

# The Long March to Innovation: R&D and Competitive Evolution in the Indian Pharmaceutical Industry

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## Abstract

TRIPS (1995) has played a major role in shaping the Indian pharmaceutical industry. Conventional theory suggests that strong intellectual property rights (IPR) frameworks should strengthen innovation incentives. Yet, two decades after TRIPS, growth in India's novel innovation pipeline has stalled. This chapter challenges the assumption that stronger IPR alone would catalyze discovery-based R&D. We utilize trial phase transition data from the *Biomedtracker* database, finding that the Indian pipeline faces a bottleneck in transitioning clinical trials specifically from Phase 1 to Phase 2, supported by a null result in transitions from Phase 1 to Phase 3, benchmarked against China and the United Kingdom. We argue that this reflects binding constraints in the Indian ecosystem that are likely orthogonal to IPR, accompanied by a within-firm shift towards non-novel programs. We corroborate these arguments through interviews with Indian pharmaceutical industry experts. Our findings should inform thinking about normative IPR in developing economies.

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# I. Introduction

Developing countries have historically been observed to strategically establish a foothold of global competitiveness in at least one sphere of industry, which can serve as a catalyst for economic growth. India today has a globally renowned pharmaceutical industry, often dubbed the “Pharmacy of the World”. For the Indian pharmaceutical industry, competitiveness is of two types: competition to improve efficiency, and competition to spur novel innovation. In the former, India has had an excellent track record, emerging as a global leader in generic pharmaceutical production<sup>1</sup>. The latter type of competition has been a puzzle for the industry, though there are recent exceptions. Wockhardt, an Indian pharmaceutical firm, in May 2026 became the first to receive US FDA approval for its own fully developed new chemical entity – Zaynich, a step forward in the global effort to address antimicrobial resistance. Wockhardt chairman Habil Khorakiwala stated: “The philosophy was that if you enter new chemical entity research, you must commit for 25 to 30 years”<sup>2</sup>. Although Zaynich’s success is impressive, it raises questions about why such a philosophy has been necessary to achieve innovation in an already highly competitive industry.

Intellectual property rights (IPR) frameworks play a key role in the global positioning of these industries. For the pharmaceutical industry, one framework of consequence is the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)<sup>3</sup>. It has been argued that the introduction of pharmaceutical product patents through TRIPS substantially restructured the Indian pharmaceutical industry<sup>4</sup>. Cross-country studies of the impact of national pharmaceutical patent laws show that the positive relationship between IPR

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<sup>1</sup> Brenda Waning et al., “A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries,” *Journal of the International AIDS Society* 13, no. 1 (2010): 35, <https://doi.org/10.1186/1758-2652-13-35>.

<sup>2</sup> Paran Balakrishnan, “India Takes on the Superbugs as Wockhardt Moves on from Copycat Antibiotics,” *Telegraph (India)*, July 17, 2026, <https://www.telegraphindia.com/business/india-takes-on-the-superbugs-as-wockhardt-moves-on-from-copycat-antibiotics/cid/2170467>.

<sup>3</sup> Waning et al., “A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries.”

<sup>4</sup> Shubham Chaudhuri et al., “Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India,” *American Economic Review* 96, no. 5 (2006): 1477–514, <https://doi.org/10.1257/aer.96.5.1477>.

protections and innovation is stronger in developed nations<sup>5</sup>. The innovation-protecting rationale underlying the TRIPS proposal derives, to some extent, from this relationship, but it is not necessarily a function of development. India was one of the most vocal opponents of the TRIPS proposal, and agreed to it rather unwillingly, contending that the higher prices resulting from stronger IPR would harm nascent industries<sup>6</sup>.

Qualitative evidence indeed suggests this shift was difficult to navigate for Indian pharmaceutical firms. Since the Indian Patent Act of 1970 did not recognize patents for pharmaceutical ingredients themselves, but rather for process improvements over a shorter term than typical patents, local firms were able to compete in the process of developing generics, and their rise coincided with the exit of multiple pharmaceutical MNCs<sup>7</sup>. This, along with new laws that introduced drug price controls, led to the burgeoning generics industry and its ascension to the world stage in terms of global export volume<sup>8</sup>.

The impact of this shift in the post-TRIPS era has been documented across the Indian pharmaceutical industry. For instance, the oral anti-diabetics market in India showed that differential pricing and voluntary licensing can significantly improve consumer welfare, but only when developing countries are offered the drugs at a significantly lower price<sup>9</sup>. These results suggest a delicate balance between the incentive for competition and innovation. Attempts to strike such a balance have had some basis in regulations such as the Drug Price and Patent Term Restoration Act, otherwise known as the “Hatch-Waxman Act”<sup>10</sup>. The authors also study the impact of Paragraph-IV certifications, a provision under the Hatch-Waxman Act that allowed

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<sup>5</sup> Yi Qian, “Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002,” *Review of Economics and Statistics* 89, no. 3 (2007): 436–53, <https://doi.org/10.1162/rest.89.3.436>.

<sup>6</sup> Jean Lanjouw, *The Introduction of Pharmaceutical Product Patents in India: “Heartless Exploitation of the Poor and Suffering”?*, no. w6366 (National Bureau of Economic Research, 1998), w6366, <https://doi.org/10.3386/w6366>.

<sup>7</sup> Edmond Differding, “The Drug Discovery and Development Industry in India—Two Decades of Proprietary Small-Molecule R&D,” *ChemMedChem* 12, no. 11 (2017): 786–818, <https://doi.org/10.1002/cmdc.201700043>.

<sup>8</sup> Differding, “The Drug Discovery and Development Industry in India—Two Decades of Proprietary Small-Molecule R&D.”

<sup>9</sup> Chirantan Chatterjee et al., “The Consumer Welfare Implications of Governmental Policies and Firm Strategy in Markets for Medicines,” *Journal of Health Economics* 44 (December 2015): 255–73, <https://doi.org/10.1016/j.jhealeco.2015.09.001>.

<sup>10</sup> Lee Branstetter et al., “Regulation and Welfare: Evidence from Paragraph IV Generic Entry in the Pharmaceutical Industry,” *The RAND Journal of Economics* 47, no. 4 (2016): 857–90, <https://doi.org/10.1111/1756-2171.12157>.

generic manufacturers to enter the market before the expiration of a particular patent, estimating that Paragraph-IV entry led to a net social benefit of US\$9.5 billion<sup>11</sup>. The balance that the Hatch-Waxman Act attempted to strike was similar to the results of the interaction between the post-TRIPS environment and the downstream results of the 1970 Patent Act in India. In this context, we argue that the result is puzzling: the arrival of stronger appropriability, should have, in theory, strengthened novel innovation, and yet India's novel pipeline has shrunk, not scaled. Here, we take novel innovation to mean the introduction of new molecule formations, and the extent to which they are innovated upon, measured by the presence of such molecules amongst early-stage clinical trials. Evidence has shown that generic entry in the U.S. market has an impact on the nature of innovation that takes place in the pharmaceutical industry, specifically, a shift away from chemical-based products to biologic-based products<sup>12</sup>. This is significant for the Indian context – while biologic-based generics only entered U.S. markets in 2015, India's strength in generics has been primarily on the biosimilar frontier, with biosimilar development being a primary target for firms, and the first biosimilar approval in India coming as early as 2000<sup>13</sup>.

This chapter focuses on an observed “long march to innovation” signaled by the sustained shift to biosimilars within the Indian pharmaceutical industry. Theory suggests that stronger IPR should strengthen innovation by protecting appropriability, which leads to sustained increases in both novel entry and conversion of downstream clinical trials to Phase 2 and beyond. We find, however, that early-stage novel entry improvements in India post-TRIPS are not sustained in the long term. Among programs that do enter early-stage trials, conversion from Phase 1 to Phase 2 is muted. Of the 12 Indian firms running both novel and non-novel programs, the non-novel share of new entries rises from roughly a quarter to about a half of all programs between 2000-09 and 2015-19. We argue that this phenomenon reflects countervailing mechanisms in complementary environments, particularly the lack of a coherent national architecture for science and innovation that bridges various stakeholders in the innovation ecosystem. The binding constraint, therefore, is not IPR protection but the frictions in these complementary environments that prevent novel

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<sup>11</sup> Branstetter et al., “Regulation and Welfare.”

<sup>12</sup> Lee Branstetter et al., “Generic Competition and the Incentives for Early-Stage Pharmaceutical Innovation,” *Research Policy* 51, no. 10 (2022): 104595, <https://doi.org/10.1016/j.respol.2022.104595>.

<sup>13</sup> Bikash R. Meher et al., “Biosimilars in India; Current Status and Future Perspectives,” *Journal of Pharmacy And Bioallied Sciences* 11, no. 1 (2019): 12, [https://doi.org/10.4103/JPBS.JPBS\\_167\\_18](https://doi.org/10.4103/JPBS.JPBS_167_18).

pharmaceutical innovation from being scaled and sustain an incentive structure that rationalizes generics drift over fundamental innovation.

## II. Literature Review

### A. Organizing Expectations

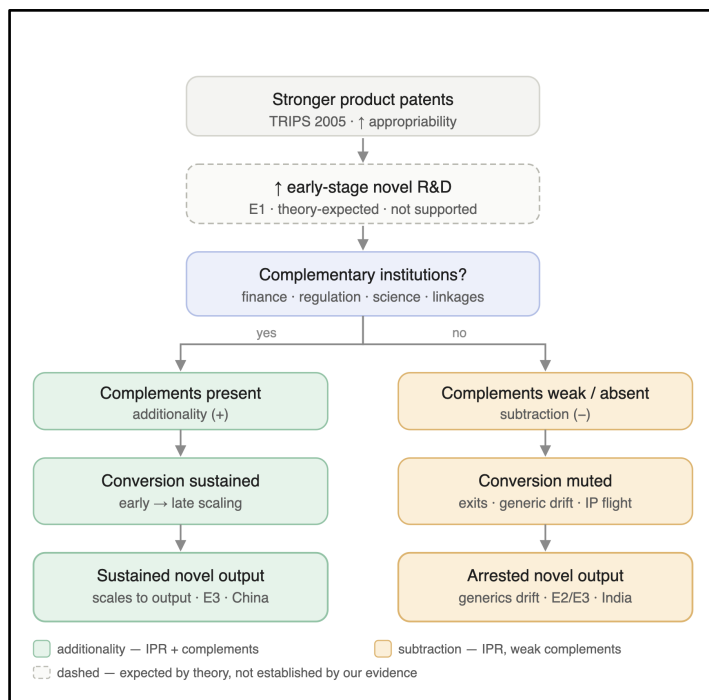


*Figure 1: A conceptual framework of organizing expectations and evidence*

Our discussion of the literature below is intended to cover the broad range of arguments relating to the global innovation environment, and particularly how this environment shifts in the context of pharmaceutical industries in general, and the Indian industry specifically. We organize our review of the literature around three expectations, which are evaluated considering the empirical evidence, and use them to frame the qualitative findings of our interviews with experts on the Indian pharmaceutical industry. These expectations are as follows:

**Expectation 1:** Under standard appropriability theory, the stronger IPR framework enabled by TRIPS should support a sustained expansion of early-stage novel entry via appropriability protections for the Indian pharmaceutical industry.

