June 20, 2024

Sen. Elizabeth Warren
309 Hart Senate Office Building
Washington, D.C. 20510

Rep. Pramila Jayapal
2346 Rayburn House Office Building
Washington. DC 20515

Dear Sen. Warren and Rep. Jayapal:

I am writing in response to your June 6, 2024 letter regarding the Federal Trade Commission's (FTC) recent statements disputing the "accuracy or relevance" of certain patent listings in the Food and Drug Administration (FDA) publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) for five Teva products—AirDuo Respiclick®, ArmonAir Respiclick®, AirDuo DigiHaler® 40, ArmonAir DigiHaler®, and QVAR RediHaler®. On June 3, 2024, Teva notified FDA that the patents identified by the FTC are properly listed in the Orange Book under Orange Book listing statutes and regulations. In that statement, Teva confirmed the correctness of listing those identified patents for these four products, and thus confirmed that it does not intend to delist these identified patents in the future. We also confirm that at this time Teva does not intend to voluntarily delist any other patents the company currently has listed in FDA's Orange Book.

Our decision to maintain our patent listing comes following serious and thoughtful consideration of the FTC's contentions and our concern for Teva's strict compliance with law. Indeed, as one of the industry's only remaining "blended" companies that has both (1) an innovative product portfolio and pipeline, and (2) a global and U.S. critical portfolio of generic and biosimilar medicines, we understand the need to balance innovation with access to medicines for a wide cross section of U.S. and global patients. As such, Teva diligently reviewed all the patents identified against applicable laws and regulations, as well as the First Circuit's ruling in *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1 (1st Cir. 2020). After careful review, Teva confirmed its belief that the underlying statute and regulatory guidance support the appropriateness of listing the challenged patents.

At no time did Teva use these patent listings to raise prices or stifle competition by preventing cheaper generic drugs from entering the market as your letter contends. To the contrary, robust patent listings are inherently pro-competitive as they provide (1) notice to our competitors about the patents that apply to our products, and (2) a mechanism under the Hatch-Waxman framework to litigate patent infringement and validity in parallel with FDA review. This system benefits everyone – especially patients – since it can provide certainty on when generic competition will occur and, in some instances, actually accelerate generic entry. Hatch-Waxman litigation allows for early determination of patent infringement; if a generic developer is found not to have infringed valid patents, the generic is able to receive such a determination early and launch a competitive product. Conversely, if the generic is found to

infringe valid patents—which, as outlined below, was the case in June 2023 concerning a number of challenged QVAR® patents—the innovator is able to receive that determination before any market harm has been done and before the generic has incurred any financial liability. In other cases, the innovator and the generic may decide to settle their patent litigation on terms that provide the generic with a license to enter the market before patent expiration, thus facilitating earlier generic competition. This system has created a generic drug industry that is the envy of the world; American patients rely on generics for 90% of their prescriptions, more than any other developed nation, and Teva fills nearly 10% of all generic prescriptions in the U.S.[1]

It is important to note also that patent listings are mandatory, and a critical aspect of the legal and regulatory landscape described above. If a company concludes that a patent claims an approved product, the company is ***required*** by statute to list the patent in FDA's Orange Book. This is particularly important since FDA has steadfastly refused to tell Teva and other pharmaceutical innovators how to list patents related to components of a drug product, despite repeated requests from industry for this information since at least 2005. Similarly, patent listings do not result in multiple 30 month stays. Indeed, since 2002, U.S. law has provided only a single 30-month stay per generic applicant, no matter how many patents an innovator lists in the Orange Book. It should also be noted that for these types of products, the FDA review and approval process often takes longer than 30 months. Thus, a 30-month stay is seldom the limiting factor in generic entry.

In light of the considerations above, we believe it is also important to point out the regulatory challenges that FDA and the Environmental Protection Agency (EPA) are creating for a competitive asthma inhaler market. Recent communications from FDA and EPA suggest that the propellants used in some Teva inhalation products may be subject to required conversion to alternate propellants with low global warming potential. While this transition itself may be warranted from an environmental perspective, FDA's apparent decision to require clinical trials for the approval of a product with a new propellant will not only increase development time and costs for generics, but it could also diminish competition in the asthma inhaler market as new clinical studies bring new market exclusivities to innovators. Such an outcome is inconsistent with our shared goals—and those identified by FTC—of balancing innovation and access. Congressional attention to this dynamic is long overdue and we would welcome the opportunity to partner with you on it.

In conclusion, Teva remains strongly committed to promoting innovation, including through the appropriate pursuit and defense of intellectual property, and also to ensuring broad based access by all patients to safe, effective and affordable generic medicines. We welcome and

[1] IQVIA. (April 2023) "The Use of Medicines in the U.S. 2023: USAGE AND SPENDING TRENDS AND OUTLOOK TO 2027." Accessible at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2023/the-use-ofmedicines-in-the-us-2023.pdf.

embrace any opportunity to work with you for the benefit of patients and to restore much of the Hatch-Waxman framework that has eroded over the last forty years.

Sincerely,

Brian Savage
General Counsel, Global Litigation