

The Impact of the Inflation Reduction Act of 2022 on Pharmaceutical Innovation, Patent Litigation and Market Entry

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Key Points:

- The new drug price negotiation process under the IRA takes into account a complex mix of price, competitive status, market exclusivity and scientific data.
- New price setting provisions built into the IRA may impact research and development as well as investment decisions for small-molecule drugs and biologics.
- The IRA may also influence patent litigation and market entry strategies for both branded and generic/biosimilar companies.

The **Inflation Reduction Act of 2022** (IRA) was signed into law by President Biden on August 16, 2022, and includes key sections addressing climate and clean energy, corporate taxes and health care.¹ The health care provisions contain significant changes to prescription drug pricing that could have far-reaching, rippling effects on the health care industry and its stakeholders. This client alert examines some nuances of the pricing reform provisions and how they may change pharmaceutical drug research and development, patent litigation and market entry opportunities for competitor drugs.

I. Medicare Price Negotiation for High-Expenditure, Single-Source Drugs

a. CMS Selection, Negotiation and Enforcement

Prior to the IRA, a non-interference clause in the Social Security Act prohibited the Secretary of Health and Human Services (HHS) from negotiating with drug manufacturers. The IRA ends that prohibition with a brand-new framework enabling the Centers for Medicare & Medicaid Services (CMS) within HHS to negotiate a “maximum fair price” (MFP) for a limited number of high-expenditure, single-source drugs every year. There are a number of factors CMS is directed to consider during the price negotiation, including whether federal financial support was ever provided for drug development. The IRA portrays its approach to pricing as a negotiation between the government and a drug manufacturer, yet it caps the MFP based on a percentage of the non-federal average manufacturer price (Non-FAMP). That percentage is based

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on the amount of time that has passed since the Food and Drug Administration (FDA) approval. For example, “long-monopoly drugs” (16 years since approval) will be capped at 40 percent of the Non-FAMP. “Extended-monopoly drugs” (more than 12 years, but less than 16 years since approval) and “short-monopoly drugs” (less than 12 years since approval) will be capped at 65 percent and 75 percent, respectively.

The government’s drug pricing program will commence in 2023 with CMS selecting 10 eligible Medicare Part D drugs for negotiation.² Negotiations are expected to last seven months, and the selected price will go into effect two years later, beginning in 2026. However, as discussed *infra* in Section I.c., biologics may receive a two-year delay for negotiations if a biosimilar product is soon to launch. The total number of drugs selected for negotiation will rise to 20 Medicare Part B and Part D drugs per year in 2029 and beyond. Thus, as time progresses, eventually all eligible drugs will be swept into the ambit of the government’s drug pricing reform. For additional details on IRA implementation dates, please see our recent [Health Policy and Legislation Alert](#).

Failure to comply with the price negotiation provisions comes with significant penalties, including: (i) civil monetary penalties up to 10 times the change in price for each unit charged above the MFP; (ii) \$1 million per day for failure to provide required information; (iii) \$100 million for each item of false information that is knowingly provided; and (iv) an escalating excise tax starting at 65 percent of prior year sales, increasing to 95 percent of sales after the 270th day of noncompliance.

b. Drugs Subject to Negotiations

A single-source pharmaceutical product generally qualifies for selection and negotiation if it is: (i) a small-molecule drug for which at least seven years have passed since the date of approval from the FDA and there is no generic on the market; or (ii) a biologic for which 11 years have passed since the date of FDA licensure and there is no biosimilar on the market.³ Given that a pharmaceutical drug is selected for negotiation two years prior to the negotiated price taking effect, small-molecule drug manufacturers and biologic manufacturers are afforded at least nine years and 13 years, respectively, before they must sell their product under Medicare Part B and Part D, as applicable, at the CMS-negotiated price.

While the IRA targets high-expenditure drugs that have been on the market for several years without generic or biosimilar competition, it excludes from eligibility certain categories of products. Among those excluded are products with only one Orphan Drug indication, low Medicare spend drugs, plasma-derived products, and certain small biotech products (under a short-term exemption set to expire in 2029). The CMS price-negotiated MFP does not apply to any drug sales covered by private insurance, or paid for in cash by patients; nor does it impact patient co-pays, deductibles, co-insurance or other out-of-pocket costs.

c. Delaying Negotiations for Biologics

The IRA contemplates delaying negotiations for an otherwise eligible biologic when a biosimilar applicant is expected to enter the market. Specifically, if particular requirements are met, the IRA empowers CMS to delay negotiations for up to two years from the date the biologic is selected for negotiation. There is not an analogous provision for small-molecule drug companies facing impending generic entry.

