No. 2020-1037

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IMMUNEX CORPORATION, AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Appellees,

HOFFMANN-LA ROCHE INC.,

Plaintiff,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants-Appellants.

Appeal from the U.S. District Court for the
District of New Jersey, Case No. 2:16-cv-1118

CORRECTED BRIEF FOR APPELLEES IMMUNEX CORPORATION AND AMGEN MANUFACTURING, LIMITED

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FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Immunex Corporation **v.** Sandoz Inc.

Case No. 20-1037

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☒ (appellee) ☐ (amicus) ☐ (name of party)

Counsel for Immunex Corporation and Amgen Manufacturing, Limited

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Immunex Corporation	None	Amgen Inc.
Amgen Manufacturing, Limited	None	Amgen Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

Sidley Austin LLP: Erik J. Carlson*, Richard M. Chen, Peter S. Choi, Sona De, Matthew S. Jorgenson*, Ryan C. Morris, Jill J. Schmidt*, M. Patricia Thayer*, Samuel N. Tiu, Sue Wang
Walsh Pizzi O'Reilly Falanga LLP: Christine I. Gannon, Marc D. Haefner, Colleen M. Maker, Eleonore Ofosu-Antwi, Liza M. Walsh

*Formerly of Sidley Austin LLP

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Immunex Corporation et al. v. Samsung Bioepis Co., Ltd., 2:19-cv-11755-CCC-MF (D.N.J.)

December 13, 2019
Date

/s/ Constantine L. Trela, Jr.
Signature of counsel

Please Note: All questions must be answered

Constantine L. Trela, Jr.
Printed name of counsel

cc: Counsel of Record

Reset Fields

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

STATEMENT OF RELATED CASES

This is an appeal from a final judgment entered in the U.S. District Court for the District of New Jersey, in which Defendants Sandoz Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, "Sandoz") were found to infringe two valid patents: U.S. Patent Nos. 8,063,182 ("the '182 patent") and 8,163,522 ("the '522 patent") (collectively, the "Roche patents"). No other appeal from the district court proceeding has previously been before this or any other appellate court.

The Roche patents have also been asserted in *Immunex Corp. v. Samsung Bioepis Co., Ltd.*, No. 19-cv-11755 (D.N.J.), currently pending in the U.S. District Court for the District of New Jersey.

INTRODUCTION

The district court held a ten-day trial and issued an 85-page opinion describing in detail why Sandoz's arguments challenging the validity of the Roche patents are wrong, both legally and factually. On appeal, Sandoz identifies no clear error in any of the court's findings, and Sandoz's numerous attempts to manufacture legal error fail.

The Roche patents describe and claim etanercept: a novel fusion protein that met a long-felt need for treatment of rheumatoid arthritis. Indeed, Sandoz itself has said that etanercept changed the practice of medicine. The Roche inventors were first to invent etanercept, but Immunex later developed and brought etanercept (tradename Enbrel®) to market. And when Immunex learned that Roche's pending patent applications covered etanercept, Immunex took a license and agreed to pay substantial royalties.

In this case, Sandoz admitted infringement of the Roche patents but asserted a variety of invalidity defenses, each soundly rejected by the district court. Rather than show any clear error in the court's thorough assessment of the facts, Sandoz reargues the evidence and the positions it advanced below—as if there had never been a trial.

On points of law, Sandoz presses legal theories contrary to the statute and precedent. Sandoz argues that the term of the Roche patents is "too long," but that term—17 years from issuance—is the result of a carefully-wrought legislative compromise in the Uruguay Round Agreements Act ("URAA"). Sandoz seeks to cut that statutory term short by radically expanding the doctrine of obviousness-type double patenting ("ODP") to encompass later-filed patents invented by different people, at different times, and at different companies, based on a license agreement executed long after the Roche inventions were made. No court has ever accepted such a theory, and Sandoz offers no basis for this Court to do so now.

ODP is grounded in §101 of the Patent Act, which provides that "[w]hoever invents or discovers" may be entitled to "*a* patent" for their invention. Consistent with the statutory text, ODP bars a single *inventor* from obtaining multiple patents for obvious variations on the same invention. Following congressional guidance, courts and the PTO also apply ODP to a single company that owned, at the time of invention, rights to multiple indistinct inventions, treating that company, for double-patenting purposes, *as though* it contributed to the

"invent[ing] or discover[ing]" of those inventions. Such common-ownership-based ODP closes a gap created by the prior-art safe harbor of 35 U.S.C. §103(c),[1] which likewise treats work commonly owned at the time of invention as if it were made by the same inventor. Common-ownership-based ODP is thus a narrow, gap-filling doctrine with roots in §101's text.

Sandoz's theory of ODP does not consider actual ownership or rights at the time of invention, nor is it rooted in §101. Instead, Sandoz invokes a test from the law of prudential standing—the "all-substantial-rights" test—to impute "common ownership" of the Roche patents to Immunex by virtue of an exclusive license (the 2004 Accord & Satisfaction ("A&S")) executed more than a decade after the Roche inventions. Adopting Sandoz's test would render otherwise-valid patents spontaneously invalid upon transfer or license to the "wrong" entity and would thus discourage later conveyance of patent rights to those companies best suited to bring the underlying technology to market. This Court should decline Sandoz's invitation to expand ODP law.

[1] All citations are to pre-AIA law, unless otherwise indicated.

Even under its preferred test, Sandoz's theory fails on multiple grounds. The parties agreed below that the "all-substantial-rights" inquiry is driven here by *factual* questions, and the district court resolved every relevant factual dispute in Immunex's favor. It found, for example, that the A&S did *not* transfer all substantial rights in the Roche patents to Immunex, that the parties intended to maintain a license relationship, and that Roche retained substantial rights and obligations consistent with that intent. Moreover, the court found that even if there were "common ownership," the various claims are patentably distinct from one another: the Roche patents claim the fusion protein and a method of making it, while the Immunex patents claim distinct methods of treatment.

The facts here show no "unjustified timewise extension" of patent rights, as Sandoz argues. To be sure, under the 17-year statutory term, the Roche patents would expire sooner had they issued sooner, but, as the court found, the prosecution of the Roche patents was marked by the PTO losing the files, years with no action from the examiner, and meritless rejections that were reversed on appeal. In view of these facts, Sandoz understandably abandoned its prosecution laches defense

before trial. Its attempt to repackage that defense as an ODP theory cannot be squared with the statute or precedent.

The district court also soundly rejected Sandoz's written-description arguments. The court properly found that the two components of the claimed fusion—the extracellular portion of the p75 TNF receptor ("p75") and a specific portion of an IgG1—were described in the patents and known and available in the art. The court also properly found that the specification provides a recipe for fusing these components and demonstrates possession of that fusion. Sandoz's rehashed §112 arguments cannot overcome these facts.

Nor can Sandoz overcome the court's careful analysis of non-obviousness. The record established, and the court entered extensive findings regarding, the state of the art, the reasons a skilled artisan would not have selected or combined the extracellular p75 with the hinge-CH2-CH3 of IgG1, and the unexpected properties that made etanercept such a dramatic success. Sandoz largely takes aim at "motivation to combine," arguing that the court paid too much attention to therapeutic motivations—but Sandoz fails to mention not only that its *own* invalidity case focused on the therapeutic applications it now

tries to dismiss, but also that the alternate motivations it now advances similarly fail on the facts. Sandoz also attempts to find error in the court's assessment of "nexus," but this, too, fails. It is undisputed that the Roche patents claim etanercept and a method of making it, so nexus is presumed, and Sandoz failed to overcome that presumption.

The court's careful, and correct, decision should be affirmed.

STATEMENT OF ISSUES

1. Whether the district court properly rejected Sandoz's ODP defense, which is based on patents claiming different inventions made by separate inventors at different companies and at different times.

2. Whether the district court clearly erred in finding that the Roche patents adequately described the claimed fusion proteins to a skilled artisan in 1990.

3. Whether the district court erred in its assessment of certain subsidiary inquiries relating to Sandoz's obviousness defense, including its findings that (a) a skilled artisan in August 1990 would not have been motivated to combine specific portions of p75 and IgG1 to create etanercept, and (b) the objective indicia supported nonobviousness.

STATEMENT OF THE CASE

I. The Inventions of the Patents-in-Suit

The compound at the center of this case is etanercept—a novel bio-engineered "fusion" protein. Etanercept is the active ingredient in Enbrel, a breakthrough therapy that, in Sandoz's words, "changed the practice of medicine." (Appx4699.)

Autoimmune diseases, such as rheumatoid arthritis, hijack the body's normal immune response. (Appx4256–4257.) They are often marked by an excess of a circulating immune system protein called "TNF." (Appx4112–4113.) The body, seeing its own tissues as foreign, increases TNF to combat a nonexistent threat. (*Id.*) When TNF binds to cell-bound "TNF receptors" on certain immune cells, an inflammatory response is initiated. (*Id.*; Appx4785–4786.) Etanercept treats certain such diseases, like rheumatoid arthritis, by binding and neutralizing TNF. (Appx4119–4120.)

A. Roche's Invention of Etanercept

Etanercept, a fusion protein, was invented in 1990. Fusion proteins are made using recombinant DNA techniques to provide cells with genetic instructions for specific parts of different proteins,

programming cells to make a hybrid that combines these parts into a new protein. (*See, e.g.*, Appx6; Appx5324–5326.)

Early research into fusion proteins focused on a very specific problem: the then-raging AIDS epidemic. (Appx34; Appx4227–4228; Appx5219–5221; Appx28024–28030; Appx26983–26985.) AIDS patients have weakened immune systems, and so scientists sought ways to enhance their immune responses. One idea researchers pursued was using portions of antibodies[2] to make fusion proteins to trigger an immune response against HIV-infected cells. (Appx4795; Appx5115; Appx5219–5221.)

