IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN BIOTECH, INC.,

Plaintiff,

v.

AMGEN, INC.

Defendant.

C.A. No. 22-cv-01549-MN

[redacted]

MEMORANDUM IN SUPPORT OF
JANSSEN'S MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

This lawsuit challenges Amgen's plan to launch a new drug that infringes several Janssen patents. If Amgen's proposed launch goes forward [redacted], it will inflict irreparable harm on Janssen and irrevocably alter the market for STELARA®, a blockbuster biologic drug that has helped hundreds of thousands of patients suffering from autoimmune disorders. Janssen asks this Court to grant a preliminary injunction that will block the launch and preserve the status quo until the Court can resolve the underlying patent dispute on the merits.

Over the past two decades, Janssen has invested countless hours—and hundreds of millions of dollars—developing novel antibody treatments for patients suffering from life-altering diseases. Those efforts have borne fruit, creating numerous drugs that help patients fight a wide range of illnesses. One of Janssen's most important innovations is STELARA®—a first-in-class antibody drug that FDA has approved to treat serious autoimmune diseases. STELARA® has helped hundreds of thousands of adults and children overcome debilitating conditions like psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis (UC).

Amgen, a leading rival of Janssen's, has now decided to piggyback on Janssen's success by launching a biosimilar copy of STELARA®. Known as ABP 654, Amgen's biosimilar is specifically designed to replace STELARA® and capture market share from Janssen. Amgen has informed Janssen that it intends to launch ABP 654 [redacted]

Janssen welcomes innovation among market participants and is fully prepared to compete with Amgen and others to deliver the highest quality drugs that help patients. But Amgen's at-risk launch of ABP 654 would infringe several Janssen patents, defying settled rules of competition. As set forth in Janssen's Amended Complaint, Dkt. 20 ("Am. Compl."), Amgen's ABP 654 infringes at least six Janssen patents, including a compound patent covering STELARA®'s active

ingredient (ustekinumab), a UC patent covering its use in that indication, and four manufacturing patents. To streamline the issues, this motion focuses on just two manufacturing patents.[1]

If Amgen launches ABP 654 on its planned timetable, the effect will be to inflict substantial and irreparable harms on Janssen, including to the market for STELARA® and to Janssen's key relationships with payors and patients. To prevent these harms, Janssen seeks a preliminary injunction that would block Amgen from rushing ABP 654 to market before this Court can resolve the underlying patent infringement dispute. Such relief is directly contemplated by the Biologics Price Competition and Innovation Act (BPCIA), which Congress designed to give parties "the opportunity to litigate the relevant patents *before* the biosimilar is marketed." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1671-72 (2017) (emphasis added). The BPCIA authorizes this Court to grant injunctive relief under the traditional four-factor test. 42 U.S.C. § 262(l)(8)(b). All four factors weigh strongly in Janssen's favor here.

First, Janssen is likely to succeed on the merits. As part of its efforts to develop STELARA® and other innovative drugs, Janssen has developed and acquired various patents, including the two patents for using living cells to manufacture therapeutic antibodies that form the basis of this motion (the "Manufacturing Patents"). Amgen directly infringes the Manufacturing Patents because Amgen's manufacturing process for ABP 654 [redacted]. *See* Croughan Decl. ¶¶ 168-244; Ex. A18, Amgen_ABP654_000035015 at -35019; Ex. A19, Amgen_ABP654_000015424 at -16483. This was no accident. Amgen used these patents to make

[1] Janssen reserves its rights to pursue additional injunctive relief based on the record evidence and/or in the event that Amgen seeks to launch ABP 654 with a label that would induce infringement of the UC patent prior to expiration of that patent.

ABP 654 as close a copy to STELARA® as possible. These patents were invented for this exact purpose: to enable biosimilar manufacturers to better achieve equivalence to the originator product, also called the "reference product." And Amgen took full advantage of those inventions, so much so that Amgen is seeking not only a biosimilarity designation, but also an "interchangeability" designation, meaning that the two products can be swapped without the prescribing physician's instruction or consent. In copying Janssen's product, Amgen infringed Janssen's patents.

Second, Amgen's launch of ABP 654 will cause Janssen immediate, lingering, substantial, and irreparable harm that cannot be adequately compensated by money damages. Access to STELARA® is determined largely by the Pharmacy Benefit Managers (PBMs), which decide whether and how the insurance companies will cover prescription drugs. Using this leverage, PBMs force competition between manufacturers by demanding concessions based upon volume of sales of the manufacturers' individual drugs and portfolios. Amgen's infringing launch of ABP 654 will cause a seismic shift in Janssen's ability to maintain access to STELARA® and its broader portfolio, and result in irretrievable loss of Janssen's STELARA® market share, as well as price erosion, damage to Janssen's R&D, loss of goodwill, and harm to Janssen's ongoing relationships with payors and customers. By the time Janssen ultimately prevails at trial, it will be extraordinarily difficult—if not impossible—to fully quantify how STELARA® and other drugs would have fared absent Amgen's untimely launch. And it will be virtually impossible to revert to the contractual status quo preceding that launch.

Third, the balance of hardships favors a preliminary injunction. While a premature launch would significantly and irreparably harm Janssen, a preliminary injunction would cause Amgen no meaningful harm, other than delaying its ability to profit from ABP 654 until the infringement issues are decided on the merits.

Fourth, the public interest favors an injunction. The patent system encourages innovation by ensuring inventors can make a return on the substantial investments required for pharmaceutical R&D. And because ABP 654 provides no unique clinical benefits and Janssen already offers significant financial support for low-income patients using STELARA®, patients will not be harmed by an injunction preventing Amgen from selling its infringing product until trial.

For all these reasons, preliminary relief is appropriate. This Court should grant the injunction pending its full consideration of Amgen's patent infringement on the merits.

STATEMENT OF FACTS

Janssen is a major inventor and manufacturer of groundbreaking pharmaceuticals that treat a host of medical conditions affecting countless people around the world. In addition to conducting its own innovative research, Janssen acquires industry-leading technologies from smaller pharmaceutical companies and scales them at levels that can make a serious impact on the nation's health. As part of these efforts, Janssen developed the biologic at issue here, STELARA®, and acquired the Manufacturing Patents that Amgen currently infringes to produce ABP 654, its biosimilar copy of STELARA®.