**Expectation 2:** Countervailing mechanisms in ecosystems surrounding the Indian pharmaceutical pipeline should mute the conversion of early-stage innovation at the first transition – Phase 1 to Phase 2 – contributing to a generics-oriented drift in R&D activity, as opposed to a generalized late-stage conversion deficit.

**Expectation 3:** These countervailing mechanisms should limit the local ecosystems’ ability to support new entrants and scale the overall innovation pipeline, and this may be most evident in India when compared to China.

Figure 1 above provides the conceptual framework to situate our expectations and highlight where they deviate from the evidence. In the following subsections, we expand on the literature related to each of our expectations and how they inform the foundation for our empirical analyses.

## B. Appropriability and the Pharmaceutical Case

The standard foundation for intellectual property rights begins with the definition of a patent as a temporary property right on an invention – the enforcement of the patent, along with the innovations that are considered patentable, patent terms and administration, and patent design, all constitute key policy levers that impact the innovation incentives enabled by the patent system<sup>14</sup>. It has also been argued that, despite the benefits of patents, innovation is better rewarded by first-mover advantages, especially if these advantages are protected by other frictions such as barriers to entry, though evidence suggests that patents play a role in profit protection even if such frictions may exist in parallel<sup>15</sup>. The key question that follows is that of appropriability: firms must be allowed to appropriate at least some of the value of their innovations to protect innovation incentives, and patents are a key policy instrument impacting appropriability<sup>16</sup>. Whether patents

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<sup>14</sup> Katharine Rockett, “Chapter 7 - Property Rights and Invention,” in *Handbook of the Economics of Innovation*, Vol. 1, vol. 1, ed. Bronwyn H. Hall and Nathan Rosenberg, Handbook of the Economics of Innovation (North-Holland, 2010), [https://doi.org/10.1016/S0169-7218\(10\)01007-5](https://doi.org/10.1016/S0169-7218(10)01007-5).

<sup>15</sup> Rockett, “Chapter 7 - Property Rights and Invention.”

<sup>16</sup> Wesley M. Cohen et al., “R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States,” *Research Policy* 31, nos. 8–9 (2002): 1349–67, [https://doi.org/10.1016/S0048-7333\(02\)00068-9](https://doi.org/10.1016/S0048-7333(02)00068-9).

can truly protect incentives to innovate hinges on the specific industrial context, and the extent to which the patent design allows for appropriability.

Estimations of the impact of patents on realized innovation value show that patents do stimulate incentives for further R&D, though this is uneven across industries<sup>17</sup>. A novel study analyzes pharmaceuticals that are “Napsterized” via the elimination of all patent rights on branded prescription drugs without compensating the patent holders<sup>18</sup>. This discussion foregrounds the question of competition in the context of branded versus generic drugs, which is of great consequence in the Indian context. Other evidence shows support for such appropriation strategies as complements rather than substitutes, especially in the pharmaceutical industry, where patents remain important, since novel drug innovations are typically composed of a small, discrete set of patentable elements. This contrasts with industries where a product may require many protections for hundreds of patentable elements, making it difficult for firms to retain proprietary control<sup>19</sup>. It follows, therefore, that a singular patent, or a few connected patents, can have a strong protection effect in the pharmaceutical space, as opposed to other industries.

Empirical studies add nuances to the debates surrounding patents as policy levers. One study spotlights the Japanese pharmaceutical industry, focusing on a provision in the 1988 reforms that provided patent term restoration for certain drugs if there were examination process delays, (essentially a patent length increase), finding no significant impact of a patent scope expansion on R&D – they point out that this is despite the potential strengthening that can be brought about by increases in patent length in this industry in particular<sup>20</sup>.

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<sup>17</sup> Ashish Arora et al., “R&D and the Patent Premium,” *International Journal of Industrial Organization* 26, no. 5 (2008): 1153–79, <https://doi.org/10.1016/j.ijindorg.2007.11.004>.

<sup>18</sup> James W. Hughes et al., “‘Napsterizing’ Pharmaceuticals: Access, Innovation, and Consumer Welfare,” Working Paper no. 9229, Working Paper Series (National Bureau of Economic Research, September 2002), <https://doi.org/10.3386/w9229>.

<sup>19</sup> Wesley M. Cohen et al., “R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States,” *Research Policy* 31, nos. 8–9 (2002): 1349–67, [https://doi.org/10.1016/S0048-7333\(02\)00068-9](https://doi.org/10.1016/S0048-7333(02)00068-9).

<sup>20</sup> Mariko Sakakibara and Lee Branstetter, “Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms,” *The RAND Journal of Economics* 32, no. 1 (2001): 77, <https://doi.org/10.2307/2696399>.

### C. Complementary Institutions and the Limits of Appropriability

Further studies explore the conditions required for patent laws to be effective. Research shows patent laws alone are not sufficient to support domestic innovation, unless the nation has high levels of development, economic freedom, and education<sup>21</sup>. The same work also provides support for an inverted-U-shaped relationship between IPR strength and innovation, particularly for pharmaceutical patents, supporting the idea that the effectiveness of IPR in the Indian pharmaceutical industry is contingent upon multiple factors, and that appropriability does not guarantee or determine innovation<sup>22</sup>. More recent work asserts that IP rights promote innovation in conjunction with complementary factors<sup>23</sup>. These complementary factors can either be ecosystem-based, through regulations or tax regimes<sup>24</sup>, or in the form of appropriation strategies such as lead time and secrecy<sup>25</sup>. It is pointed out, however, that even though technology protections and their harmonization across countries could induce diffusion, so long as they remain net importers of intellectual property, they will be liable to pay higher amounts for those technologies while their firms do not reap the benefits from stronger protection standards<sup>26</sup>.

National innovation systems constitute another important conceptual foundation. A national innovation system is characterized as a social system, with the dynamic nature of learning via reproduction and feedback loops at the core of this system<sup>27</sup>. In addition, the sectoral system approach is used to reflect the multidimensional nature of production at a national level, comprising new and established products and the agents that carry out both the market and non-

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<sup>21</sup> Yi Qian, "Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978–2002," *Review of Economics and Statistics* 89, no. 3 (2007): 436–53, <https://doi.org/10.1162/rest.89.3.436>.

<sup>22</sup> Qian, "Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment?"

<sup>23</sup> Walter G. Park, ed., *Handbook of Innovation and Intellectual Property Rights: Evolving Scholarship and Reflections* (Edward Elgar Publishing, 2024), <https://doi.org/10.4337/9781800880627>.

<sup>24</sup> Park, *Handbook of Innovation and Intellectual Property Rights*.

<sup>25</sup> Arora et al., "R&D and the Patent Premium."

<sup>26</sup> Keith Maskus, "The New Globalisation of Intellectual Property Rights: What's New This Time?," *Australian Economic History Review* 54, no. 3 (2014): 262–84, <https://doi.org/10.1111/aehr.12049>.

<sup>27</sup> Bengt-Åke Lundvall, "INTRODUCTION," in *National Systems of Innovation*, ed. Bengt-Åke Lundvall, *Toward a Theory of Innovation and Interactive Learning* (Anthem Press, 2010), JSTOR, <http://www.jstor.org/stable/j.ctt1gxp7cs.6>.

market interactions required to develop and sell such products<sup>28</sup>. Scholars argue that certain models predict that stronger patents in developing nations can increase the marginal benefit of knowledge transfer, though they note that this requires a market of a particular size<sup>29</sup>. The same scholars also point out that expected improvements in net social welfare from technology transfer are contingent on developing countries' absorptive capacity<sup>30</sup>. For India, therefore, the positive technology transfer results are potentially blunted on two fronts: the first is that regulation does not adequately account for the design friction in basic versus applied innovation, and the second is that the lack of local absorptive capacity prevents IPR protections from having the expected impact. The VC ecosystem is of particular importance here – researchers find that the impact of VC investment on firm innovation is increased by stronger IPR protections<sup>31</sup>.

While the 20th century was marked with many examples of scientific advancement within corporate industrial laboratories, in more recent decades, such laboratories have been in decline<sup>32</sup>. This impacts the ways in which technology cycles operate, where new technologies replace old ones – research finds that firms' choices and investments are a key factor, especially when they choose to invest in maximizing the value of old technology they have already captured, while other firms move to newer paradigms<sup>33</sup>. This “last resort” effort to extend the value pathway of old technology, especially when firms face limitations in addressing the challenges associated with the emergence of new technologies<sup>34</sup>, can limit the precise types of technology transfers that yield improved innovations and welfare benefits in sectors such as pharmaceuticals. National innovation systems allow for the synthesis of various stakeholders in the technology transfer process. However, this construction reveals IP rights are just one node in the innovation process – the

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<sup>28</sup> Franco Malerba, “Sectoral Systems of Innovation and Production,” *Research Policy* 31, no. 2 (2002): 247–64, [https://doi.org/10.1016/S0048-7333\(01\)00139-1](https://doi.org/10.1016/S0048-7333(01)00139-1).

<sup>29</sup> Lei Yang and Keith E. Maskus, “Intellectual Property Rights, Technology Transfer and Exports in Developing Countries,” *Journal of Development Economics* 90, no. 2 (2009): 231–36, <https://doi.org/10.1016/j.jdevco.2008.11.003>.

<sup>30</sup> Yang and Maskus, “Intellectual Property Rights, Technology Transfer and Exports in Developing Countries.”

