# Intellectual Property at the Science And Technology Frontier: AI, Biotechnology, and Quantum Computing

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Lecture 5

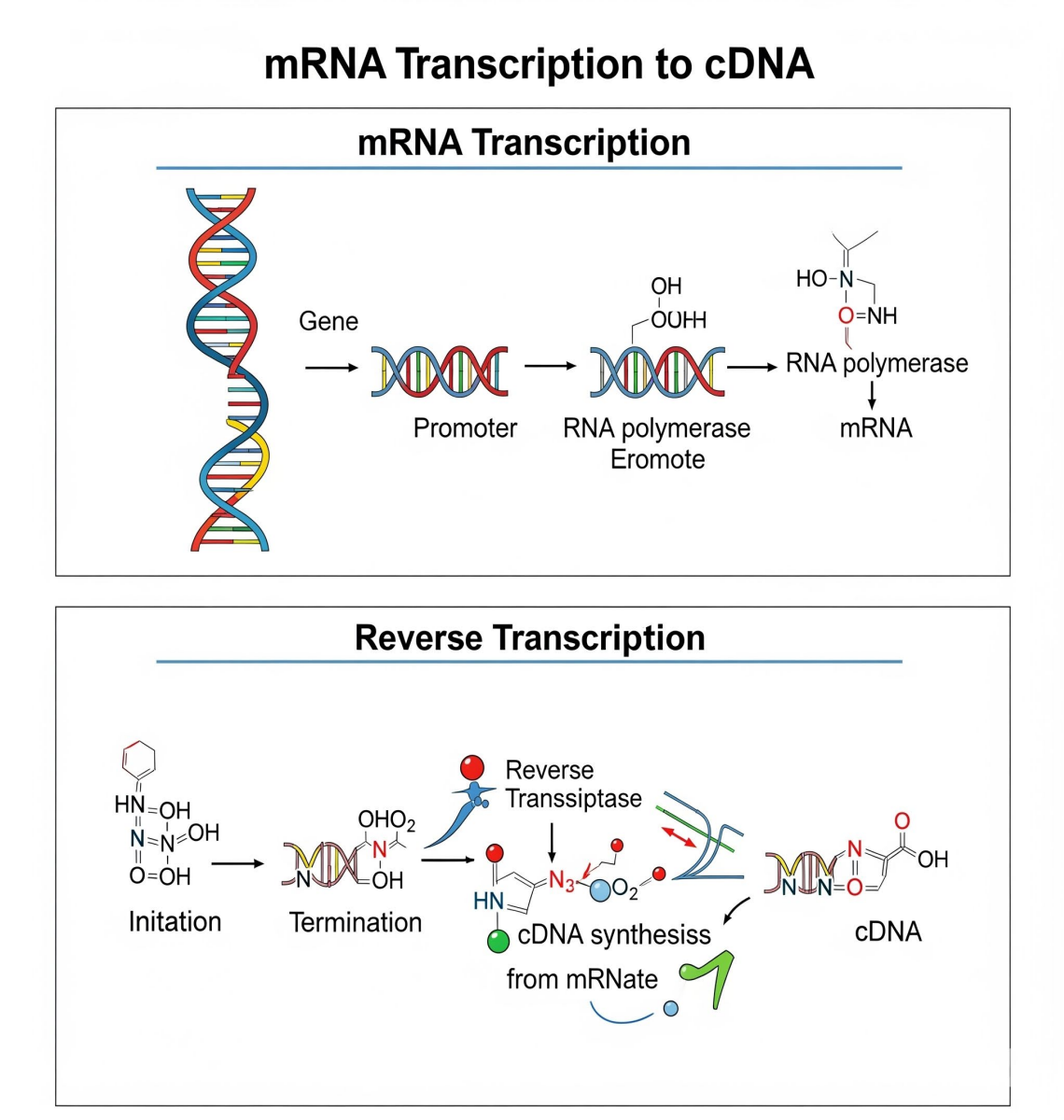
# Biotechnology

- Patents and biotechnology
- Technological development in the biotech sector is proceeding rapidly, and IP protection plays a substantial role in fostering innovation and dissemination of new products and services. Most of this rapid evolution does not challenge basic tenants of IP law in the same way that AI is challenging.
- Scientists are better at manipulating genetic structures through innovations such as CRISPR-cas9. But scientists have been manipulating genes and their components for many years, and while the differences may be sharp in terms of the potential for developing new drugs and diagnostic tools, most of the basic principles of patent appear to remain applicable.