A. STELARA®

STELARA® is a blockbuster medication that has helped hundreds of thousands of patients—adults and children alike—overcome autoimmune diseases, including psoriasis, psoriatic arthritis, Crohn's disease, and UC. Autoimmune diseases are a class of conditions in which the body's immune system mistakenly attacks the body's own cells as if they were harmful, foreign cells. Physicians do not know what causes autoimmune diseases, but patients can take certain steps to treat them. STELARA® represents a breakthrough development in the treatment of such diseases. A first-in-kind biologic, STELARA® works by targeting certain proteins—interleukin-12 (IL-12) and interleukin-23 (IL-23)—that patients with autoimmune diseases

produce in excess. STELARA® attaches to those proteins and neutralizes them, thereby reducing the chronic inflammation that is a hallmark of autoimmune diseases. STELARA®'s novel treatment approach has been particularly useful for patients who fail treatment with other drugs, such as REMICADE®, HUMIRA®, and SIMPONI®, each of which presents safety risks associated with immunosuppression. U.S. Patent No. 10,961,307 (the "UC patent") at 2:20-25. Physicians have prescribed STELARA® to hundreds of thousands of patients since the product launched in 2009. Smith Decl. ¶ 56.

Scientists at Janssen spent years inventing and developing ustekinumab, the active ingredient in STELARA®. Ustekinumab is a fully human, high-affinity, neutralizing therapeutic antibody that, as explained above, targets the IL-12 and IL-23 proteins. Ustekinumab and thus STELARA® belong to the class of drugs called biologics, which are large-molecule drugs synthesized from living cells or organisms. Biologics are far more complex than standard chemically synthesized drugs like Advil or Tylenol. The latter can be manufactured simply by combining raw materials in a lab; the former must be grown inside living cells. Producing ustekinumab and other biologics requires choosing the right host cell and manipulating that cell so it produces the right compound.

To make STELARA®, Janssen [redacted]. Janssen then conducted over 100 clinical trials to identify the safest and most effective uses of ustekinumab in treating patients. Janssen's continuing investment and innovation led to the initial FDA approval of STELARA® to treat not only plaque psoriasis in 2009, but also psoriatic arthritis in 2013, Crohn's disease in 2016, and UC in 2019.

Alongside its development of STELARA®, Janssen has made significant investments in research and development for generating and manufacturing other biologics for therapeutic use.

As relevant here, those efforts have included acquiring technologies in the antibody manufacturing industry. On October 1, 2020, Janssen purchased Momenta Pharmaceuticals, Inc. ("Momenta"), a company whose research and development included methods of manufacturing antibodies like STELARA®. As a result of its Momenta acquisition, Janssen now owns the Manufacturing Patents asserted in this litigation.

Today, STELARA® is Janssen's largest-selling product both in the United States and worldwide, delivering roughly $6.4 billion in net U.S. sales revenue and roughly $9.7 billion in worldwide sales revenue in 2022. Ex. C5, J&J SEC Form 10-K, pp. 75-79. Janssen reinvests a substantial portion of these revenues to fund research and development of novel (and potentially life-saving) drugs, as well as, patient programs that provide financial and medical support. Smith Decl. ¶¶ 48-61. For example, Janssen offers several programs to help onboard patients, including co-pay assistance, infusion support, injection training, treatment support and education, and insurance and affordability support. *See* Ex. B3 at 6, 24.

Janssen sells STELARA® [redacted]—who in turn sell to specialty pharmacies, hospitals, health care providers, and infusion therapy providers—who then provide it to patients (who typically pay for the drug using insurance). Smith Decl. ¶ 11. Insurance companies work with PBMs to manage their prescription drug benefits. *Id.* ¶¶ 7-9. In practice, access to STELARA® is determined largely by the PBMs, which decide whether and how the insurance companies will cover prescription drugs. The PBMs develop lists of covered drugs—known as "formularies"—that classify drugs into particular tiers. *Id.* ¶¶ 17-20. The tiers affect the rate at which the drugs are reimbursed by insurers and can determine patients' access to those drugs. For instance, PBMs use formularies to place restrictions on the drugs, such as requiring doctors to try other treatment options before prescribing a particular drug. *Id.* ¶¶ 21-22.

PBMs exact significant rebates and other concessions from pharmaceutical manufacturers, using as leverage their ability to dictate which drugs will be included on the PBM formularies. *Id.* ¶ 13. PBMs pit one manufacturer against another, demanding rebates on individual drugs and manufacturers' portfolios, to optimize their aggregate concessions. [redacted].

B. The Manufacturing Patents

The Manufacturing Patents resulted from substantial investment in developing manufacturing processes to control certain antibody characteristics known as "post-translational modifications." Croughan ¶¶ 31-49. These are chemical changes made to an antibody. Even antibodies having identical amino acid sequences can have different post-translational modifications, which in turn can cause even otherwise identical antibodies to have different biological properties—including properties that can impact their efficacy and safety. *Id.* ¶¶ 47-49. As a result, controlling post-translational modifications is an important aspect of biologic and biosimilar production.

Dr. Holly Prentice, the sole inventor of both Manufacturing Patents, investigated and developed methods of modifying the antibody manufacturing process to control two particular types of such post-translational modifications. The first—in U.S. Patent No. 9,217,168 (the "'168 patent")—is a novel method of controlling "glycans." The second—in U.S. Patent No. 9,475,858 (the "'858 patent")—is a novel method of controlling "C-terminal variants." Together, the two Manufacturing Patents describe novel methods of controlling antibody characteristics by selecting

certain chemicals, in specific amounts, to be used during manufacturing in the cell culture medium (i.e., the liquid in which cells grow to express antibodies).

1. Adjusting Glycans With Putrescine Levels

The '168 patent recites methods of controlling glycans, which are types of post-translational modifications—specifically, carbohydrates attached to certain of an antibody's amino acids. Glycans come in several forms, and antibodies typically have a characteristic ***distribution*** of those forms. Croughan ¶¶ 45-46, 49. As with other post-translational modifications, different forms (and distributions) of glycans can alter the biological properties of the antibody—even for antibodies that are otherwise identical. *Id.* ¶¶ 37, 48. For example, the body can more quickly eliminate antibodies having ***high mannose glycans*** (potentially lowering the antibody's efficacy or requiring higher dosing), whereas the presence of ***sialylated glycans*** on an antibody can impart anti-inflammatory effects. *Id.* ¶ 48.

Inventor Dr. Prentice developed and designed a novel cell culture medium to tailor antibody characteristics, including glycan profiles, by varying the amount of a chemical called ***putrescine*** in the medium. Janssen's '168 patent is directed to aspects of this invention.

