United States Court of Appeals

for the

Third Circuit

Case Nos. 24-1820
and 24-1821

BRISTOL MYERS SQUIBB CO,

Appellant,

– v. –

SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES; ANANDA V. BURRA.

ON APPEAL FROM AN ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY IN NOS. 3-23-CV-03335 AND 3-23-CV-03818, HONORABLE ZAHID N. QURAISHI, TRIAL JUDGE

AMICUS CURIAE BRIEF FOR FRESENIUS KABI IN SUPPORT OF APPELLANT

NEIL LLOYD
ARENTFOX SCHIFF LLP
Attorney for Amicus Curiae
233 South Wacker Drive, Suite 7100
Chicago, Illinois 60606
(312) 258-5500
neil.lloyd@afslaw.com

CP COUNSEL PRESS (800) 4-APPEAL • (624150)

CORPORATE DISCLOSURE

Pursuant to Federal Rule of Appellate Procedure 26.1, Amicus Curiae Fresenius Kabi, USA LLC hereby makes the following disclosures:

1. Fresenius Kabi USA, LLC is a wholly owned by Fresenius Kabi Pharmaceuticals Holding, LLC.

2. Fresenius Kabi Pharmaceuticals Holding, LLC is wholly owned by Fresenius Kabi AG.

3. Fresenius Kabi AG is wholly owned by Fresenius SE & Co. KGaA, a German partnership limited by shares. Fresenius SE & Co. KgaA has no parent company and is a publicly traded company in Germany. No publicly held company has an ownership interest of 10% or more in Fresenius SE & Co. KgaA.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Case:

Statutes & Other Authorities:

INTEREST OF AMICUS

Amicus Curiae Fresenius Kabi USA, LLC ("Fresenius Kabi"), is a health care company that specializes in bringing affordable medicines to patients with critical and chronic conditions.[1] Fresenius Kabi manufactures injectable medicines, biosimilars and medical technologies and employs more than 4,000 people in the United States with key domestic manufacturing, research and development, and distribution centers in Illinois, Nevada, North and South Carolina, New York, Pennsylvania, and Wisconsin. Fresenius Kabi writes in support of Plaintiffs' position in this action, but from the perspective of a company that develops generic and biosimilar medications.

Fresenius Kabi believes innovation is critical to the future of our society, and the pharmaceutical industry cannot survive without it. There can be little argument that affordable drugs for patients are needed today. The regulatory scheme at issue in this case, however, amounts to arbitrary price controls, which may be intended to reduce prices but actually reduce generic and biosimilar availability. The price controls undermine incentives for companies to develop new drug products as well as for competitors to develop and provide generic and biosimilar alternatives, and

[1] Counsel for Amicus Fresenius Kabi USA, Inc. prepared this brief in whole without financial contributions from any other party. Counsel for all other parties to the above-captioned appeals consented to the filing of this amicus brief.

generic and biosimilar medicines provide more effective and more sustainable reductions in drug prices than the Inflation Reduction Act ("IRA").

ARGUMENT

I. THE IRA WILL ADVERSELY IMPACT THE AVAILABILITY OF GENERIC AND BIOSIMILAR PRODUCTS, WHICH PROVIDE REAL CONSUMER SAVINGS

Most prescriptions filled in the United States are for generic drug products, which provide consumers billions of dollars in cost savings. Market projections show that American patients will save $54 billion from 2017-2026 with the introduction of biosimilar products.[2] Plaintiffs' brief describes the deleterious effects of the IRA on biologics companies that first launch a new biologic, but the IRA also affects the generic and biosimilar drug industry. Because the IRA is likely to undermine incentives to develop new products, as noted in Plaintiffs' submissions, so too will generic and biosimilar manufacturers have fewer viable target products to pursue. This translates to fewer new drugs in the short run, and fewer lower-cost options for the quality care of American patients in the long run. Moreover, the generic industry serves a vital role in maintaining supply for many older, but essential, life-saving drugs, which must remain viable in order to avoid likely drug shortages. Furthermore, generic and biosimilar companies can provide more

[2] Building a better market for biologics: the US vs. Europe. Bionest blog, July 1, 2019. Accessed May 20. 2022. https://bionest.com/biologics-us-vs-europe.

effective and more sustainable price reductions for drugs than the IRA, but free market competition may never occur if the IRA discourages development of generic and biosimilar medicines in the first place.