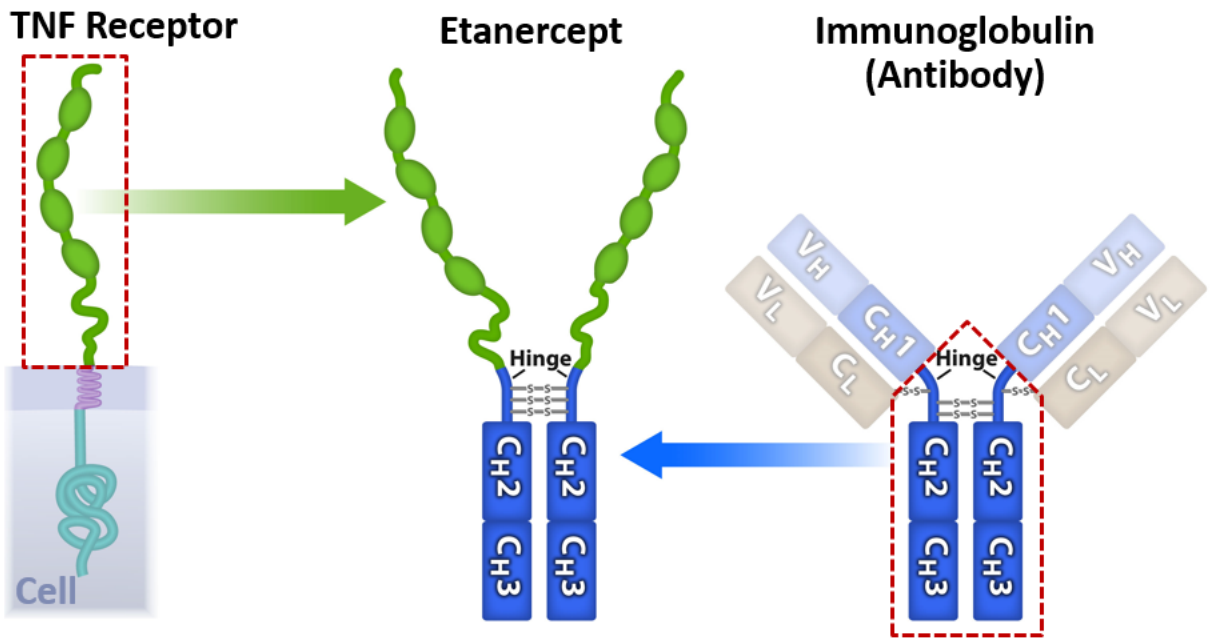
Around the same time, scientists at Roche were addressing a different problem: conditions linked to abnormally high levels of TNF. (Appx4785–4786, Appx4795; Appx28348–28350.) Whereas AIDS involves under-active immune systems, the Roche scientists focused on diseases involving over-active immune systems. The Roche scientists were thus looking for ways to *suppress* rather than *enhance* immune

[2] Antibodies are also known as immunoglobulins (or "Ig"s). There are various classes of human antibody, such as Ig**G**, and various subtypes, such as IgG**1** through IgG**4**. (Appx4283–4284; Appx4959–4960.)

system responses. (Appx4256–4257; Appx4795.) Their counterintuitive solution, a fusion protein that combined a portion of an antibody with a portion of a TNF receptor, is embodied in etanercept. (Appx5220–5221; Appx4795.)

Etanercept is a fusion made from parts of two different proteins, combined in a particular way: (1) the extracellular region of the 75 kilodalton, or "p75," TNF receptor[3] (shown in green below), and (2) all of the heavy chain constant region of an IgG1 antibody other than its first domain (CH1), *i.e.*, the antibody heavy chain's hinge, CH2, and CH3 domains (shown in blue below).

[3] The "extracellular" or "soluble" portion of the cell-bound p75 TNF receptor protrudes from the cell and can bind circulating TNF. (Appx4114–4115; Appx5087.)



(Appx7013 ("Etanercept" label added).) The TNF-receptor portion binds TNF, while the IgG1 portion gives the molecule its Y-shape, with two receptor portions on each molecule. (Appx643; Appx4119.)

The Roche scientists' choice to include the hinge-CH2-CH3 portion of an antibody carried risk. That portion is known as an "effector" region, because it *stimulates* the immune system's inflammatory response (referred to as the "effector function")—the opposite of what the Roche scientists wanted to accomplish. (*See generally* Appx5115–5121; Appx5404–5405.)

The Roche scientists' decision to include a portion of a TNF receptor was also counterintuitive. TNF was just one of many signaling proteins, or cytokines, known to be involved in initiating immune

responses. (Appx5201–5202; Appx28904; Appx28963.) And researchers were concerned that the use of TNF receptors might increase TNF activity and *aggravate* conditions caused by excess TNF. (Appx32; Appx5209–5213.) Researchers understood that cytokines were often redundant and that removing one (*e.g.*, TNF) just left others to provide the same pro-inflammatory functionality. (Appx33; Appx5203.)

Nevertheless, the counterintuitive combination was surprisingly effective. (*E.g.*, Appx5023–5027.)

B. The Roche Patents

1. The Asserted Claims

The asserted claims of the Roche patents—claims 11–12 and 35–36 of the '182 patent and claims 3, 8, and 10 of the '522 patent—are specifically directed to the fusion protein embodied in etanercept (those of the '182 patent claim the fusion protein, and those of the '522 patent claim methods of producing it). (Appx1.) The asserted claims all recite the specific combination of the extracellular region of p75 and the hinge-CH2-CH3 portion of IgG1. They further define the known p75 TNF receptor by reference to known sequences either identified in the specification or found in a publicly-deposited plasmid containing the full

p75 sequence that the Roche inventors had constructed before the priority date. (*See* Appx12717–12718; Appx12765–12766; Appx22–23.)

2. The Roche Patent Specification

The Roche patents claim priority to a U.S. patent application filed September 10, 1990, which described etanercept and other TNF receptor/antibody fusion proteins.[4] (Appx639–640; Appx642.)

Among other things, the Roche application describes the two known TNF receptors (p55 and p75), receptor/antibody fusion proteins based on each, DNA and amino acid sequences useful to make the fusions, and methods of making the fusions. (*See generally* Appx25081–25133.) For example, the application explains that the invention includes "a combination of two partial DNA sequences, with one . . . coding for those soluble fragments of non-soluble proteins which bind TNF," *i.e.*, p55 or p75, and the other "coding for all domains other than the first domain of the constant region of the heavy chain of . . . in particular IgG1 or IgG3." (Appx25091.)

[4] This application itself claimed priority to a European patent application filed on August 31, 1990. (Appx640.)

The specification includes detailed descriptions of both the p55 and p75 receptor. (*E.g.*, Appx25090.) Indeed, the specification describes the known p75 receptor in several different ways, including by referring to its known molecular weight ("75 kD") and by providing several sequences found *only* in the known p75 receptor, such as sequences later labeled SEQ ID NO:7 and SEQ ID NO:10. (Appx14; *see also* Appx4966, Appx4970–4971, Appx4976–4977.) The specification also cites a seminal paper by a competing team of scientists from Immunex (Smith 1990) published earlier that year, which disclosed the entire sequence of p75 and reported that the sequence had been deposited at GenBank, a public repository into which researchers in 1990 could deposit, and from which they could receive, known nucleotide and amino acid sequences. (Appx14–15; Appx25090 (citing "Science 248, 1019–1023, (1990)"); Appx4332–4334; Appx26980.)

In addition to the receptor-related disclosures, the specification describes the antibody portion of the fusion proteins, including the hinge-CH2-CH3 portion of the known IgG1. (Appx19–20.) Not only does the specification refer directly to "all domains other than the first domain of the constant region of the heavy chain" of "IgG_1," it also

refers to publicly accessible genetic materials (a deposited vector referred to as "pCD4-Hγ1") that contain a DNA sequence that encodes the hinge-CH2-CH3 portion of IgG1. (Appx25091; Appx25097.)

The specification then provides a "recipe" to make the disclosed fusion proteins, including etanercept. (Appx20; Appx4844–4945.) Specifically, Example 11 teaches the illustrative assembly of one of four preferred fusion constructs, combining the full extracellular p55 with the hinge-CH2-CH3 portion of IgG3. (*See id.*) The specification teaches skilled artisans that the same method can be used to make fusions that combine the extracellular p55 with IgG1, the extracellular p75 with IgG3, and the extracellular p75 with IgG1 (etanercept). (Appx4826–4829; Appx4615–4616.)

The inventions disclosed in the Roche application arose out of Roche's early work to identify and characterize both TNF receptors: the inventors worked on p55 and p75 in parallel and made foundational contributions to the knowledge of each. (Appx4790; Appx4796–4798; Appx4801–4802; *see generally* Appx26957–26965; Appx26966–26970.) Indeed, the names given to the two receptors—p55 and p75—come from a Roche publication in which the inventors were the first to confirm

that there were two distinct receptors, one with a molecular weight of about 55 kilodaltons and the other with a weight of about 75 kilodaltons. (Appx4790, Appx4796–4798; Appx26966.) The Roche inventors also published the complete amino acid sequences of both p55 and p75. (Appx4801–4803.)

Consistent with its developmental work, Roche sought claims relating to p75 TNF receptor fusions in the United States and abroad, well before Immunex had any role in prosecution of the Roche patents. (Appx28327; Appx28339–28340; Appx5746–5748.) For example, the original U.S. application in 1990 presented claims to p55 and p75 TNF receptors, as well as claims to DNA and fusion proteins that combined relevant portions of a TNF-binding protein and an antibody. (*See, e.g.*, Appx25127–25132 (claims 3, 5, 19, and 23).) And a 2003 Roche European patent contained claims relating to a fusion protein where one part included a portion of a "TNF-binding protein having apparent molecular weight of 75kD/65 kD" and the other contained "all domains except the first domain of the constant region of the heavy chain" IgG. (Appx32286, Appx32304.) Other patents in the family cover other distinct inventions disclosed in the original application, such as p55

fusion proteins (Appx66–67; Appx24474, Appx24493), and the DNA sequence of the variant Figure 4 p75 TNF receptor fragment (Appx30905, Appx30923).