For example, Claim 23 of the '168 patent (which depends from any one of Claim 1, 10, 13 or 16—and as shown below and relevant here, depends from Claim 1) recites adding specific amounts of ***putrescine*** to control levels of high mannose glycans and sialylated glycans:

> 1. A method of producing a recombinant protein preparation having a target value of one or more of galactosylated glycans, high mannose glycans, and sialylated glycans, the method comprising:
>
> (a) providing a cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising 0.1 mg/L to 10 mg/L putrescine under conditions in which the cell expresses the recombinant protein; and
>
> (c) harvesting a preparation of the recombinant protein produced by the cell that meets the target value of the one or more of galactosylated glycans, high mannose glycans, and sialylated glycans,

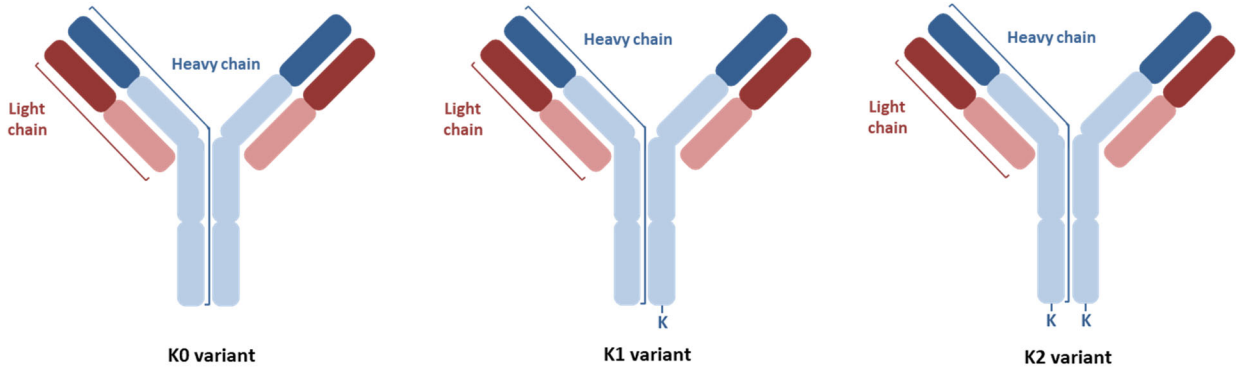
wherein the target value of galactosylated glycans, or sialylated glycans is a level at least 10% higher than a level of galactosylated glycans, or sialylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine; or

wherein the target value of high mannose glycans is a level at least 10% lower than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

23. . . . wherein the cell is a Chinese Hamster Ovary (CHO) cell.

2. Adjusting C-Terminal Variants With Arginine Levels

The second of the two Manufacturing Patents, the '858 patent, recites methods of controlling another type of post-translational modification, called "C-terminal variants." This refers to different antibodies in a population having different forms, or variants, at the ends ("C-termini") of their amino acid chains. Even antibodies having otherwise identical amino acid sequences can nonetheless differ based on the presence or absence of one extra amino acid, usually a lysine, which may be found at the end of the antibody's amino acid chains. Croughan ¶¶ 39-43. An antibody can have either zero, one, or two such terminal lysines (illustrated below; "K" is the standard single-letter abbreviation for lysine). Across a population of antibodies, these three forms—antibodies having either no lysine, one lysine, or two lysines at the C-termini—are called the "C-terminal variants" of that antibody.



Controlling C-terminal variants in antibody manufacturing—i.e., controlling what fraction of the antibodies produced have either zero, one, or two lysines at the end—can help a biosimilar maker not only to achieve close similarity to the reference product, but also meet internal targets and achieve product consistency among its own lots. *Id*. ¶¶ 63-64.

Inventor Dr. Prentice developed methods of modifying the antibody manufacturing process to adjust and control the C-terminal variants produced for a given preparation of antibody. For example, Claim 33 of the '858 patent (which depends from Claim 20) recites adding a specific amount of ***arginine*** to control the distribution of C-terminal variants:

> 20. A method of manufacturing a preparation of a recombinant antibody, comprising:
> culturing a cell in a medium comprising 2 g/L arginine to 8 g/L arginine under conditions in which the cell expresses a recombinant antibody;
> isolating the recombinant antibody, thereby producing a preparation of the recombinant antibody;
> and formulating the preparation into a drug product if the preparation meets a target value of C-terminal variants of the recombinant antibody, wherein the C-terminal variants differ in amino acid sequence only by the presence or absence of a lysine at their carboxyl termini.
>
> 33. . . . wherein the cell is a CHO [Chinese hamster ovary] cell.

As explained above, by following these manufacturing methods, a scientist can adjust the levels of C-terminal variants in the resulting antibody preparation.

Thus, both Manufacturing Patents claim methods of adjusting cell growth media to contain certain amounts of ***arginine*** or ***putrescine*** in order to achieve desired characteristics in the resulting antibodies—either adjusting arginine to control C-terminal variants, or adjusting putrescine levels to control glycans (specifically, high-mannose glycans and sialylated glycans) to make a biosimilar product.

C. Amgen's Biosimilar ABP 654

Amgen develops, manufactures, markets, and sells both innovative biologics and biosimilars, including ABP 654—Amgen's proposed biosimilar of STELARA®. But Amgen manufactures ABP 654 using the same techniques that Dr. Prentice invented for controlling relevant post-translational modifications in a biosimilar product. Specifically, Amgen's manufacture of ABP 654 infringes the Manufacturing Patents by deliberately targeting the claimed effects and including the claimed levels of arginine and putrescine to achieve them. *See infra* I.

By Amgen's own admission, ABP 654 adds nothing new to the treatment of autoimmune diseases. Indeed, Amgen has publicly stated that its Phase III study "evaluating the efficacy and safety of ABP 654 compared to STELARA® … demonstrat[ed] ***no clinically meaningful differences between ABP 654 and STELARA***." Am. Compl. Ex. B at 1 (emphasis added); *id.* at Ex. C; *see id.* at Ex. D at 41 ("Preliminary results from a Phase 3 study evaluating the efficacy and safety compared to STELARA® in adult patients with moderate to severe plaque psoriasis met the primary efficacy endpoint."). Amgen is also conducting a separate Phase III study to investigate interchangeability of ABP 654 for STELARA®. *See id.* at Ex. E; *see also id.* at Ex. F at 40 ("A Phase 3 study to support an interchangeability designation in the U.S. is ongoing.").

