COMMENTARY

NIH Licensing Would Benefit from Free-Market Provisions

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Abstract: Government encouragement of free markets is a highly effective means of fostering pharmaceutical innovation; the NIH, by including "free-market provisions" in its licensing agreements that discourage anti-competitive and research-impeding behavior, can do a great deal to support this goal even without legislative overhaul.

In approaching the subject of how government can foster meaningful pharmaceutical innovation, it's worth touching upon the idea of "free markets." It is through the mechanism of the free market, alongside the essential foundational research carried out by organizations like the National Institutes of Health (NIH), that the most effective and powerful medical innovations arise. And through those same mechanisms of free markets, medications ultimately become affordable. The imperative should be to see how the United States government can support effective and healthy markets in the pharmaceutical industry, guaranteeing quality and safety while assuring that competition pushes firms to produce truly transformative therapies.

Such a goal is easier said than done. One of us (RF) has written elsewhere about the way current dynamics within the industry and within current intellectual property and regulatory regimes undermine the power of the markets to produce innovative medicines and bring down prices.[1] We see this dynamic in Professor Kesselheim's work outlining the rising prices of new medications that offer little additional therapeutic benefit to patients. The pattern is, in part, a result of market and regulatory structures that encourage brand companies not to innovate but to rely on existing work, protecting products in hand. It is more profitable to sell an old drug to a new market or in a new variation than to put in the work of making something new.

The behavior is unsurprising, reflecting industry incentives. Nevertheless, policy makers can adjust existing incentives to better align the industry's interests with society's. An alignment of interests in this vein was the original purpose of the patent system and of landmark pharmaceutical legislation, such as the Hatch-Waxman Act. These initiatives were designed to encourage innovation, offering rewards to innovators not as recompense for effort but insofar as they ultimately produce social benefit.

The question, then, is how we encourage healthy free markets in which innovative activity can manifest. Many fruitful proposals require legislative action, yet the power of pharmaceutical lobbying makes such reform challenging. This is not to suggest that we abandon legislative reform efforts such as Professor Kesselheim's call to afford Medicare a wider capacity to negotiate fair drug prices. What is challenging is not necessarily impossible. In addition, however, individ-

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ual agencies, such as the NIH, have the capacity within their mandates to make changes that do not require legislative overhaul.

Professor Kesselheim describes the critical role played by the NIH in the development of pharmaceuticals. The analyses he cites are compelling and illuminating, and we particularly echo the call for increased funding. A recent report by the Senate Health, Education, Labor, and Pensions (HELP) committee similarly drew attention to both the essential role that scientists at the NIH played in the development of a number of medications, as well as to the high prices at which those same medications are sold to United States patients when they reach the market.[2] Such prices, in most cases, far exceed those in other developed countries. The HELP committee staff recommended that the NIH return to a briefly explored strategy of including reasonable pricing provisions in their licensing agreements.[3]

The NIH first introduced reasonable pricing provisions into their licensing agreements in 1989 following controversy surrounding the high price of some government-funded drugs hitting the market.[4] The agency stopped putting in such provisions several years later, following industry claims that such provisions discouraged industry partnerships with the NIH.[5] In addition to the HELP Committee's calls to reintroduce reasonable pricing provisions, others have urged the NIH to fund studies of expensive drugs already on the market that would assess lower, shorter duration, or less frequent dosing as well as evaluate less-expensive alternatives.[6] In addition to this panoply of ideas, we suggest the NIH deploy what one of the authors has called "free market" provisions, aimed at reducing anticompetitive behaviors. The same author has written broadly about this concept in the context of university licensing agreements,[7] but the government's power to ensure appropriate market behavior, as well as its responsibility to ensure an appropriately functioning free market, is far greater than that of universities. For both reasons, the NIH license provisions could be drafted to require that companies licensing patents from the NIH refrain from certain anticompetitive behaviors that would move the industry further from a free and fair market.

