PABST PATENT GROUP

IP STRATEGY BASICS FOR YOUR START UP

Patrea L. Pabst
Pabst Patent Group

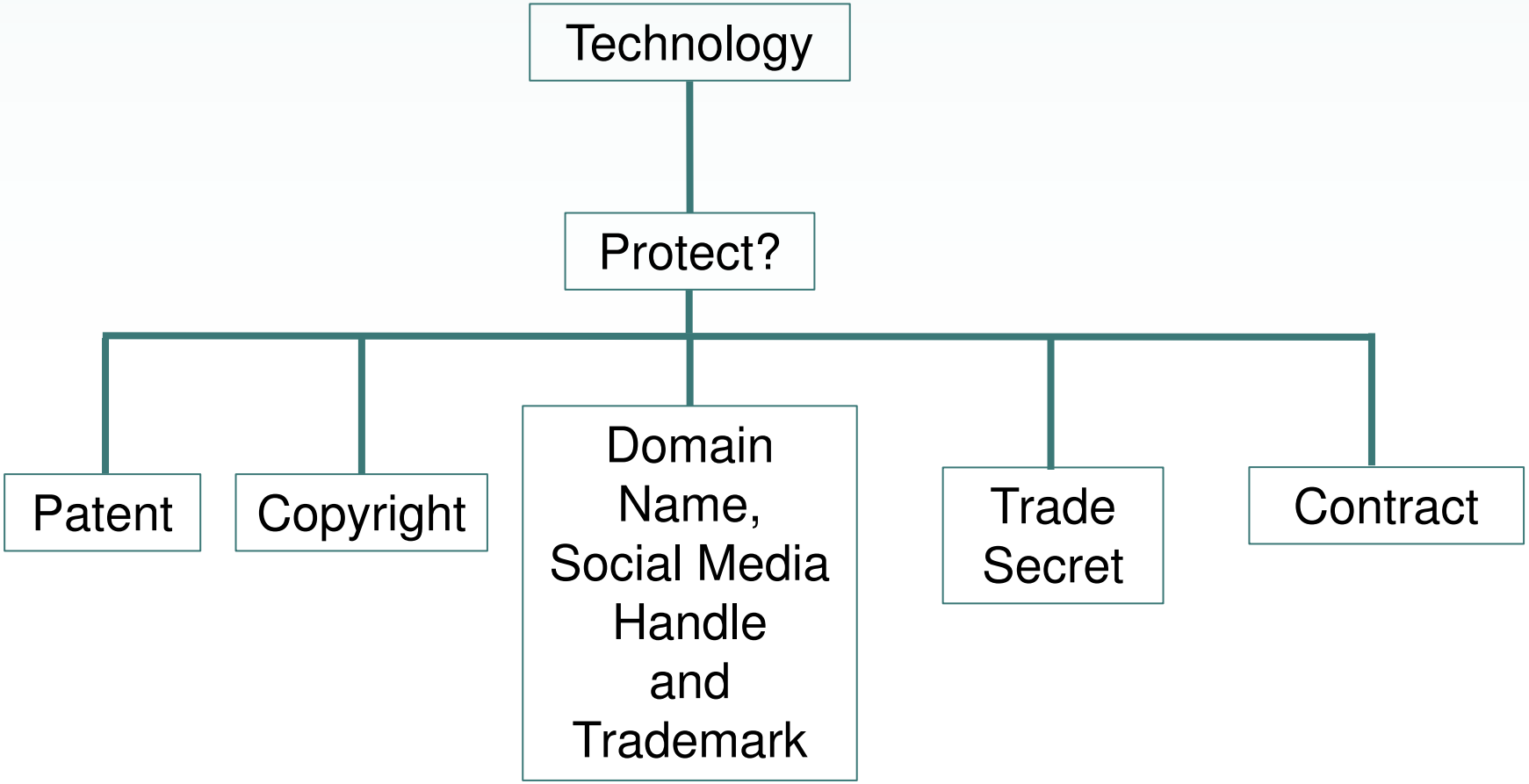
The Purpose of Intellectual Property

- **TO EXCLUDE COMPETITION** and thereby increase the **value** of an entity's commercial products; no market means no return, in most cases, and no competition
- One must consider all forms of IP to maximize the market and scope of exclusion, and therefore the valuation
- IP can be used to enhance valuation, but it is important to define the marketable technology and market first

The Most Important Questions to Ask When Trying to Value Technology

- What is it?
- What is protectable?
- How can I protect it?
- Is there a market?
  - Is there a need?
  - Are you blocked from marketing?