A. The IRA Disincentivizes Innovation, Which Means No Development of Cost-Saving Generic and Biosimilar Versions of New Drugs.

The IRA undermines the incentives that brands would have in a true free market to develop new products and for generics to develop low-cost alternatives. In particular, the "negotiation" requires that the price of the branded products to be at a lower price than the existing marketed price. Moreover, the current scheme would allow the government a "take it or leave it" proposition of reducing the price of a drug to below its production cost, thus entirely destroying the value of the property. If the manufacturer doesn't agree, it owes an outsized "tax" or is forced to take, not just the product in question out of Medicare, but ***all*** products produced by the manufacturer must exit the program. Similar issues affect generics and biosimilars, only slightly later in time.

Plaintiffs described in detail how the IRA rules improperly force enormous price discounts from branded companies—25%-60% or even more in some cases—under the pressure of extreme penalties. Plaintiffs further described how this scheme undermines the incentive for branded companies to develop new drug products because of the purported high costs of development and risk of not ultimately

making a profit. The market dynamics in turn affect generic and biosimilar companies, who would like to see true market competition as a way of price-setting, rather than the artificial regulations implementing the IRA.

Indeed, one impact of the IRA Guidance is that branded companies are actively discouraged from investigating new indications for existing products. In the pre-IRA system, if a company conducted clinical trials to determine if an already-existing drug can be used to treat a different condition—e.g., a fertility treatment can also be used to treat prostate cancer—then that company can potentially receive additional patents and additional regulatory protections and incentives. These incentives encourage research in expanding the use of current drugs, in addition to seeking costly new drugs.

These incentives also help the generic industry. In particular, if an FDA-approved drug is approved for multiple indications, and there are separate patents for the different indications, then this creates a pathway for generic and biosimilar manufacturers to gain approval for a version of the drug that only seeks approval for one of the off-patent indications. This benefits consumers because the expansion of indications often increases the number of treatment options for physicians, while also creating a pathway for lower-cost treatments.

The IRA strips away the incentive for branded companies to pursue new indications for approved drugs. In particular, the Centers for Medicare and Medicaid

Services ("CMS") Guidance make clear that it only considers the amount of time the active ingredient has been FDA-approved in determining whether a product should be listed for negotiations. As a result, if a drug has been on the market for seven years, and the innovator tests it for another disease state, that drug will not be considered a new product, and so the drug will still be eligible for selection for negotiations. In fact, if proposing a new indication would increase the sales of a particular drug, then it would make that drug ***more likely*** to be selected for negotiation because it would more likely rise into the top sellers list. More concretely, if a brand owns a drug with sales that are below the threshold for selection for negotiations, then it would not want to add an indication, potentially moving that drug into the negotiation list, without the opportunity to recover the investment needed to add that indication in the first place. As such, the IRA actively discourages branded companies from seeking new indications for existing drugs.

One particularly troubling consequence of the IRA is that it could incentivize branded drug companies to slow-walk obtaining their initial FDA approval on new drugs for indications that affect small populations of patients until the branded drug company is ready to obtain FDA approval for a more valuable set of label indications for their new drug. This is because the IRA provides branded drug companies with 11 years to reap their return on investment, as compared to the patent statutes that

provide up to 14 years for patent term extension (PTE).[3] In a post-IRA world, we would likely see other countries gaining access to new drugs before the U.S., a scenario that hasn't happened in recent history. This harms consumers by potentially reducing and/or delaying treatment options, and harms generic and biosimilar manufacturers by reducing pathways for securing approval of lower-priced versions of drugs for at least some indications.

B. If Generic and Biosimilar Manufacturers Exit The Industry, There Will Be Increased Drug Shortages And Fewer Low-Cost Options For Drugs In The Private Market

The unreasonable pricing pressure that results from implementation of the IRA may disincentivize generic and biosimilar companies from pursuing existing pharmaceutical products. Upon entry of competing products, generic and biosimilar companies offer their products at reduced list prices as compared to the associated reference branded product to benefit purchasers who choose their product.

Entering a market where the branded drug is subjected to government price negotiation is a particularly acute problem when it comes to biosimilar products. The development costs for biosimilar products are extremely high and the timeline for development and approval are long—approximately $150 million over eight years.[4]

[3] 35 U.S.C. § 156(c)(3).