On [redacted] Amgen submitted [redacted] abbreviated Biologics License Applications ("aBLAs") to the FDA pursuant to the BPCIA, seeking approval to market ABP 654 in the United States.[2] The BPCIA provides an abbreviated regulatory pathway by which biosimilar makers can apply to market their copies of existing biologic drugs. 42 U.S.C. § 262. The BPCIA requires a

[2] [redacted]

deliberate exchange of patent information between Janssen and Amgen (colloquially referred to as the "Patent Dance") to ensure issues of patent infringement and validity can be resolved *before* the biosimilar is launched. 42 U.S.C. § 262(l).

A week after Amgen submitted its aBLAs but before the FDA began its review, Amgen gave Janssen a formal 180-day notice pursuant to the same Act, signaling Amgen's intent to begin selling its infringing biosimilar product at least 180-days after its notice (May 6, 2023), or upon FDA approval. Am. Compl. ¶ 8; *id*. at Ex. A. The purpose of that 180-day notice is to authorize and trigger a separate declaratory judgment action by the biologic maker, to ensure that all patent issues can be litigated before the biosimilar launches. *See* 42 U.S.C. § 262(l)(8). Amgen also stated its intent "to commercially market its ABP 654 drug products with a full label that includes all the FDA approved indications for the STELARA® drug products." Am. Compl. at Ex. A. Those indications include Janssen's patented use of ustekinumab to treat UC, which is also at issue in this case. *See, e.g.*, *id*. at ¶¶ 58-60.

D. Procedural History

On November 29, 2022, Janssen filed this suit seeking a declaratory judgment that Amgen infringed two patents protecting Janssen's groundbreaking advances: U.S. Patent No. 6,902,734 (the "compound patent"), covering ustekinumab, the active compound in STELARA®; and the UC patent, protecting the use of ustekinumab to treat UC. Dkt. 1 ("Compl."). On January 23, 2023, Amgen agreed [redacted]. Am. Compl. at Ex. P, Stipulation. However, Amgen has indicated its intent to launch ABP 654 [redacted]. After Janssen filed suit, Amgen provided Janssen with information about Amgen's process for manufacturing ABP 654. That information established that Amgen infringes at least four Janssen patents reciting methods of manufacturing antibodies. On February 21, 2023, Janssen

filed its amended complaint asserting those four additional patents, including the two Manufacturing Patents described above (the '168 and '858 patents). Am. Compl. To streamline the proceedings, Janssen now seeks preliminary relief based only on the two Manufacturing Patents, i.e., the '168 and '858 patents.

ARGUMENT

Janssen seeks a preliminary injunction barring Amgen's infringement of the Manufacturing Patents during the pendency of this litigation. Janssen's requested relief is grounded in both the BPCIA and 35 U.S.C. § 271(e)(4)(B). As the Supreme Court has explained, "[t]he BPCIA sets forth a carefully calibrated scheme" for adjudicating patent disputes, which is intended to give parties "the opportunity to litigate the relevant patents *before* the biosimilar is marketed." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1671-72 (2017) (emphasis added). As part of that scheme, the BPCIA grants reference product sponsors, like Janssen, the ability to "seek a preliminary injunction prohibiting the [biosimilar] applicant from engaging in the commercial manufacture or sale of such biological product" upon receipt of a biosimilar's notice of commercial marketing. 42 U.S.C. § 262(l)(8)(B). Likewise, the Patent Act provides this Court with the authority to grant "injunctive relief … against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States" of the infringing "biological product." 35 U.S.C. § 271(e)(4)(B).

Whether to grant a preliminary injunction is within the Court's discretion, based upon its assessment of four factors: (1) the movant's likelihood of success on the merits of the underlying litigation, (2) whether irreparable harm is likely if the injunction is not granted, (3) the balance of hardships as between the litigants, and (4) the public interest. *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 926 (Fed. Cir. 2012). The Federal Circuit has emphasized that "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on

the merits can be held." *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1344-45 (Fed. Cir. 2008) (quoting *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981)).

Given the vast, varied, and unquantifiable damages at stake, a preliminary injunction is appropriate and necessary to preserve the status quo until the Court can properly consider Amgen's infringement of Janssen's patents on a complete record.

I. JANSSEN IS LIKELY TO SUCCEED ON THE MERITS

Although this motion is based just on the two Manufacturing Patents (i.e., the '168 and '858 patents), Amgen need only infringe *one claim* (of *either patent*) to support a preliminary injunction. ABP 654 infringes Janssen's patents in two ways. First, Amgen's proposed launch of ABP 654 will infringe Janssen's Manufacturing Patents under 35 U.S.C. § 271(a), which provides that a biosimilar applicant infringes a reference product sponsor's patents if it "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent." *See also* 35 U.S.C. § 271(g). Second, Amgen's submission of its aBLA for ABP 654 is itself an act of infringement under 35 U.S.C. § 271(e).

A. Amgen's ABP 654 Will Infringe The '168 Patent By Using Putrescine to Control Glycans

ABP 654 will infringe at least Claim 23 of the '168 patent. As noted, the '168 patent discloses and claims novel methods of cell culture to produce a recombinant antibody, including (among other things) by adding defined amounts of ***putrescine*** to the cell culture preparation to affect glycans, a form of post-translational modification on the antibody itself. *Supra* at B.1.

Claim 23 of the '168 patent is directed to a method of (1) producing a recombinant antibody in a medium that comprises putrescine in an amount between 0.1 mg/L and 10 mg/L, and (2) harvesting an antibody that meets a target value of glycan forms (e.g., ***high mannose*** glycans

or ***sialylated*** glycans) where that target value is changed by at least 10% compared to what it would have been without the specified amount of putrescine. *Supra* at I.B.1.

As Janssen's expert Dr. Matthew Croughan explains, Amgen's commercial manufacture of ABP 654 will infringe at least Claim 23 of the '168 patent. Croughan Decl. ¶¶ 202, 243. Amgen's manufacturing method involves [redacted]. For example, Amgen's own documents reveal that "[redacted] Ex. A28, Amgen_ABP654_000035142 at 35156-158. Furthermore, in its ABP 654 manufacturing process, Amgen [redacted]. Croughan Decl. ¶ 167.

[redacted] Croughan Decl. ¶ 129; Ex. A18, Amgen_ABP654_000035015 at -35019; Ex. A19, Amgen_ABP654_000015424 at -16483.