<sup>31</sup> Di Guo and Kun Jiang, “Venture Capital Investment, Intellectual Property Rights Protection and Firm Innovation: Evidence from China,” *Entrepreneurship & Regional Development* 34, nos. 5–6 (2022): 434–70, <https://doi.org/10.1080/08985626.2022.2062618>.

<sup>32</sup> G. P. Pisano, “The Evolution of Science-Based Business: Innovating How We Innovate,” *Industrial and Corporate Change* 19, no. 2 (2010): 465–82, <https://doi.org/10.1093/icc/dtq013>.

<sup>33</sup> Ron Adner and Rahul Kapoor, “Innovation Ecosystems and the Pace of Substitution: Re-examining Technology S-curves,” *Strategic Management Journal* 37, no. 4 (2016): 625–48, <https://doi.org/10.1002/smj.2363>.

<sup>34</sup> Adner and Kapoor, “Innovation Ecosystems and the Pace of Substitution.”

absence of developed, compatible nodes across risk-tolerant financing, absorptive capacity, and co-locations of science, innovation and enterprise, is a potential explanatory factor for slowdowns in innovation, rather than just patent strength.

#### D. India's Drift and the China Contrast

There is much debate on whether price controls and generic manufacturing have delivered a net welfare benefit for the Indian consumer. One study explores this question with the quinolone sub-class of antibiotics, finding that with price regulation maintaining quinolone prices at the pre-TRIPS level, Indian consumers suffered a massive welfare loss of around US\$255 million, driven not only by higher prices, but also by loss of product variety<sup>35</sup>. Another study, however, demonstrates that the implementation of product patents in India did not lead to large increase in pharmaceutical prices or market consolidations<sup>36</sup>. The changing geographies of trade in the IPR context are also relevant – researchers find that longer and stronger patents often accelerate diffusion for developing and developed nations, and that pharmaceutical price controls countervail diffusion, leading to longer drug release lags<sup>37</sup>. These are especially relevant in the Indian pharmaceutical context, which operates under extensive price control conditions, while catering to a massive domestic and international market, without necessarily being the beneficiary of innovation diffusion from abroad. Much of these forces are well-documented in the literature: the discussion on price controls is one such documentation, precisely because the price controls would cap the monopoly rents that make the product-based strategy viable, while solving a price increase problem that was modest at best<sup>38</sup>.

However, downstream findings by the same authors show that the nature of innovation itself changes in response to generic competition, and that an increase in generic competition is

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<sup>35</sup> Chaudhuri et al., “Estimating the Effects of Global Patent Protection in Pharmaceuticals.”

<sup>36</sup> Mark Duggan et al., “The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India,” *American Economic Review* 106, no. 1 (2016): 99–135, <https://doi.org/10.1257/aer.20141301>.

<sup>37</sup> Iain M. Cockburn et al., “Patents and the Global Diffusion of New Drugs,” *American Economic Review* 106, no. 1 (2016): 136–64, <https://doi.org/10.1257/aer.20141482>.

<sup>38</sup> Chaudhuri et al., “Estimating the Effects of Global Patent Protection in Pharmaceuticals.”; Duggan et al., “The Market Impacts of Pharmaceutical Product Patents in Developing Countries.”

associated with a reduction in early-stage innovation<sup>39</sup>. The interactions between external market development and Indian patent reforms, and their effects on the generics drift are also well-documented – scholars find that R&D efforts and reinvestments have primarily been focused on process innovations that allowed Indian firms to better serve foreign generics markets in a TRIPS-compliant and strategically justifiable manner<sup>40</sup>.

The relationship between the Indian pharmaceutical industry and these environmental factors is governed by various national institutions. Some scholars therefore promote a stakeholder-based view of the IPR environment, where the IPR institutions themselves are the focal institution, the local government entity forms an endogenous stakeholder, and for-profit firms and other, less directly connected state entities form the exogenous stakeholders<sup>41</sup>. The same authors assert that the Chinese IPR institutional regime is well-designed to manage stakeholder interactions<sup>42</sup>. This approach could provide lessons for India in the sense that China has clearly seen a need for stronger IP protections in areas where fundamental innovation is required to build self-reliance<sup>43</sup>. Such ecosystem-building has shown to be especially effective in the technological catch-up of latecomer economies such as China, where recent empirical studies have built upon international patent statistics, with a focus on quality as well as quantity of patents, to show that the Chinese computer manufacturing and electrical equipment manufacturing industries have caught up to their global counterparts, though the same authors note that the Chinese pharmaceutical industry itself actually fell in relation to global leaders<sup>44</sup>.

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<sup>39</sup> Lee Branstetter et al., “Generic Competition and the Incentives for Early-Stage Pharmaceutical Innovation,” *Research Policy* 51, no. 10 (2022): 104595, <https://doi.org/10.1016/j.respol.2022.104595>.

<sup>40</sup> Ashish Arora, Lee Branstetter, Chirantan Chatterjee, and Kamal Saggi, “Strong Medicine? Patent Reform and the Transformation of the Indian Pharmaceutical Industry” (paper presented at the NBER Summer Institute, Cambridge, MA, July 2008), <https://conference.nber.org/confer/2008/si2008/IPPI/branstetter.pdf>.

<sup>41</sup> Dan Prud’homme et al., “A Stakeholder-Based View of the Evolution of Intellectual Property Institutions,” *Journal of International Business Studies* 52, no. 4 (2021): 773–802, <https://doi.org/10.1057/s41267-021-00412-7>.

<sup>42</sup> Prud’homme et al., “A Stakeholder-Based View of the Evolution of Intellectual Property Institutions.”

<sup>43</sup> Minyuan Zhao, “China’s Intellectual Property Rights Policies: A Strategic View,” *Journal of International Business Policy* 3, no. 1 (2020): 73–77, <https://doi.org/10.1057/s42214-019-00046-5>.

<sup>44</sup> Zhijing Zhu and Haiyang Li, “Technological Catch-up: A New Measure and Patent-Based Evidence from China’s Manufacturing Industries,” *Research Policy* 54, no. 8 (2025): 105299, <https://doi.org/10.1016/j.respol.2025.105299>.

### III. The Three Lenses of Innovation

#### A. Quantitative Approach

The following section uses the Biomedtracker (BMT) database by expanding upon the appropriation information included within patent data, as well as the disclosure information reflected by publications by tracking the life cycle of a particular pharmaceutical compound. The unit of BMT data is the drug-indication, which we attribute to a lead country based on the domicile of the local entity. We classify a drug-indication as novel based on whether it is recorded as a new molecular entity, a biologic or a vaccine, and as non-novel where it is not a new molecular entity, or a biosimilar – a small fraction, close to 1%, are classified as unknown. We construct an event corpus from the BMT data to study the number of drug-indications across time and trial stages for each country of interest, and a separate trials corpus to study the survival of a compound across various stages. The trials corpus retains a little less than 40% of the novel programs of the event corpus in India and the UK, due to the necessity of a dated Phase 1 record. China’s count in this corpus is marginally higher due to trial entries recorded after 2019. Estimates of trial progression are therefore read as being applicable only to programs with documented trial records.

Our descriptive evidence ranges across the period from 1998 to 2019, right-censoring data in 2019 since more recent programs are not given an equal opportunity to advance. Certain sections of our analysis follow programs beyond this window – details are in the Technical Appendix. We note sparse coverage in the early 2000s, which expands in the BMT data over time for all countries of interest: for instance, Phase 1 novel program entrants in the UK rose from 10 in 2000, to 60 in 2004. Early-year counts are depressed relative to later years, biasing comparisons with later years upwards. We preserve early years with sparse coverage to establish pre-trends but do not infer from the levels themselves. We also treat conversions of drug-indication to subsequent trial phases as relative, given the likelihood of systematic understatement across countries. We use this data to form three descriptive lenses for our analysis. The volume lens tracks the absolute number of drug-indications across time and geography. The composition lens studies trial stage distributions of drug-indications over time, and the progression lens reflects the survival likelihood of programs across time. While we present most of our evidence in a visual manner for descriptive purposes,

we also model cross-country differences in progression using a regression framework (described in the Technical Appendix).

## B. Volume

After the TRIPS transition period ended in 2005, there were significant structural shifts within the largest Indian pharmaceutical firms, due to the conclusion of ongoing innovation pipelines and changes in the ecosystem and surrounding incentives. The incentive structure surrounding novel innovation changed in the post-TRIPS period, some of which could be attributed to generic entry<sup>45</sup>. We analyze the broad shifts in the industry, and the potential role of generic entry because of this structural change, by utilizing the volume of unique drug-indications in the BMT database as a lens of our analysis. Anecdotal evidence suggests that even the most established Indian pharmaceutical companies saw reasons to shift away from NCE development, and move towards efficiency improvements in drug delivery, focusing on biosimilar and generic development. Three such firms had key NCE exits in the 2008-2014 period: Piramal Enterprises Ltd., Dr. Reddy's Laboratories (DRL) and Ranbaxy Laboratories<sup>46</sup>. These exits were not without justification – DRL, Ranbaxy and Piramal all faced drug development failures in either the pre-clinical or clinical development phases, leading to various closures or divestments<sup>47</sup>.

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<sup>45</sup> Branstetter et al., “Generic Competition and the Incentives for Early-Stage Pharmaceutical Innovation.”

<sup>46</sup> Differding, “The Drug Discovery and Development Industry in India—Two Decades of Proprietary Small-Molecule R&D.”

<sup>47</sup> Differding, “The Drug Discovery and Development Industry in India—Two Decades of Proprietary Small-Molecule R&D.”