II. Immunex's License to the Roche Inventions

Though Immunex had also been researching TNF receptors and considering possible fusion proteins, Immunex did not come up with etanercept until several months after the Roche patents' August 31, 1990 priority date. (Appx28266.) Thereafter, Immunex pursued clinical development, ultimately obtaining FDA approval of Enbrel in 1998. (Appx644; Appx5427–5429; Appx27160–27171.)

Around that time, Immunex learned of Roche's applications relating to etanercept. (Appx28347–28348.) Immunex licensed Roche's applications, effective back to Enbrel's approval date. (Appx25865–25910; Appx5726–5728.) Under that license, Immunex was required to pay Roche a running royalty of up to 5%. (Appx5727.) Immunex sought and obtained the license because it expected that Roche would obtain U.S. patents covering etanercept. (Appx5758–5759.)

Enbrel was an immediate success, meeting a long-felt need for a safe and effective therapy for rheumatoid arthritis. (Appx5427–5429;

Appx5441; Appx5448–5449.) Existing therapies typically treated only symptoms, and the most common therapy (methotrexate) provided reasonable disease control to only about 30 percent of patients, many of whom could not tolerate it for extended periods. (Appx5426–5429.) But Enbrel halted or slowed the progression of the disease and was effective in approximately 70 percent of Enbrel-treated patients. (Appx5441; Appx5428–5429; Appx5435–5437; Appx5450–5451.) Enbrel so revolutionized the treatment of rheumatoid arthritis that, in the early years, Immunex could not keep up with demand. (Appx5443; Appx5446–5448; Appx5452–5453.)

Amgen Inc. acquired Immunex in 2002. (Appx5725.) At that time, Enbrel was heavily burdened by ongoing royalty obligations, including the original Roche license, under which Immunex had paid tens of millions of dollars. (Appx5728–5729.) Shortly after the acquisition, Amgen sought to reduce Enbrel's royalty burden by "buy[ing] out" future royalties to Roche. (Appx5729.) Those efforts resulted in the 2004 Accord & Satisfaction—so called because it satisfied all royalty obligations between the parties under the original license agreement. (Appx5728; *see also* Appx25836–25864.)

Under the A&S, Roche was paid $82.5 million to buy out future royalty obligations for the Roche patents in North America.[5] (Appx5731.) Immunex[6] also obtained a broader license than it had under the earlier agreement. Whereas the earlier license was "co-exclusive"—both Roche and Immunex could practice the Roche patents commercially (Appx5727)—the A&S granted Immunex an "exclusive license," the right to direct prosecution of the patent applications, and control of any Immunex-initiated litigation. (Appx25839–25841.) Roche would have been willing to assign the North American patents to Immunex outright, but Immunex wanted Roche to remain the owner so that (1) Roche would have an affirmative duty of candor to the PTO, and (2) Roche would have an obligation to participate—and provide discovery—in any future litigation as a party. (Appx5733–5735.) Immunex worried that Amgen and Roche might soon be adverse in

[5] Sandoz suggests the payment was only $45 million (Br. 16), but that omits Wyeth's contribution, which was based on a co-promotion and profit-sharing relationship between Immunex and Wyeth in the United States. (Appx5731.)

[6] For simplicity, this brief treats Immunex as the relevant licensee because all rights granted to Amgen and its affiliates were ultimately consolidated in Immunex. (*See* Appx69 n.36.)

litigation relating to other products (as they had been in the past) and did not want to rely on a mere contractual promise to cooperate, given how litigation might affect the parties' relationship. (*Id.*)

The A&S reflects this intent to maintain a license relationship:

- Roche was required to "prosecute and maintain" the patents (at Immunex's direction and control) and participate in litigation. (Appx25840–25841.)
- Roche retained a right, in "its sole discretion and under its sole control," to sue an alleged infringer if Immunex declined to sue within 180 days of a Roche request to sue. In any such suit, Roche would "retain the entirety of any award of damages." (Appx25841.)
- Roche "reserve[d] for itself and its Affiliates the right to practice" the patents "for internal, non-clinical research." (Appx25839.)
- Immunex had the option to obtain an assignment, but doing so required "the payment by Amgen of additional consideration" of $50,000. (Appx25840.)
- Immunex could not assign any interest under the agreement without Roche's consent. (Appx25849.)
- The Immunex license was treated as a "license[] of rights to 'intellectual property'" for "purposes of Section 365(n) of the U.S. Bankruptcy Code" (Appx25848), which protects Immunex's rights in the event of a Roche bankruptcy. *See* 11 U.S.C. §365(n).

Roche's patents outside North America were handled differently. Wyeth, which had rights to Enbrel outside North America, did not

share Immunex's interest in Roche's ongoing participation in prosecution and litigation. (Appx5735–5736.) Wyeth thus took an outright assignment to the Roche patents outside North America. (Appx25838.)

After the A&S was executed, Immunex directed prosecution of the Roche applications, pursuing a successful appeal in the prosecution of the '182 patent and then citing that appeal in the '522 patent's prosecution. (Appx9–10; Appx28783–28792; Appx24028.) In addition to the unjustified rejections that delayed issuance by requiring an appeal, the examiner failed to advance prosecution of the '522 patent for several years—notwithstanding six status inquiries—and actually lost the file for the '182 patent "for a couple of years." (Appx5584–5585; Appx19430–19431.) Moreover, a Director in the relevant technology center acknowledged in the '522 patent's prosecution that a prior decision had "mistakenly contained papers from an unrelated application," and he expressed "regret[]" for any "delay." (Appx23315.) The Director's letter noted that the examiner had issued "only one substantive office action" over "the last five years," and that "the Examiner" was directed to "expedite . . . prosecution to conclusion."

(Appx23316.) Ultimately, the '182 patent issued in November 2011 (Appx12686), and the '522 patent issued in April 2012 (Appx12721).

III. Sandoz's Purported Double-Patenting References

Sandoz's ODP theory on appeal focuses on patents owned by Immunex, which claim inventions made by separate inventors working independently from the Roche inventors—at an unrelated company and at different times.

A. Jacobs

U.S. Patent No. 5,605,690 to Jacobs issued in February 1997 from an application that claims priority ultimately to an application filed in 1989.[7] (Appx27295.) The Jacobs patent does not claim either the etanercept protein or a method of making it.

While the Jacobs specification includes references to etanercept and a "TNFR:Fc fusion" (*see* Br. 44–45 (citing such references)), Sandoz ignores that those were new material added by a 1992 continuation-in-part application. (Appx5804.) During Jacobs's prosecution, Immunex

[7] U.S. Patent No. 5,395,760 to Smith, which issued from an application in the same family (but was filed before additional disclosures were added in 1992 (*see* Appx27295)), was among Sandoz's primary obviousness references below. (Appx29.) The court found that it neither disclosed etanercept nor rendered it obvious. (Appx41–45.)

attempted to obtain claims to etanercept (*e.g.*, Appx10015–10016 (claim 6)), but the examiner rejected the proposed claims because the original specification did not support them. (Appx5804; *see also* Appx10387, Appx10440, Appx10285–10287.) Immunex never obtained the claims it sought covering "TNFR . . . fused to the Fc region of a human immunoglobulin molecule." (Appx10016; *see also* Appx10297 (pointing, after amendment, to original "chimeric antibody" disclosure).)

Jacobs ultimately issued with six claims to methods of lowering levels of TNF-α by administering certain TNF antagonists (including a TNF receptor). (Appx27320–27321.) Two of the claims—2 and 5—recite the administration of a TNF receptor comprising a portion of the p75 receptor amino acid sequence. (Appx5748–5749.) Because Enbrel is an FDA-approved TNF blocker and includes that p75 sequence, the Enbrel product was marked with the Jacobs patent. (*Id.*; Appx27141.)

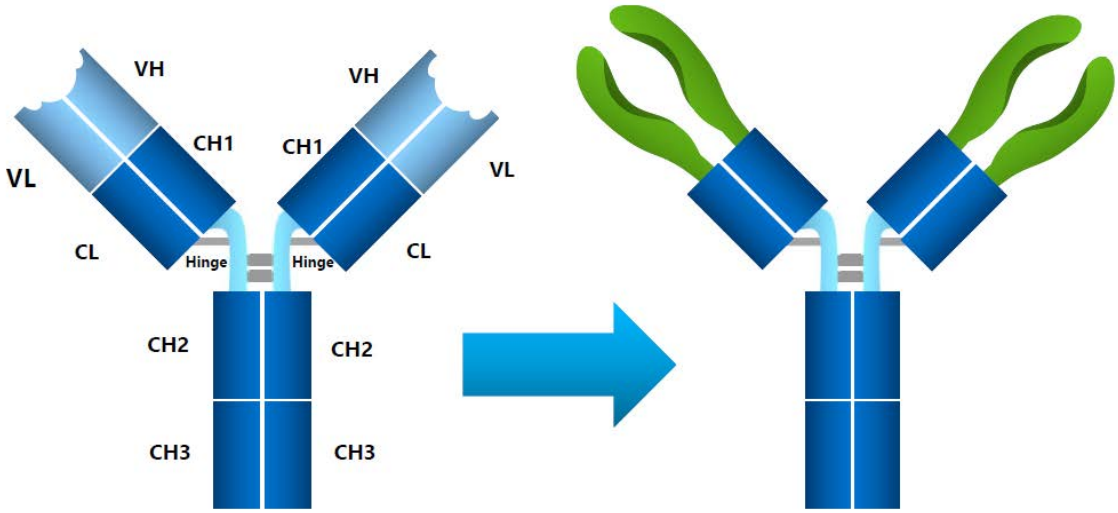
Sandoz's ODP challenge is not based on claims 2 and 5, but rather on claim 3, which recites:

> A method for lowering the levels of active TNF-α in a mammal in need thereof which comprises administering to said mammal a TNF-lowering amount of a *chimeric antibody* comprising the sequence of amino acids 3–163 of SEQ ID NO:1 fused to *the constant domain* of an immunoglobulin molecule.

