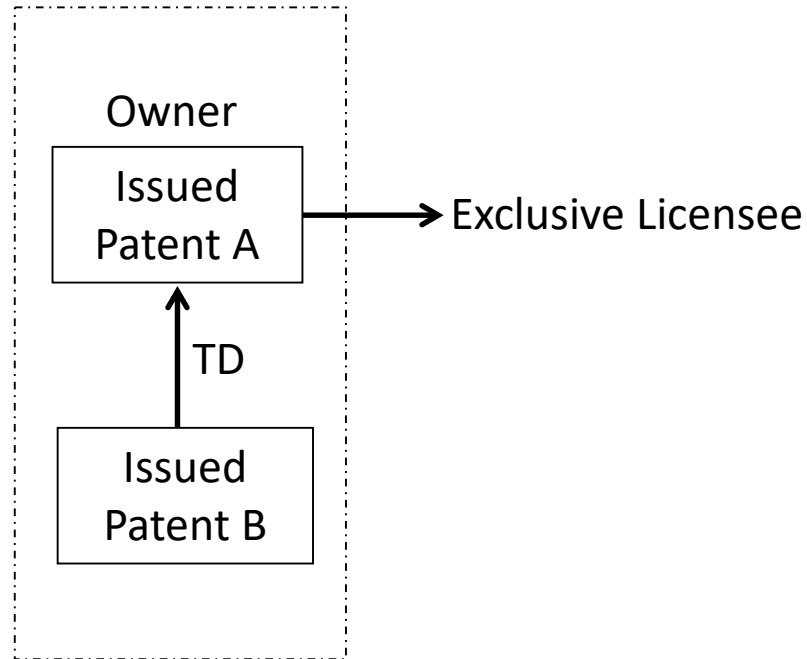


- Over 10 years of law firm experience
- Organic Chemistry Background
- Ph.D. Degree, Chemistry
- Harvard University, Ph.D.
- Boston University Law School, J.D.
- Experience with the preparation and prosecution of both U.S. and foreign patents involving small molecules
- Practices in areas of pharmaceuticals, chemistry, and biotechnology

Exclusive Patent Licenses

- In an **exclusive patent license**, a licensor agrees not to practice the invention or grant other exclusive licenses to other licensors in a specified field and/or territory
- An exclusive patent license can, but need not, confer independent standing to sue under a patent
- An exclusive patent license that confers independent standing to sue is a ***de facto* assignment** of the patent

Exclusive Patent Licenses and Ownership



Does Owner co-own Patents A and B or does the exclusive license operate as a *de facto* assignment of Patent A?

- An exclusive patent license that transfers “**all substantial rights**” in a patent is a *de facto* assignment of the patent

“All Substantial Rights”

- Rights that, once relinquished, result in *de facto* assignment of the patent
 - Exclusive Right to Make, Use and Sell Under the Patent;
 - Right to Control (Past, Present and Future) Litigation Decisions;
 - Right to Sublicense;
 - Reversionary Interest;
 - Right to Exclude in All Field(s) of Use; *and*
 - Right to Assign

Insubstantial Rights

- Rights that, though retained, are insufficient to foreclose *de facto* assignment
 - Financial Interests, including royalties and damages sharing
 - Notification Rights
 - Limited Control Over Sublicensing
 - Termination Provisions, especially when associated with a self-renewing provision or predicated on license breach
 - Territorial Limitations (*e.g.*, ex-U.S.)
 - Right to Make, Sell and Use, especially when retained by a non-practicing entity

Substantial Rights

- Right to Sue, when retained, is sufficient to foreclose *de facto* assignment
- Right to bring suit, even when right is secondary to licensee's right to bring suit
 - *E.g.*, “In the event that Licensee is unsuccessful in persuading the alleged infringer to desist or fails to initiate an infringement action within a reasonable time after Licensee first becomes aware of the basis for such action, **Licensor shall have the right, at its sole discretion, to prosecute such infringement...**”

Substantial Rights

- Right to Sue, when retained, is sufficient to foreclose *de facto* assignment
 - Right to join lawsuit alleging infringement of the licensed patent
 - *E.g.*, “Licensor shall have the **right to participate in any action** to prosecute any Third Party infringement of the Patent Rights in the relevant Field in the Territory through its own counsel.”
 - Consultation rights
 - *E.g.*, “Prior to commencing any such action, **Licensee will consult with Licensor** and shall consider the views of Licensor...”
- Veto rights/Right to consent