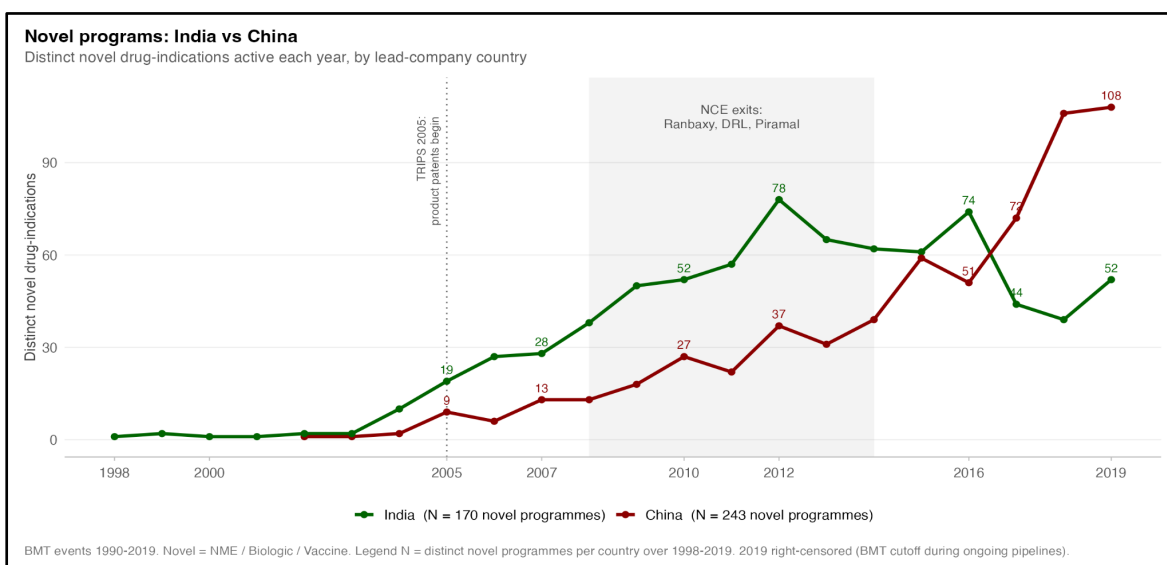


*Figure 2: Novel compound innovation pipelines, India and China, 1998-2019*

This NCE exit window aligns with a parallelism observed between the Indian and Chinese pharmaceutical industries across the last 25 years, as illustrated by Figure 2, which displays that the gap between the volume of Indian and Chinese novel drug discovery programs remained relatively stable between 2005 and 2013, with India peaking in 2012 with 78 programs, relative to China's 37. However, just 5 years later, in 2017, India had only 44 active novel drug-indications, relative to China's 72. By 2019, China had over double the novel drug-indications, compared to India.

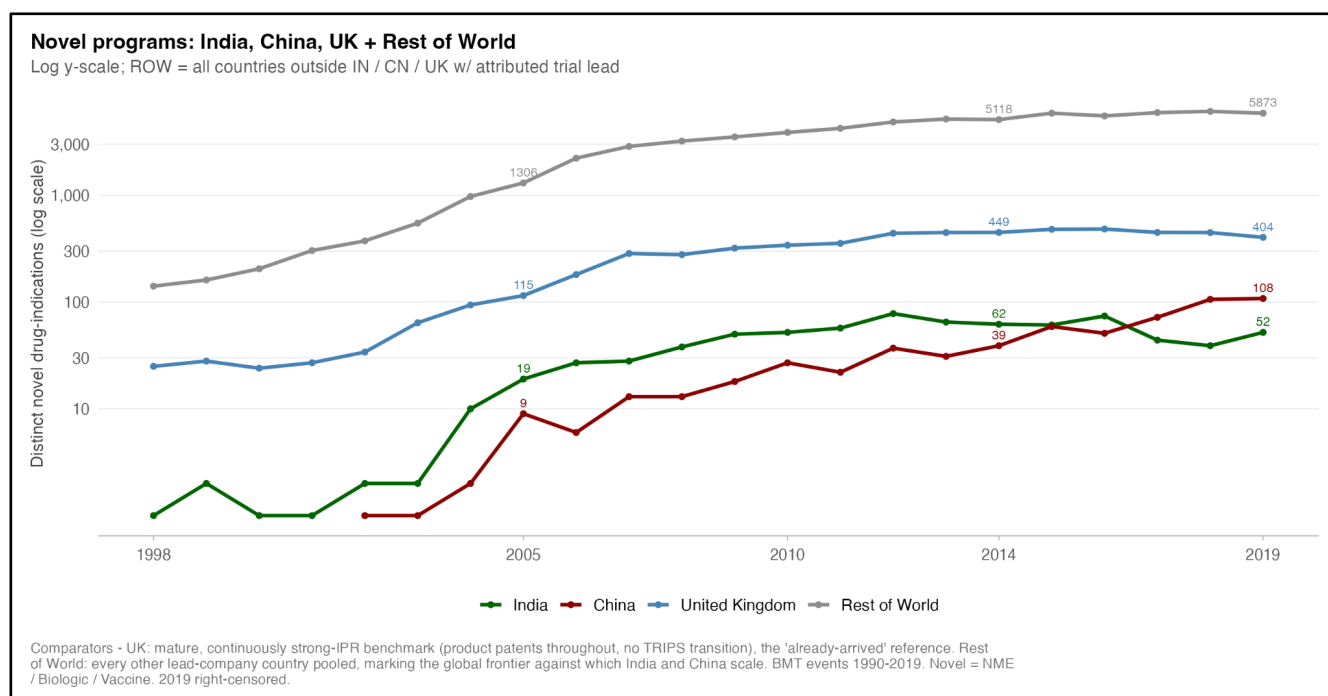


*Figure 3: Novel compound innovation pipelines, India, China, UK + ROW, 1998-2019*

The sharp decline in novel drug-indications post the NCE-exit window suggests that an anticipation of increased competition in generic would have led competitors to all make similar pivots to capture a share of a safer market. However, this unilateral shift was associated with a slowdown in novel drug research. Figure 3 illustrates that, after the NCE exit window closed in 2014 with Piramal's exit, India's novel drug-indication count underwent a slow decline. While India began a non-monotonic yet steady decline between 2014 and 2019, China surged, and the UK remained relatively stable over the same period. This trend has held consistent since then, as shown by company-specific analyses conducted as recent as 2025<sup>48</sup>. At the end of 2024, the value of the Indian bioeconomy was over 16 times its value in 2014<sup>49</sup> – the structural change seems to have driven value up significantly, but with a continued drift away from NCE drug discovery. The restructuring in innovation activity corroborates volume analyses as a method to quantify the direction of innovation – India's NCE drug-indications peak around 2012, and despite a few reversions, see an overall decline by 2019, as the same firms shift away funds to alternate efforts,

<sup>48</sup> Edmond Differding, "India's Drug Discovery and Development Industry: The Quest for Novel Therapeutic Treatments," *ChemMedChem* 21, no. 11 (2026): e70304, <https://doi.org/10.1002/cmdc.70304>.

<sup>49</sup> Differding, "India's Drug Discovery and Development Industry."

and newer entrants to the industry find more lucrative innovation opportunities outside of the NCE space. In Figure 4 below, we shift to a measure of program flow, rather than program stock, by measuring the number of new novel entrants in Phase 1 each year. After 2012, the number of novel programs entering each year declined, from roughly 17 programs a year over a 10-year period, to just under 12 programs a year.

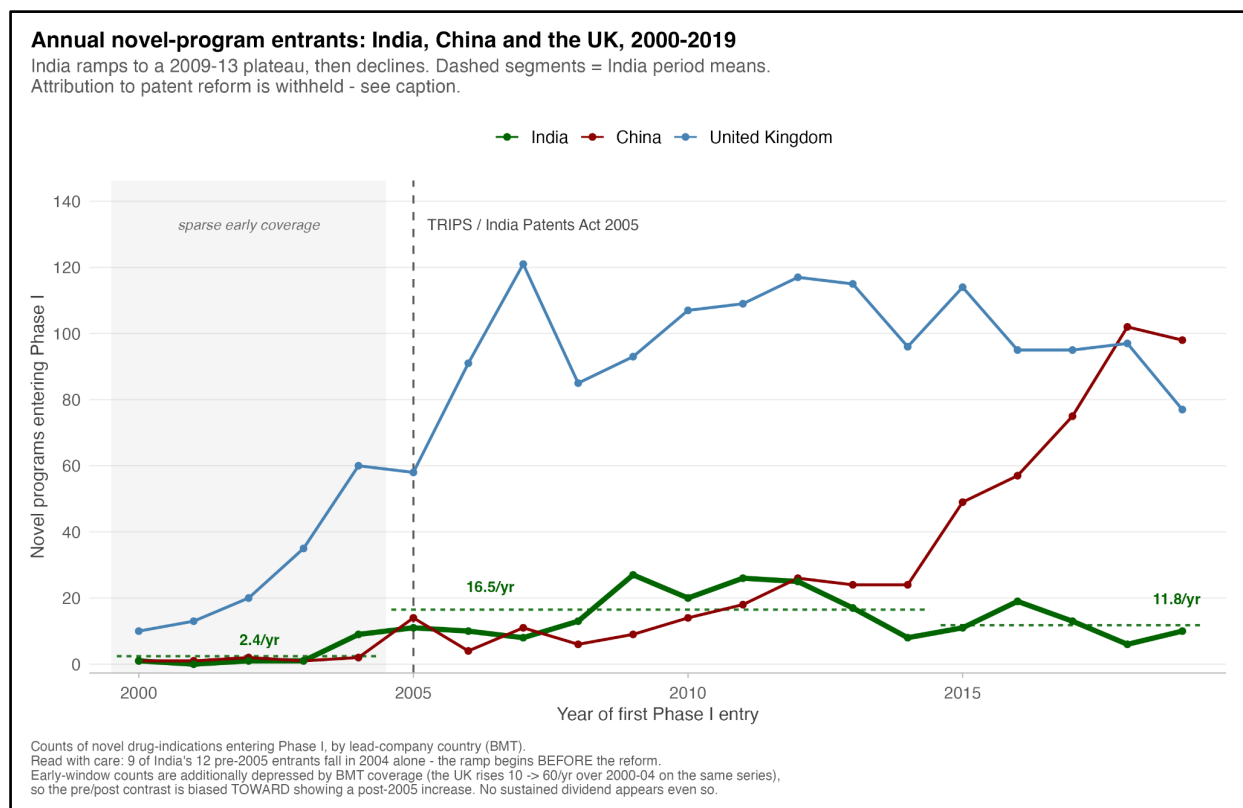


Figure 4: Annual novel-program entry, India, China, UK + ROW, 1998-2019

Annual entry peaked for India in 2009, with 27 entries, and declined to just 6 new entries in 2018, reflecting the tightening pipeline of novel innovation even in the early stage. Chinese year-on-year entry fluctuated around the same time, but entered a phase of stable increase post-2008, and overtook India in 2012, after which it saw an even greater acceleration.