# Patentable Subject Matter

- Can unmodified human genetic information be patented? The US Supreme Court decided in *AMP v. Myriad Genetics*, 569 U.S. 576 (2013). Myriad discovered that a portion of a woman's genes – the BRCA1 and BRCA2 genes – when containing mutations in comparison to the so-called wild type (typical unmutated) genes signals a predisposition for ovarian and/or breast cancer. Myriad secured patents on the wild type genes and developed a testing procedure for comparing the BRCA1 and BRCA2 genes of patients to those wild type genes. A finding of mutation might lead a physician to recommend treatment options such as preventive surgery.

- Myriad also patented certain complementary DNA (cDNA) sequences. Complementary DNA strands can be produced by taking the mRNA sequence that includes only the exons (or functioning parts) of the genetic sequence and eliminates the introns (or non-functioning parts), then producing a new DNA strand that includes only the exons (unlike the "original" that includes both exons and introns) through a process known as reverse transcription.



# Patentable Subject Matter – from Myriad to Mayo

- The US Supreme Court found with respect to DNA that the genetic sequences as patented by Myriad merely identified natural phenomena or properties of nature and were thus unpatentable pursuant to long standing Supreme Court jurisprudence. The Supreme Court did not invalidate the cDNA patents finding that cDNA is not produced in nature; it is rather the product of human genetic engineering intervention. The Supreme Court was not persuaded that because the cDNA merely constituted a transposition of the information generated by mRNA that it also constituted identifying properties as found in nature.

- The Supreme Court was careful to caution that it was not rendering a decision about the patentability of inventions based on modification of DNA, but rather on the patenting of DNA sequences as found in nature.

- In *Mayo v. Prometheus,* 566 U.S. 66 (2012), the US Supreme Court considered the subject matter patentability of a method for treating certain autoimmune diseases (such as Crohn's disease and ulcerative colitis) with a thiopurine drug.

# Mayo v. Prometheus

- In general, when a patient ingests a drug – typically some type of pharmaceutical crystal or salt – it is converted in the human body into a different form known as a metabolite that is carried in the bloodstream to deliver the operative drug substance to where it is intended to have its therapeutic effect. Different patients metabolize drugs differently, and the level of metabolites for a particular drug for any given patient may differ when the same dosage of the drug is administered. The patent owner (Prometheus Laboratories) used information indicating that patients receiving a thiopurine drug were subject to adverse effects if the dosage was too high and did not benefit from therapeutic effect if the dosage was too low. It claimed the use of certain benchmark metabolite levels for which physicians could test, adjusting the dosage for the individual patient up or down depending on that level.
- The method claim in the *Mayo* case instructed the physician to administer the thiopurine drug to the patient, measure the metabolite level in the patient who received the drug, and use the benchmark metabolite levels to determine whether that level was too high (so as to cause adverse effects) or too low (so as to be ineffective) and to reconsider the dosage in light of those levels. The patent owner had not discovered the relationship between metabolite levels and the effects of the thiopurine drug, but it had refined the correlations and embodied that correlation in the patent claims.

# Evolution of the Alice/Mayo Two-Part Test

- The Supreme Court said that the patent owner/inventor had merely identified a natural phenomenon or law of nature in determining the correlation between metabolite levels and the effectiveness of the pharmaceutical product. As such, this scientific fact was not patentable. The patent owner had attempted to overcome this potential obstacle by instructing physicians on a method for using this natural law or phenomenon, but this did not sufficiently "transform" the natural law to constitute patentable subject matter. In other words, the patent claims had simply taken a natural law and instructed the physician to apply it.
- Along with a case involving a software algorithm (Alice v. CLS Bank, 573 U.S. 208 (2014)), the doctrine adopted by the Supreme Court in *Mayo* has become known as the Alice/Mayo two-part test (see discussion in AI above).

# Enablement

- In Amgen v. Sanofi, 598 U.S. 594 (2023), the US Supreme Court, dealt with the question of whether a party claiming a large number of antibody variants could do so without having determined how those antibodies could be created and whether they would work, relying simply on previous research which created a few representative antibodies.
- Amgen had developed an antibody treatment (marketed as “Repatha”) to assist in lowering LDL cholesterol. It obtained several patents. Two of these went beyond the specific antibody used in Repatha, identifying 26 additional antibodies and their amino acid sequences, with two depicting three- dimensional structures. Amgen made claims to the entire genus of antibodies that performed the function ascribed to its patented drug (binding to specific amino acid residues on PCSK9 and blocking PCSK9 from binding to LDL receptors).