For example, patents are designed to provide a time-limited period in which innovator companies have the opportunity to obtain a return on their invention through the ability to exclude others from the market. Enshrined in the constitutional language is the notion that patents should come to an end.[8] Competitors should then enter the market and drive prices down to competitive levels. The modern reality, however, has deviated far from the ideal, and companies have become adept at extending their periods of market protection. Techniques include making minor modifications to patented inventions, obtaining new patents or piling protections onto existing ones. In fact, 78% of drugs associated with new patents are not new drugs coming on the market but existing ones.[9]

These pile-on patents can be of questionable validity. Those who challenge secondary or tertiary patents typically win when Hatch-Waxman litigation is carried to completion,[10] and roughly 90% of litigated FDA Orange Book patents are secondary or tertiary patents.[11] Challenging a patent absorbs time and resources, however, creating a drag on generic competition.

Additional anticompetitive behaviors by brand companies include introducing their own generic versions of drugs, known as authorized or captive generics. Captive generics have the effect of keeping generic prices higher, rather than bringing prices down.[12] They also deter generic entry by cutting into the potential profits of the generic entrant. Other smaller, but no less potent, attempts to interfere with new market entrants include the filing of frivolous citizen petitions against a generic drug or refusing to provide drug samples to generic manufacturers.

Markets thrive on information, and a free-market environment must ensure an appropriate flow of information so that competitors can both prepare to

> The claim that price terms negotiated between parties might constitute a trade secret is highly suspect under trade secret doctrine for numerous reasons, including that it defies the notion of a negotiation. For example, if the idea is that price is developed through adverse negotiation between the pharmaceutical company and the middle-players, how can price constitute something developed and owned by the pharmaceutical company alone?

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enter the market and obtain traction once they enter. Current pharmaceutical markets fall short on these measures, again, due to strategic behaviors that have been allowed to flourish. The problem manifests in two contexts, both related to overreaching claims of protection for trade secrets and confidential information. First, companies claim to have trade secret protection over price and pricing terms, casting a dark shadow over the drug distribution system in which middle-players, such as pharmacy benefit managers (PBMs), negotiate for rebates. The claim that price terms negotiated between parties might constitute a trade secret is highly suspect under trade secret doctrine for numerous reasons, including that it defies the notion of a negotiation.[13] For example, if the idea is that price is developed through adverse negotiation between the pharmaceutical company and the middle-players, how can price constitute something developed and owned by the pharmaceutical company alone? And if the idea is that the price is developed as a joint invention of the middle-players and the pharmaceutical companies, the concept is even more strange. How can the middle-players claim to be representing the interests of health plans in the negotiations if they also claim that the negotiation is an invention session with the other side? Worse yet, if price terms are a trade secret, companies could not offer the same terms to other middle-players or health plans without risking that the "secret" becomes widely known among them, which would dissolve the trade secret protection.

Second, the patent system and the related regulatory regimes are predicated on providing sufficient information for competitors so that when the protection ends, competitors can readily enter the market. The Patent Act requires that patents teach those skilled in the art how to make and use the invention.[14] Similarly, the Hatch-Waxman Act and the Biologics Price Competition and Innovation Act created pathways for rapid entry of follow-on drugs in which generic and biosimilar companies can use the safety and efficacy data developed for the brand reference product without having to subject patients to a new round of clinical trials. With biologic medicine, however, companies have managed to avoid the openness dictated by all of these legislative initiatives.[15] Some patents on biologics provide no more than ranges for critical aspects of making the drug, such as temperature and concentration, or even a wide variety for the type of host cell — bacterial, mammalian, yeast, and insect — in which a drug might be produced, without identifying what, specifically, manufactuers need to do to make the drug. It is a little like saying, "gather materials; figure out what works; good luck!" Similarly, companies have been able to delay providing clinical trial information or to convince the FDA to provide the information in summary only. All of these strategic behaviors raise the barriers to competition and interfere with the free market that should prevail when patents expire.

NIH free-market licensing could help alleviate the problems described above. Such licensing could focus on downstream products or activities eventually developed as a result of the insights garnered through government funding. Requirements could include that relevant companies refrain, in appropriate circumstances, from secondary patenting activities, captive generics, and "citizen" petitions. Licenses also could require companies to provide adequate pricing, clinical trial, and manufacturing information through the appropriate mechanisms.