[4] Blackstone, E. & Fuhr Joseph, P., The Economics of Biosimilars, 6(8) AM. HEALTH DRUG BENEFITS 469, 469 (Sep.-Oct. 2013), available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/; Chen et al., An

Before committing to these costs and years of resources, biosimilar companies need certainty of return on investment However, the IRA creates huge uncertainty as to how the market will form after price negotiation because the legislation sets out a price ceiling but not a price floor. For example, the government could demand a 90% discount under the threat of the extreme penalties under the IRA. Furthermore, there is no way to determine which drugs will eventually be negotiated at the time when biosimilar companies are initiating their 8-year development programs. Uncertainty is bad for business. Without the certainty of knowing whether there will be a return on investment, fewer generics and biosimilars may be developed and companies may start to exit this industry entirely before the biosimilar industry has had the chance to take off and_achieve meaningful cost savings. With competitors exiting the market, there will also likely be less price reduction in the private health care market as well as increased risk of drug shortages. The American public is currently facing shortages of several essential medicines, in markets where unreasonable pricing pressure has forced the procurement price below the cost of production.[5] These market dynamics are unsustainable and are forcing manufacturers into difficult

Inflection Point for Biosimilars, McKinsey & Co., (Jun. 7, 2021), https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars.

[5] https://www.cbsnews.com/news/generic-drugs-pharmaceutical-companies-60-minutes-2022-05-22/

choices – even to reduce or discontinue production of certain products. As but one example, the main generic manufacturer of cisplatin, an important but inexpensive cancer drug, exited the market for quality reasons driven by unsustainable pricing pressures, leaving uncertainty in the market about whether demand can be met for U.S. patients.[6] We fear similar consequences in several years for "negotiated" drugs that mimic the cisplatin scenario, especially if the originator manufacturer remains the only supplier. Although Government "negotiation" could be beneficial in the short-term, the long-term effects of having only a single brand supplying aging drugs will not be effective, and could even be dangerous, as the branded manufacturer looking to innovate newer treatments would have little incentive to keep producing the old drugs that may cannibalize their new products. The IRA cudgel is short-sighted.

C. The IRA Fails to Address the Root Cause of High Drug Prices, Which Should Be the Focus of Congress Instead of Undermining the Market and Harming Medicare

Market distortions and barriers to competition are causing the health care market to fail and drug prices to rise. The IRA acts as a blunt tool that does not treat the root cause of market failures. Because of this, unintended consequences will arise from the IRA that will ultimately make an already distorted market worse

[6] https://www.nbcnews.com/specials/cisplatin-shortage-cancer-drug-chemotherapy-us/index.html

and further reduce access to drugs for American patients. Manufacturers of generic and biosimilar medicines can provide cost savings to Americans if the true root causes of market distortions are corrected, which unfortunately are not at issue in this litigation because the IRA did not address them. But what the IRA did address ignored the Constitution and ignored the long-term impact on generic and biosimilar drug availability to the public.

The two root causes of high drug prices in need of Government intervention are branded manufacturer patent abuse that prolongs monopolies past when drugs are considered innovative, and the misaligned incentives in Medicare Part D that have become warped over time and have made higher list price products more attractive to Medicare at the expense of excluding lower list price competition. Solving for these market manipulations would correct the problem and yield no long-term unintended consequences. Unintended consequences typically occur when root causes are not addressed, in favor of treating downstream symptoms, which is what the IRA price negotiation provision has done at the expense of Medicare beneficiaries in the long-term.

One of the root causes of high drug prices is the practice by branded drug manufacturers to use terminal disclaimers to amass large numbers of continuation patents having patentably indistinct claims. This behavior generates patent thickets, which prolong drug monopolies long past the time such drugs were truly

innovative. Even though terminally disclaimed patents expire at the same time as each other, the sheer number of duplicative patents in the pharmaceutical field drives up the costs and reduces the efficiency of patent litigation and path clearing by generic and biosimilar firms. Empirical data demonstrates that this causes uncertainty on loss of exclusivity dates, leading to delayed market entry of generic and biosimilar drugs in the US as compared to abroad.