Multi-Party Interests In Patent Prosecution

- AUTM's Model Inter-institutional Agreement (MIIA)
 - Divides rights amongst a Lead Institution and Other Institution(s)
 - Nearly all patent prosecution and licensing authority lies with the Lead Institution
 - Other Institution(s) retain limited rights, such as the right to license patent rights to other non-profit research institutions for research and educational purposes
- Clarity results from assigning roles
- Be the Lead, when possible

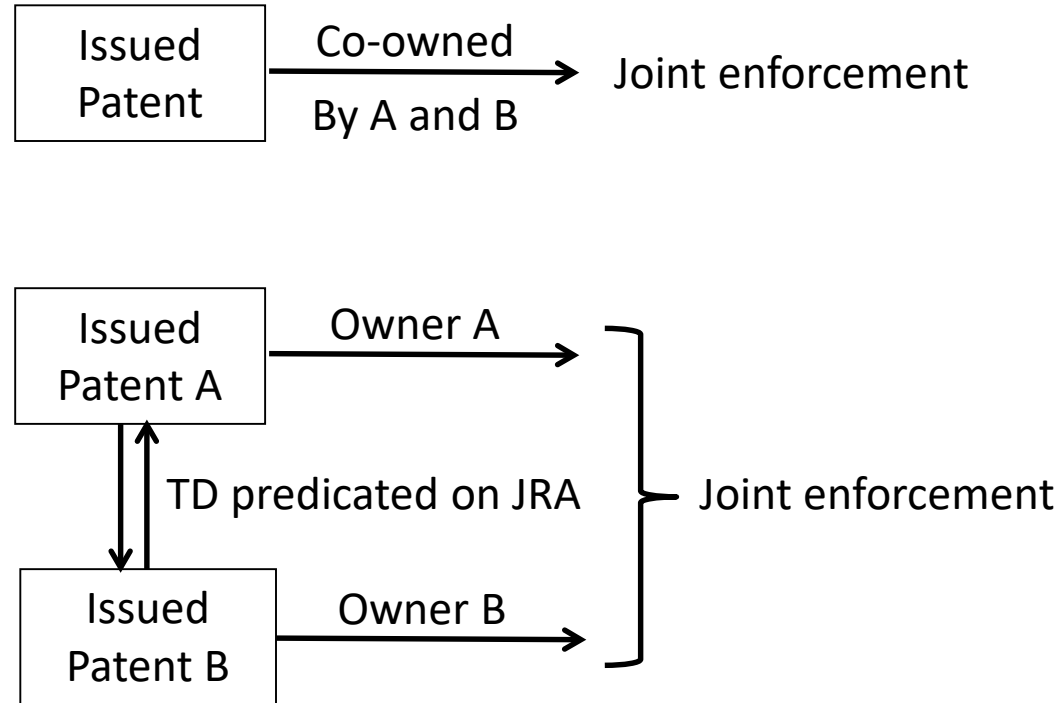
Multi-Party Interests in Patent Litigation

- AUTM's MIIA not designed to address patent litigation
- Exclusive Patent Licenses
 - Retaining “substantial rights” often delegates rights and duties related to patent litigation
- Joint Research Agreements

Joint Research Agreements

- To be effective, a JRA must be in effect **on or before** the effective filing date of the claimed invention
- Inventions subject to the JRA are deemed to be commonly owned
 - A terminal disclaimer filed in reliance on a JRA must include a provision waiving the right to separately enforce the disclaimed patent and reference patent(s)
 - Separate enforcement of the disclaimed patent and reference patent(s) renders the disclaimed patent unenforceable

JRAs and Patent Enforcement



Because Terminal Disclaimers predicated on a JRA must include a waiver to enforce separately, JRAs should address enforcement issues

JRAs and Patent Enforcement

- **Right to File** a Terminal Disclaimer in Reliance on the JRA
- **Right to Notice** of Owner B's Terminal Disclaimer
- **Right to Consent** to Owner B's Terminal Disclaimer
- **Enforcement Considerations**
 - Right to Sue/Right to Indulge Infringement
 - Right to Notice of Owner B's Enforcement Action
 - Right to Consent to Owner B's Enforcement Action
 - Owner B's Obligation to Sue/Owner B's Right to Indulge Infringement
 - Rules of Joinder

Technology Licensing Officer (TLO) Toolbox



For more information ...



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