While reforms related to pricing address the symptoms of inappropriate market power, free-market licensing provisions address the root of the problem itself. If the NIH can help foster a more vibrant free and fair market, competition itself can lead to pricing reform. If, however, brand companies persist in limiting the generic market, meaningful price decreases, sometimes as great as 95%,[16] will remain out of reach for many drugs. Moreover, the capacity for true innovation as imagined by our nation's founders, through the widespread dissemination of technology in the pubic domain, will continue to elude us.

Disclosure

Professor Feldman and her husband have funds that are invested through Goldman Sachs in stocks across a range of public companies. They do not direct or participate in the choice of stocks which may, at times, include companies with interests in the pharmaceutical industry.

References

1. R. Feldman, "Perverse Incentives: Why Everyone Prefers High Drug Prices — Except for Those Who Pay the Bills," *Harvard Journal on Legislation* 57, no. 2 (2020): 303–376, *available at* <https://www.doi.org/10.2139/ssrn.3162432> (last visited November 16, 2023); R. Feldman, "May Your Drug Price Be Evergreen," *Journal of Law and the Biosciences* 5, no. 3 (2018): 590–647, *available at* <https://www.doi.org/10.1093/jlb/lsy022> [hereinafter cited as "Evergreen"]; R. Feldman, "Regulatory Property: The New IP," *Columbia Journal of Law and the Arts* 40, no. 1 (2016): 53–103, *available at* <https://www.doi.org/10.7916/jla.v40i1.2062> (last visited November 16, 2023).
2. Majority Staff Report, Senate Health, Educational, Labor, and Pensions Committee, *Public Investment, Private Greed* (Jun. 12, 2023).
3. *Id,* at 2.
4. *Id.*
5. *Id.*
6. M.J. Ratain, *The Best Way for the NIH to Reduce Drug Prices is to Address Drug Spending,* STAT First Opinion (August 15, 2023), *available at* <https://www.statnews.com/2023/08/15/nih-director-monica-bertagnolli-drug-prices-spending/> (last visited Aug. 30, 2023).

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7. R. Feldman, B. Chang Rowe, and R. Oral, "Viral Licensing: Ensuring the Public Interest When Taxpayers Fund Pharmaceutical Research," *Santa Clara Law Review* 59, no. 3 (2020): 641–661, *available at* <https://www.doi.org/10.2139/ssrn.3292337> (last visited November 16, 2023).
8. US Const. art. I, § 8, cl. 8.
9. See Feldman, *supra* note 2.
10. B.N. Sampat and K. Shadlen, *The Effects of Restrictions on Secondary Pharmaceutical Patents: Brazil and India in Comparative Perspective*, University of California, Moral Economies, Economic Moralities Conference, June 24, 2016, *available at* < https://economics.harvard.edu/files/economics/files/sampat-bhaven_effects_of_restrictions_on_secondary_pharma_patents_brazil_and_india_3-4-16.pdf> (last visited November 16, 2023); Federal Trade Commision, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), *available at* <https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf> (last visited November 16, 2023).
11. S. Tu and M. Lemley, "What Litigators Can Teach the Patent Office About Pharmaceutical Patents," *Washington University Law Review* 99 (2022): 1673-1731: <doi.org/10.2139/ssrn.3903513> (last visited November 16, 2023).
12. *See* R. Feldman, "Captive Generics: The Wolf in Sheep's Clothing," *Harvard Journal on Legislation* 59, no.2 (2022): 383–426, *available at* <https://www.doi.org/10.2139/ssrn.3868436> (last visited November 16, 2023).
13. R. Feldman and C. Graves, "Naked Price and Pharmaceutical Trade Secret Overreach," *Yale Journal of Law and Technology* 22 (2020): 61–128, *available at* <https://www.doi.org/10.2139/ssrn.3426225> (last visited November 16, 2023).
14. 35 U.S.C. §112 (a) (2012).
15. R. Feldman, "Trade Secrets in Biologic Medicine: The Boundary with Patents," *Science and Technology Law Review* 24, no. 1 (2023): 1–54, *available at* <https://www.doi.org/10.52214/stlr.v24i1.10455> (last visited November 16, 2023).
16. R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, U.S. Food & Drug Administration (Dec. 2019).

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