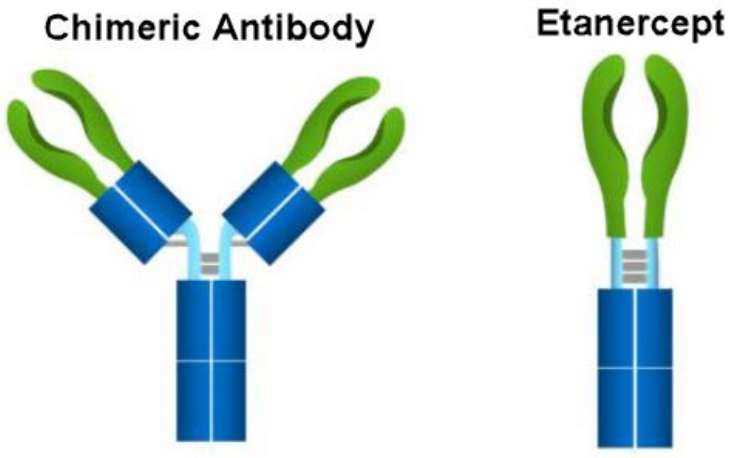
(Appx27320 (emphasis added).)

The only mention of a "chimeric antibody" in the Jacobs specification teaches that a "chimeric antibody" can "be produced having TNF-R sequences *substituted for the variable domains* of either or both of the immunoglobulin molecule heavy and light chains and having *unmodified constant region domains*." (Appx27307(7:42–46) (emphasis added).) In other words, unlike etanercept, the antibody portion of the claimed "chimeric antibody" was not limited to the hinge-CH2-CH3 portion of IgG1, but includes the entire constant region, both light and heavy chains, intact and unmodified. (Appx5272–5273.) Additionally, the Jacobs chimeric antibody replaces one or both of the variable domains with a TNF receptor:

Example: Chimeric Antibody with TNF-R Replacing Variable Domains



(Appx7036; *see also* Appx7036; Appx5271–5273; Appx76–77.) The chimeric antibody construct is different from etanercept, as shown in the side-by-side comparison below:



(Appx60089 (labels amended).) Thus, as Sandoz's technical expert acknowledged, the "constant domain" referenced in claim 3 of Jacobs "would include CH1, the hinge, CH2, [and] CH3," whereas in etanercept, as claimed in claim 11 of the '182 patent, the constant domain is modified to *exclude* CH1 as well as the light chain. (Appx4393–4394; Appx4396; *see also* Appx75–77.)

B. Finck

Sandoz also advanced an ODP theory based on three Immunex-owned patents invented by Finck, but on appeal Sandoz has dropped all but one: Finck's U.S. Patent No. 7,915,225. (*See* Br. 37–42.) That patent issued in March 2011 from an application filed in 2009, claiming

priority to an application filed August 13, 1999, almost a decade after the Roche inventions and years before the A&S. (Appx27246.) The '225 patent relates to methods of treating psoriasis and psoriatic arthritis using etanercept. (Appx60.) The '225 patent does not claim either the etanercept protein or a method of making it.

Claim 1 of the '225 patent reads as follows:

> A method for treating a patient having psoriasis comprising administering to the patient a therapeutically effective dose of TNFR:Fc, wherein the patient attains at least fifty percent improvement in PASI score.

(Appx27261.) "TNFR:Fc" refers here to etanercept. (Appx27252(4:46–47).) Thus, this claim covers using etanercept to treat psoriasis, with a specific clinical outcome ("fifty percent improvement in PASI score").

IV. Proceedings Below

Immunex and Roche filed this case in February 2016,[8] asserting that Sandoz's application seeking FDA approval to market an Enbrel biosimilar infringed the Roche claims under 35 U.S.C. §271(e)(2)(C), and that any launch of that biosimilar would infringe the Roche patents under §271(a) and (g). (Appx148–149.) Sandoz asserted a host of

[8] "Immunex" refers to Immunex Corporation and Amgen Manufacturing, Limited, and "Roche" refers to Hoffmann-La Roche Inc.

defenses, including non-infringement, prosecution laches, indefiniteness, subject-matter eligibility, and anticipation (Appx493), but by trial, Sandoz stipulated to infringement and abandoned all defenses except obviousness, ODP, and lack of written description/enablement. (Appx631–633; Appx637.)

The district court held a ten-day bench trial. It heard testimony from 28 witnesses—13 live and 15 by deposition—and admitted tens of thousands of pages of exhibits. After receiving post-trial briefs and proposed findings (including 262 from Sandoz), it heard closing arguments. The court issued a detailed, 85-page opinion rejecting each of Sandoz's defenses and finding that the Roche patents are not invalid, based on its "observations and credibility determinations of the witnesses who testified, and a thorough review of all the evidence admitted at trial." (Appx2.)

Relevant here, the district court rejected Sandoz's ODP defense on several independent grounds. First, as a threshold matter, the court questioned whether Sandoz's proposed test for common ownership—derived from "prudential standing" cases—could be applied (as no court

had done before) to "render a patent invalid pursuant to the obviousness-type double patenting doctrine." (Appx70 n.37.)

Even assuming the prudential-standing test applied, the court found that the A&S did *not* transfer "all substantial rights" in the Roche patents to Immunex. (Appx70.) Among other things, the court found that the parties "specifically intended" that Roche remain the owner, and that Roche retained substantial rights, including a "second right to sue for infringement." (Appx70–71.) That right was substantial because, among other reasons, Immunex had no power to moot a Roche-initiated suit by granting a sublicense: any such suit would be "solely within the control of Roche," and Immunex would have "a duty to cooperate." (Appx72.) Because Sandoz could not establish common ownership, its ODP defense failed. (Appx73.)

But even assuming common ownership, the court determined that Sandoz failed to prove that the Roche patents, on the one hand, and *any* of the Immunex-owned reference patents, on the other hand, claimed obvious variations of the same invention, as required for ODP. (*See generally* Appx74–84.)

As to Jacobs, the court concluded that claim 3 "requires the use of the CH1 domain and the light chain of the IgG1, while the Patents-in-Suit specifically require removal of both of these items." (Appx76.) And the court further found that it would not have been obvious to modify the chimeric antibody of claim 3 to arrive at etanercept. (Appx77.)

As to Finck, the court rejected Sandoz's ODP challenge on two independent grounds. First, the claimed inventions were patentably distinct under the two-way test for distinctness, which applied because the PTO was "solely responsible" for delays in prosecution, while "Plaintiffs acted in good faith to diligently prosecute the Patents-in-Suit." (Appx80–81; *see also* Appx83–84.) Second, because "an act of Congress"—namely, the URAA, Pub. L. No. 103-465, 108 Stat. 4809 (1994)—"rather than improper gamesmanship by the patentee or strategic abuse of the patent system" led to the Roche patents' longer term, the court held "that the statutory term for the Patents-in-Suit may not be cut short to mirror the statutory term for the Finck Patents." (Appx82–83 (internal quotations omitted).)

The court also found that Sandoz failed to prove its written-description defense. (Appx12–13.) The court found that the

specification disclosed the components of the claimed fusion protein and the fusion itself, "provid[ing] a recipe to fuse" the receptor portion to the antibody portion. (Appx20; *see also* Appx15–22.)

Finally, the court rejected Sandoz's obviousness defense, explaining—in 30+ pages of detailed and mostly unchallenged findings—why Sandoz did not meet its clear and convincing burden. (Appx28–59.) The court found that a skilled artisan would not have selected the hinge-CH2-CH3 portion of an IgG1 or the extracellular portion of the p75 TNF receptor, much less have been motivated to combine them. (*See generally* Appx28–46.) The court also found that objective indicia (unexpected results, praise and clinical success, long-felt need and failure of others, and licensing) supported nonobviousness, and that near-simultaneous invention, put forth by Sandoz, failed to support obviousness. (Appx46–58.)

Based on its findings and a stipulation regarding injunctive relief, the court entered final judgment and a permanent injunction. (Appx86–94.)

SUMMARY OF ARGUMENT

1. The centerpiece of Sandoz's appeal is an unprecedented theory of ODP that fails on several independent grounds.

First, common-ownership-based ODP arises only when the relevant inventions were *entirely owned* by the same entity *at the time of the invention*. This test—applied by the PTO—is squarely supported by the relevant statutory text, history, and purposes of double patenting. The test also follows Congress's direction to close a narrow statutory gap created by the prior-art safe harbor of §103(c). Because that provision treats certain work commonly owned at the time of invention as if it were made by the same inventor for prior-art purposes, applying double patenting ensures that the PTO does not issue two independent patents covering essentially the same invention when a prior-art rejection becomes unavailable because of the safe harbor. Either element of the applicable test—"entirely owned" or "time of invention"—disposes of Sandoz's double-patenting theory at the threshold.

Sandoz asks this Court to import the "all-substantial-rights" test from prudential standing into ODP. No court has ever done so. The

test has nothing to do with patent validity and adopting it would lead to perverse consequences—such as a patent that was unquestionably valid when issued becoming invalid years later because it was transferred or licensed to the "wrong" entity. Even under Sandoz's test, however, the court's extensive factual findings confirm that the 2004 A&S was not intended to transfer, and did not transfer, all substantial rights from Roche to Immunex.

And even if there were "common ownership" sufficient to trigger ODP, Sandoz's challenge based on the Finck '225 patent, which claims methods of treating psoriasis, would fail for three additional, independent reasons:

- The court correctly concluded that the post-URAA Finck patents cannot cut short the statutory term of the pre-URAA Roche patents;
- The two-way test for patentable distinctness applies, and Sandoz does not even suggest that it satisfied that test; and
- The claims are patentably distinct even under the one-way test.

Finally, Sandoz's challenge based on claim 3 of Jacobs fails, again even assuming that patent were a proper reference. The court correctly understood claim 3 to cover a different protein than etanercept, and

Sandoz does not even try to establish obviousness under the court's construction.

2. Sandoz's written-description appeal is largely an attempt at a do-over. Written description is a question of fact reviewed for clear error. The district court heard extensive testimony regarding how a person of ordinary skill would have understood the disclosure of the Roche patents, and ultimately credited Immunex's witnesses over Sandoz's. As the court found, the original Roche specification describes the known p75 TNF receptor and says that it is "especially" preferred. This finding was supported by a number of facts, including the reference in the patents to the common name of the p75 receptor; disclosure of several partial amino acid sequences that are found in and unambiguously identify the known p75 receptor; and a citation to the seminal Smith article that first published the full sequence of the p75 receptor. The court also found that the specification describes the fusion of that receptor and the hinge-CH2-CH3 region of an IgG1 antibody, providing a recipe that an artisan can follow to make etanercept. There is no clear error in the court's decision rejecting Sandoz's alternate version of the facts.