These findings shed light on our organizing expectations in different ways: while our second and third expectations are consistent with the evidence, we do not identify either a positive or negative impact of TRIPS on early-stage innovation. While the expansion of novel programs

sustains further for China, and the UK count remains relatively stable, India's expansion tapers off and declines post-2012. But this does not entirely explain why innovators struggle to find a foothold in novel drug discovery. The progression of small-molecule research in clinical trials beyond Phase 1 has been slow in India<sup>50</sup>, and this points to a separate bottleneck in the innovation pipeline: the progression of clinical trials from the preclinical stage to advanced clinical stages and eventual approval. The fact that regulators only approved one drug in two decades does not fully reveal the frictions faced by innovators, one of which is progression itself: while many small-molecule candidates have been discovered by the top labs, very few make it even to the approval stage. Therefore, a reduction in volume may itself be symptomatic of anticipated downstream frictions in inter-trial approvals.

### C. Composition

The Indian drift towards generics and biosimilars as the key focus of drug development has, through our analysis, been shown to be contemporaneous with key NCE exits of large labs. More recent data shows that R&D has moved towards incremental product-oriented innovation, such as in medical devices<sup>51</sup>. We disaggregate the drug-indication data into its relevant trial compositions to frame these bottlenecks and visualize another axis of comparison across countries. Figure 5 demonstrates cross-country differences – the United Kingdom chart displays that pipeline maturity manifests itself in a stable share of drug-indications in each trial stage over time, implying that a novel drug-indication is not likely to be clustered in one stage, relative to the other. In contrast, India's stage distribution is historically dominated by mid-stage trials, and post-2016, the share of early-stage trials seems to display a consistent drop. China, on the other hand, displays a clear sign of increased R&D spending. While the late 2000s and early 2010s saw mid-stage trials dominate the share, by the late 2010s, we see a steady increase in the number of early-stage trials, most likely along many different prospective NCE candidates.

To an extent, the existing non-novel ecosystem in India can explain the compositional drift away from novel drug discovery, and why biologics and biosimilars were a natural pathway for

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<sup>50</sup> Differding, "India's Drug Discovery and Development Industry."

<sup>51</sup> Differding, "India's Drug Discovery and Development Industry."

the pharmaceutical industry in the relatively risk-averse environment after the NCE exits. India has been a global leader in biosimilars for much longer than the US and Europe, and due to regulatory ambiguities and challenges in biosimilar development and approval, the Indian Central Drugs Standard Control Organization (CDSCO) involved itself relatively early in smoothening the process of biosimilar approval<sup>52</sup>. For instance, the CDSCO allowed the biosimilars to use reference biologics that were approved and marketed either in India or in other countries, such as Japan, the US or Canada<sup>53</sup>.

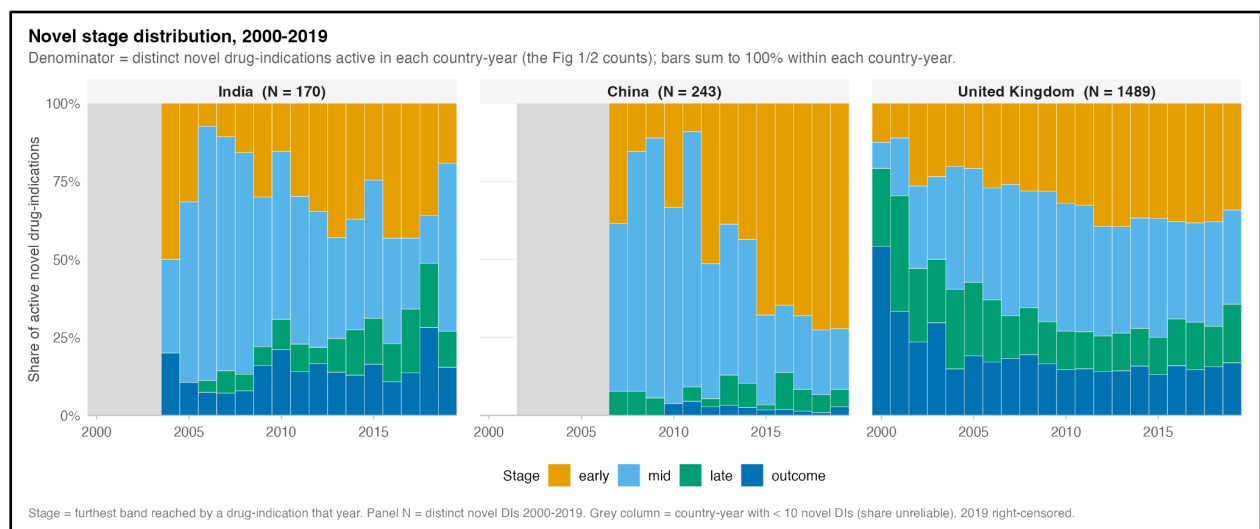


Figure 5: Novel stage drug-indication distribution, India, China & the UK, 2000-2019

Table 1: Within-firm non-novel program share across countries, 2000-2019

| Period    | India (12 dual-track firms) | India (all) | China | United Kingdom |
|-----------|-----------------------------|-------------|-------|----------------|
| 2000-2009 | 23.3%                       | 25.0%       | 5.6%  | 14.3%          |
| 2010-2014 | 33.7%                       | 27.8%       | 13.8% | 12.3%          |
| 2015-2019 | 51.2%                       | 44.9%       | 15.7% | 9.5%           |

<sup>52</sup> Meher et al., “Biosimilars in India; Current Status and Future Perspectives.”

<sup>53</sup> Meher et al., “Biosimilars in India; Current Status and Future Perspectives.”

These CDSCO regulations may have precipitated existing skepticisms surrounding novel development and may have made a focus on generics seem more predictable, where the regulatory process was clearer. Table 1 above quantifies this phenomenon through a time-series of the share of non-novel programs within firms, observed across countries. We observe that among Indian firms that ran both novel and non-novel pharmaceutical programs, the share of non-novel programs doubled in two decades. Indian firms in general saw a similarly large increase.

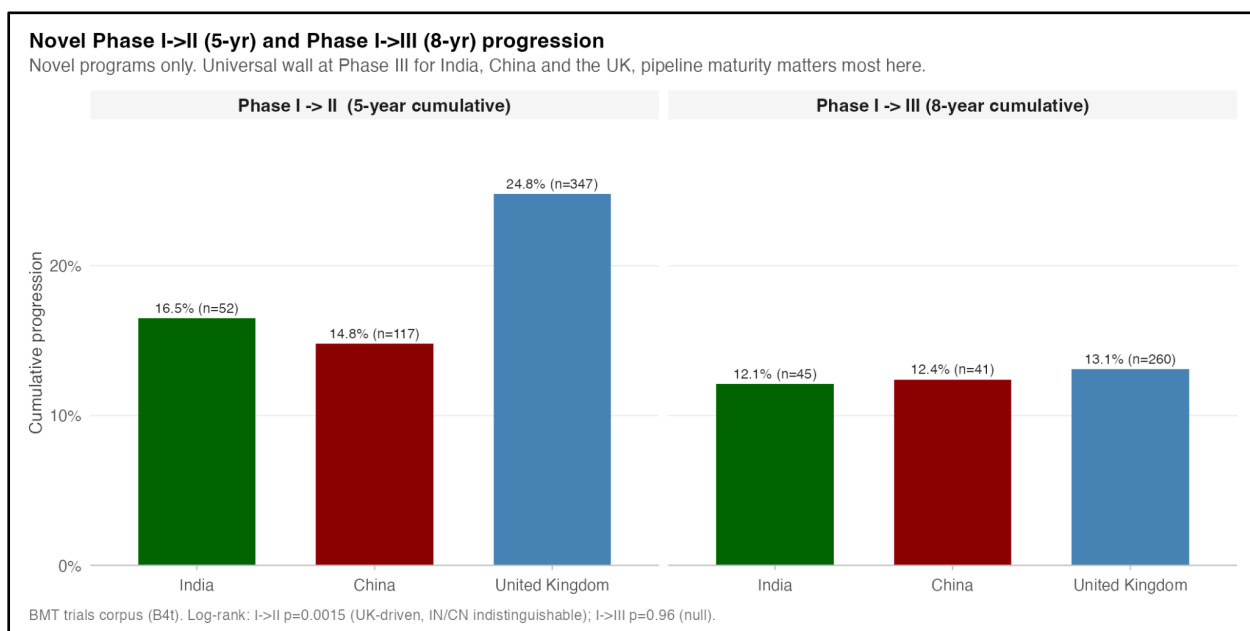


*Figure 6: Cumulative inter-phase transitions for novel drug programs, India, China & the UK*

This increase is not only on the margin – non-novel programs increase in share while novel programs decline, and it is not compositional, since it is within-firm. The mature ecosystem in the UK moves in the opposite direction across the same period, indicating that the expansion of BMT coverage does not explain this phenomenon, and neither does better representation of a particular subclass of non-novel development – both biosimilar and non-NME programs increase in share over time.

This finding is consistent with the empirical evidence that an increase in generic competition is associated with restructurings of R&D activity, away from chemical-based products

and towards biologic-based products<sup>54</sup>. Figure 6 above helps us consolidate the volume and composition axes to understand the value of pipeline maturity. The initial transition from Phase 1 to Phase 2 is lower for India and China when compared to the UK, which has a transition rate of nearly 1 in 4 for novel programs. There is a universal wall when the transition range is expanded to Phase 3, and this is precisely where regulatory mechanisms can support innovating pharmaceutical labs with provisions such as the ones China has passed in the last decade. The Indian ecosystem, in contrast, seems to reflect a jagged frontier: while there is historical precedent of prudent regulation in certain domains, this regulatory environment has not yet been replicated in the novel drug discovery space. While successes in biosimilars do reflect innovation potential, they also reflect that the pathways for success across the novel and non-novel margins are separate.

#### D. Progression

The data so far has established a link between the protections that patent reform can provide, and the downstream pipelines required to maintain an incentive structure amenable to innovation. Pipeline maturity can be established by observing which novel drug-indications survive through consecutive trial phases. We assess trial survivability by calculating the cumulative incidence of Phase 1 entrants that survive to reflect a Phase 2 update in the BMT dataset. Figure 7 reflects the drug-indications observed in the years after the first Phase 1 trial, with the number-at-risk table below denoting the volume count. The United Kingdom has a much higher volume of early-stage trials. In contrast, China has 252 drug-indications starting out at Phase 1, relative to India's 67.

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<sup>54</sup> Branstetter et al., "Generic Competition and the Incentives for Early-Stage Pharmaceutical Innovation."

