Section III: Life Science Patents in Practice

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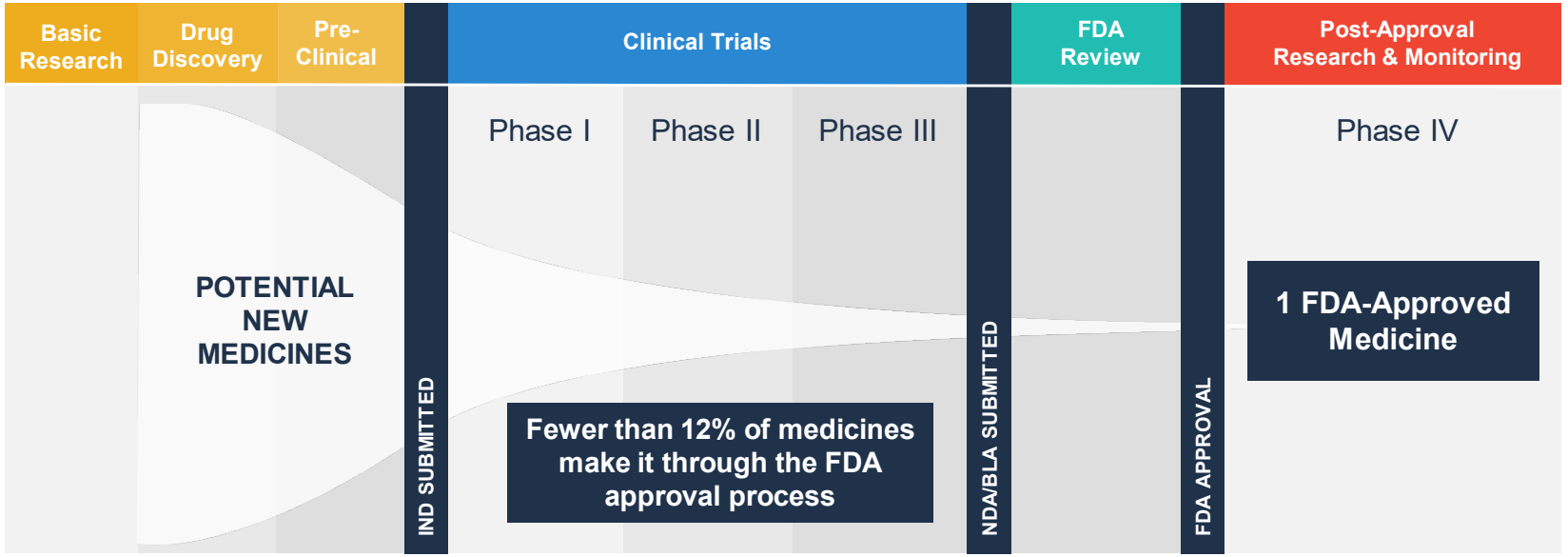
Patents Enable Biopharmaceutical Companies to Invest in the Lengthy, Costly and Uncertain R&D Process for New Medicines

From drug discovery through FDA approval, developing a new medicine typically takes 10 to 15 years and costs an average of $2.6 billion, more than double the cost just a decade ago.[1]



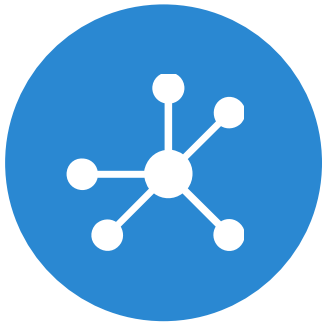
Key: IND= Investigational New Drug Application, NDA= New Drug Application, BLA= Biologics License Application

"The typical science-based business startup is not unlike a long-range multistage rocket mission: Each stage must fire perfectly for the next step of the mission to begin. If any stage fails to execute, the entire mission fails. Even investors with a high tolerance for risk are deterred by the uncertainty of the risk.

MIT PROFESSOR ANDREW W. LO AND HARVARD PROFESSOR GARY P. PISANO[2]

1. PhRMA adaptation of DiMasi J et al. (2016). Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. Journal of Health Economics. 47:20-33. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/26928437
2. Lo, A. et al. (2016). Lessons from Hollywood: A New Approach to Funding R&D. MIT Sloan Management Review. 47-57. Retrieved from: https://dialnet.unirioja.es/servlet/articulo?codigo=5724539.

Patents Incentivize Different Forms of Biopharmaceutical Innovation; a Medicine May Be Covered by Multiple Types of Patents

Active Ingredient or Component	Drug Product	Methods of Manufacturing	Methods of Use / Treatment
			
The pharmacologically active component(s) of a medicine.	The particular state in which the medicine is supplied to the patient, such as the dosage form.	The process or steps required to manufacture a medicine.	The use of a medicine to treat a particular disease.

Post-FDA Approval Medical Advances Take Many Forms and Require Additional Costly and Time-Consuming Research and Development

Research and development of new forms, new uses, and combination therapies requires significant investments of time and resources. These innovations can lead to critical benefits for patients, including new treatment options, and new and improved forms or methods of delivery can be more convenient and improve adherence.

Key incentives—including regulatory data protection and patents—to promote investment in additional research on existing medicines to explore new medical advances are critical. While a new innovation can be patented, provided it meets the standards, the new patent only covers the new innovation, not the original or prior version of the medicine.

Innovative forms are held to the same rigorous FDA standards as the initial medicine approved by FDA and must undergo testing, including in many cases Phase III trials.

Public-Private Collaboration Fuels the US Biopharmaceutical Ecosystem

Exchange of Scientific Knowledge

Private industry, academic, and government scientists all work to understand the function of newly discovered molecular compounds and cells, strange phenomena in the body, or little-understood disease processes. When that knowledge is shared in peer-reviewed publications, scientific meetings, patents, and licensing of intellectual property, and then expanded upon, this exchange of scientific knowledge fuels the creation of ideas for new medicines.

PHARMA & BIOTECH

NIH & ACADEMIA

MEDICINES FOR PATIENTS

SCIENTIFIC KNOWLEDGE ABOUT PATIENTS

Patents & Licenses

Patents allow researchers to protect and license their inventions for further development and potential commercialization, enabling the US biomedical research and development ecosystem to lead the world in biopharmaceutical progress. They also play an important role on the collaboration side, as the patents help companies identify who has the right assets and intellectual capital to bring together. The security that patents provide is fundamental to encouraging collaboration and investment, and incentivizing ongoing research and development into new medicines for patients.

Research Collaboration

Because the NIH does limited research related to drug development, without the scientific and industrial expertise of the biopharmaceutical industry the knowledge resulting from basic science research would generate many ideas for potential drugs and drug targets – but very few new medicines. Though industry, academic, and government scientists are encouraged to collaborate on research questions, the biopharmaceutical industry's ability to take the necessary risks is required to build on and advance basic science research into safe and effective treatments that can be made available to patients.