On May 10th, 2024, the US Patent and Trademark office issued a proposed rule to address this practice. The proposed rule would require terminal disclaimers to include an agreement by the patent applicant that they will not enforce the patent if any claim of the terminally disclaimed patent has been finally held unpatentable or invalid. In other words, duplicative patents with invalid claims would rise and fall together. The surgical nature of the proposed rule allows for strong patent protection for truly innovative activity, while only impacting those entities purposefully using terminally disclaimed patents to delay market entry of generic and biosimilar drugs.

If finalized, the USPTO's proposed rule would allow for entry of generic and biosimilar drugs at a more appropriate time, bringing back a balance between innovation and competition and extending drug cost relief through competition, to both the commercial market and to Medicare. Patients suffering from disease states like Multiple Sclerosis (MS) and HIV, may feel disadvantaged by Medicare

negotiation, as the majority of patients treating these diseases are under the age of 65. For example, using data from the Medicare dashboard, one can see that, Ocrevus, a leading treatment for MS patients, has only 22% of its revenue tied to utilization from Medicare and Medicaid programs, meaning that 78% of MS patients treated with Ocrevus are covered in the commercial market. But the policy of the USPTO's proposed rule would bring low-cost drugs to all patients of every age, universally.

In short, the generic drug market as well as the burgeoning U.S. biosimilars market could thrive if anti-competitive barriers were simply removed and market forces restored. True market competition is the most effective driver of lower prices, not arbitrary Government controls. Although the generics market has provided huge savings to patients, there is a market distortion and cost problem that has impacted the most expensive complex drugs in the market, especially in Medicare Part D. These issues prompted Congress to "fix" high costs in this category with the IRA so-called "negotiation" provision. Instead, the negotiation provision restrains generic and biosimilar free market competition and sacrifices the public-health and economic benefits of competition and innovation in an effort to control prices. Solving the root causes of high drug prices, instead of curing symptoms of the problem, prevents unintended consequences and avoids adding further complexities to the U.S. payment system.

II. THE CMS GUIDANCE DISCOURAGES INVESTMENT IN GENERIC AND BIOSIMILAR DRUG PRODUCTS AND WILL DISRUPT SETTLEMENTS THAT BENEFIT PATIENTS

Plaintiffs' brief makes clear that there is a strong incentive for branded companies to have their products removed from the list of drugs subject to negotiations. The most appealing way appears to be that a drug is a "Reference Listed Drug," or RLD, for a generic or biosimilar drug that is being marketed. According to the FDA, an RLD is the drug that generic companies use to compare efficacy. As discussed above, when a generic product comes on the market, the price of a drug becomes somewhat lower, but that price reduction is a direct function of the number of competitors on the market. More specifically, it is understood that in a two-player market, pharmaceutical net costs reduce to about 75% of the previous net cost.[7] The cost can drop to about 50% when a third competitor enters the market, and continues to fall, until a highly competitive market results.[8]

Based on these well-understood principles, a branded manufacturer is incentivized under the CMS Guidelines to enter into an agreement to provide the appropriate licenses to allow a single generic to come to market, and then only on limited terms, to avoid the negotiations list. Outside the context of the IRA,

---

[7] *See* FDA Report, Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020, at p. 4, available at https://www.fda.gov/media/161540/download (last visited Aug. 22, 2023).

[8] *Id*. at p. 9.

settlements have been positive for consumers, especially recently. For example, for both small molecules and biosimilars, settlements encouraged resolution of patent infringement lawsuits with strongly-positioned parties and led to earlier entry of lower-cost versions of drugs before patent expiry, generating savings for users.

In June 2013, the Supreme Court rendered its decision in *FTC v. Actavis, Inc*, which held so called "pay for delay" settlements to be anti-competitive. 570 U.S. 136. Since then, potentially anti-competitive settlements have been seriously curtailed through actions by Congress and through robust review of settlement agreements by the DOJ and FTC. Today, the reliance on pro-competitive settlements enables biosimilars and generic medicines to reach the market prior to patent expiry.

Also, the reliance on pro-competitive settlements in the current environment is a symptom of a key root cause of delayed generic and biosimilar market entry which is branded drug patent thickets, asserted against biosimilar and generic competition after the basic product patent has expired. Both the Food and Drug Administration (FDA), Department of Health Human Services (HHS) and the

academic community have pointed to "patent thickets" as an important way that drug companies inappropriately delay competition[9,10].