As Dr. Croughan explains, Amgen's use of cell culture media [redacted]. Croughan Decl. ¶¶ 212-235; Ex. A24, Amgen_ABP654_000035675 at -35722-730 (Glycan map for ABP 654 with percentages of glycans in these two groups). Amgen's manufacturing process for ABP 654 [redacted]

[redacted]. Croughan Decl. ¶¶ 163-167.

Adjusting the glycan levels of ABP 654 can serve two purposes. First, controlling glycan profiles in [redacted]. *Id*. ¶¶ 156-162. The '168 patent specification demonstrated a greater than 10 percent change in glycan levels using substantially lower levels of putrescine [redacted]. *Id*. ¶¶ 239 and 241; Ex. A2, '168 patent at 32:40-33:38 & Figs. 2-4. Second, controlling glycan profiles in ABP 654 through the claimed method helps [redacted] Croughan Decl. ¶¶ 163-167. [redacted]. *Id*. ¶¶ 163-167. Note that close similarity to STELARA® is particularly important to Amgen, given its public statement that it intends to seek approval of ABP 654 as *interchangeable* to STELARA®. *See* Compl., Ex. F at 40 ("A Phase 3 study to support an interchangeability designation in the U.S. is ongoing.")). That interchangeability designation will allow ABP 654 to be substituted for STELARA® at the pharmacy level, without notice to—or permission from—either physician or patient.

For these reasons, Amgen's commercial manufacture of ABP 654 will infringe at least Claim 23 of the '168 patent.[3]

[3] The asserted patents are presumed valid. *See* 35 U.S.C. § 282(a). Amgen has not challenged the asserted patents, and to the extent it does, Janssen will respond to those challenges in its reply brief.

B. Amgen's ABP 654 Will Infringe The '858 Patent By Using Arginine Levels To Control For C-Terminal Variants

ABP 654 will infringe at least Claim 33 of the '858 patent. As explained above, the '858 patent discloses and claims novel methods of manipulating a cell culture to produce a recombinant antibody, including (among other things) using a cell culture having defined amounts of arginine to affect a particular post-translational modification to the antibody: the distribution of C-terminal variants. *Supra* at B.2.

Specifically, Claim 33 of the '858 patent is directed to methods of producing a recombinant antibody by culturing Chinese hamster ovary (CHO) cells in a medium that comprises arginine in an amount between 2 g/L and 8 g/L, and formulating the preparation into a drug product if the preparation meets a target value of C-terminal variants of the recombinant antibody. *Supra* at B.2.

As Janssen's expert Dr. Croughan explains, Amgen's commercial manufacture of ABP 654 will infringe at least Claim 33 of the '858 patent. Croughan Decl. ¶¶ 168, 200. As with [redacted] *Id*. ¶¶ 140-151. [redacted] *Id*. ¶¶ 119, 175.; Ex. A18, Amgen_ABP654_000035015 at -35019; Ex. A19, Amgen_ABP654_000015424 at -16483.

As Dr. Croughan explains, Amgen [redacted]. Croughan Decl. ¶¶ 143-151 and 178-195 (discussing target levels and infringement); Ex. A32, Amgen_ABP654_000018206; Ex. C2, Amgen_ABP654_000032804 ("[redacted]");

Ex. C3, Amgen_ABP654_000033068 at -33070 ("[redacted]."); Exs. A31-A33 ([redacted]

As with glycans above, adjusting the C-terminal variant levels of ABP 654 can contribute to [redacted]. Croughan Decl. ¶¶ 143-151, 181-193, 196.

Thus, Amgen's commercial manufacture of ABP 654 will infringe at least Claim 33 of the '858 patent.

II. JANSSEN WILL SUFFER IRREPARABLE HARM WITHOUT A PRELIMINARY INJUNCTION

Janssen will suffer immediate, substantial, and irreparable harm if Amgen is not enjoined from launching ABP 654 prior to the expiration of the Manufacturing Patents. Once Amgen launches, the leading PBMs will demand renegotiation of the complex web of contracts governing how STELARA® is treated on their formularies. The inevitable result will be (1) long-lasting loss of market share across all indications of STELARA®, (2) irreversible price erosion across all indications, and (3) massive disruption to Janssen's existing contractual relationships with payors, harming its goodwill, reputation, consumer relations, as well as sales and market trajectory across Janssen's full suite of drugs.

Such varied harms simply cannot be adequately remedied through monetary damages. As the Federal Circuit has recognized, "erosion of markets, customers, and prices, is rarely reversible." *Abbott Labs.*, 544 F.3d at 1362; *see also Aria Diagnostics, Inc. v. Sequenom, Inc.*, 726 F.3d 1296, 1304 (Fed. Cir. 2013) ("price erosion, loss of goodwill, damage to reputation, and

loss of business opportunities are all valid grounds for finding irreparable harm") (citation omitted). Even if Janssen ultimately prevails at trial, it will be difficult—if not impossible—to fully quantify how STELARA® and other contractually linked drugs would have fared absent Amgen's premature launch. And even if ABP 654 were subsequently removed from the market, its presence there would have already irreparably altered the market and disrupted Janssen's web of interrelated contracts.

A. STELARA® Would Suffer Lasting Loss Of Market Share

A premature launch of ABP 654 would cause Janssen to suffer accelerated, long-term loss of market share. Amgen would force Janssen into a Hobson's choice: either compete with ABP 654 on price, preserving market share but eviscerating revenues, or keep prices the same and lose market share. Either option would dramatically reduce Janssen's revenue from STELARA®, leading to additional compounding harms as set forth below. And none of these harms are remediable. As Amgen itself has argued in another case, "[i]n the context of patent litigation, '[t]here is no effective way to measure the loss of sales or potential growth—to ascertain the people who do not knock on the door or to identify the specific persons who do not reorder because of the existence of the infringer.'" Ex. C4, *Amgen v. Sandoz*, No. 14-04741, Dkt. 56 at 23 (N.D. Cal. Feb. 5, 2015) ("Amgen PI Mot.") (quoting *CellzDirect*, 664 F.3d at 930). Where, as here, the loss of market share cannot be easily quantified and compensated on the back end, a preliminary injunction is necessary and appropriate.

