UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN BIOTECH, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 22-cv-01549-MN
AMGEN INC.,	)	[redacted]
Defendant.	)	

DECLARATION OF BRIAN SMITH IN SUPPORT OF JANSSEN'S MOTION FOR PRELIMINARY INJUNCTION

I, Brian Smith, declare as follows:

1. I am currently employed as a Vice President of Immunology Portfolio Strategy at Janssen Biotech, Inc. ("Janssen"). I have been at Janssen since 1990 and have held various marketing roles before assuming my current position in September 2021. I have a Bachelor's in Business Administration from Florida Atlantic University.

2. Within the course of my career at Janssen, I have been involved in the marketing of STELARA®, which includes overseeing market access and contracting strategies, creating brand plans, and managing communications with payors, physicians, and patients about STELARA®. I have also participated in discussions and decisions related to finances, budgeting, sales, insurance coverage, payor negotiations, formulary placement, and contracting for STELARA®.

3. Based on my professional roles at Janssen, I have substantial experience with, and knowledge and understanding of, the contractual relationships between Janssen and pharmacy benefit managers ("PBMs") and payors in regards to STELARA®.

4. I submit this Declaration in support of Janssen's Motion for Preliminary Injunction. I have personal knowledge of the facts set forth in this Declaration, and, if called on as a witness, I could and would competently testify as to the matters set forth therein.

A. The Purchase Process: From Janssen To Patients

5. Janssen works closely with payors and PBMs to ensure STELARA® is broadly accessible for patients.

6. PBMs are independent entities that manage prescription drug benefits on behalf of payors.

7. Payors and PBMs provide different services. The term "payors" refers to health insurers that pay and/or administer plans for health services, procedures, and treatments for

individuals enrolled in their plans. Individuals (or their employers) pay premiums to payors in exchange for health benefits offered by these plans. Payors negotiate or set rates for health services, collect revenue through member premiums, and process individual claims. Examples of payors include commercial health insurers (such as UnitedHealth Group, Anthem, or Humana) and government insurers (such as Medicare or Medicaid).

8. PBMs, on the other hand, are intermediaries between manufacturers and payors that purport to help payors manage prescription drug spending and claims. They provide prescription drug benefit services for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, state government employee plans, and other health and welfare plans.

9. PBMs work with payors and assist with the administrative aspects of providing prescription drug benefits to their members and members' beneficiaries, including processing and paying for prescription drug claims, developing and maintaining lists of drugs covered by health insurance plans, negotiating rebates and discounts with pharmaceutical manufacturers, and contracting with pharmacies to reimburse drugs dispensed to patients.

10. The three largest PBMs are CVS Caremark (owned by CVS Health), Express Scripts (owned by Cigna), and OptumRX (owned by UnitedHealth Group). Each of these PBMs is affiliated with a group purchasing organization (Zinc, Ascent Health Services, and Emisar Pharma Services, respectively). These three PBMs collectively manage prescriptions for more than 80% of all individuals enrolled in commercial plans. They own, or are owned by, some of the largest payors in the country. The smaller PBMs include Humana Pharmacy Solutions, Prime Therapeutics, and MedImpact.

11. Pharmaceutical manufacturers contract with and supply drugs to wholesalers. Wholesalers then sell and distribute drugs to specialty pharmacies, hospitals, health care providers, and infusion therapy providers, who then provide the drugs to patients.