The CMS Guidance creates an entirely new set of considerations to enter into a settlement that are less beneficial to the public. Under the CMS Guidance, branded manufacturers are incentivized to enter into settlement agreements not because of the threat of generic competition, but instead to do the bare minimum to avoid being placed on the negotiation list. In other words, a brand may license a company on very limited terms and use its patents to prevent further competition by others, thereby locking in a weak two-player market, a "duopoly."

Typically, the strongest patent in the portfolio is the basic product patent and Congress has provided for statutory patent term extensions (PTE) to allow for the patent to stay in force up to 14 years from FDA approval.[11] Under the IRA, branded manufacturers are incentivized to enter into settlement agreements with generic and biosimilar manufacturers at 11 years from FDA approval to avoid the price

[9] Secretary Xavier Becerra, U.S. Department of Health and Human Services, *Comprehensive Plan for Addressing High Drug* Prices (Sept. 9, 2021); Letter from Janet Woodcock, Acting Commission of Food and Drugs (Sept 10, 2021).

[10] Rachel Goode , Bernard Chao, Biological patent thickets and delayed access to biosimilars, an American problem, Journal of Law and the Biosciences, Volume 9, Issue 2, July-December 2022, lsac022, https://doi.org/10.1093/jlb/lsac022

[11] 35 U.S.C. § 156(c)(3).

negotiation process.[12] Negotiation of a patent settlement with a generic or biosimilar manufacturer, while the strongest patent in the portfolio is still in force, can provide branded drug companies with unreasonable leverage over biosimilar/generic competitors who would need a license to the patent to be able to compete. For example, branded drug companies could give a limited settlement to a biosimilar/generic competitor to reduce their market penetration, which has a direct relationship with drug pricing.

The CMS created even more problems with the "Initial Delay Request" protocol, whereby a branded manufacturer can seek to avoid the negotiation period, which thanks to CMS regulations will end up nearly impossible to meet for all practical purposes. That is because the Special Rule Delay (also known as "the two-year pause" on price negotiation) contains competition-restraining statutory eligibility requirements, which the CMS guidance took to another extreme. In

[12] The Public Health Service (PHS) Act provides a 12-year market exclusivity period for branded biologics, meaning that the FDA is prevented from approving a biosimilar until 12 years have passed from the date of first licensure of the branded biologic. (FDA Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act. https://www.fda.gov/media/89049/download.) The 11-year grace period before drug selection offers little relief for biosimilars, as a biosimilar cannot be approved, let alone marketed, for 12 years after approval of an exclusivity-eligible reference product.

particular, the CMS guidance sets out three alternative criteria for triggering the two year pause by year 11:

> "CMS will consider this requirement met if (1) there are no non-expired approved patent applications relating to the Reference Drug that are applicable to the Biosimilar; (2) one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable non-expired patent relating to the Reference Drug that the patent holder asserted was applicable to the Biosimilar; or (3) the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar in one or more dosage form(s), strength(s), and indication(s)…"[13]

As described in more detail below, all three criteria are effectively impossible to meet and would render the Special Rule Delay dead-on-arrival, in contravention of Congress's clear intent to preserve this avenue for biosimilar competition.

CMS's first criterion, that there are no, non-expired patents "relating" to the reference product and "applicable" to the biosimilar, fails to acknowledge the practices of reference product sponsors and realities of the patent system. Reference products typically have extensive patent portfolios, that can include hundreds of patents. If just one of those patents were filed and issued after approval, a biosimilar could not satisfy this criterion. There is always a risk that some patent exists that could conceivably cover the biosimilar. That does not mean, however, that such

[13] CMS Revised Guidance, at 19, available at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf (last visited Aug. 22, 2023).

patents pose a risk to launch. Indeed, a biosimilar manufacturer may have robust evidence that a patent is likely invalid or not infringed and plans to launch notwithstanding ongoing litigation. Meeting this threshold becomes even more strained when considering CMS's broad language of "related" to the reference product and "applicable" to the biosimilar. Such language could encompass patents on anything from a piece of equipment, a particular assay, or a spring used in an autoinjector. It is thus simply not feasible that all such patents would have expired within 11 years post-approval of the reference product.