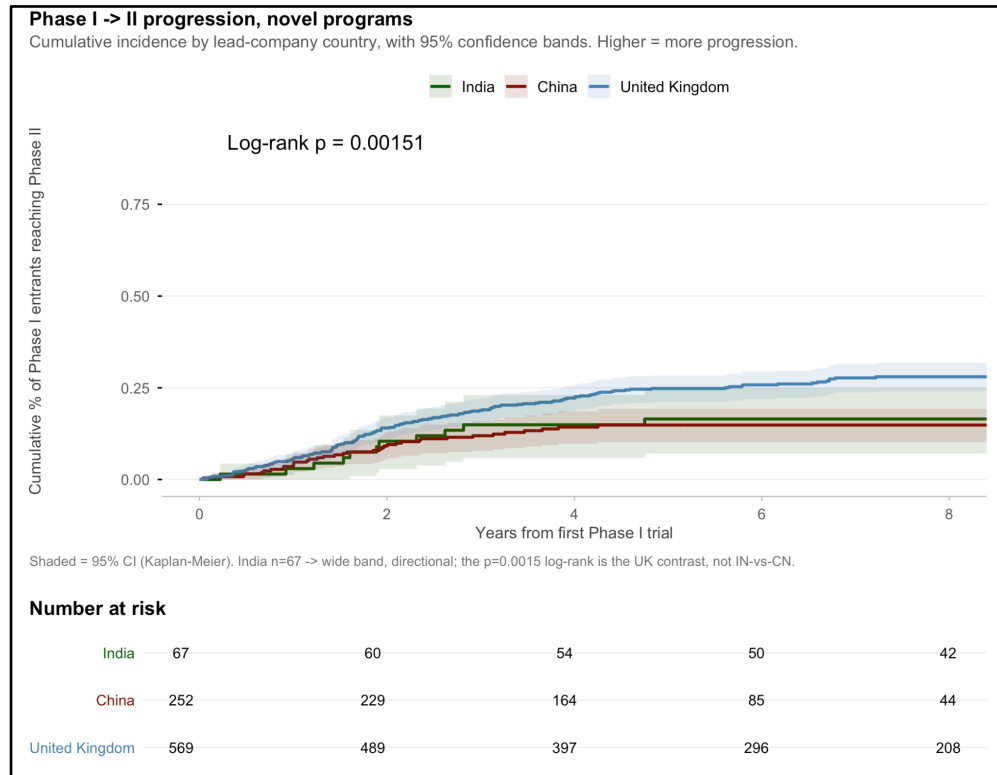


*Figure 7: Phase 1 to Phase 2 drug-indication survival for novel drug programs, India, China & the UK*

While China's drug-indication count may be inflated by the last decade's acceleration, there is a clear finding: that transitions from Phase 1 to Phase 2 were muted. The coefficient on adjusted Phase 1 to Phase 2 transition for India against the UK is  $-0.72$ , significant at the 5% level. Around a quarter of the UK's trials survive to the Phase 2 transition window, while China and India are both substantially slower in the same transition, though the Chinese volume makes this more indicative compared to India, which is instead taken as directional – China had 252 programs at Phase 1 stage relative to India's 67. The curves in Figure 7 describe unweighted progression across all therapeutic compositions, which does not account for heterogeneities in these compositions across countries. For instance, over 70% of China's novel programs are oncology-focused, where progression is naturally slower. Therefore, we model progression differences explicitly, by estimating annual probabilities of novel program transitions from Phase 1 to Phase 2, using the UK as a reference group and controlling for therapeutic area, entry year and time since entry, and clustering at the firm level. We estimate the yearly odds of a trial advancing in India

through a log-odds coefficient of  $-0.721$  relative to the UK, which translates to roughly 51% lower odds of trials progressing in India.

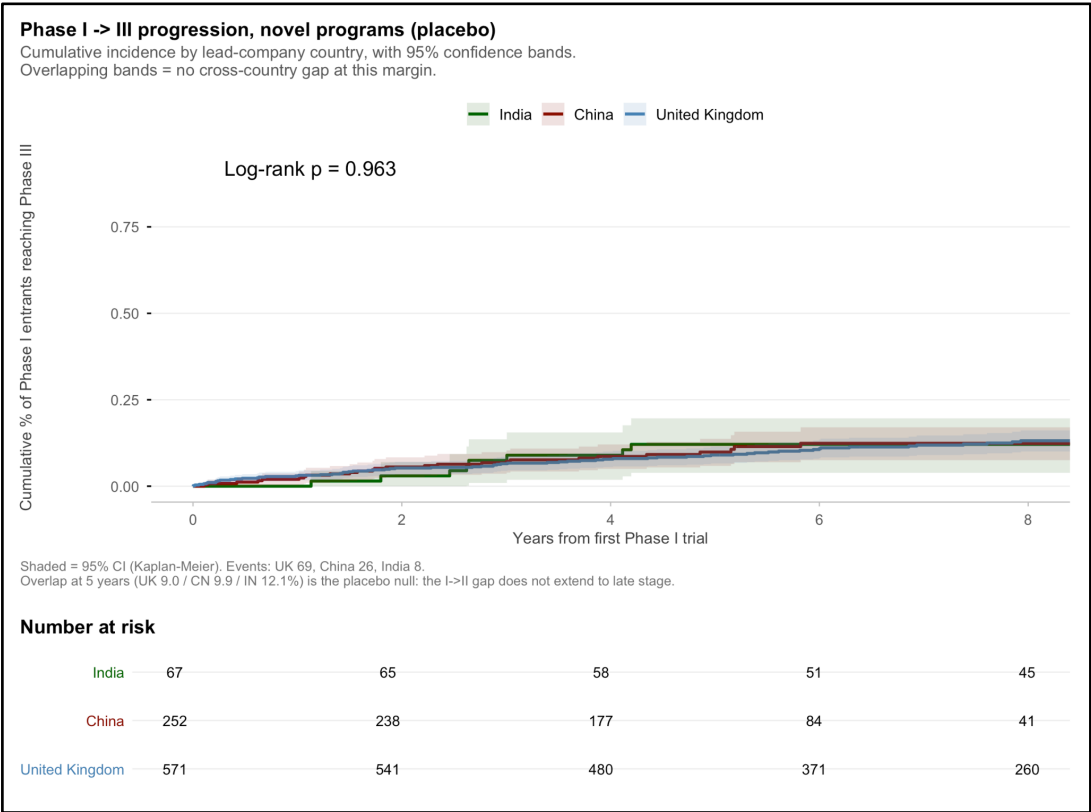


Figure 8: Phase 1 to 3 drug-indication survival for novel drug programs, India, China & the UK

Furthermore, we find that predicted progression of novel programs over 5 years for oncology trials specifically is 16.8% for the UK, 12.3% for China and 8.6% for India – the narrowing of the gap between the UK and China reveals the importance of accounting for therapeutic categories. The overlaps in confidence intervals for the unadjusted survivability estimates between India and the UK, and the lower number of events in India, mean that we can read the results only as directional, though the results are otherwise robust to the inclusion of the full therapeutic classification, as well as the exclusion of oncology or biologic classifications.

We extend the progression axis to Phase 3 survivability in Figure 8. The log-rank p-value of 0.963 and the overlapping confidence intervals suggest that at this margin, the three countries cannot be statistically distinguished. Applying the same specification to analyze the transition between Phase 1 and Phase 3, we find null results for India and China, with p-values of 0.73 and

0.2 respectively on the estimated coefficients of 0.34 and -0.14. This supports the argument that the most severe constraint lies upstream at the Phase 1 to Phase 2 transition, and China's volume advantage at the early stages provides further evidence that the missing complementary architectures that support pharmaceutical innovation need to be built out with a focus on scalability.

Firm composition across countries also contains heterogeneities that are significant for analysis. India's 67 Phase 1 programs are spread across only 17 companies, with a median founding year of 1983, where only five companies are privately held and two were founded after 2000. By contrast, China has 252 programs in Phase 1, which are conducted across 84 companies, 65 of which are private. 60 of these Chinese companies were also founded after 2000 – the median founding year is 2010. In Figure 9, we review flagship novel drug discovery programs in the Indian pharmaceutical space during our study period and find that most flagship programs entered early-stage trials prior to 2015. Post-2015, the documented slowdown in early-stage trials, coupled with the existing progression wall faced by even mature innovation pipelines, seems to suggest that the shift towards generics is a systematic and rational response to the current incentive structure and regulatory environment.

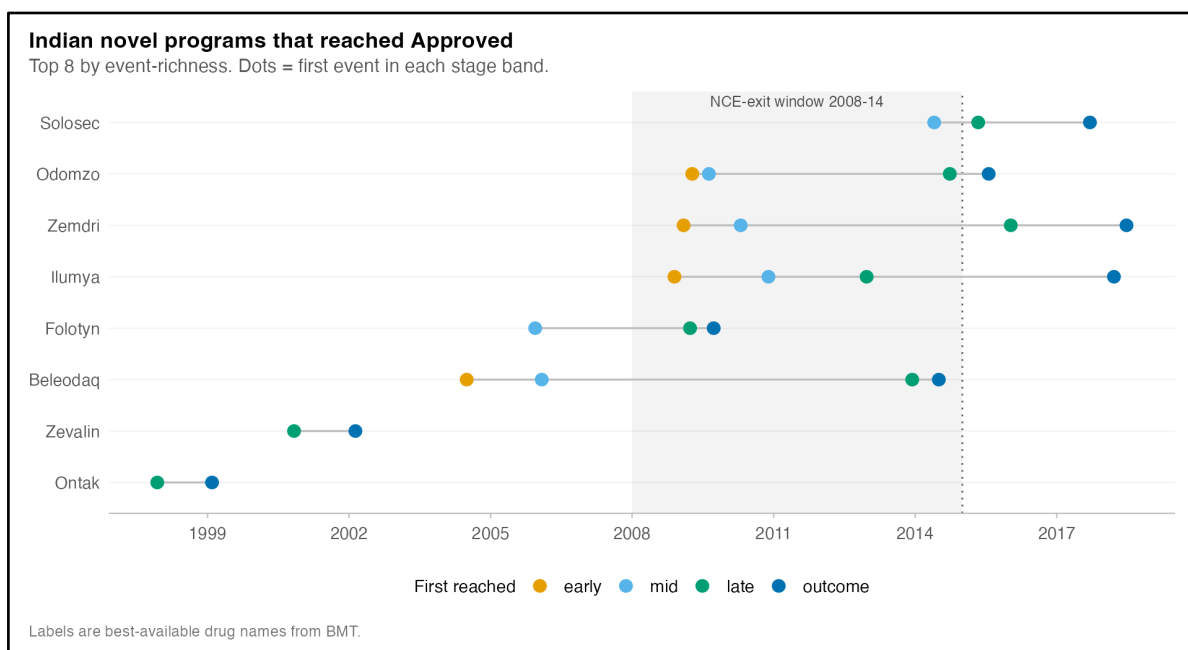


Figure 9: Representative Indian novel drug-indications with approvals, 2000-2019

The Phase 2 transition bottleneck in India aligns with an increase in generic competition, and theoretical and empirical literature support this phenomenon. IP protections, therefore, are a necessary but not a sufficient condition for the promotion of sustainable novel innovation in the pharmaceutical industry. Before proceeding, we acknowledge that several alternative explanations may also explain the documented patterns, such as therapeutic groups heterogeneities – testing for the sensitivity of estimates to the exclusion of oncology and biologics groups, we find a stable gap relative to the UK for India and China, indicating the gap is not an artifact of therapeutic composition. We also note the potential of strategic relocation: if firms react to regulatory frictions by outsourcing their molecules or licensing them in other countries, this only shifts the location of official acknowledgement of the innovation – any bias introduced by these measures is likely to result in an understatement of Indian innovation. Finally, we note that global business cycles may affect funding inflows to all pharmaceutical industries – despite this, we still find divergences in India relative to China and the UK.