3. Sandoz ends with a brief discussion of subsidiary factual questions relating to obviousness, including motivation to combine and the weight of the objective evidence of nonobviousness. Again, there is no clear error in the district court's fact-finding, and Sandoz's attempt to locate legal error where none exists fails.

STANDARD OF REVIEW

Double Patenting. — This Court considers the ultimate conclusion on double patenting "without deference" but reviews "predicate findings of fact for clear error." *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012).

Written Description. — Because written description is "a question of fact," this Court reviews the district court's determination "[f]ollowing a bench trial . . . for clear error." *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1166 (Fed. Cir. 2012).

Obviousness. — Obviousness is ultimately a question of law reviewed *de novo*, but "[f]actual determinations underlying the obviousness issue are reviewed for clear error." *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 993 (Fed. Cir. 2009).

ARGUMENT

I. The District Court Properly Rejected Sandoz's Unprecedented Double-Patenting Defense.

Sandoz's ODP defense is unlike any accepted by this Court or any other—ever. Adopting it would upend settled understandings of ODP, in conflict with not only 35 U.S.C. §101 but also the history and limited purpose of the doctrine. Under Sandoz's proposed expansion of the concept of "common ownership" for ODP, a patent otherwise valid in the hands of its original owner at the time of invention could be spontaneously rendered invalid upon its later license or transfer to another entity that had no ownership interest in the patent at the time of invention.

The district court's sound rejection of Sandoz's unprecedented defense cannot be disturbed unless Sandoz prevails on every one of the following threshold questions:

- Whether the all-substantial-rights test from prudential standing law governs "common ownership" for double patenting;
- Whether inventions patentable upon their invention can be rendered invalid by a license executed more than a decade later; and
- Whether the district court clearly erred in finding—even on Sandoz's test—that the parties neither intended to transfer,

nor in fact transferred, "all substantial rights" to the Roche patents.

Even if Sandoz could prevail on each of these threshold questions, it would face additional, independent hurdles that it cannot clear for each reference.

A. Patents Are "Commonly Owned" for Double-Patenting Purposes Only If They Are Entirely Owned by the Same Entity at the Time of Invention.

ODP is grounded in §101, which provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain *a* patent"—one patent—"therefor." 35 U.S.C. §101 (emphasis added); *see also AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1372 (Fed. Cir. 2014) (ODP, while "often described" as "court-created," is "grounded in the text of the Patent Act"). Section 101's text refers only to those who "invent[] or discover[]," not patent *owners*, and indeed double patenting is often described as a limitation on inventors. *See, e.g.*, *AbbVie*, 764 F.3d at 1373.

To be sure, "commonly-owned applications by different inventors" have sometimes been "treated . . . as though they were filed by the same

inventor" for double-patenting purposes. *In re Longi*, 759 F.2d 887, 893 (Fed. Cir. 1985). Not everyone can be "treated" as an inventor, however, lest the doctrine lose its statutory mooring. Common-ownership-based ODP rejections exist to fill a narrow statutory gap, and the proper test for "common ownership" is commensurate with the gap the doctrine is designed to fill. That test, which has been adopted in the PTO's *Manual of Patent Examining Procedure* ("MPEP"), requires that the patents or applications be *entirely* owned by the same entity at the time of invention. *See* MPEP §804.03(II).

The applicable test for common-ownership-based ODP has a clear history. By the 1960s, the PTO had come to recognize that common-ownership-based double patenting rejections were unnecessary: examiners could avoid issuing multiple patents to a common owner simply by rejecting the later claims for anticipation or obviousness. *See Commissioner's Notice on Double Patenting*, 834 O.G. 1615, 1616 (Jan. 9, 1967) ("*Commissioner's Notice*") ("In situations involving cases filed by different inventive entities, regardless of ownership, Sections 102 and 103 of 35 U.S.C. preclude the granting of two or more patents [on the same invention, or obvious variations thereof]."). In his 1967

Notice, the Commissioner thus directed examiners not to issue double-patenting rejections absent identical sets of inventors. *See id.* at 1615 ("'double patenting' . . . should not be applied to situations involving commonly owned cases of different inventive entities"); *see also In re Fout*, 675 F.2d 297, 300 n.2 (C.C.P.A. 1982) ("if the inventors are different, no [double patenting] rejection can be made").

A statutory gap opened with the passage of the Patent Law Amendments Act of 1984, Pub. L. No. 98-622, §104, 98 Stat. 3383 *et seq.* (Nov. 8, 1984) ("1984 Act"). That statute prohibited the use of "[s]ubject matter developed by another person" as "prior art" under §102(f) or (g) "where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." 98 Stat. 3383 (codified in 35 U.S.C. §103(c)). Where this prior-art safe harbor applied, the PTO could no longer rely on §§102 and 103 to avoid issuing multiple patents on the same invention. The Act's legislative history reflects an expectation that double patenting would fill this gap: "The Committee expects that the Patent and Trademark Office will reinstitute in appropriate circumstances the practice of rejecting claims in commonly

owned applications of different inventive entities on the ground of double patenting." 130 Cong. Rec. H10525 (daily ed. October 1, 1984).[9] Indeed, this Court cited this very legislative history in *Longi* when it rejected the argument that the *Commissioner's Notice* altogether foreclosed the application of common-ownership-based ODP. 759 F.2d at 895.

The MPEP's test for "common ownership" in double patenting is narrowly tailored to close the gap created by the 1984 Act. The MPEP defines "common ownership" to require that applications or patents be "*entirely* owned by the same person(s) . . . *at the time the claimed invention was filed or made*." MPEP §804.03(II) (emphasis added); *see also Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1216 (Fed.

[9] Congress has, by statute, directed the PTO to follow similar legislative history for subsequent amendments to §103(c). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, §3(b)(2), 125 Stat. 284, 287 (2011) (uncodified) (directing PTO to administer safe harbor "consistent with the legislative history of the CREATE Act"); H.R. Rep. 108-425, at 5–6 (2004) (report on CREATE Act, noting that §103(c) creates prior-art safe harbor for "'common owner' inventors," subject to "the same double patenting principles that apply when inventions are made by a single inventor").

Cir. 2014) (looking to "PTO's guidance" in MPEP §804).[10] And the MPEP cross-references the substantively identical common-ownership test for the §103(c) safe harbor. *See* MPEP §706.02(*l*)(2); *see also Novartis Pharms. Corp. v. Noven Pharms., Inc.*, 125 F. Supp. 3d 474, 487 (D. Del. 2015) (applying MPEP test); *Ex parte Brookhart*, No. 2005-2463, 2005 Pat. App. Lexis 2485, *4 (B.P.A.I. Sept. 19, 2005) (same). Indeed, the MPEP's test is the very test Congress expected courts to apply when it enacted the 1984 Act. *See* S. Rep. No. 98-663, at 8 ("The term 'commonly owned' means wholly owned by the same person, persons, or organization at the time the invention was made.").[11]

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[10] Although Immunex invoked this test below (Appx60263–60264), Sandoz asserts that Immunex urged the district court to apply state law. (Br. 28–30.) Not so. Immunex referred to state law to rebut Sandoz's contention that the "all-substantial-rights" test was the *only* test for ownership. This Court generally looks to state law for patent ownership questions. (*See* Appx60265 (citing *Jim Arnold Corp. v. Hydrotech Sys., Inc.*, 109 F.3d 1567, 1572 (Fed. Cir. 1997)).)

[11] Below, Sandoz pointed to ¶ 8.28 in MPEP §804.03, which directs examiners to include both a prior art rejection *and* a double-patenting rejection when the examiner is unsure which one applies. (*See* Appx4031–4032.) But this form paragraph is designed to elicit information; it is followed by a paragraph advising the applicant to "resolve this issue" by "show[ing] that the patentably indistinct inventions were commonly owned at the time the claimed invention in this application was made or nam[ing] the prior inventor of the subject matter at issue." ¶ 8.28.01.fti.

Without "common ownership" sufficient to trigger the §103(c) prior-art safe harbor, there is no gap for common-ownership-based double patenting to fill.

The MPEP's test also fits the statutory text. Because double patenting is "grounded" in §101, *AbbVie*, 764 F.3d at 1372, which refers only to those who "invent[] or discover[]," the interpretive question is this: when can patents be treated "as though they were filed by the same *inventor*"? *Longi*, 759 F.2d at 893 (emphasis added). The MPEP test interprets the person who "invents or discovers" to include the entity that owned the product of the inventor's work when it was invented—often the inventor's employer, or some other entity directing and funding the inventive activity. This parallels §103(c), which treats work commonly owned at the time of invention *as if* it were made by a common inventor for prior-art purposes.

Sandoz searches for "textual links" to support its unprecedented double-patenting theory (Br. 27), but it looks at the wrong text. Although Sandoz acknowledges that double patenting is "grounded" in §101 (Br. 25), it nonetheless points to §281—which gives the "patentee" standing to sue—and §100(d)—which defines "patentee" to include

"successors in title." (Br. 27–28; *see also* Br. 28 (citing §253(a), regarding terminal disclaimers).) Sandoz never provides the text of §101—where "patentee" nowhere appears—let alone any explanation of how "[w]hoever invents or discovers" could reasonably be interpreted to include an entity that had nothing to do with the invention or discovery.