As to the second criterion, a court decision on the merits, patent litigation is slow and generally takes three to five years to reach final decisions by the district court and Federal Circuit. As a starting point, the earliest that BPCIA litigation can start is the FDA acceptance of the biosimilar aBLA. This would necessitate biosimilar 351(k) BLA submission by 6-7 years following FDA approval of the reference product in order to finalize the litigation by year 11. But biosimilar development cannot begin until FDA approval of the reference product, due to the need to purchase reference product samples for characterization. Biosimilar development then can easily take 8-9 years, rendering it almost impossible to submit the 351(k) BLA submission by year 7. Outside of the context of the IRA, biosimilar development programs typically target FDA approval at year 12 upon the expiry of the market exclusivity period or by year 14 upon the expiry of the patent PTE.

Expecting a biosimilar to have somehow predicted the IRA and submitted its 351(k) BLA under this accelerated timeframe is unreasonable and unworkable.

The CMS therefore essentially "strong arms" the third and only remaining criterion to demonstrate "high likelihood" of marketing, namely to enter into a patent settlement. As explained above, negotiation of a patent settlement at year 11, while the strongest patent in the portfolio is still in force, can provide branded drug companies with unreasonable leverage over biosimilar/generic competitors who would need a license to the patent to be able to compete. Contrarily, as explained below, in its updated Guidance of June 30, 2023, CMS explained that it would not allow the two-year pause if the biosimilar manufacturer entered into any agreement with the Reference Manufacturer that incentivizes the biosimilar manufacturer to submit an Initial Delay Request.[14] Therefore, on the one hand, CMS requires a biosimilar manufacturer to obtain a patent settlement far earlier than it would normally outside of the context of the IRA, while on the other hand, the settlement must not incentivize the biosimilar to submit the request for the two-year pause. These requirements are contradictory and unworkable.

Settlements entered into under the duress of the IRA also devalue potentially valid patents and are a serious threat to innovation. Settlements in general under

[14] https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf, see page 21.

normal market conditions avoid the potential for gamesmanship by branded drug companies under the CMS structure.

CMS seems to have realized the problems created by its Guidelines, but even its subsequent "fixes" provide more potential problems than solutions. In its updated Guidance of June 30, 2023, CMS attempted to restrict access to the Initial Delay Request on price negotiation if a settlement agreement between an originator and a biosimilar competitor was entered into in contemplation of delaying the IRA's price negotiation process.[15] However, patent settlements are the wrong target. As explained above, settlements are a critical tool that enable biosimilars and generic drugs to get onto the market as early as possible and prior to patent expiry. So long as there is a valid and infringed patent in force, then a settlement is the only way for a biosimilar or generic medicine to compete. Closing the door on pro-competitive settlements further undermines the generic and biosimilar industry. For biosimilar and generic drugs to be able to compete, patent settlements should be protected and strengthened to promote competitive pricing.

In the context of the IRA loophole that allows settlements that provide for limited volume launches by a competitor (a "duopoly"), CMS recently proposed a fix, namely a "bona fide marketing" standard that requires the brand to participate

[15] https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf, see page 21

in the negotiation program if a biosimilar or generic competitor does not capture a certain market share percentage in a certain time period post launch as one criteria.[16] However, the problem is the IRA's undefined and potentially ever-shifting definitions for appropriate market shares, particularly because market share does not have any bearing on actual cost savings a generic or biosimilar provides by entering the market. For example, AbbVie's Humira has kept a large share of the market after biosimilar entry, but the entrance of biosimilars have caused a bigger cost savings to the Medicare program—even for AbbVie's own product—in the form of a bigger rebate provided by the company, that leads to a lower net cost.