# Enablement

- There were potentially millions of antibodies that would perform these functions beyond the 26 that Amgen included in its specification, and Amgen provided little guidance as to how others might identify similarly functional antibodies other than to suggest that scientists develop and test additional antibodies to see whether they worked, or use antibodies known to perform the desired functions and substitute amino acids to create new ones, again testing to see whether they would work.
- The Supreme Court relied on a long line of cases establishing the proposition that an invention must be sufficiently enabled across the scope of the claims, including O'Reilly v. Morse, 15 How. 62 (1854)(Morse's telegraph) and The Incandescent Lamp Patent, 159 U. S. 465 (1895)(Edison's electric lamp). Amgen, it said, had done nothing more than propose a research program. It had not provided sufficient guidance to enable the range of functional antibodies that it had claimed. Amgen's patent claims were invalidated under Section 112 of the US Patent Act for lack of sufficient enablement.

# Utility

- To be eligible, the invention must have a specific and credible utility (or be capable of industrial application).

- Developments in combinational chemistry, and more recently developments such as AlphaFold, allow researchers to create a large number of "new" molecules or structural maps, without necessarily understanding what could be done with these molecules or structures. This raises the challenge of meeting the utility criterion since it is not enough to say that an invention is available for further research or testing. There must be a specific and credible demonstration or sound prediction of utility.

- Moreover, if a prediction of the structure of a folded protein (for example) is accurate, it might not be patentable because it is a natural phenomenon or property of nature.

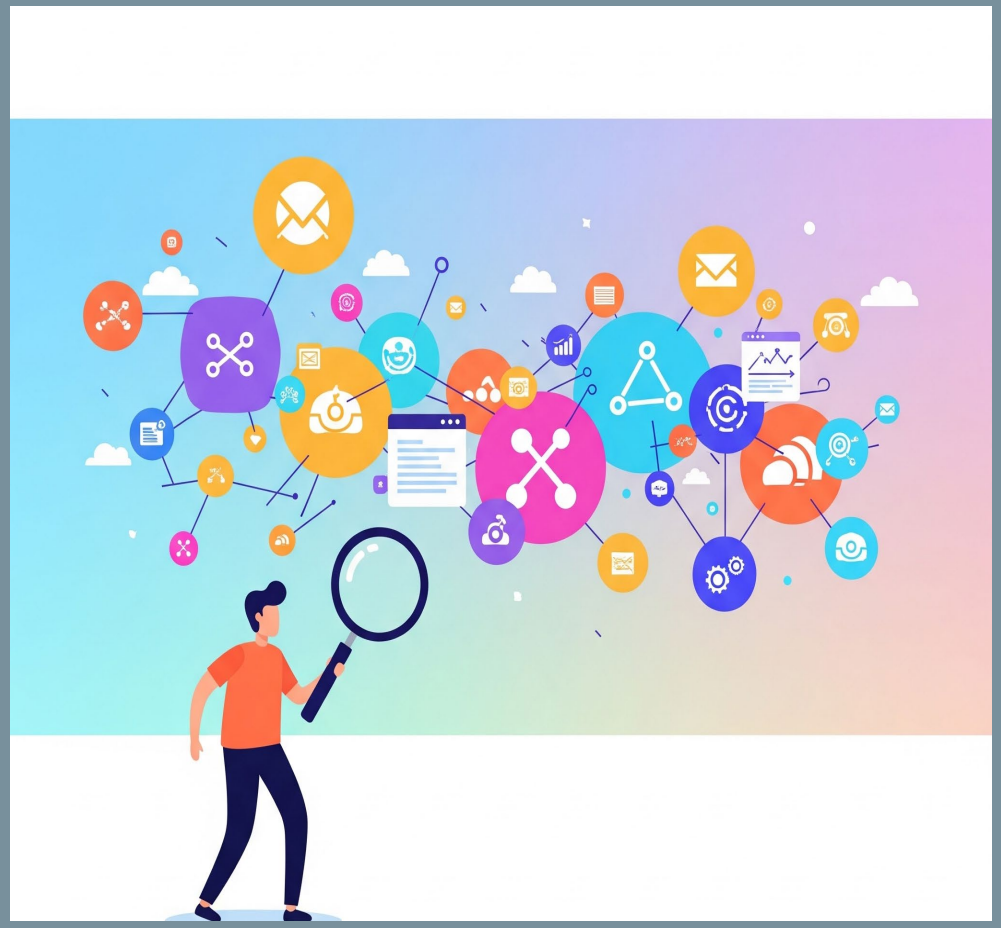
- Should a folded protein modeled by computer be patentable prior to demonstration of a specific utility? What about a folded protein and a molecule the AI suggests might bind to the protein and have a therapeutic effect? Where along the spectrum do you grant a patent?