Decision Tree



What Is A Patent?

- A business asset that gives the patent owner the legal right to **exclude** others from making, using, selling, or importing the claimed invention into the patent jurisdiction
- Freedom to Operate is critical – If another party can exclude you from the market, you have no market share
- A patent does not give the patent owner the right to practice the patented invention
- Defined by its **claims**, which must identify a novel and inventive (non-obvious) composition device or component thereof, method of making or method of using

Patentability is determined with respect to what is claimed. All patents describe subject matter that is well known, indeed all inventions build on what others have done and described

Patentability requires five things:

1. Patentable subject matter: device, composition, process of making, process of using. As a general rule, algorithms are not patentable subject matter but the method they define may be. Humans and parts thereof are not patentable subject matter. Naturally occurring materials which have been isolated but not modified are not patentable subject matter. Surgical methods not using novel devices or compositions, or new ways of using them, are not patentable

2. Novelty over the prior art: what is known (orally, in writing, in electronic media, in use)

– i.e., the claims must define subject matter that has not been previously publicly disclosed, offered for sale, sold, imported, or used. A process or materials that are used privately, not disclosed to the public or under the terms of a confidentiality agreement

Patentability is determined with respect to what is claimed. All patents describe subject matter that is well known, indeed all inventions build on what others have done and described

3. The claims must not be obvious from what is known, alone or in combination

4. The application for patent must enable one of skill in the art to make and use that which is claimed.

5. The application and claims must be clear and sufficiently definite to know what is being claimed, so that one skilled in the art can know whether or not they infringe the claims by making, using, selling or offering for sale, or importing, the claimed subject matter

How to Balance What You Have and Know At The Time of Filing With Where You Will Be In 5-10 years

- The problem with patents is that you have to describe what the invention is, how to make it and how to use it, when you file. You cannot modify or add to the disclosure after filing
- So the dilemma is how to predict the future – where the technology will be in five to ten years – and what will be marketable. This is called constructive reduction to practice

Enablement

- US: The legal standard for enablement and written description in the US is defined by 35 USC 112 – one must describe that which is claimed so that one of ordinary skill in the art can make and use it without undue experimentation. Examples and actual reduction to practice are useful but not required
- Europe: Similar standard but has recently added an onerous standard for describing the invention exactly as described in the application as filed, with no leniency for lack of explicit basis

Trade Secrets

The Uniform Trade Secrets Act ("UTSA") defines a trade secret as:

- **Information**, including a formula, pattern, compilation, program, device, method, technique, or process
- Deriving **independent economic value**, actual or potential, from not being generally known to or readily ascertainable through appropriate means by other persons who might obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy
- Enforced under state civil and criminal law