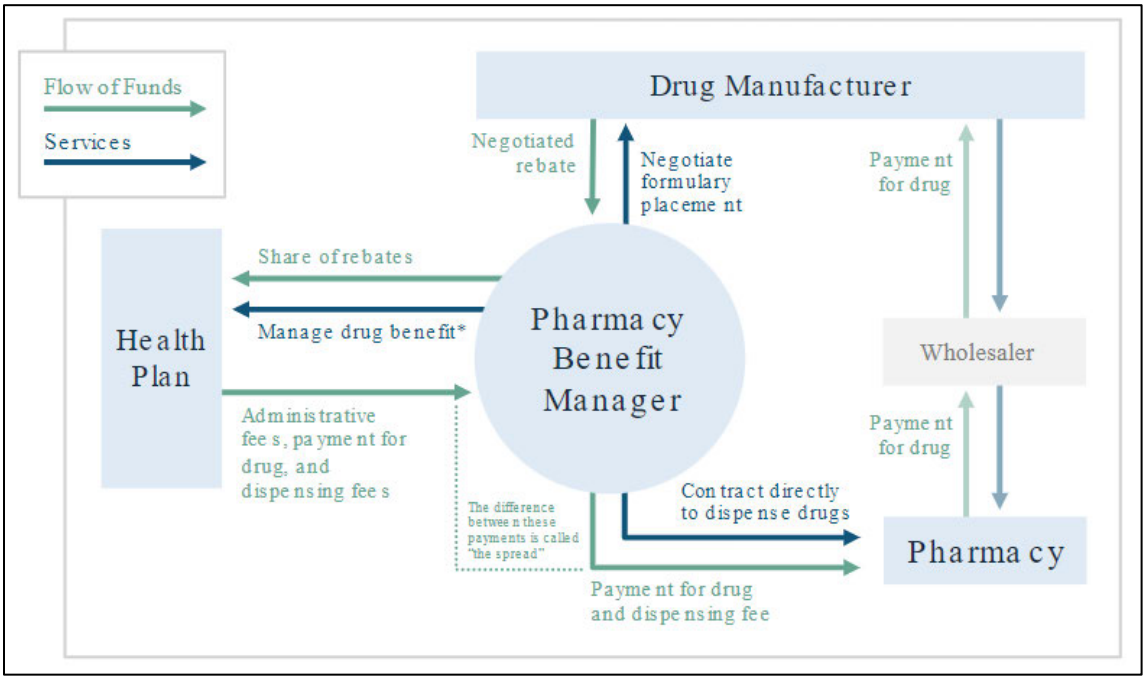
12. PBMs do not purchase drugs directly, but rather reimburse pharmacies for covered drugs utilized by patients. To do so, PBMs negotiate with pharmaceutical manufacturers—such as Janssen—over the prices that the PBMs will pay for these covered drugs. Pharmaceutical manufacturers offer rebates and discounts to PBMs in exchange for formulary coverage and placement.

13. PBMs leverage their ability to dictate which drugs will be included on their formularies to obtain significant rebates and other concessions from pharmaceutical manufacturers. PBMs do this by having manufacturers compete against one another, demanding rebates on individual drugs and portfolios before PBMs will agree to cover a given pharmaceutical manufacturer's product(s).

14. PBMs also contract directly with pharmacies to pay for drugs dispensed to patients.

15. PBMs earn revenues through shared savings split with payors, whereby PBMs keep part of the rebates they negotiated with pharmaceutical manufacturers.

16. The following diagram provides an overview of the role that PBMs play as intermediaries in the broader drug supply and reimbursement system:



Commonwealth Fund, adapted from Congressional Budget Office, *Prescription Drug Pricing in the Private Sector* (Jan. 2007).

17. PBMs create lists—called "formularies"—of approved prescription drugs covered by their plans, along with any requirements or limits on coverage for each drug. PBMs use formulary coverage and placement to influence choices of drugs for physicians and patients, in order to encourage utilization of specific products, and contain costs while promoting safety and efficacy. Formulary coverage and placement have a large impact on drug selection and utilization by physicians and patients.

18. As an initial matter, PBMs decide whether to include prescription drugs on their formularies. PBMs may also decide to exclude certain prescription drugs. These formulary exclusions make it difficult to access excluded drugs. If physicians or patients want access to an excluded prescription drug, they may have to pay the full purchase price for the drug (instead of simply paying a co-pay, co-insurance, or a deductible), or seek a medical exception.

19. Drugs listed on the formulary are assigned to one of several "tiers"—these tiers may include "generic," "preferred brand," "non-preferred brand," and "specialty." A typical formulary uses between two to five tiers. For example, a formulary could have a Tier 1 for generic drugs, a Tier 2 for preferred brand drugs, and a Tier 5 for non-preferred drugs.

20. Typically, placing a drug on a lower tier (e.g., Tier 1) results in physicians prescribing (and patients using) those drugs instead of drugs on higher tiers (e.g., Tier 5). This is because there are typically fewer restrictions to accessing drugs on lower tiers. In addition, the different tiers reflect different co-pays or co-insurance, which are payments that patients are responsible for when acquiring the drug. Drugs listed in lower tiers typically have lower co-pays and fewer requirements or limits (if any) than drugs on higher tiers.

21. In addition to deciding which drugs to place on formulary and on what tier, PBMs also determine requirements and limits for each drug, which govern the circumstances under which PBMs will pay for the drug. Common requirements and limits used on formularies include "prior authorization," "step therapy," and "quantity limits."