At bottom, Sandoz's attempted expansion of double-patenting doctrine rests on a policy Sandoz creates for this case alone: in Sandoz's view, Enbrel has been protected by an "extraordinary" patent term.[12] (Br. 1.) But the Roche patents' term results from a careful legislative compromise in the URAA, and this Court should not craft new common-law patentability rules to effect Sandoz's preferred vision of patent policy. *See Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1366 (Fed. Cir. 2018) ("[T]o require patent holders to truncate any portion of the statutorily-assigned term of a pre-URAA

[12] Sandoz thus repeatedly invokes the chestnut that double patenting prevents a timewise extension, "*no matter how the extension is brought about*." (Br. 2–3, 30 (citing *In re Hubbell*, 709 F.3d 1140 (Fed. Cir. 2013).) But courts do not have discretion to strike down otherwise-valid patents on policy grounds, and Sandoz's quotation originated in a case that expressly *distinguished* applications involving separate inventors. *See In re Schneller*, 397 F.2d 350, 354–55 (C.C.P.A. 1968).

patent that extends beyond the term of a post-URAA patent would be inconsistent with the URAA transition statute."). Where, as here, "federal statutory regulation . . . is comprehensive and detailed," the courts' role is interpretive. *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 85 (1994). Looking to §101, those who license an invention long after it was made cannot reasonably be understood to have "invent[ed] or discover[ed]" it.[13]

B. Prudential Standing Doctrine Does Not Govern Common-Ownership-Based ODP.

Sandoz has never attempted to satisfy, and cannot satisfy, the PTO's common-ownership test. Instead, Sandoz asks this Court to import prudential standing doctrine into ODP law. Courts use Sandoz's proposed test to determine when an exclusive licensee who sues for infringement must join the patent owner: a licensee with "all substantial rights" can sue alone because there is no risk of "multiple suits on the same patent." *See Prima Tek II, LLC v. A-Roo Co.*, 222

[13] Below, Sandoz leaned on *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), to suggest that "common ownership" can arise after invention, but in that case the issue of common ownership was not disputed, and *Geneva* did not address it.

F.3d 1372, 1377, 1380 (Fed. Cir. 2000). This test has nothing to do with patent validity, or §101.

The consequences of importing the all-substantial-rights test into ODP law would be far-reaching and perverse. A patent valid upon issuance could spontaneously self-destruct upon transfer—or even license—to the wrong party. *See Thomson-Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 726 (6th Cir. 1897) (Taft, J.) (rejecting suggestion that "the owner of one patent would avoid it [i.e., render it invalid] by acquiring ownership of another" as "anomalous"); *Van Heusen Prods. v. Earl & Wilson*, 300 F. 922, 936 (S.D.N.Y. 1924) (Hand, J.) (rejecting argument that "double patenting applies between two independent inventors, merely because one has taken an assignment of the other invention"). Sandoz's test would discourage the companies best situated to bring innovative technologies and life-changing therapies to market—because they are already working on related technologies—from acquiring the rights they need to do so.

The proposed test is also at odds with a core justification for double patenting: avoiding "harassment by multiple assignees." *In re Fallaux*, 564 F.3d 1313, 1319 (Fed. Cir. 2009). Whereas ODP is

generally designed to *prevent* separate ownership of patents covering "nearly identical subject matter," *id.*, Sandoz's rule would turn this policy on its head, encouraging companies *not* to acquire or exclusively license such patents, thus leaving those patents in the hands of separate entities to enforce them in separate suits.

Sandoz's unprecedented importation of this test into ODP law would also "disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). Innovation depends on a predictable patent system with clear and understandable patentability rules. *See Aerojet-General Corp. v. Machine Tool Works, Oerlikon-Buehrle Ltd.*, 895 F.2d 736, 744 (Fed. Cir. 1990) (en banc) ("The availability of a clear, stable, uniform" patent law "facilitates effective business planning, and adds confidence to investment in innovative new products and technology."). No court has ever suggested that a license long after invention could destroy an otherwise-valid patent, so companies have entered into countless licenses without even contemplating the possibility. Moving forward, the test would needlessly complicate future transfers. Indeed,

the risk of a surprise invalidation-by-license might cause companies to forgo otherwise-efficiency-enhancing deals.

Sandoz suggests that only its test can avoid the "absurd result[]" of allowing companies to "circumvent ODP" by "reclassifying [an] assignment as a license." (Br. 29.) Sandoz's circular argument—*circumvention* assumes that ODP is supposed to apply in the first place—obscures the fact that common-ownership-based ODP is a gap-filling doctrine. If two patents or applications lack a common inventor, and they are not within §103(c)'s prior-art safe harbor, then the novelty and nonobviousness requirements already ensure that only one patent can claim a given invention. The later inventor's claims will not be allowed if they are the same as, or obvious over, the first inventor's claims.[14] *See Commissioner's Notice*, 834 O.G. at 1616. On the other hand, if the later inventor's claims satisfy the "conditions and requirements" of the Patent Act, then that inventor is entitled to a patent. 35 U.S.C. §101. And the validity of that patent should not

[14] Thus, for example, the Roche patents were issued over the Jacobs '690 patent. (*See* Appx12686 (citing '690 patent).)

depend on whatever unique portfolio of patents a subsequent licensee/transferee might have.

C. The Court Properly Rejected Sandoz's Contention That the A&S Gave Immunex Effective Ownership of the Roche Patents.

Sandoz cannot satisfy its own unprecedented test.

As an initial matter, Sandoz misstates the standard of review. Although, in the context of standing, this Court considers the "all-substantial-rights" inquiry *de novo* when there are no fact disputes on a motion to dismiss, as in the case Sandoz cites (Br. 32 (citing *Lone Star Silicon Innovations LLC v. Nanya Tech Corp.*, 925 F.3d 1225 (Fed. Cir. 2019)), questions of *intent* based on evidence outside a contract are fact issues "review[ed] deferentially." *Alfred E. Mann Found. for Sci. Research v. Cochlear Corp.*, 604 F.3d 1354, 1359 (Fed. Cir. 2010); *see also Pullman-Standard v. Swint*, 456 U.S. 273, 288 (1982). And Sandoz itself urged that the all-substantial-rights analysis presented a factual issue for trial. (Appx661–662; *see also* Appx60034–60038 (proposed factual findings).) Because the issue goes to validity, Sandoz bore the burden of proof by clear and convincing evidence. *See generally Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91 (2011).

Sandoz also ignores half of its own test. This Court has held that, "[t]o determine whether a license agreement has conveyed all substantial rights in a patent , . . . [courts] must [1] ascertain the *intention of the parties* and [2] examine the substance of what was granted." *Prima Tek II*, 222 F.3d at 1378 (citation omitted; emphasis added). Sandoz does not address intent, but the district court did. The court found "that the parties specifically intended for the [A&S] to be a license such that Roche would remain the owner of the Patents-in-Suit." (Appx70–71.) Sandoz cannot show that this finding was clearly erroneous. It does not even try.

What Sandoz does do is attempt to discredit Stuart Watt, an Immunex witness the court found to have "credibly testified" regarding the parties' intent based on his role in the negotiation of the A&S. (Appx72.) Watt testified that Immunex wanted Roche to remain the owner because the parties might soon be adverse in litigation on other products, and Immunex wanted Roche to participate as a party in litigation regarding the Roche patents—a contractual duty to cooperate was not sufficient. (Appx5733–5735.) Sandoz misrepresents Watt's testimony—he never said ODP "could apply to patents that *became*

commonly owned through assignments," for example (Br. 17 (emphasis added))[15]—and Sandoz's recitation of "facts" (Br. 4–20) entirely fails to grapple with the court's contrary findings and credibility determinations, let alone the standard of review.

Beyond the court's unchallenged finding that Immunex and Roche intended to maintain a license, the substance of the A&S confirms that Immunex did not obtain all substantial rights. Four provisions are particularly important.

1. Roche's Right to Sue

Roche's right to sue disposes of Sandoz's theory all by itself. *See, e.g.*, *Abbott Labs. v. Diamedix Corp.*, 47 F.3d 1128, 1132 (Fed. Cir. 1995) (second right to sue was substantial). As this Court has explained, "[w]here the licensor retains a right to sue accused infringers, that right often precludes a finding that all substantial rights were transferred." *Alfred E. Mann*, 604 F.3d at 1361. That Roche has a second right to sue is undisputed. But in Sandoz's view, that right is "illusory" (Br. 31–33), which would mean that Immunex has the "ability to settle licensor-

[15] Indeed, Watt testified that an assignment would not even have "raised a question" of double patenting. (Appx5785–5786.)

initiated litigation by granting royalty-free sublicenses to the accused infringers." *Alfred E. Mann*, 604 F.3d at 1361.

The court correctly rejected Sandoz's argument, finding that Immunex could *not* moot a Roche-initiated suit by granting a sublicense to a defendant. (Appx72–73.) As Watt testified, it would be inconsistent with Roche's "sole" right to "rectify infringement" under §3.6, as well as Immunex's duty to "cooperate" in a Roche-initiated suit, for Immunex to moot a Roche suit by sublicense. (Appx5743; *see also* Appx25841.) Sandoz's only answer is to point to §3.5 (Br. 31–34), which governs Immunex's "*first* right" to rectify infringement. (Appx25840 (emphasis added).) But after 180 days' notice, the "right to rectify infringement" passes to Roche under §3.6, and that right under §3.6 is "solely within the control of Roche." (Appx25841.)

To be sure, Immunex can sublicense an infringer during the 180-day notice period. But that was true in *Alfred E. Mann*, too: the licensee could sublicense or settle its own suits before the licensor had the chance to sue. *See* 604 F.3d at 1361–63. What matters is that Immunex cannot "settle [Roche]-initiated litigation by granting royalty-free sublicenses to the accused infringers." *Id.* at 1361. Nor does

Immunex enjoy the "right to indulge infringements," *Abbott Labs.*, 47 F.3d at 1132—if Roche gives notice, the patents must be litigated or licensed.

That Immunex has the first right to sue does not make Roche's second right insubstantial. Indeed, Roche's rights in a second suit are, if anything, more substantial than the licensor's rights in *Alfred E. Mann*. There, the licensee would share the recovery from any licensor-initiated suit and might also moot a licensor-initiated suit by sublicense. 604 F.3d at 1361–62. Here, Immunex cannot sublicense after Roche sues, and Roche keeps "the entirety of any award of damages." (Appx25841.)