Indeed, Amgen plans to sell ABP 654 *in order to* capture market share from STELARA®. As Amgen itself noted in its 2022 Biosimilar Trends report, biosimilar entrants typically are successful at doing just that: "Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced. Additionally, first-to-launch biosimilars tend to capture a greater portion of the segment compared to later entrants." Ex. B27, Amgen 2022

Rpt. at 14 (also noting that "[f]or therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%," whereas "[f]or therapeutic areas with biosimilars launched prior to 2019, the average share after 3 years was 39%"). Indeed, a recent report issued by Cardinal Health confirms that "[a]doption of biosimilars typically accelerates quickly after market introduction." Ex. B25, Cardinal Health Rpt. at 16; *see also* Ex. B26, JAMA Network at 4 ("Biosimilars in the US that entered the market more recently were estimated to experience a faster uptake (as measured by the market share 1 year after launch)").

Like all biosimilars attempting to gain market share, ABP 654 will do so by compromising Janssen's preferred position on the pharmacy and insurance formularies generated by PBMs. *Supra* at I.A. If Amgen is permitted to launch ABP 654 prematurely, that could trigger PBMs to drop STELARA® from their formularies entirely, replacing it with ABP 654. Smith Decl. ¶ 35. Amgen itself has recognized how pervasive this effect can be, noting in a recent report that each of the three largest PBMs has previously discontinued coverage of an original reference product entirely in favor of a biosimilar version. Ex. B27, Amgen 2022 Rpt. at 78 (noting that none of the three PBMs cover biologic reference product RITUXAN®, and two out of the three no longer cover biologic reference product REMICADE®). Because of that, ABP 654's launch will also impact prescriber confidence in STELARA®'s broad insurance coverage. Confusion or concerns about whether STELARA® remains covered may drive practitioners to alternative products, leading to permanent loss of market share. And even if STELARA® is covered at all, it could appear on a disfavored tier relative to ABP 654, thus harming its sales.

This loss of market share would be irreparable. Even at a later damages trial, it will be difficult, if not impossible, to quantify the full extent of the harm Janssen will have suffered as a result of market share losses due to a premature Amgen launch. [redacted]

[redacted]); Jarosz Decl. ¶¶ 57-62, 70; Ex. B1 at 6; Ex. B10 at 24. The entrance of Amgen's illegal, infringing biosimilar will only add to that unpredictability. And the variability of that range is further compounded by the expected launch of HUMIRA® biosimilars for treatment of overlapping immunology diseases this year. Jarosz Decl. ¶¶ 58, 122-125. Although history provides strong evidence that biosimilars erode a branded product's market share, it does not provide clear guidance for quantifying that harm. For example, three years after its first biosimilar launch, AVASTIN retained only 18% of the market. Jarosz Decl. ¶ 59. By contrast, in three years, branded RITUXAN was able to retain 36% of the market. *Id.* ¶ 60.

Over time, Janssen's losses will only become harder to quantify. The sooner physicians start new patients on Amgen's biosimilar instead of STELARA®, the sooner biosimilar adoption begins and those losses amplify over time. Jarosz Decl. ¶¶ 73-75, 126-130. Patients who are switched from STELARA® (or who start on other biosimilars) may never return to STELARA®, even if Janssen ultimately prevails after trial. Smith Decl. ¶ 45. Finally, due to the possible cascading entry of other biosimilars, the percentage of market share loss attributable to Amgen will become increasingly harder to determine and thus to fully compensate. Jarosz Decl. ¶¶ 113-116, 122-125.

The Federal Circuit has recognized that losses of market share and revenue caused by entry into the market of an additional generic manufacturer can establish irreparable harm. In *Abbott Labs*, for example, the court affirmed a preliminary injunction blocking Sandoz from entering the market with a generic that likely infringed Abbott's patents. 544 F.3d at 1343-61. Sandoz argued

that any harm to Abbott was not irreparable because two other non-infringing generic producers had already entered the market. *Id.* at 1361. But the Federal Circuit disagreed, concluding that "the market share and revenue loss upon Sandoz' entry while the litigation proceeds" is irreparable because it "cannot be quantified or adequately compensated." *Id.* at 1362.

The district court reached the same conclusion in *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 609 F. Supp. 2d 786 (S.D. Ind. 2009). There, the court granted a preliminary injunction to prevent a competitor from bringing a generic copy of Lilly's branded drug onto the market. As that court explained, because "Lilly would no longer maintain marketing exclusivity," it would face a "rapid loss of market share and revenue that [would] be difficult, if not impossible for Lilly to recover, even if the Court were to later rule in favor of Lilly and [the competing] generic [] product was removed entirely from the market." *Id*. at 811 (footnote and citation omitted). Because it will likewise be nearly impossible to quantify the full extent of the damage from Janssen's loss of market share, the Court should likewise enter an injunction here.

B. STELARA® Would Suffer Irreversible Price Erosion Across All Indications

Amgen's infringing launch of ABP 654 would also inflict harm through the premature, long-term, and irreversible price erosion of STELARA®. Janssen's losses from an at-risk launch would be massive, extending beyond mere lost sales, would be considerable even over the short haul. Jarosz Decl. ¶¶ 131-141. Those losses would be impossible to fully remedy through monetary damages. *See CellzDirect*, 664 F.3d at 930 (citations omitted) (acknowledging price erosion as an irreparable harm); *see also Aria Diagnostics*, 726 F.3d at 1304 (same); *Pharmacia & Upjohn Co. v. Ranbaxy Pharms., Inc.*, 85 F. App'x 205, 214-15 (Fed. Cir. 2003) (same); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, No. 18-1043-LPS, 2019 WL 2588450, at *4 (D. Del. June 24, 2019) (same).

Amgen will almost certainly sell ABP 654 at a lower price than STELARA®. Amgen's own analysis concludes that "biosimilars typically launch at a discount to reference product [wholesale acquisition cost] and [average sales price]." Ex. B27, Amgen Biosimilars 2022 Trends Report at 12; Jarosz Decl. ¶ 57. Price would be the key factor Amgen could use to incentivize PBMs to add ABP 654 to their formularies because, as Amgen concedes, ABP 654 does not offer any differentiating characteristics in terms of performance or safety profile. *See* Am. Compl. Ex. F at 40; *see also id*. at 43 ("The totality of the analytical data demonstrates that ABP 654 is highly analytically similar to the reference product").

