May 3, 2023

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Federal Trade Commission

Via email

Dear Elizabeth Jex and colleagues at the FTC:

We hereby request that the Federal Trade Commission (FTC) use its role to advocate for the interests of consumers and the public in a specific dispute involving a request that the Department of Health and Human Services (HHS) use the government's rights, which also involves a more general set of issues relating to excessive pricing of biomedical inventions that require the use of federally-funded inventions.

Background

The specific dispute is a petition to HHS that requests the Department use its rights in patents on the prostate cancer drug enzalutamide, sold by the Japan-based company Astellas under the brand name Xtandi. The government's rights include the march-in right (under 35 USC § 203), and the federal government's royalty-free use license under 35 USC § 202(c)(4). The facts driving this case are that the price of Xtandi in the U.S. is 3 to 6 times higher than the price is in other high-income countries. For example, the January 2023 Redbook AWP price was $136.50 per 40 mg tablet. The 2021 Medicare Part D price was $112.28 per tablet. The prices in other high-income countries typically range from $21 to $35 per tablet. The dose is 4 tablets per day, so the annual cost of the treatment at the US Redbook price is $199,270. (http://drugdatabase.info/drug-prices/)

The petition asks HHS to address a narrow and very clear issue: Is such price discrimination against U.S. residents consistent with the requirement in the Bayh-Dole Act to make the benefits of the inventions "available to the public on reasonable terms"? The petition focuses on price discrimination, not the absolute price, although both could be an issue.

The National Institutes of Health (NIH) was asked by HHS to review the petition, and on March 21, 2023 the NIH wrote to the petitioners to deny the request, stating:

> "NIH's analyses in response to the petition request have found Xtandi to be widely available to the public on the market. In addition, given the remaining patent life and the lengthy administrative process involved for a march-in proceeding, NIH does not believe that the use of the march-in authority would be an effective means of lowering the price of the drug. For

these reasons, NIH has determined that initiation of a march-in proceeding is not warranted in this case."[1]

Request that FTC address two issues

We are writing the FTC to address two issues in this case, which are highlighted in an administrative appeal filed on March 23, 2023.

1. NIH misstates the petitioner's case and the relevant statute

Issue one is the fact that the NIH never addressed the core of the petitioners' case. The NIH decision said the patent holder had satisfied the obligation to bring the inventions to practical application by bringing them to the market. This was clearly never an issue, as Astellas had generated $2.4 billion in Medicare sales in 2021, for example. The issue has always been: is the product "available to the public on reasonable terms," not simply "available to the public"?

The NIH and everyone else in this field knows what the statute and regulations state. In 2020, the National Institute of Standards and Technology (NIST) tried to modify the regulations to eliminate prices to the consumer from the scope of practical application requirements and received more than 80,000 comments in opposition. Subsequently, this issue was addressed in the President's Executive Order on Competition and a report to the President on drug pricing from HHS, both stating that a march-in case seeking enforcement of the "available to the public on reasonable terms" part of the statute could raise the price to consumers.

We are not asking the FTC to weigh in on whether or not the price discrimination against U.S. residents is reasonable, at this point. Rather, we are asking the FTC to instruct HHS that the petitioners are entitled to have HHS determine if the price discrimination is consistent with "available to the public on reasonable terms" and that the NIH decision was flawed as it never acknowledged how the statute defines practical application, even though this was the clearly communicated crux of the case, a case that has been the subject of media coverage and Congressional outreach to the NIH.