22. "Prior authorization" refers to the requirement for a physician to obtain advance approval from the patient's payor or PBM prior to having a prescription for a covered drug dispensed to a patient. "Step therapy" refers to the requirement that a physician prescribe another drug for the same disease or indication prior to authorizing approval for a particular drug. "Quantity limits" refer to when a formulary limits the quantities of a drug that it will cover during a particular period.

23. These utilization management tools, in addition to formulary coverage and tier placement, can be used to encourage or influence physicians to prescribe (and patients to use) one drug over another.

24. Overall, PBMs purport to consider numerous factors in deciding which drugs to cover on their formularies, on which tier to place each drug, and whether to impose any requirements or limits on any particular drug. Rebates are a significant driver in determining coverage. In addition, PBMs evaluate the clinical and therapeutic profile of a drug to determine whether the drug provides any advantages over other drugs used to treat the same disease or indication. Other factors that PBMs may consider include net price, market share, drug utilization trends, the number of other drugs on their formularies used to treat the same disease or indication, and any disadvantages of the drug (e.g., safety or administration concerns).

25. PBMs routinely make changes to their formularies—to include new drugs, to exclude existing drugs, to change tiering or requirements, or to make certain drugs more favorable over others.

26. For all the reasons explained above, PBMs play a major role in influencing which prescription drugs are ultimately prescribed by physicians and utilized by patients.

B. Janssen's Negotiations With PBMs For STELARA®

27. Access to STELARA® is determined primarily by PBMs, which decide whether and how payors will cover STELARA®.

28. [redacted]

29. For example, [redacted].

30. [redacted]

[redacted]

31. [redacted]

32. [redacted] The impact of this loss of Janssen's ability to secure favorable formulary placement for [redacted] will be incredibly difficult to quantify.

C. Irreparable Harm Caused By ABP 654's Launch

33. There are currently no biosimilars of STELARA® available on the market. I am aware that Amgen is planning to launch a proposed biosimilar of STELARA®, called ABP 654. Amgen is expected to launch ABP 654 at a potentially lower list price (and/or with greater rebates) than STELARA®.

34. Based on my expertise and experience, I anticipate that ABP 654's launch will upend and disrupt Janssen's existing contractual relationships with PBMs for STELARA® in multiple ways.

35. If ABP 654 became available on the market, PBMs would require Janssen to renegotiate its contracts for STELARA®. PBMs would demand additional rebates from Janssen or could drop STELARA® from their formularies entirely and replace it with ABP 654, or revise the formulary placement Janssen was able to negotiate for STELARA® before any biosimilar launch for a less favorable formulary placement.

36. Terminations of contracts are standard in the prescription drug benefit industry. PBMs frequently end contracts when they feel they may be able to extract better deals or additional rebates based on market dynamics.

37. Even if PBMs decided not to exclude STELARA® from their formularies, they could instead place STELARA® in the same tier as ABP 654, or in a disadvantaged tier (e.g., tiers carrying higher co-pays or imposing requirements, such as step therapy, in order to incentivize utilization of ABP 654).

38. However, there is a high likelihood that PBMs would exclude STELARA® from their formularies altogether if ABP 654 were to enter the market. Over the years, PBMs have increased the number of prescription drugs they exclude from their formularies, including biologics. For example, for years the PBM Express Scripts included AVASTIN® on its formulary for the treatment of various cancers. In July 2019, Amgen launched a biosimilar version of the drug, called MVASI. Pfizer subsequently followed with another biosimilar version called ZIRABEV in January 2020. Express Scripts immediately excluded the branded AVASTIN® from its formulary, replacing it with biosimilars MVASI and ZIRABEV. *See* Express Scripts, 2020

National Preferred Formulary Exclusions (Oct. 2020), www.express-scripts.com/art/pdf/NPF_Preferred_Formulary_Exclusions2020.pdf.

39. Upon ABP 654's launch, Janssen would face two choices: either (i) offer further rebates and discounts to PBMs for STELARA® which, while minimizing loss of market share, would result in significant reductions in revenue, or (ii) maintain the net price and suffer significant market share and revenue losses due to formulary exclusions or less favorable formulary placement. Either approach would require negotiating new contracts with PBMs and both approaches would result in great harm to Janssen.

