



July 13, 2021

Testimony by

Rachel Moodie, Ph.D.
Vice President, Biosimilars Patents and Legal
Fresenius Kabi

Before a hearing of the Committee on the Judiciary
Subcommittee on Competition Policy, Antitrust, and Consumer Rights

*A Prescription for Change: Cracking Down on Anticompetitive Conduct
in Prescription Drug Markets*

Introduction

Chairwoman Klobuchar, Ranking Member Lee and esteemed members of the committee, my name is Rachel Moodie and I am the vice president for Biosimilars Patents and Legal for Fresenius Kabi, a health care company that specializes in injectable medicines, biosimilars and medical technologies. Thank you for the opportunity to address the subcommittee today about this important issue.

Fresenius Kabi 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 specializes in bringing affordable, off-patent medicines to patients with critical and chronic conditions. During the pandemic, our injectable medicines were used routinely to treat patients in ICUs and several of our medicines and devices are currently held in the U.S. strategic national stockpile. A product of ours is also used in the injection process for COVID-19 vaccines. A fair and balanced patent and rebate system is critical to being able to continue this lifesaving work and reforms are needed to realize the many benefits of a new class of drugs known as biosimilars. We have already introduced biosimilars in Europe and Canada, turning the promise of effective and affordable biologic therapies into reality for many patients. And we are working to bring high-quality biosimilars to the United States as well.

Misusing Patents to Maintain Monopolies

A balanced patent system provides branded drug companies with time to recoup their investments and to fund the next generation of innovative drugs before biosimilars come to market. However, Fresenius Kabi has experienced a system shift whereby branded drug companies have misused patents and rebate schemes to maintain monopolies over drugs for 20 years or more, long after such drugs are considered innovative. This hurts patient access

Fresenius Kabi

801 Pennsylvania Ave., NW
Washington DC 20004
(202) 923-0217

rachel.moodie@fresenius-kabi.com
www.fresenius-kabi.com/us

to more affordable treatments and stresses payment systems that must be kept solvent to allow for true innovation.

Higher Costs for Patients

Prolonged monopolies exacerbate rebating practices and intensify already mis-aligned incentives to health plans and pharmacy benefit managers (PBMs) by extending the number of plan years a rebate and list price can grow before lower cost competition enters the market. This sustains and grows higher out-of-pocket costs for patients and increases the pressure for PBMs to prefer the higher cost branded product in order to maintain their rebate income rather than preferring the lower cost generic and biosimilar (these savings given to PBMs are not applied to patient out-of-pocket costs).

Thus far, the current policy debate around drug pricing has failed to address the root cause - numerous, but low-quality patents that do not provide true benefits to patients. We appreciate the committee's interest in tackling the root cause of the problem and addressing its negative impact on innovation and cost to consumers.

The Root Cause: Patent Thickets

Because of the misuse of so-called "patent thickets" and rebates as marketing tools, and the use of product hopping as an additional tool used to prevent competition, the U.S. branded pharmaceutical industry is not currently operating in a true free market system with downward pressure at the appropriate time. We urge Congress to take action now to preserve competition and reinstate market forces in the U.S. pharmaceuticals and biologics market.

I'd like to explain how it is possible to build a patent thicket to create an inappropriate monopoly. To be clear, Fresenius Kabi is in favor of the granting of truly innovative, high-quality patents.

Patent thickets comprise mostly secondary patents, which are those patents that are filed after the core drug patents are filed. Not all secondary patents are bad. However, the key to forming a patent thicket is to take each secondary patent (e.g., a weekly dosing regimen) and to multiply it by filing divisional/continuation patents (taking the same example: patent 1 claims dosing every 6-8 days; patent 2 claims dosing every 5-7 days, etc.). This results in a patent family containing multiple divisional/continuation patents having incrementally different claims. A hypothetical thicket may contain 10 patent families and each family may contain around 15 divisional/continuation patents, resulting in a thicket of 150 patents, all derived from just 10 original patent filings. However, the majority of these patents are those incremental divisional/continuation patents that do not typically provide new clinical benefits to patients.

I am not suggesting that **all** secondary patents are of low quality – the problem is that the sheer volume of patents, strategically, thicketed around a drug, shields most of the patents from scrutiny. Biosimilar companies do not have the funds or other resources to litigate scores of patents. Furthermore, courts cannot effectively litigate scores of patents in a single

lawsuit. Challenging even a single patent at trial can cost tens of millions of dollars in litigation fees. A patentee only needs to succeed on a single claim of one patent to potentially delay generic and biosimilar medicines by many years.

How do we know some patents are of low quality? The patent system allows third parties, like Fresenius Kabi, to challenge the validity of a patent by filing an inter partes review or post grant review (IPR or PGR). Statistics from the U.S. Patent and Trademark Office (USPTO) show that in 2020 third-parties were successful in having their IPRs instituted against 56% of all patents that were challenged.¹ This suggests that more than half of the patents granted are of at least questionable quality.

Patent thickets can be created at a cost that is easily affordable to a branded pharmaceutical company (approximately \$25,000 to obtain and maintain a patent). Conversely it can cost as much as \$1 million to challenge a single patent via an IPR or PGR).² A biosimilar applicant cannot economically use IPRs or PGRs to clear a thicket that contains hundreds of patents. This is why building a patent thicket is a numbers game designed to shield patents, sidestep the scrutiny of IPRs and PGRs, and create an inappropriate monopoly.

Among the root causes of patent thickets are the examination procedures and incentives at the U.S. patent office that make it possible to grow large thickets around a single biological drug. The patent thicket trend around expensive biologic drugs appears to be specific to the United States. While we see scores of patents litigated against a single biosimilar in the U.S., we see low single digit numbers of patents litigated in Canada and Europe for corresponding molecules.

It is true that the U.S. is the innovation capital of the world, which is why a strong patent system is important, but we must be careful that the pendulum for encouraging innovation does not swing too far in an anti-competitive direction. A robust patent system must strike the right balance between encouraging development of new drugs and enabling access to affordable treatments for patients.

Take Action to Reinstate Market Forces

We request Congress to address the “numbers game” by tightening up the USPTO rules and regulations that currently permit an excess of continuation/divisional patents to be filed from a single patent filing. To address the USPTO rules that enable the granting of an army of divisional/continuation patents that have only incrementally different claim wording. We also request that a cap be instated to limit the number of patents that can be asserted against a biosimilar product.

Delayed competition, through inappropriate monopolies, allows rebates and list prices of branded drugs to grow unchecked and forces eventual biosimilar entrants to fight for market share in an environment where rebates perversely incentivize the prescribing of more expensive drugs. Inappropriate monopolies also allow branded drugs to develop sophisticated life cycle strategies thereby making the biosimilar irrelevant once it actually launches. Furthermore, patent thickets in the U.S. are discouraging development and launch of biosimilars of certain blockbuster biological drugs because of the dynamics I have

described here today. While biosimilars of these drugs will eventually reach the U.S., it will be years after they are available in foreign markets.

In sum, we urge Congress to address the root cause of the drug pricing problem and look beyond policies in the jurisdiction of traditional health care entities. Instead, we urge Congress to put an end to inappropriately long patent monopolies and rebate schemes that reward prescribing high-priced drugs when lower-cost alternatives are available.

Thank you again for the opportunity to speak on behalf of my company, and on behalf of patients and physicians who benefit from access to affordable and essential medicines.

Respectfully submitted,

Rachel Moodie, PhD

Vice President, Biosimilars Patents and Legal
Fresenius Kabi