#### IV. Expert Insights from the Indian Pharmaceutical Industry

Following our empirical analysis, we reached out to various experts on the Indian pharmaceutical industry. In our discussions, we observed multiple cross-cutting themes which contextualized our findings. We anonymize the interviewees to present the contributions in an objective manner, though we distinguish them by specialization and role.

Perhaps the most salient theme of discussion was the early-stage bottleneck in the pharmaceutical innovation pipeline. One of our interviewees, a prominent Indian oncologist and entrepreneur, discussed how, for a first-in-class biologic, most of the funding was taken up in Phase 1 trials, and that he had to eventually shift Phase 1 trials to the US. Another expert, the founder of a leading Indian novel-biologics startup founded in 2013, had told us that domiciling in the US was required to get credible Phase 1 data for early-stage novel biology work. A policy economist, the CEO of an independent Indian think tank specializing in technology and innovation research discussed the lack of a distinct corporate-VC culture which prevents startups with bold, innovative ideas from finding compatible funders. Our empirical observations corroborate the broader theme here: the early-stage bottleneck for India, and the complementary ecosystems –the

funding ecosystem in particular – prevents this bottleneck from being widened in the short term. Additionally, we find no comparable gap in downstream transitions at Phase 3 and beyond, echoing interviewee accounts that the early transition bottleneck is the most constraining.

Another central theme was cost recovery. Our discussion with the oncologist-entrepreneur showed that Indian markets struggle with the input discovery costs necessary for early-stage innovation, and it is infeasible to expect to recover the cost from patients. In the US and the EU, it was discussed, the ecosystem's ability to absorb discovery costs spurred novel innovation, whereas in India, the lack of such an ecosystem disincentivized novel drug discovery. The policy economist surfaced an interesting tension: price caps inhibit innovation, but removing these caps is politically sensitive. One potentially valuable framework proposed by a pharmaceutical industry veteran centered around an India-specific drug development pipeline. Rather than developing a novel molecule for all markets, focusing on the domestic market, it was argued, could cut development costs substantially, and could therefore improve fund availability for further stages, using the initial approval to derisk a global development strategy.

Implementing these frameworks requires precisely the type of ecosystem complementarity discussed earlier. For instance, our discussion with the oncologist-entrepreneur touched upon the defensiveness of the Indian drug control regulator, which could hamper long-term innovation potential. Some of these limitations were also framed as a trust deficit between entrepreneurs and regulators. In our discussion with the founder of the novel biologics startup, it was brought up that even with good patent design, a lag in the provision of the patent can further impact the trust deficit. The founder also stated that the prevailing R&D schemes only benefited already large companies, and that regulators were yet to fully address the lack of support required on their end. The policy economist also pointed out that mergers and acquisitions led by pharmaceutical firms were driven more by a need for portfolio breadth rather than true absorption of innovative pathways. These discussions suggest that the ecosystem is not yet providing a stable pathway to innovation and is incentivizing short-term reactions instead of long-term bets.

Our discussions with the oncologist-entrepreneur also covered the state mandate that the Chinese government put forth regarding elevating their pharmaceutical industry to global

standards and discussed how their strategies to attract foreign scientists and provide large-scale funding eventually resulted in drug development at a sixth of the cost it would have required in India. China's complementary strengths here are certainly playing an important role, specifically in their development of a national innovation system, and expansion of IPR enforcement to foster self-reliance and fundamental innovation<sup>55</sup>. This has allowed China to compete at the global scale, and we were told by the novel-biologics startup founder that US companies are now willing to onboard Chinese novel molecules, which would have been extremely unlikely even just a decade ago. The industry veteran emphasized the importance of self-reliance here, and how it has helped build the credibility of Chinese pharmaceutical firms, because they are originating and scaling ideas rather than focusing purely on reverse-engineering or process-based improvements. This view was nuanced by the management scholar, who told us that Chinese firms invest just enough to stay close to the progress of extremely successful firms, and then focus on developing low-cost analogs which eventually allows them to get relatively better overall success.

Another theme of these discussions was the national innovation architecture in India, and the frictions that were associated with building it. One example was given by both the policy economist and the management scholar: an underdeveloped public R&D base. This, according to the policy economist, manifested itself in both a funding crunch as well as institutional opacities. The funding crunch was represented in the fact that only about 5-6% of India's R&D budget was spent on health-related endeavors. A central point made here was that research needs to happen not just inside public R&D labs, but also inside academic institutions, and that this academic research requires clear structural support. A related point was made by the management scholar, who pointed out that there was little dialogue in the public R&D space for pharmaceuticals, and that even a top director at public R&D labs struggled to find funding for their startups, potentially displaying a structural funding gap.

The industry veteran provided a further connection, stating that regulations and risk capital go together, and that even large public research funds required compliance with a large set of guidelines. He noted that the incentive structure for academics required a more direct method for their participation in wealth creation, particularly because it was the whole ecosystem that was

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<sup>55</sup> Zhao, "China's Intellectual Property Rights Policies."

required to spur innovation, rather than a few scientists alone. The other recurring structural aspect of these discussions was the need for bridges between industry, academia and government – the policy economist provided one concrete example here of research universities, where interdisciplinary research was an explicit mandate. The novel-biologics startup founder had advocated for public-private partnerships and mentioned the role of startup incubators in supporting academic spinouts of potentially novel innovations. The industry veteran pointed out that if academia could position itself in a role of neutral arbitrator between industry and regulatory entities, it would play a crucial role in improving ecosystem complementarities, by allowing scientific, economic and policy expertise to live under one roof.

Across the various themes of these discussions, we close with the synthesis that, broadly, these accounts all describe the underlying mechanisms of the constrained conversion of Phase 1 to Phase 2 trials in India – foreign domiciling, cost-prohibitive markets, a lack of risk-tolerant corporate venture capital or complimentary institutional environments. The corroboration of this qualitative evidence with our empirical findings provides us with a platform to discuss paths forward for the Indian pharmaceutical industry.

## V. Conclusion

This chapter argues for the thesis of a “long march to innovation” in the Indian biopharmaceutical industry, utilizing empirical evidence and qualitative insights to study the relationship between R&D, competition and intellectual property rights in the Indian pharmaceutical industry. We frame the observed arrests in novel pharmaceutical innovation in India as being structural and upstream, at the point of conversion of clinical trials from Phase 1 to Phase 2. The observed null result we estimate in conversions of trials from Phase 1 to Phase 3 supports the argument that the bottleneck is at the transition to Phase 2. We argue that addressing this requires the creation of a robust national innovation architecture, that aligns incentives across academia, industry and government, and that particularly addresses the efficacy of public R&D funding and the lack of a risk capital environment. India’s comparative advantages on the generics manufacturing and longevity frontiers are well-poised for such structural alignments, and we argue that a national innovation architecture that accounts for this can bring tangible productivity and

innovation improvements, ultimately improving the self-sufficiency of India's intellectual property production. In Table 2 below, we organize connections between the bottlenecks identified in our analysis, and the interventions we propose, including the motivating empirical observation and operating mechanism.

We acknowledge several limitations to the scope of our arguments. First, this chapter aims to document patterns in the Indian pharmaceutical industry, rather than identifying causal effects. Any cross-country estimates are based on level comparisons against a stable reference group and are not interpreted as treatment effects. We acknowledge uneven power limitations – the Indian novel cohort only contains 11 complete downstream transitions across 17 companies. We treat all evidence from this cohort as directional, and present only the China-UK comparisons as being sufficiently powered contrasts.