In this regard, the petitioners are not obligated to what price would be reasonable, only that the price discrimination is not consistent with "reasonable terms." The petitioners and others supporting the petitioners have asked HHS to announce that for a drug that has earned substantial revenues, it is not reasonable to engage in such extreme price discrimination against U.S. cancer patients. HHS is being asked to address this issue. If HHS wants to declare that the Xtandi pricing discrimination is consistent with "reasonable terms", then the petitioners will at least have a federal agency acknowledging the central issue of the petition and the actual language of the statute. We acknowledge HHS has discretion in deciding the case, but we do object to mistaking what the petition is about and neglecting to even acknowledge the statutory basis of the petition. These three

[1] https://www.keionline.org/wp-content/uploads/NIH-rejection-Xtandi-marchin-12march2023.pdf

words, “on reasonable terms” should not have disappeared as if we are living in an alternate world where the law is only the language we choose to quote.

2. **The NIH incorrectly states that there is not sufficient time left on the patent to achieve a useful outcome.**

The second issue is that the NIH asserted that a short remaining term of patent life would not make a march-in remedy an “effective means of lowering the price of the drug.“ Here, we ask the FTC to make a submission in the administrative appeal supporting the contention that HHS has two additional mechanisms that can be used to enable generic versions to enter the market now: the 35 USC § 202(c)(4) government-use license and the 28 USC § 1498(a) authority to enable sales to federal programs. These mechanisms can be used to enable access while any march-in appeals are pursued, and this leverage can be used to reach a favorable settlement of the march-in case, which would allow generics to be sold to all market segments. These arguments are outlined in more detail in “How Soon Could President Biden Enable Generic Competition to Xtandi? Very Quickly, If There Is the Will,” *Bill of Health,* March 28, 2023.

Price discrimination and reasonable terms

In defining practical application to include an obligation that the benefits of inventions are “available to the public on reasonable terms,”[2] Congress used an inclusive term that allows funding agencies to address a variety of actions that constitute an “unreasonable use of inventions.”[3] The particular issue raised by the petitioners was that of price discrimination against U.S. cancer patients. As the FTC staff is well aware, price discrimination is common, and not always actionable. For instance, we are all familiar with paying different prices for the same airline destination, for the price of groceries with our coupons, for large or small quantities of the same good, for admission for children, adults, or seniors, and for drugs, depending upon our health insurance, the 340B program, or other situations. That said, there are some types of price discrimination that governments can declare to be unreasonable. For example, there is unlawful price discrimination under the Robinson-Patman Act,[4] if the price discrimination is considered discriminatory against a protected class (e.g., if based on gender, race, religion or sexual orientation). Price discrimination can also be considered unreasonable in the geographic or international context. In the past Japan has considered both civil and criminal sanctions relating to restrictions on parallel trade that were used

[2] 35 USC 201, Definitions.
[3] 35 USC 200, Policy and Objective.
[4] 15 U.S.C. §§13 et seq.

to allow pianos to be priced higher in Japan than in Europe,[5] and the European Commission has also fined Yamaha for actions relating to geographic price discrimination of pianos sold in Europe.[6]

If the recipient of a federal grant was to sell patent-protected pianos at a higher price in the United States than in Europe, say by a factor of 3 to 6 times higher in the US, I don't think there would be much debate about the relevance of "available to the public on reasonable terms" being violated.

What the petitioners are asking for, and the NIH tried to avoid addressing, is a decision on whether or not the price discrimination for Xtandi is consistent with "available to the public on reasonable terms." Astellas and Pfizer are free to argue that there is a justification for charging $199,270 per year in the US versus $30,000 to $45,000 per year in other high-income countries. In this case, given the extreme cost of the medicine, the large burden on Medicare and other federal programs, the high co-payments required of insured patients, and the demonstrated reality of restrictive Tier 5 formularies for Xtandi, the burden to justify the price differences should be on Astellas and Pfizer, and not on the patients bringing the complaint.

While we acknowledge that drugs and pianos are different goods, it is also the case that politicians from both parties have harvested votes by promising to curb the pricing differentials between the US and other high-income countries, and furthermore this is the topic of the 2020 Presidential Executive Order 13948 and a 2017 the Senate Armed Services Committee (ASC) directive in the NDAA reauthorization.

