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

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. PISANO²

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

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