Table 2: Bottlenecks, associated evidence and policy interventions

| <b>Bottleneck</b>                                                                                                  | <b>Associated evidence</b>                                                                                                                       | <b>Proposed intervention(s)</b>                                                                                                                                                                                 | <b>Operating mechanism(s)</b>                                                            |
|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| Conversion of novel programs from Phases 1 to 2 is slower against the UK benchmark; gap does not extend to Phase 3 | <ul style="list-style-type: none"> <li>• Transition regression and Kaplan-Meier estimates</li> <li>• Phase 1 to Phase 3: null placebo</li> </ul> | <ul style="list-style-type: none"> <li>• Translational financing with a particular focus on transitions directly downstream of Phase 1</li> <li>• Redirection of public R&amp;D to phase transitions</li> </ul> | Capital concentration at point of attrition addresses the transition constraint directly |
| Only 17 companies run                                                                                              | <ul style="list-style-type: none"> <li>• Analysis of firm composition and</li> </ul>                                                             | <ul style="list-style-type: none"> <li>• Public-private partnerships to</li> </ul>                                                                                                                              | The scale ceiling for India is related to the                                            |

|                                                                                                                                              |                                                                                                                                                                                                              |                                                                                                                                                                                                   |                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| the Indian novel pipeline, 2 of which have been founded after 2000; 60 of China's 84 novel pipeline-driving companies are founded after 2000 | <p>age across countries</p> <ul style="list-style-type: none"> <li>• Qualitative interview evidence of corporate VC constraints</li> </ul>                                                                   | <p>bolster startup formation and incentivize exits</p> <ul style="list-style-type: none"> <li>• Incubators to support academic spin-offs and leverage scientific breakthroughs quickly</li> </ul> | limited number of entrants rather than increased output from established firms, therefore requiring improved incentive structures to generate new entrants                       |
| In price-controlled markets, discovery costs are difficult to recover                                                                        | <ul style="list-style-type: none"> <li>• Qualitative interviews on frictions in Indian drug discovery</li> <li>• Academic literature and evidence on outcomes from price controls</li> </ul>                 | <ul style="list-style-type: none"> <li>• Differential pricing during the patent period, with reductions introduced as the patent lapses and generics can be introduced</li> </ul>                 | Protects the incentive to innovate while also promoting access after patent lapse, addressing the static-dynamic tradeoff                                                        |
| Regulatory guidance is uneven across the biosimilar and novel pathways                                                                       | <ul style="list-style-type: none"> <li>• Qualitative interviews on the importance of regulatory support and friction reduction in the novel drug discovery space</li> <li>• Empirical evidence on</li> </ul> | <ul style="list-style-type: none"> <li>• Industry-supported regulatory capacity building</li> <li>• Academia as a neutral arbitrator between regulators and private firms</li> </ul>              | Pharmaceutical firms are incentivized to follow innovation pathways that are well-defined, and collaborations on building such pathways should involve all relevant stakeholders |

|  |                                                   |  |  |
|--|---------------------------------------------------|--|--|
|  | composition<br>across stages and<br>generic drift |  |  |
|--|---------------------------------------------------|--|--|

Additionally, the BMT data may understate Chinese programs prior to 2015, as well as absolute conversion rates across trial phases – we therefore treat all progression-related observations as relative and directional. Further, the right-censoring of the data truncates longer pathways of interest. Finally, the nature of our data is such that it provides evidence that sheds light more directly only on certain aspects of the innovation architecture – our policy discussion on the latter aspects of the architecture draws on evidence from interviews to bridge the discussion to the quantitative results.

These findings contribute to the discussion of the functioning of IP rights within an innovation system. While appropriability protections may support novel research, its conversion to consumer welfare is ultimately determined by a broad set of complementary institutions. India’s trajectory in the last two decades illustrates the distinction between entry and conversion efforts, and that they require a broader conception of the innovation ecosystem. The Zaynich example shows that Indian firms have the capability to fully develop and launch world-class pharmaceuticals. Addressing IP outmigration and shortening the long march to innovation is possible, by harnessing this existing potential and proven strength of sections of the Indian pharmaceutical industry and developing national architectures as a natural path forward for the march towards transformative innovation.

## VI. Technical Appendix

### A. Data source and construction

**Unit of analysis:** A drug-indication, which is a compound paired with a specific therapeutic indication. The country attribution follows the domicile of the lead company. The event corpus is drawn from Biomedtracker's event stream and underlies the volume and composition lenses (Figures 2, 3 and 5). The trials corpus is restricted to drug-indications with a dated Phase 1 trial record and underlies all survival and regression analysis (Figures 7 and 8, and Tables A2 and A3). All survival estimates come from the trials corpus. Novelty classification is derived from Biomedtracker's drug classification field, taking the modal classification per drug-indication. New molecular entities, biologics and vaccines are classified as novel; non-NMEs and biosimilars as non-novel. Roughly 1 per cent, recorded as unknown or device, are excluded.

### B. Corpus coverage

**Table A1: Novel programs by corpus and country**

|                | Event corpus | Trials corpus |
|----------------|--------------|---------------|
| India          | 170          | 67            |
| China          | 243          | 252           |
| United Kingdom | 1,493        | 571           |

The trials corpus requires a dated Phase 1 record and extends past 2019. For India and the United Kingdom it holds under 40 per cent of the event corpus's novel programs; China's trials count exceeds its event count because 18 Chinese programs entered Phase 1 after 2019, against 11 for the United Kingdom and none for India. Progression estimates therefore apply only to programs with a documented trial record.

### C. Observation windows and censoring

Descriptive evidence covers 1998–2019 and the entry analysis in Figure 4 covers 2000–2019. Phase 1 entry dates in the trials corpus run from March 1992 to September 2020, and the latest observed Phase 2 transition is August 2020 and the latest Phase 3 transition March 2021. An administrative censoring date of 31 December 2022 is applied, roughly 21 months after the last observed event. Censored programs are carried as at-risk through a window in which no event could have been recorded, depressing progression rates in absolute terms. The effect is identical across all three countries, so comparisons are directionally unaffected; absolute levels should be read comparatively rather than as conversion shares.

Active-in-year stock counts distinct novel drug-indications active each year; India peaks at 78 in 2012. Annual entrants count novel programs entering Phase 1 each year; India peaks at 27 in 2009.

### D. Progression: Kaplan-Meier estimates

**Table A2: Cumulative progression, novel Phase 1 to Phase 2, with 95% confidence intervals**

| Country        | 3-yr  | 5-yr [95% CI]     | 8-yr  | n at risk (3/5/8 yr) |
|----------------|-------|-------------------|-------|----------------------|
| United Kingdom | 18.8% | 24.8% [21.1–28.4] | 28.0% | 452 / 347 / 208      |
| China          | 11.9% | 14.8% [10.2–19.2] | 14.8% | 204 / 117 / 44       |
| India          | 14.9% | 16.5% [7.1–25.0]  | 16.5% | 57 / 52 / 42         |

Log-rank  $p = 0.0015$ , and the contrast is against the United Kingdom. The UK-China intervals are disjoint, but the United Kingdom and India intervals overlap (21.1 against 25.0), so India is directional on this evidence. China's number at risk falls from 204 to 44 between years 3

and 8, so its 8-year estimate rests on early entrants. At the Phase 1 to Phase 3 margin all intervals overlap at every horizon, with a log-rank p of 0.963.

### E. Regression specification and results

**Specification.** A discrete-time hazard model: a logit on person-years, accommodating right-censoring. The outcome is whether a program records the relevant transition in a given year. Reference category is the United Kingdom; controls are coarsened therapeutic area (five groups, oncology base), centered Phase 1 entry year, and duration since entry pooled at six or more years. Errors are clustered by company and follow-up capped at eight years; the Phase 1 to Phase 3 transition serves as a placebo.

**Table A3: Cross-country transition models, novel cohort**

|                           | (1) DTH<br>1→2,<br>primary | (2) DTH<br>1→3, placebo | (3) 5-yr 1→2        | (4) 5-yr 1→3        |
|---------------------------|----------------------------|-------------------------|---------------------|---------------------|
| China                     | −0.342<br>(0.211)          | 0.338 (0.263)           | −0.434*<br>(0.255)  | 0.599**<br>(0.286)  |
| India                     | −0.721**<br>(0.336)        | −0.140<br>(0.402)       | −0.767*<br>(0.396)  | 0.232 (0.421)       |
| Entry year<br>(centered)  | −0.052***<br>(0.015)       | −0.105***<br>(0.025)    | −0.014<br>(0.024)   | −0.047<br>(0.052)   |
| TA:<br>Immunology         | 0.640***<br>(0.240)        | −0.696*<br>(0.374)      | 0.772***<br>(0.280) | −0.571<br>(0.411)   |
| TA: Infectious<br>Disease | 1.35***<br>(0.195)         | 0.970***<br>(0.310)     | 1.53***<br>(0.275)  | 0.992***<br>(0.348) |
| TA: Neurology             | 0.563<br>(0.413)           | −0.532<br>(0.666)       | 0.657 (0.468)       | −0.253<br>(0.708)   |
| TA: Other                 | 0.593***<br>(0.179)        | 0.436*<br>(0.234)       | 0.718***<br>(0.210) | 0.575**<br>(0.246)  |

|              |                     |                     |                     |                     |
|--------------|---------------------|---------------------|---------------------|---------------------|
| Constant     | −3.15***<br>(0.329) | −3.75***<br>(0.320) | −1.47***<br>(0.218) | −2.44***<br>(0.196) |
| Observations | 5,140               | 5,655               | 680                 | 680                 |

*Clustered standard errors in parentheses; \*\*\*  $p < 0.01$ , \*\*  $p < 0.05$ , \*  $p < 0.1$ .*

Duration dummies are included in columns (1) and (2) and omitted here for space. A negative coefficient indicates slower progression than the United Kingdom. India and China are each estimated against the United Kingdom, not against each other. Neither firm type ( $p = 0.996$ ) nor founding cohort ( $p = 0.859$ ) independently predicts progression, and the country gap is unchanged when both are added, so the gap is compositional rather than a function of firm characteristics.

## F. Construction of the drift measure

Table 1 in the chapter reports the non-novel share of new drug-indication entries. Novelty uses the modal classification in Section A; entry year is the first year a drug-indication appears in the event corpus; dual-track firms are Indian firms recording at least one novel and one non-novel program, of which twelve qualify. The measure reconciles with the series underlying Figure 4: novel entries for all Indian firms are 81, 96 and 59 across the three periods, matching the annual Phase 1 entrant counts exactly, including the 2009 peak of 27. The non-novel rise is spread across both subclasses — biosimilars 8, 7 and 15; non-NMEs 19, 30 and 33 — so it does not reflect better coverage of one classification.

## G. Robustness

**Table A4: Sensitivity to therapeutic composition, Phase 1 to Phase 2, novel cohort**

| Specification       | n   | China coef (p) | India coef (p) |
|---------------------|-----|----------------|----------------|
| Baseline            | 890 | −0.342 (0.104) | −0.721 (0.032) |
| Excluding oncology  | 385 | −0.371 (0.126) | −1.329 (0.011) |
| Excluding biologics | 556 | −0.391 (0.104) | −0.779 (0.016) |

|                                     |     |                |                |
|-------------------------------------|-----|----------------|----------------|
| Excluding oncology<br>and biologics | 266 | -0.367 (0.213) | -1.260 (0.015) |
|-------------------------------------|-----|----------------|----------------|

Direction and magnitude are stable across every exclusion, so the gap is not an artifact of oncology or biologics composition; India's coefficient strengthens when oncology is excluded. The full twenty-category classification gives China -0.356 ( $p = 0.078$ ) and India -0.701 ( $p = 0.048$ ).