Notably, Amgen itself has previously launched four biosimilars (of other biologics, not STELARA®) into the U.S. market, in each case at a significant discount—ranging from 15% to 57%—off the wholesale acquisition cost of the reference biologic product. Ex. B27, Amgen Biosimilars 2022 Trends Report at 12, Fig. 4; *see also id.* at 6 ("The average sales price . . . is declining, due to competition, for both reference products and biosimilars. . . . The prices of most reference products have decreased at a negative [compound annual growth rate] of -4% to -21%."); Ex. B25, Cardinal Health Rpt. at 6 ("Biosimilars are expected to be priced 15% to 30% lower than their reference products."). Faced with Amgen's cut-price biosimilar, PBMs would immediately pressure Janssen to provide significant price concessions, reducing STELARA®'s net purchase price—the price net of rebates and discounts—to retain its position on formularies. Beyond that immediate price erosion, PBM's continued demands for price concessions would also contribute to an accelerated trajectory of price erosion as more biosimilars eventually come on the market.

Amgen has cited exactly this sort of price erosion when defending its own branded products against would-be biosimilar competitors. For example, Amgen previously argued that a competitor's premature entry into the market would force Amgen to slash the price of its branded

drug and raise serious "concerns about price erosion that courts recognize as irreparable harm." Ex. C4, Amgen PI Mot. at 21-22; *see also id*. at 23 ("The law recognizes this price erosion as irreparable harm."). The same is true here.

Such price erosion is often lasting and irreversible. Even if ABP 654 were later removed from the market, the harms from Amgen's infringing entry would persist, and Janssen would be unable to return to the original net purchase price of STELARA®. Jarosz Decl. ¶ 97; Smith Decl. ¶ 40. Any attempt to raise prices to pre-entry levels during that period would be met with considerable resistance, if not refusal, by payors. Jarosz Decl. ¶ 97; Smith Decl. ¶ 45. *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (affirming irreparable harm because requiring purchasers to pay higher prices after paying lower prices to infringers "is not a reliable business option"); *see also Purdue Pharma L.P. v. Boehringer Ingelhein GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001). As this Court has previously explained in a similar case involving generics, "After what might be as long as a year of generic competition by the time we get to trial and I get a post-trial opinion done, Novartis will not be able to raise the price back to where it is now, or to where it would have been at that post-trial date in the absence of defendants' at-risk infringement." *Novartis Pharms. Corp.*, 2019 WL 2588450, at *4.

Once again, Amgen has made this same exact point when defending its own branded products against biosimilars. *See* Ex. C4, Amgen PI Mot. at 22 ("The price erosion for [Amgen's pioneering products upon generic entry] would be permanent and irrevocable."). Here, it is extremely difficult—if not impossible—to quantify the specific harm Janssen will suffer as a result of price erosion due to Amgen's at-risk launch. Jarosz Decl. ¶¶ 54-62, 104-130.

C. Janssen Would Suffer Irreparable Disruption Of Its Contracts With PBMs And Related Loss Of Goodwill

Amgen's premature launch would also inflict irreparable harm by disrupting Janssen's contractual relationships with PBMs and more generally diminishing its goodwill among physicians, pharmacies, patients, and payors. As explained above, PBMs exact rebates from pharmaceutical manufacturers, using their ability to determine which drugs are listed on formularies as leverage. *Supra* at I.A. Janssen has invested considerable time and effort into its relationships with the major PBMs and [redacted]. Smith Decl. ¶ 29. [redacted]. *Id.* ¶¶ 35-36. [redacted] *Id.* They are virtually certain to do so here if and when ABP 654 hits the market and undermines Janssen's bargaining power. *Id.* And the result is almost certain not to be as favorable to Janssen [redacted].

Significantly, the impact of [redacted] will extend far beyond just STELARA®. As explained above, [redacted]. PBMs demand rebates, pitting drug manufacturers against each other, in return for listing drugs on their formularies. Smith Decl. ¶ 13. That is a necessary feature of the PBM system, in which PBMs expect Janssen

to provide rebates on its best-selling prescriptions to exact the highest rebates. *Id.* ¶ 32. Amgen's infringing launch will mean that Janssen will not be able to offer the rebates that PBMs expect and, in turn, [redacted]. *Id.* ¶ 30. The impact of this loss on Janssen's ability to secure favorable formulary placement for [redacted] will be all but impossible to quantify in terms of loss of market share, price erosion, and the public's reduced access to these groundbreaking treatment options. And even if it could somehow be quantified, it would be extraordinarily difficult for Janssen to obtain monetary damages associated with [redacted] *Id.* ¶ 42.

Moreover, [redacted] means that if Janssen ultimately wins this case on the merits, it would be extraordinarily difficult to [redacted]. In the year or more that it takes to resolve this case, ABP 654 will have significantly eroded the price of STELARA®. Smith Decl. ¶ 40. As a result, even if Janssen prevails, it will not be able to meet the PBM's demands for rebates as it can today based on STELARA®'s sales. Preserving the status quo through a preliminary injunction will avoid upending [redacted]. *See, e.g.*, *Fed. Trade Comm'n v. Qualcomm Inc.*, 935 F.3d 752, 756 (9th Cir. 2019) (granting a stay so as to avoid "require[ing] Qualcomm to enter new contractual relationships and renegotiate existing ones on a large scale," thus avoiding

"fundamental business changes" that could not "be easily undone should Qualcomm prevail on appeal").[4]

Finally, there is no dispute that the negative reputational impact caused by the unplanned loss of exclusivity and [redacted] will likewise be virtually impossible to quantify. That is especially so with respect to Janssen's patient relationships. If Janssen loses its formulary position, many insurers would no longer cover the cost of the drug, effectively forcing patients currently on STELARA® to immediately switch to another medication. Smith Decl. ¶ 45. Such a change will be especially disruptive for patients who currently take advantage of Janssen's co-pay support program. As a result, those patients may have to go through additional steps with insurance companies and physicians to obtain the necessary paperwork to switch their medication, which can lead to gaps or disruption in treatments. *Id.*

As Amgen itself acknowledged when defending its own patents, "there is no effective way to quantify the effect of [a generic's] entry into the market on Amgen's reputation—all the more reason to conclude the harm is irreparable." Ex. C4, Amgen PI Mot. 23. The same goes for Janssen here. For all these reasons, Janssen will suffer significant and irreparable harm from Amgen's early entry.

III. THE EQUITIES FAVOR A PRELIMINARY INJUNCTION

Finally, the two equitable factors—the balance of hardships and the public interest—strongly favor a preliminary injunction.