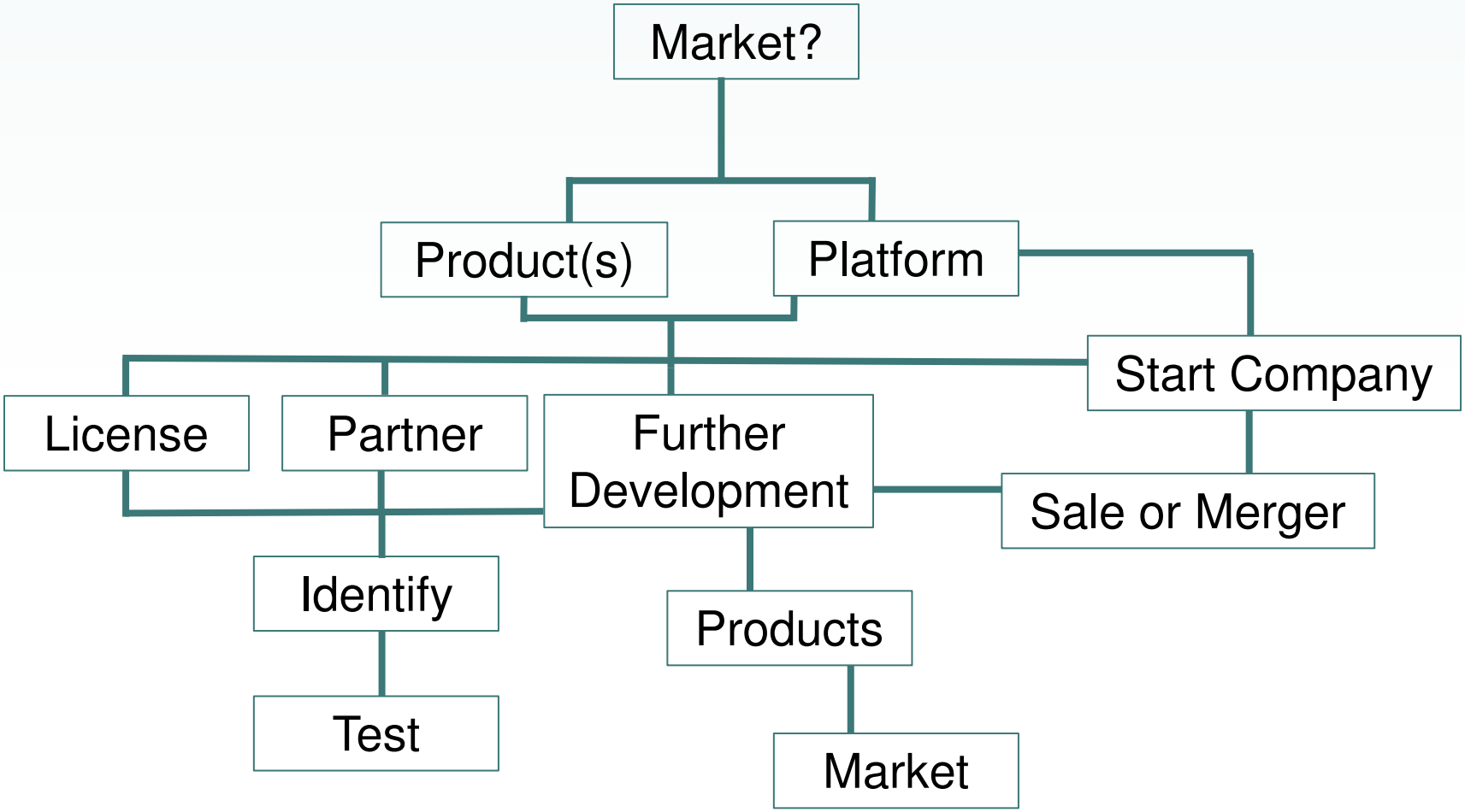
Copyright

- **Copyright** is a form of intellectual property law protecting original works of **authorship** including:
  - Literary (poetry, novels)
  - Dramatic (movies)
  - Musical (songs)
  - Computer software
  - Architecture
- Copyright protects original works of authorship, while a patent protects inventions or discoveries
- Ideas and discoveries are not protected by the copyright law, although the way in which they are expressed may be

Contractual Rights

- Non-compete Agreement
- Employment Agreement
- Confidential Disclosure Agreement
- Materials Transfer Agreement
- License Agreement

How to Market



The Two Most Common Avenues to Commercialize University Technology

- License to a company to develop one or more products, paying a royalty and/or equity and potentially sponsored research (lower risk, less personal investment, less control)
- Convince investors that the technology is a platform that could form the basis of a company for the development of a product, or better, product line (very high risk: requires developing leadership, identifying and obtaining investors, having a long-term plan, immediate and future products, need to ensure sufficient cost-benefit to justify investment)

Market and Market Share

- The market size is determined by using standard business analysis. Basically, one predicts the value of total purchases, adjusted by the share of the market held by other parties [*to determine the overall market size one does not need to adjust by share held of other parties*]
- The market may change over time, for example, due to development of more desirable alternatives or changes in public perception
- The purpose of a patent is to exclude as much competition as possible. Therefore, the broader the claims of the patent, the more competition that can be excluded, in the geographical region covered by the patent, for the time period during which the patent is granted and not expired
- This is why investors value patents based first on whether or not they exclude competitors from making the patent owner's product(s) or using its methods, as well as how much of the market share they can prevent others from taking using an alternative product
- A patent cannot be used to stop others from making or using that which was known before it was filed