40. Even if ABP 654 was later removed from the market, Janssen would not be able to meet the PBMs' demands for rebates as it can today based on STELARA® sales. It is unlikely Janssen would ever be able to convince PBMs to return STELARA® rebates to their original levels, as it would be unable to offer the same volume of rebates it can offer today due to the eroded STELARA® sales volume. Thus, it is highly unlikely STELARA® could ever return to the same prices or volume if ABP 654 were to launch prematurely.

41. Additionally, [redacted]

42. For example, [redacted]

[redacted]

43. Amgen's premature launch of ABP 654 may also reduce the willingness of pharmacies to stock STELARA®. Pharmacies could choose to only stock ABP 654.

44. Confusion or uncertainty regarding STELARA® formulary coverage may also cause some physicians or patients to try alternative drug products, thus leading to permanent loss of market share.

45. Patients currently on STELARA® could also be harmed. If STELARA® lost formulary coverage, insurers would no longer cover the cost of the drug, effectively forcing patients to switch to another medication. Patients forced to switch to ABP 654 or another medication would have to go through additional steps with insurance companies and physicians to obtain the necessary paperwork, which could lead to gaps or disruption in treatments for patients. Patients could be forced to enroll in new patient support services that are not as robust as Janssen's patient support services. This disruption would be further magnified if ABP 654 was later removed from the market, at which point patients would have to switch back to STELARA®. Such back-and-forth switching between products would cause confusion and have a negative impact on patients due to lack of continuous access to medication and treatments.

46. Finally, a premature launch of ABP 654 by Amgen could compel other manufacturers to launch biosimilars of STELARA®. With the entry of other biosimilars after ABP 654, the market share loss attributable to Amgen would become increasingly difficult to calculate.

47. In summary, Amgen's early launch of ABP 654 would broadly impact the coverage and placement of STELARA® and potentially other Janssen products on formularies managed by PBMs, resulting in a loss of market share, erosion of prices, and disruption to contractual relationships that would be both irreversible and extremely hard to fully quantify.

D. Janssen's Investment In Research And Development

48. Janssen is dedicated to developing high-quality, life-enhancing, and innovative therapeutic products. Janssen invests a substantial amount of resources every year to research and development.

49. For example, in 2021, Janssen invested $11.9 billion into the discovery and development of new treatments and cures. *See* The 2021 Janssen U.S. Transparency Report, https://transparencyreport.janssen.com/_document/the-2021-janssen-u-s-transparency-report?id=00000180-0108-dccf-a981-a52ec8300000 at 2. From 2016 to 2021, Janssen's research and development investment increased on average 11.2% annually. Janssen has invested a total of $54.1 billion in research and development since 2016. *Id.*

50. Drug research and development expenditures include discovery and testing new drugs, developing modifications and improvements for therapeutics, and clinical testing in humans to ensure efficacy and safety.

51. In particular, Janssen directs a significant portion of its research and development funds to developing biologics. Many of these biologics are intended to treat chronic, complex, or rare conditions.

52. The amount of funds that Janssen is able to channel into research and development is determined by the amount of revenue it earns from prescription drug sales, especially from best-selling products like STELARA®.

53. Janssen reinvests a substantial portion of STELARA® revenues into supporting research and development programs to advance new and potentially life-saving drugs. STELARA® sales are thus a major contributor to research and development at Janssen.

54. If Janssen loses STELARA® market share or is forced to lower STELARA® prices due to early entry of ABP 654, then funds used to support Janssen's research and development would potentially be reduced and Janssen's pipeline of new drugs would diminish.

E. Janssen's Patient Support Programs

55. In addition to research and development, Janssen also reinvests STELARA® revenues into patient programs and services that provide critical support to patients taking STELARA®.

56. STELARA® is a first-in-class, life-changing treatment that has helped hundreds of thousands of patients overcome debilitating conditions such as psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. STELARA® eases symptoms and helps patients achieve sustained remission so that they can go on to lead normal lives. For these reasons, ensuring patient access to STELARA® is essential.

57. Janssen offers a robust suite of patient services under the umbrella "STELARA® withMe" program.

58.

59. [redacted].

60. [redacted]

61. Thus, STELARA® revenues directly sustain vital programs and services that help to ensure patient access to treatment.

I declare under penalty of perjury that to the best of my knowledge, information, and belief, the foregoing statements are true and correct.

Dated: March 1, 2023

Brian Smith

Brian Smith