For a biologic to receive a one-year delay, the biosimilar applicant (not the biologic reference drug manufacturer) must request the delay and come forward with “clear and convincing evidence” of a forthcoming launch. Furthermore, CMS must determine there is a “high likelihood” that the biosimilar will be both “licensed and marketed” within the next two years. If the biosimilar applicant does not receive approval and come to market within that year, CMS may nonetheless defer selection of the biologic for an additional year under certain conditions. The biosimilar applicant must request another delay and CMS must find based on “clear and convincing evidence” there is a “high likelihood” of licensure and marketing within that year and also that the biosimilar applicant has “made a significant amount of progress” regarding the same. The IRA does not delineate what evidence would constitute a “clear and convincing” showing and is silent on whether the reference biologic manufacturer would have an opportunity to comment during this process.

If the biosimilar applicant does not launch during the delay period, the IRA imposes a stiff penalty on the biologic manufacturer in the form of retrospective rebates based on the selected MFP for the drug. Finally, there are certain circumstances that automatically foreclose CMS from delaying negotiations, including where the biologic manufacturer and biosimilar applicant have entered into an agreement that “requires or incentivizes” the biosimilar applicant to request a delay or that “directly or indirectly” limits the quantity of biosimilar products that may be sold over time in the United States.

II. Shifting Considerations in Health Care Industry

a. Research and Development (R&D)

In light of the IRA, pharmaceutical innovators focusing their drug development pipeline on small-molecule drugs may continue to re-examine R&D priorities to account for potentially favorable treatment of biologics. Biologics already receive a longer regulatory exclusivity period than small-molecule drugs.⁴ Now under the IRA, biologics will also be afforded more time on the market before becoming eligible for price-reduction negotiations. Specifically, compared to a small-molecule drug manufacturer, biologic manufacturers now have an extra four years to recoup investments before being required to sell their drug products at or below the MFP. In light of the foregoing, investors and other stakeholders may gravitate more towards companies with biologics rather than small-molecule drugs.

The price setting provisions of the IRA may also discourage further R&D into drugs that have already been approved to treat one rare disease. While the IRA makes clear that an Orphan Drug with one designation is excluded from price negotiation, it lacks any exclusionary language regarding a drug with multiple orphan indications. Faced with uncertainty surrounding eligibility of multiple orphan indications in the IRA, private investors and health care companies may be discouraged from follow-on Orphan Drug development. This would be the opposite of the intended purpose of the Orphan Drug Act, which is to encourage the development of drugs for rare diseases by providing incentives in the form of regulatory exclusivity.⁵ Market exclusivity of up to seven years is available for Orphan Drugs, compared to the five years generally available for other New Chemical Entities.⁶ However, that extended exclusivity may not be worth as much as it used to be if CMS can price-negotiate the product down to a MFP. The Orphan Drug provisions of the IRA may further be impacted by various legislative proposals to further define the scope and definition of Orphan Drugs under the Food Drug &

Cosmetic Act pursuant to legislation currently pending before Congress, as reported in our initial [Health Industry Alert](#) and our recent [Update](#), and which may be considered by Congress before the end of this year.

Finally, the IRA may discourage using federal funding for drug research because receiving federal funding is a factor that gets considered by CMS when selecting the MFP. Thus, a drug developed using government funding—such as that from the National Institute of Health (NIH)—risks being priced lower due to that collaboration. This financial risk may also discourage private entities from investing into some drug companies who have or will rely on federal funding sources. Creating further uncertainty for both investors and innovators is the fact that the IRA provides no clarity or time limitation on what constitutes “prior” financial support. Again, the incentive incorporated into the IRA goes in the opposite direction of the purpose of government organizations like the NIH—a research agency that aims to provide world-class scientific research collaboration to assist in advancing technologies that can be further developed by the private sector into important life-saving products.⁷ Now, both pharmaceutical companies and their investors may be disincentivized from pursuing the commercialization of technologies coming out of NIH and be more inclined to only develop products emanating from their own technologies and private funding sources.

b. Patent Litigation and Settlement

With the government’s new pricing reform, a branded drug company who succeeds in continuing market exclusivity through patent litigation via the Hatch-Waxman Act and Biologics Price Competition and Innovation Act process may nonetheless imminently see a price reduction if that product is selected by CMS for price negotiation. Depending on the particular economics and pricing of the product at issue, prevailing in a patent infringement lawsuit against a forthcoming competitor may no longer be as valuable for a branded drug company because high-expenditure single-source drugs are at risk of being selected for price negotiation if there is no generic or biosimilar competitor on the market.