Platform IP

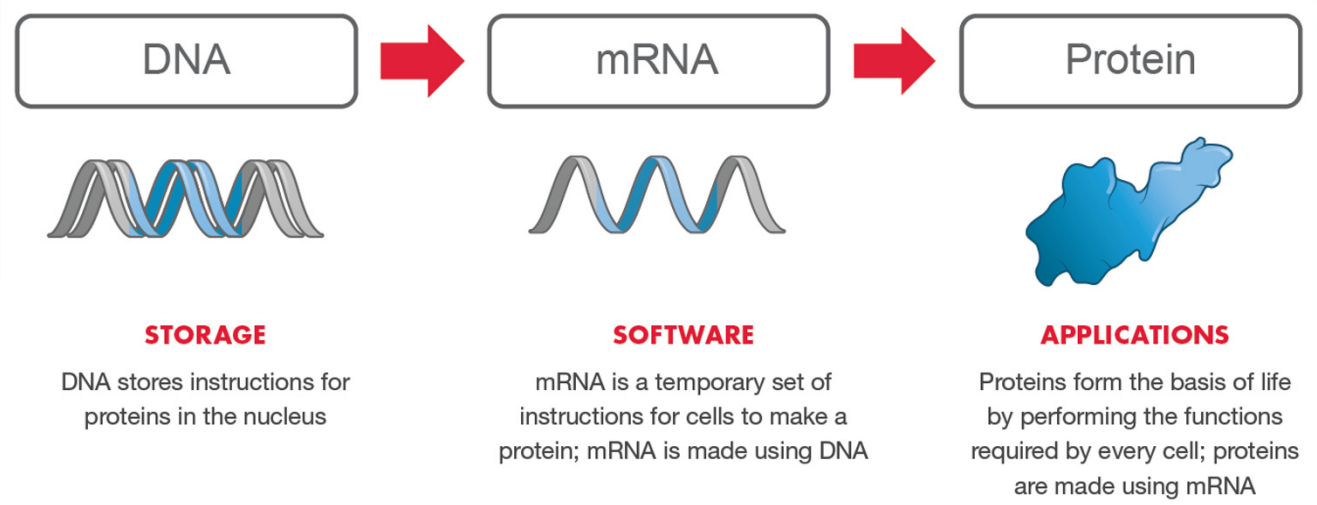
- "Platform IP" is generally viewed as a novel material, device, method of making and/or method of using a family of products. This has the advantage of covering not just what has been developed and tested, but what will be developed during further development not just by the patent owner/licensee, but competitors. Platform IP is generally valued higher since it covers what will be developed, by the patent owner or its competitors.

Platform Technology and IP

- **Platform technologies** are technologies that, once created and harnessed, allow for the intentional and repeatable generation of multiple products or technologies
- **Platform IP** are the patent rights that protect the technologies that form the base from which new applications or technologies are developed
- Pros:
  - Protects the technology fundamental to generating new related or unrelated products allowing these products to be generated in parallel to tackle a wide array of problems and reach the market quickly
  - Allows the flexibility to rapidly activate new initiatives in response to emerging opportunities and threats
  - Attractive to investors
- Cons:
  - Patents protecting the foundation technology will likely become prior art when seeking additional patent protection for newly derived technologies
  - Need to provide sufficient enablement and written description to cover products arising in the future as a result of research and development

Example: the Moderna mRNA Platform

Platform invention:

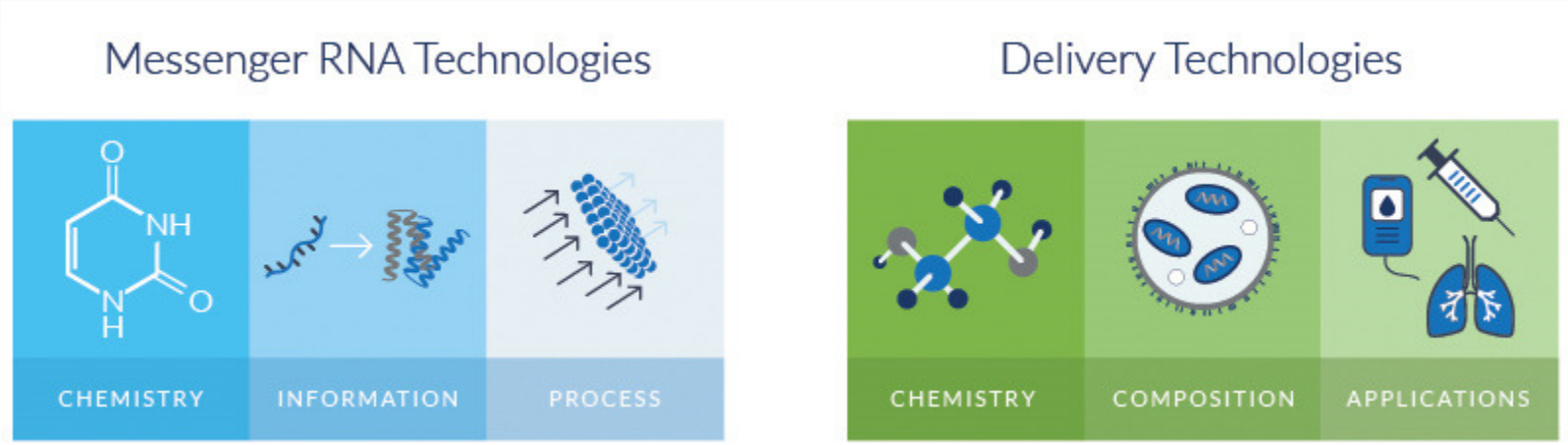


- Platform patent application:
  - WO 2012/19168: Engineered nucleic acids and methods of use thereof
  - Filed: August 5, 2011
  - Abstract:

    "Provided are compositions and methods for delivering biological moieties such as modified nucleic acids into cells to modulate protein expression. Such compositions and methods include the use of modified messenger RNAs, and are useful to treat or prevent diseases, disorders or conditions, or to improve a subject's heath or wellbeing."

Example: the Moderna mRNA Platform

Technologies arising from platform:



- To date:
  - 20 programs using modified mRNA technologies
  - New patents and patent applications cover modified mRNA technologies and delivery technologies with applications in infectious disease, cancer (immuno-oncology) and cardiometabolic diseases
  - 240 granted patents in the United States, Europe, Japan and other jurisdictions
    - Example: 7 patents in the U.S. alone directed to the mRNA-1273 vaccine against COVID-19
    - US 10,703,789, US 10,702,600, US 10,577,403, US 10,442,756, US 10,266,485, US 10,064,959 and US 9,868,692

Product Specific IP

- "Product Specific IP" generally refers to IP that is drawn to a specific, or small class of, materials, devices, methods of making or methods of using
- These are usually easier to enable and reduce to practice, avoiding issues with rejections for being too broad or overlapping with the prior art, and less challenging to license. However, they are more limited if the technology evolves during development, or if a competitive product takes more of the market share

Product Specific IP

Example: Merck and Ridgeback's Investigational Oral Antiviral Molnupiravir

- See https://www.keionline.org/36648 for background
- Discovered at Emory University; licensed to Ridgeback Biotherapeutics to continue its development as a potential treatment for COVID-19; partnered with Merck for further clinical trials, manufacturing and marketing
- Extensive government funding
- Bayh-Dole Rights apply

Platform, Product and Method Specific Patent Applications

Table 1. Emory U.S. patent applications directed to N4-hydroxycytidine derivatives

publication	GOVT	file date	priority	status	patent id
20210252033	yes	2/8/2021	2/7/2020	pending	–
20210060050	yes	7/6/2020	12/26/2014	pending	–
20200276219	yes	12/7/2018	12/7/2017	pending	–
20190083520	yes	3/10/2017	3/10/2016	issued	10874683
20190022116	yes	12/16/2015	12/26/2014	abandoned	–

Summary

- Valuation of a technology is highly dependent on the associated IP
- IP can be used to package and present the technology, identifying the market (i.e., the problem to be solved) as well as the technology (i.e., the solution to the problem)
- IP can be used to delineate and expand the scope of the technology and its value

Please see our website www.pabstpatent.com for a copy of this and other presentations

Thank you

Patrea L. Pabst, Esq.
Pabst Patent Group
1355 Peachtree Street, NE, Suite 800
Atlanta, GA 30309
patrea@pabstpatent.com
(404) 879-2150