2. Roche's Right to Practice the Patents

Roche insisted upon retaining the right to practice the patents for internal non-clinical research. (Appx5736–5737; Appx25839.) Retention of this right might not preclude "the transfer of all substantial rights" by itself, but it contributes to a "totality" that is "sufficient to do so." *AsymmetRx, Inc. v. Biocare Med., LLC*, 582 F.3d 1314, 1321 (Fed. Cir. 2009); *see also id.* at 1320 (noting right to use for "academic research"). Moreover, in this case, Roche specifically

requested a right to practice, which Immunex viewed as a substantial concession, because Immunex suspected that Roche planned to use the technology to develop a second-generation product to compete with Enbrel. (Appx5737.)

3. Immunex's Option to Purchase

Wyeth received an outright assignment of the foreign Roche patents, but Immunex's license could not be converted into an assignment unless Immunex made an additional payment to Roche. (Appx25840 (§3.3).) Sandoz contends that the amount is nominal, but Immunex cannot reasonably be said to *already own* what it must pay $50,000 to buy, and this Court has long distinguished between present assignments and future promises to assign. *See DDB Techs., L.L.C. v. MLB Advanced Media, L.P.*, 517 F.3d 1284, 1290 (Fed. Cir. 2008). Immunex may be $50,000 away from someday owning the Roche patents if it wants to, but for now its obligation to pay only further underscores its current status as exclusive licensee.

4. Roche's Right to Veto Assignments

Finally, Immunex does not have "all substantial rights" because Roche retained an absolute right to veto the assignment of any

Immunex interest under the A&S to any unrelated party. (Appx25849 (§11.4).) This veto right is dispositive on its own. *See Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 979 (Fed. Cir. 2005) (restriction on "right to assign" was "fatal"); *see also Propat Int'l Corp. v. RPost, Inc.*, 473 F.3d 1187, 1191 (Fed. Cir. 2007) ("restriction" on the "right to dispose of an asset" was "strong indicator" that licensee did not receive "all substantial rights"); *Intellectual Prop. Dev., Inc. v. TCI Cablevision, Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001) ("limits on the assignment of rights" suggest "transfer of fewer than all substantial rights"). If Immunex owned the Roche applications, it could prosecute them itself or sell them to someone else who wanted to prosecute them, but the §11.4 veto ensures that Roche controls who will be its partner in prosecution. Although §11.4 also applies to Wyeth's interests under the A&S generally, §11.5 makes clear that Wyeth entirely owns and thus can assign the "Ex-North America" patents outright—so anyone Wyeth chooses can prosecute or enforce those patents outside North America, whether Roche likes it or not. (Appx25849.)

* * *

All parties agreed below that—if the all-substantial-rights test were to apply—its application would be a *factual* question. (Appx661–662; Appx687–688.) Based on its findings regarding the intention of the parties and the substance of the A&S, the district court was correct to find that Roche did *not* transfer all substantial rights in the Roche patents to Immunex.

D. Sandoz's Challenge Based on the Finck '225 Patent Fails.

Even if Sandoz could establish "common ownership" sufficient to trigger double patenting, its challenge based on the Finck '225 patent would nonetheless fail on three independent grounds.

1. The Post-URAA '225 Patent Cannot Cut Short the Roche Patents' Pre-URAA Terms.

Sandoz seeks to invalidate two pre-URAA patents based on a post-URAA patent, something this Court has never done. *See, e.g.*, *Novartis*, 909 F.3d at 1360. Were it not for the URAA, the Roche '182 patent and the Finck '225 patent, which both issued in 2011, would both have expired in 2028, with the '225 patent expiring eight months before the '182 patent. (Appx12686; Appx27246.) But due to the "happenstance of an intervening change in patent term law," *Novartis*, 909 F.3d at 1364,

the '225 patent has already expired. Sandoz wants to exploit this happenstance by "truncat[ing a] portion of" the Roche patents' "statutorily-assigned term," but doing so "would be inconsistent with the URAA transition statute." *Id.* at 1366.

Novartis did not involve an earlier-issuing, post-URAA reference patent, but its analysis—especially its emphasis on "gamesmanship"—is instructive. *Id.* at 1364. Here, the court expressly found that "an act of Congress, rather than improper gamesmanship by the patentee or strategic abuse of the patent system, led to the Patents-in-Suit having a longer patent term." (Appx82–83 (internal quotation marks and alterations omitted).) The court held that it would therefore be inappropriate for "the statutory term for the Patents-in-Suit" to be "cut short" to "mirror the statutory term for the Finck Patents." (Appx83.) Sandoz does not challenge the court's findings or conclusion on this score. This dooms Sandoz's Finck-based double-patenting defense.

2. Sandoz's Challenge Fails Under the Applicable Two-Way Test.

Sandoz's challenge also undisputedly fails if, as the court correctly concluded, the two-way test for patentable distinctness applies. That test arose out of a concern about applying ODP "when the applicants

filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing." *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). The concern is exacerbated where—as here—the inventions were made by separate inventors working separately, and thus could not have been pursued in a single application. *See, e.g.*, *In re Stanley*, 214 F.2d 151, 159 (C.C.P.A. 1954) (rejecting view that inventors of "generic invention" should be denied a patent based on an earlier-issuing but later-filed patent on an improvement "merely on the basis of the common assignee").

As the court found, the patents here issued out-of-order "solely" due to delays attributable to the PTO—lost files, unresponsiveness, and unnecessary appeals—while the applicants were "diligent[]." (Appx80–81.) These "factual findings underlying" the decision to apply the two-way test are reviewed "for clear error," *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997), and there is no clear error here.

On appeal, Sandoz points to ordinary amendments and extensions of time (Br. 38–39), without citing a single case holding that such ordinary prosecution activities authorized by statute and PTO rules

can, by themselves, constitute "delay." *See, e.g.*, 35 U.S.C. §41(a)(8); 37 C.F.R. §1.136(a) (permitting extensions up to six-month statutory period); *cf. also* Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56,366, 56,379 (Sept. 18, 2000) (recognizing that extensions are not "unreasonable *per se*"). The court's well-supported findings require the application of the two-way test.

3. The Claims Are Distinct Under the One-Way Test.

Even under the one-way test, Sandoz's challenge fails. Double patenting looks to what a claim "defines," not what the patent "discloses," and courts must therefore read claims "as a whole," without picking out part of a claim "as though it were a prior art reference." *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1278–80 (Fed. Cir. 1992). Taken as a whole, claim 10 of the '522 patent—culturing a Chinese hamster ovary cell with DNA that encodes etanercept and purifying the product—is a very different invention from claim 1 of the '225 patent—treating psoriasis with etanercept. (Appx12765–12766; Appx27261.) More broadly, claims to a method of treating psoriasis, taken as a whole, are fundamentally distinct from claims to a compound (as in the '182 patent) or a method of

manufacture (as in the '522 patent). Sandoz did not offer any evidence to establish that the claims, *as a whole*, are patentably indistinct.

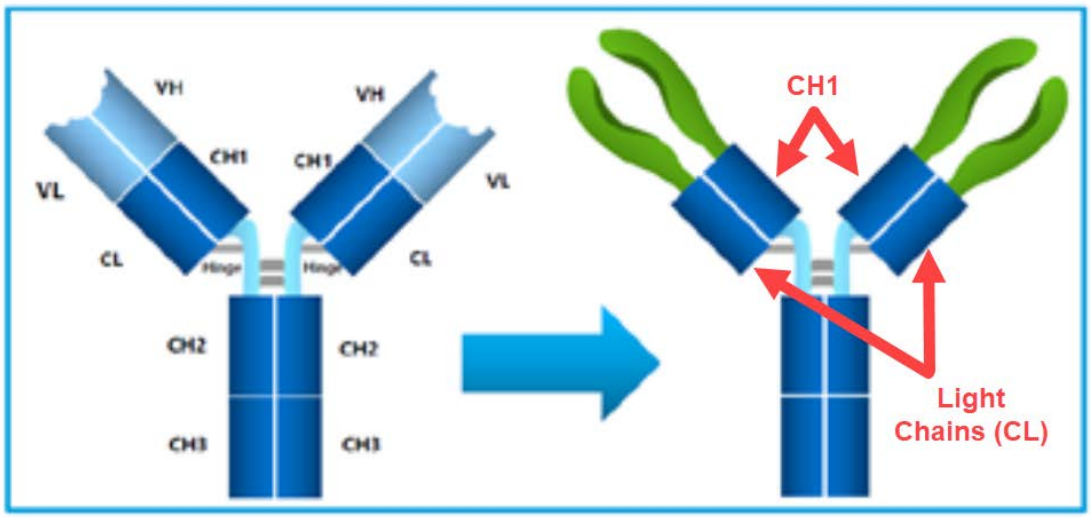
E. Sandoz's Challenge Based on Jacobs Likewise Fails.

Sandoz invokes ODP based on Jacobs claim 3, but not as the court construed it. Sandoz's argument rests on an alternative construction, rejected below, that treats Jacobs claim 3 as if it were specifically directed to etanercept. Sandoz's construction is incorrect.

Claim construction starts with the "words of the claims themselves," *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), yet Sandoz ignores how the claim language undercuts its proposed construction. Claim 3 calls for administration of "a chimeric antibody comprising a TNF receptor comprising the sequence of amino acids 3–163 of SEQ ID NO:1 fused to the constant domain of an immunoglobulin." (Appx27320.) Based on this language alone, the protein differs from etanercept. In particular, the receptor is "fused to *the constant domain* of an immunoglobulin." (*Id.* (emphasis added).) It is undisputed that "*the* constant domain"—in the singular—of an IgG1 includes CH1 and the constant region of the light chain, *neither* of which is in etanercept. (Appx4393–4394.)

The Jacobs specification further supports this understanding. The specification's only mention of a "chimeric antibody" refers to a protein "having TNF-R sequences substituted for the variable domains of either or both of the immunoglobulin molecule heavy and light chains and having *unmodified constant region domains*." (Appx27307(7:42–46) (emphasis added).) "[U]nmodified constant region domains" means *none* of the constant domains—of the heavy or light chain—are changed, particularly when contrasted with the suggestion to "substitute[]" TNF-R "for the variable domains," including the variable domains of the "light chains." Attaching TNF-R to the light chains would require having light chains—which etanercept does not. (Appx76.)