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[4] *See also, e.g.*, *Fields PAG, Inc. v. CDK Glob., LLC*, No. 16-CV-01876-MCA-MAH, 2016 WL 9185293, at *4 (D.N.J. June 10, 2016) (finding irreparable harm where release of confidential contract provisions could cause other customers to "dispute the pricing and provisions in their agreements, which could strain CDK's relationship with those customers, or cause CDK to have to renegotiate numerous agreements"); *Pharm. Care Mgmt. Ass'n v. Mulready*, No. CIV-19-977-J, 2020 WL 12787578, at *8 (W.D. Okla. July 9, 2020) (granting preliminary injunction where law would "require Plaintiff to restructure their pharmacy networks").

The harms to Janssen of denying a preliminary injunction greatly outweigh any possible harms to Amgen of granting one. STELARA® accounts for [redacted] of J&J's U.S. pharmaceutical sales and supports J&J's substantial continuing investment in R&D. If ABP 654 is allowed to come on the market—even briefly—it will irreparably shrink Janssen's market share, erode STELARA®'s net purchase price, delay or eliminate promising medical trials funded by STELARA®, and irretrievably damage Janssen's contractual relationships with payors. *Supra* at II. By contrast, the chief harm to Amgen would be preventing its ability to profit by selling an infringing product, at least until a full trial can be held. Courts have found minimal hardship to an alleged infringer who is either not on the market yet or is in the early stages of marketing its product.[5]

Amgen's at-risk launch will also harm the public interest. The overarching purpose of the patent system is to encourage and reward innovation in ways that promote the greater good. *See, e.g.*, *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999). Patents achieve that objective by granting inventors exclusive rights to reap the rewards of their ingenuity. As the Federal Circuit has explained "public policy favors the protection of the rights secured by . . . valid patents." *Smith Int'l, Inc. v. Hughes Tools Co*., 718 F.2d 1573, 1581 (Fed. Cir. 1983).[6]

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[5] *See, e.g.*, *Glaxo Grp. Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003) ("The district court did not clearly err in finding that, without the preliminary injunction, Glaxo would lose the value of its patent while Apotex would only lose the ability to go on to the market and begin earning profits earlier."); *Novartis Pharms. Corp.*, 2019 WL 2588450, at *6 ("Defendants stand to lose the opportunity to earn on the order of $50 million collectively by not being able to compete over approximately the next year whereas Novartis will irreparably lose a market in which they sell approximately $1.8 billion of drugs [each] year," a balance that "clearly favors Novartis under the circumstances."); *Impax Lab'ys, Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) ("The Court finds that granting the Motion for Preliminary Injunction will cause Impax only minimal hardship since doing so will leave Impax in the same position as it was in before the injunction was granted, i.e., excluded from the riluzole market.").

[6] *See also Edwards Lifesciences AG v. CoreValve, Inc.*, No. 08-91-GMS, 2014 WL 1493187, at *11 (D. Del. Apr. 15, 2014) ("[T]he court cannot downplay the strong public interest favoring

The public interest in enforcing patents is particularly acute in the pharmaceutical space, where new drugs can save lives and alleviate suffering. Developing new medical treatments depends largely on the expectation of patent protection, given the extensive costs of bringing a new drug to market and the substantial risks of failure along the way. Jarosz Decl. ¶ 159. Thus, "the public interest favors encouraging investment in drug development by protecting and enforcing ... valid pharmaceutical patent[s]." *Ortho McNeil Pharm., Inc. v. Barr Lab'ys, Inc.*, No. 03-4678 (SRC), 2009 WL 2182665, at *11 (D.N.J. July 22, 2009); *see Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383-84 (Fed. Cir. 2007) ("We have long acknowledged the importance of the patent system in encouraging innovation."). As Amgen itself explained, "there is a strong public interest in encouraging investment in drug development." Ex. C4, Amgen PI Motion at 23.

Patients will ultimately benefit from a preliminary injunction in this case. STELARA® already provides all the medical benefit that ABP 654 could offer—and Janssen stands willing and able to supply patients with all the STELARA® they need. Smith Decl. ¶¶ 55-56. Janssen also invests heavily in numerous support programs for patients using STELARA®, including a copay support program, benefit investigation services, programs for underinsured or uninsured patients, and a "Nurse Navigator" program that assists STELARA® patients with at-home injection procedures and questions about their treatment. *Id.* ¶¶ 57-59. As a result of Janssen's copay support system, some patients will likely pay ***lower*** out-of-pocket costs when treated with STELARA® than they would if treated Amgen's biosimilar product, even if that biosimilar product were sold at a lower retail price. *Id.* ¶ 60. On the flip side, if Amgen's early entry causes

enforcement of patent rights."); *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005) (affirming "preliminary injunction that enforces a valid patent against an infringer").

STELARA® to lose its formulary placement, patients who rely on Janssen's copay support system may be forced by their insurers to switch to ABP 654, thereby losing access to that important source of financial support. Such a forced switch would also be burdensome and disruptive in forcing patients to obtain additional necessary paperwork from insurance companies and physicians. That disruption would be magnified further if and when Janssen ultimately succeeds in obtaining a permanent injunction on the merits, at which point patients might have to switch back to STELARA®. *Id.* ¶ 45.

Finally, ABP 654 launch would impact Janssen's ability to fund research and development of new breakthrough treatments like STELARA®. The vast majority of pharmaceutical research in the United States is funded by existing sales. And STELARA® revenues are a substantial contributor to the R&D budget of Janssen's parent company, J&J, not least because STELARA® revenues are a substantial fraction of J&J's income overall. In 1Q-3Q 2022, U.S. STELARA® revenues were 57.9% of all U.S. J&J Immunology product revenues, 22.5% of J&J U.S. pharma products, and 13.2% of total U.S. revenues overall. (Globally, U.S. STELARA® revenues accounted for 37.2% of all J&J Immunology revenues worldwide, 12.1% of worldwide J&J pharma revenues, and 6.7% of J&J total worldwide revenues). *See* Ex. C1, J&J 3Q 2022 SEC Form 10-Q, p. 23-25. STELARA® is thus a major contributor to R&D. Smith Decl. ¶¶ 48-54. If Janssen is forced to prematurely lower the price of STELARA®, it will be forced to make corresponding cuts to its ongoing research. The public will suffer as a result.

In short, the public interest strongly favors preliminary injunctive relief here.

CONCLUSION

For the foregoing reasons, Janssen respectfully requests that the Court grant Janssen's motion to enjoin Amgen from launching its ABP 654 biosimilar product until this case is fully resolved on the merits.

CONFIDENTIAL

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Respectfully submitted,

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