Concluding comments

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[5] Unreasonable Restrictions on Parallel Imports Prohibited, By Richard Y. Sako, August 5, 1996:

On February 29, 1996, the FTC ordered Hoshi Shoji Kabushiki Gaisha to cease its practice of restricting parallel imports. . . . The FTC ruled that Hoshi Shoji violated the Antimonopoly Law by obstructing imports of Herend products by a Japanese discounter which was selling the products at prices 30% lower than Hoshi Shoji's list prices. . . . According to the FTC, Hoshi Shoji was able to determine that the discounters were purchasing Herend products from various authorized European distributors of Herend by checking the serial numbers on products sold at the discounters' stores. Hoshi Shoji, with the assistance of Herend, notified the European distributors to stop selling products to the discounters, thus effectively cutting off the discounters' access to Herend products. . . . [T]he FTC ordered Hoshi Shoji to immediately cease in its conduct or face the threat of administrative proceedings which could ultimately result in the assessment of civil fines and criminal penalties.

On April 5, 1996, the FTC issued a similar warning to Kabushiki Gaisha Matsuogaki Shokai, the exclusive Japanese distributor for U.S.-based Steinway & Sons. According to the FTC, Matsuogaki, with the assistance of Steinway & Sons, acted jointly to prevent Steinway & Sons' Holland distributor from selling Steinway pianos to discount importers in Japan. Matsuogaki was able to determine the place of origin of the pianos sold by discounters by checking the manufacturer's numbers on the pianos. As in the case of Hoshi Shoji, the FTC ordered Matsuogaki to immediately cease its practice or face administrative proceedings with possible civil fines and criminal penalties.

[6] COMMISSION DECISION of 16.07.2003 relating to a proceeding under Article 81 of the EC Treaty and Article 53 of the EEA Agreement (Case COMP/37.975 PO/Yamaha), https://ec.europa.eu/competition/antitrust/cases/dec_docs/37975/37975_91_3.pdf.

KEI is not asking the FTC to give an opinion on the price of Xtandi, or even whether HHS should be using its Section 202(c)(4) or Section 1498 authority to enable generic drugs to enter the market now. We are asking that the FTC tell HHS that the petitioners were never questioning if Xtandi was "available to the public", and instead, were asking HHS to intervene because Xtandi was not available "on reasonable terms," and raised serious and actionable concerns about that issue as regards the reasonableness of the price discrimination against U.S. cancer patients.

The FTC could highlight the following:

1. Many political figures have campaigned on promises to ensure that Medicare prices are not the highest in the world.
2. International reference pricing for Medicare is the subject of 2020 Executive Order 13948.[7]
3. In 2017 the Senate Armed Services Committee (ASC) adopted a directive to the Department of Defense to use march-in or other rights when the price of a government-funded "drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States."[8]
4. In 2021, Pfizer, a partner with Astellas in U.S. sales of Xtandi, signed a contract with DOD that included a "Most Favored Nation Clause" for Paxlovid (a drug to treat COVID-19), and that reference pricing was included in other contracts with large drug companies, making it clear that an international reference price is a well known and accepted contractual term.[9]
5. The combination of the Section 202(c)(4) license and 28 USC § 1498(a) gives HHS considerable leverage to address an issue of excessive pricing of a government-funded drug, separately or in parallel with a march-in case.

We would like to follow up on this with the FTC at a time that works for you.

[7] Executive Order 13948—Lowering Drug Prices by Putting America First September 13, 2020. Sec. 2. Policy. (a) It is the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most favored-nation price.

[8] 115TH Congress, 1st Session, 2017, Senate Report 115–125. National Defense Authorization Act for Fiscal Year 2018. Report to accompany S. 1519, on page 173. July 10, 2017. Licensing of federally owned medical inventions. "The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States."

[9] Claire Cassedy, Reference Pricing in US Government COVID-19-related Contracts, April 20, 2023. https://www.keionline.org/38677

Sincerely,

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