Lecture 6

# Rights to data

- Issues regarding the relationship between pharmaceutical innovation and rights to data have been part of the sector landscape since at least the early 1980s. This focus primarily was on the extent to which follow-on producers would have rights to use clinical trial and related data developed by innovators in obtaining approval for marketing of their products. The subject matter was addressed in Article 39.3 of the TRIPS Agreement that established an obligation to protect data submitted for regulatory purposes with respect to new pharmaceutical products, with certain exceptions.
- It has become important to explore the issue of access to patient data for use in AI and LLM analysis. Data of individual patients is protected by legislative schemes in the United States and Europe. For the United States it is the Health Information Portability and Accountability Act of 1996 (HIPPA), and for Europe it is the General Data Protection Regulation of 2016 (GDPR).

# Rights to data



- Each the US and the EU system has rules allowing for use of anonymized data in research, with the EU rules being stricter than those in the United States. The extent to which companies such as Google DeepMind/Isomorphic are able to accelerate research into patient populations and their relationship to disease is at least somewhat dependent on access under the acts.
- There are risks associated with access to patient data, even if that that is nominally anonymized, because of the possibility for misuse of such data, including for determining eligibility for health insurance, among others. This is another area where public policy choices regarding individual interests and generalized interests in promoting innovation require balancing.

# Genetic resources

- Genetic resources are a primary source of information and materials regarding prospective pharmaceutical products. Ownership of genetic resources is generally recognized as being with the country where the resources are located. This was made explicit in the Convention on Biological Diversity (CBD), and this has also been recognized as a matter of customary international law.
- Because pharmaceutical researchers rely on genetic materials and information, questions arose as to whether there was an obligation on the part of those researchers to disclose the origin of the resources they used in the process of invention. And, as a corollary, whether there was an obligation to seek the permission of a country from which the resources were extracted prior to doing so. The CBD provided that countries providing access to resources should share in the benefits of that access, including through the negotiation of access and benefit sharing agreements. It was a matter for individual CBD parties to decide whether and how to implement those conditions. A subsequent agreement, the Nagoya Protocol provided a regularized system for maintaining access and benefit sharing arrangements. The United States is not a party to the CBD or Nagoya Protocol.

# From the WTO to WIPO

- More than 20 years ago, a proposal was introduced at the WTO for mandatory disclosure of the source and origin of genetic resources in patent applications as part of the TRIPS Agreement. Those negotiations did not make progress. However, under the auspices of WIPO there has recently been concluded a Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (adopted at Geneva on May 24, 2024). If and when it enters into force, this treaty will create a mandatory obligation on patent applicants to disclose in patent applications the origin, and if origin is not known then the source, of genetic resources on which an invention is based. Neither China, the European Union (or its member states) nor the United States is a signatory or party to this agreement.
- The recently adopted WHO Pandemic Agreement seeks to establish a system for access to genetic resources used in creating vaccines, pharmaceuticals and diagnostics to address pandemics. However, negotiating countries were unable to reconcile differences regarding obligations that would be imposed on users of genetic resources at the time the agreement was adopted, and this remains a pending matter at WHO. The status of the Pandemic Agreement is not entirely clear at the moment given uncertainty about completion of what has been the most difficult part of the negotiations. Developing countries have demanded substantial mandatory contributions of vaccines and treatments as a condition of access to genetic resources. So far, the text refers only to the potential for participating companies to make contributions in exchange for access.

# Genetic Resources in the High Seas

- Relatedly, there is an outstanding issue of genetic resources on the high seas. At the moment, the high seas appear to be open for genetic resource prospecting, but there is a recently adopted international instrument (July 19, 2023), commonly referred to as the Biodiversity Beyond National Jurisdiction (BBNJ) Agreement on the High Seas Treaty, not yet entered into force, prohibiting any nation from claiming or exercising sovereignty over maritime genetic resources (MGRs) on the high seas, and providing for the equitable sharing of benefits from MGRs. The details of such sharing arrangement remain to be worked out. Both China and the United States have signed the agreement, but neither has yet ratified.
- So long as the United States remains outside the CBD, Nagoya, Pandemic Agreement and BBNJ systems it seems unlikely that these arrangements will significantly inhibit researchers within the United States. Whether other countries will try to extract some form of concessions from US innovators in exchange for access to their markets based on compliance with domestic law based on international instruments is an open question.