As a result, patent litigation strategies may change. For example, branded drug companies may seek settlements and licenses to allow a generic and biosimilar manufacturer to enter the market shortly before the reference drug will be eligible for negotiation—i.e., seven years, post-approval for a generic and 11 years, post-licensure for a biologic. And those settlements have the added benefit of eliminating litigation costs that would have otherwise been incurred.

But those financial benefits must be balanced against other potential legal and commercial risks. For example, the Federal Trade Commission (FTC) may take interest in such settlement agreements, looking closely at whether the arrangement is anticompetitive or otherwise violates antitrust and consumer protection laws. Additionally, there are restrictions in place under the IRA regarding agreements that limit certain market behavior, such as the quantity of a biosimilar product that can be sold over a specific period of time. Likewise, allowing market entry of a competitor drug through settlement may drive down the branded drug price to a number that is less than what would have otherwise been set as the MFP. In that circumstance, keeping the generic or biosimilar manufacturer off the market through a successful patent infringement lawsuit would have likely been the better economic option to pursue. Finally, settling with one generic or biosimilar will not prevent additional patent challenges (and the associated litigation costs) from other competitors seeking to enter

the market, and the IRA provides no pricing benefit for a branded pharmaceutical company facing multiple sources (as opposed to a single source) of generic competition.

Patent litigation and settlement strategies may also be influenced by certain timing requirements specified in the IRA. The law provides that a product which is part of the price negotiation process will exit the program at the beginning of the first calendar year, which is nine months after market entry of the generic or biosimilar. This could potentially impact the value of the timing of negotiated market entry dates in a material way, for both brand and generic companies. Though the law was just passed, there are already members of Congress who are concerned that manufacturers may engage in “gaming,” including raising list prices after generic or biosimilar entry.⁸

c. Market Penetration Opportunities for Biosimilar Applicants

If a biologic is approaching its ninth year since approval and no biosimilar has yet to receive FDA licensure or come to market, assisting a biosimilar with the regulatory approval process may be of value to the biologic reference drug since it will exempt that biologic from price negotiation. However, both the FTC and CMS might carefully scrutinize such an arrangement. For example, if an agreement between the biologic manufacturer and biosimilar applicant incentivizes the biosimilar to request a delay, the delay provisions of the IRA will be unavailable for that biologic. Moreover, we have already seen the FTC’s significant interest in oversight of and litigating cases of “Pay-for-Delay” between brand and generic/biosimilar manufacturers. The incentives of the IRA may inspire a new generation of “Pay-to-Launch” agreements which are, as of yet, untested but are sure to gain the interest of at least the FTC.

Next Steps

Drug and biologic innovators, generic and biosimilar applicants, and their investors will need to consider the impact of the IRA’s drug price negotiations on drug discovery and development, sources of investment, patent litigation and settlement, and new opportunities for competitor drug approval and market entry. We can expect significant interest of all of these stakeholders in the regulations from CMS that are likely forthcoming in order to implement the complex framework of the IRA statute.

¹ Inflation Reduction Act of 2022, Pub. L. No. 117-169.

² Medicare Part B drugs will not be eligible for selection until 2028.

³ An authorized generic does not constitute a generic or biosimilar under this provision.

⁴ Compare Food, Drug and Cosmetic Act (FDCA) § 505(j) (providing a five-year exclusivity period for small-molecule drugs), with Patient Protection and Affordable Care Act, 42 U.S.C. § 262(k) (providing a 12-year exclusivity period for biologics).

⁵ See Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983).

⁶ See 21 C.F.R. § 316.31 (2011); FDCA § 505(j).

⁷ See, e.g., *Impact of NIH Research: Our Society*, NIH (May 1, 2018), <https://www.nih.gov/about-nih/what-we-do/impact-nih-research/our-society>; *What We Do: Mission and Goals*, NIH (July 27, 2017), <https://www.nih.gov/about-nih/what-we-do/mission-goals>.

⁸ See, e.g., Letter from Congresswoman Cathy McMorris Rodgers and Congressman Kevin Brady to Sec’y of U.S. Dep’t of Health and Human Servs. (Aug. 29, 2022), <https://republicans-energycommerce.house.gov/wp-content/uploads/2022/08/08.29.22-Letter-to-HHS-re-IRA22-Drug-Pricing-Implementation.pdf>.