It is not in the control of the biosimilar or generic manufacturer which list price or rebate package a PBM or the health plan in Part D prefers and the extraction of that rebate. Because a generic and biosimilar competitor cannot control its market share nor its market access, the bona fide marketing standard creates further uncertainty that will chill the incentives for companies to invest the resources and take the risks necessary to develop generics and biosimilars. This is highly

[16] CMS Revised Guidance, at 74-75, available at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf (last visited Aug. 22, 2023).

problematic because generic and biosimilar medicines can provide more effective and more sustainable reductions in drug prices than the IRA.[17]

Instead of measuring the success of market share, in the context of the IRA, the Government should simply confirm that limited-volume settlements will not be accepted to stop negotiation and should not tie success to market share or other tangential measures that may not be directly related to cost savings. The Government should consider a solution to the problem of "duopolies" by allowing all subsequent FDA-approved generic and biosimilar competition to launch at risk for a reduced patent infringement remedy to achieve multiple competitors and bigger cost reduction, only in cases where the branded manufacturer has chosen competition over "price negotiation." This policy is needed to achieve true downward market pressure because Congress and the Administration have not addressed the root cause of patent thickets and other inappropriate patent schemes. When a brand chooses competition, they should choose true competition, including unfettered access to the market and multiple competitors. This is only achievable by continuing to allow patent settlements with clear ground rules.

[17] See Report: 2022 U.S. Generic and Biosimilar Medicines Savings Report | Association for Accessible Medicines (accessiblemeds.org), where generic and biosimilar medicines generated $373 billion in savings for the U.S. health care system.

CONCLUSION

Amicus Fresenius Kabi urges this Court to grant Plaintiffs' Motion for Summary Judgment. As detailed in Plaintiffs' brief, the current statute is not properly drafted to protect the rights of the Plaintiffs. Just as important, the current statute also fails in its alleged purpose—to secure lower cost drugs for consumers—because it ignores the root causes of high drug costs in a specific category of drugs. IRA upends the incentives that drive lower costs through true competition and replaces them with a system that will ultimately reduce innovation and meaningful competition, and may also threaten the drug supply.

Dated: July 19, 2024

Respectfully submitted,

/s/ Neil Lloyd

Neil Lloyd
Imron T. Aly
Kevin M. Nelson
Joel M. Wallace
ARENTFOX SCHIFF LLC
233 S. Wacker Dr.
Suite 7100
Chicago, IL 60606
312.258.5500
imron.aly@afslaw.com
kevin.nelson@afslaw.com
joel.wallace@afslaw.com

Attorneys for Amicus Curiae Fresenius Kabi USA, LLC

CERTIFICATION OF ADMISSION TO BAR

I, Neil Lloyd, hereby certify as follows:

I am a member in good standing of the bar of the United States Court of Appeals for the Third Circuit.

Pursuant to 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing is true and correct.

Dated: July 19, 2024

Respectfully submitted,

/s/ Neil Lloyd

Neil Lloyd
Imron T. Aly
Kevin M. Nelson
Joel M. Wallace
ARENTFOX SCHIFF LLC
233 S. Wacker Dr.
Suite 7100
Chicago, IL 60606
312.258.5500
imron.aly@afslaw.com
kevin.nelson@afslaw.com
joel.wallace@afslaw.com

Attorneys for Amicus Curiae
Fresenius Kabi USA, LLC

CERTIFICATION OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(a) AND LOCAL RULE 31.1

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify the following:

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure because this brief contains 4,882 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure.

This brief complies with the typeface requirements of Rule 32(a)(5) of the Federal Rules of Appellate Procedure and the type style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because this brief has been prepared in a proportionally spaced typeface using Word for Microsoft 365 in 14 point Times New Roman font.

This brief complies with the electronic filing requirements of Local Rule 31.1(c) because the text of this electronic brief is identical to the text of the paper copies, and a virus detection program the Vipre Virus Protection, version 3.1 was run on the file containing the electronic version of this brief and no viruses have been detected.

Dated: July 19, 2024

Respectfully submitted,

/s/ Neil Lloyd

Neil Lloyd
Imron T. Aly
Kevin M. Nelson
Joel M. Wallace
ARENTFOX SCHIFF LLC
233 S. Wacker Dr.
Suite 7100
Chicago, IL 60606
312.258.5500
imron.aly@afslaw.com
kevin.nelson@afslaw.com
joel.wallace@afslaw.com

Attorneys for Amicus Curiae
Fresenius Kabi USA, LLC

CERTIFICATE OF FILING AND SERVICE

I, Melissa Pickett, hereby certify pursuant to Fed. R. App. P. 25(d) that, on July 19, 2024 the foregoing was filed through the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. The required copies have been sent to the court on the same date as above.

/s/ Melissa Pickett

MELISSA PICKETT
COUNSEL PRESS