Notably, when interpreting the same language in the Jacobs patent's parent (the Smith '760 patent), Sandoz acknowledged that the "chimeric antibody" described in the specification includes CH1 and the light chains, as illustrated by Sandoz's own proposed findings:



(Appx60086 (red annotations added); Appx28154(10:53–58).)

Sandoz does not explain how it can interpret the same words to mean something different in Jacobs. The Jacobs file history does not point to that conclusion, notwithstanding Sandoz's extensive reliance on it. Indeed, Sandoz ignores the most significant fact regarding the Jacobs prosecution: Immunex *tried* to get claims to a TNFR:Fc fusion (*i.e.*, etanercept) based on its added disclosures in the 1992 continuation-in-part, and the examiner rejected them because they were not supported by the original specification—Immunex needed to amend its claims to keep its 1989 priority date. (*See* Appx5804; Appx10387, Appx10440, Appx10285–10287.) For example, Immunex sought (but did not obtain) a claim that called for "soluble human TNFR . . . fused to the Fc region of a human immunoglobulin molecule." (Appx10016; *see*

also Appx4119 (explaining that "Fc" refers to hinge-CH2-CH3).) Having failed to obtain a TNFR:Fc claim, Immunex had to settle for a claim based on the same "chimeric antibody" disclosure that appeared in the original Smith '760 patent, which by Sandoz's own admission *does not* disclose etanercept. (*See, e.g.*, Appx60086.)

II. The Court Properly Rejected Sandoz's Written-Description Defense.

Written description "is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006). Here, the parties "relied heavily on" expert witnesses (Appx12 & n.5), and the court found that Immunex's experts "credibly testified," while declining to adopt Sandoz's experts' testimony or explicitly assigning it "little weight." (Appx11–24.) Those credibility determinations undergirded detailed *factual* findings confirming that "a POSA could understand the subject invention and recognize that the inventor possessed it" from the written description. (*Id.*)

Sandoz's brief reprises the same factual contentions and testimony the court considered and rejected, positing imagined "legal errors" along the way. The court made no legal error, and there was no

factual error, much less clear error, in its determination that the specification established the inventors' possession of the claimed inventions in August 1990 by describing not only the two components of the claimed protein (the extracellular region of p75 and the hinge-CH2-CH3 of IgG1), but also their fusion.

A. The Specification Described p75.

The p75 receptor was undisputedly known in September 1990, and the court found that the specification unambiguously identified that receptor in numerous ways. (Appx16.) *See Yeda Research & Dev. Co. v. Abbott GmbH*, 837 F.3d 1341, 1345–46 (Fed. Cir. 2016) (describing a partial amino acid sequence and protein's functional properties satisfies §112). The specification consistently identifies "two TNF receptors, p55 and p75" (Appx16), and goes on to label proteins that weigh "about 55 or 75 kD" as "especially" "preferred" (Appx12699(4:5–10)). Example 6, moreover, "explains that the inventors isolated the p75 TNFR." (Appx16.)

The court explained that this was not the fragment of p75 shown in Figure 4, as Sandoz suggests, because "[s]equence identification numbers . . . correspond[ing] to p75[] are mentioned throughout the

specification"—sequences that correspond *only* to the known p75 receptor. (Appx16.) One is "the N-terminus sequence designated SEQ ID NO: 10," which "matches the first 18 amino acids at the N-terminus of the known p75" and is not present in the Figure 4 sequence. (Appx18.) Another is "the 18 amino acid sequence[] close to the C-terminus of the known p75 protein designated SEQ ID NO: 7," establishing that the Roche inventors had isolated the full length p75. (*Id.*)

Immunex's expert "credibly testified" that sending *either* of those disclosed sequences to GenBank would have resulted in return of "the complete p75 sequence" with "less than a one-in-a-million chance" that a different protein would be returned, and "zero chance" if both sequences were sent. (Appx19.) The specification would thus have "directed a POSA to the full p75 sequence at the time of the invention." (Appx18.) Sandoz has no contrary evidence given that its expert was concededly "not qualified to opine" on the topic. (Appx19 n.12.)

Further, the court credited additional evidence showing that the inventors had possession of p75 in August 1990. The specification, for example, references "already known sequences" for TNF receptors as

one source of "partial sequences which code for soluble TNF-BP fragments" to use in fusion proteins. (Appx12701(7:42–46).) The evidence was also clear and undisputed that p75 was "already known," and that the Roche inventors "published the full-length p75 TNFR" in July 1990, *before* their August patent 1990 filing—making referring to p75 without reciting its sequence perfectly acceptable. (Appx16–17.)

The district court properly dispatched Sandoz's contrary theories, including the "truncated/mutated Figure 4" theory that is the focus of Sandoz's appeal. As the court found, Figure 4 is a partial sequence (Appx18 & n.10), and it differs from sequences recited in the claims.[16] (*See* Appx12717–12718; Appx12765–12766.)

Likewise, Sandoz argues on appeal that the specification's reference to Smith 1990 (which reported the p75 sequence) would not have been understood by a skilled artisan. (Br. 52–53.) But Immunex's

[16] A skilled artisan would not have confused Figure 4 with the full-length p75 sequence disclosed elsewhere because the specification explicitly describes the "cDNA sequences shown in FIG. 4" as "*partial*" (Appx12700(5:35–38) (emphasis added)), making clear that Figure 4 was not the receptor called for by the asserted claims. (Appx4994–4995.) Also, the claims expressly refer to sequences (such as SEQ ID NO: 10) not present in Figure 4. (Appx4574–4575.)

expert explained that the specification would have directed a skilled artisan to read Smith 1990 and its disclosure of the p75 sequence, testimony the court expressly accepted: "despite the word 'deletion,' a POSA would have been directed to Smith 1990 and therefore the full p75 protein." (Appx18.) The court flatly rejected Sandoz's attempt to "misconstrue" the testimony (Appx18 n.10) in precisely the same way that Sandoz misconstrues that testimony on appeal (Br. 53).

Sandoz next contends that the inventors deliberately and knowingly chose not to describe the known p75. (Br. 54–56.) There is no support for this counter-narrative.

Sandoz leans heavily on the file history of the related Roche '029 patent, in which Roche obtained claims to the variant p75 sequence in Figure 4 (Br. 54), but that only confirms that the inventors knew how to claim the Figure 4 variant when they wanted to. The file history of the Roche '029 patent accurately distinguishes Figure 4's partial sequence from the full-length, known p75 sequence, because in that patent—unlike the '182 and '522 patents—the inventors were seeking to claim something *other than* the known p75 receptor sequence the '182 and

'522 patent specifications directed a skilled artisan to use for a fusion protein. (*See* Appx31502–31503.)

Though not required, the specification of the '522 patent was amended to recite the p75 sequence from Smith 1990. Similarly, the specification of the '182 patent was amended to refer to a public deposit in 2006 of a plasmid containing the p75 sequence that Roche had constructed before the priority date, which under *In re Lundak*, 773 F.2d 1216, 1223 (Fed. Cir. 1985), is treated as part of the Roche patents' written description as of the 1990 priority date. Sandoz cites these steps as admissions of lack of written description. (*See* Br. 18–19.) They are not, as the court explained in a discussion Sandoz again ignores. (Appx22–24.) Indeed, the PTO itself considered and rejected the argument that the amendments were improper, and found that "the written description supports the . . . claim scope." (Appx28783–28792.)

Finally, Sandoz notes that Roche "ask[ed] Immunex" for etanercept for clinical trials. (Br. 55.) That is "legally insignificant" because §112 does not require an actual reduction to practice. (Appx21.)

Sandoz closes by manufacturing "legal errors" in the court's opinion. (Br. 56–58.) First, Sandoz accuses the court of improperly looking outside the "four corners" of the specification. (Br. 48–49, 56–57.) But even Sandoz concedes (Br. 57) that a patent "need not teach, and preferably omits, what is well known in the art," including "genes and their nucleotide sequences." *Falko-Gunter*, 448 F.3d at 1365–68; *see also Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) (same for "nucleotide sequences of the claimed chimeric genes"); *Yeda Research*, 837 F.3d at 1345 (same for a protein's "partial N-terminus sequence and additional traits"). Sandoz's hyperbolic worry about "incorporat[ing] every *un*-invoked prior art concept related to the described invention" (Br. 57) is refuted by what the court actually held.

Second, and related, Sandoz charges the court with taking an "obviousness-based approach to written description." (Br. 24, 56.) Wrong again. The court was *required* to analyze the specification from the perspective of a skilled artisan, and that is exactly what the court did. (Appx11.) The artisan's perspective is a critical tool to recognize what a specification described and what the inventors possessed, particularly since every detail of the claim need *not* be spelled out

verbatim. (Appx11–24.) None of Sandoz's out-of-context snippets from the court's opinion (Br. 56–57) demonstrates any misunderstanding about the §112 inquiry or any clear error in the factual findings.

B. The p75-IgG1 Fusion Was Adequately Described.

The disclosure also adequately describes the IgG1 portion and the fusion of the two components that comprise etanercept. (Appx19–21.) The specification identified four preferred fusions, combining the full extracellular region of either preferred receptor (p55 or p75) with the hinge-CH2-CH3 portion of either preferred antibody (IgG1 or IgG3), and provided in Example 11 the steps required to make such combinations, demonstrating that the inventors possessed these preferred fusions.

The specification "clearly refers to use of deposited vectors (including 'pCD4-Hγ1') that contain DNA sequences encoding the exon-defined hinge-CH2-CH3 region of a human IgG1 heavy chain." (Appx19–20.) That reference "to a deposit in a public depository . . . constitutes an adequate description" of the precise human IgG1 DNA sequence encoding the portion of the heavy chain to be used in the claimed fusions. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002).

The court found that the specification demonstrates possession of the claimed fusion, too. (Appx21.) Example 11 "provides a recipe to fuse a soluble TNF-binding fragment directly to that exon-encoded hinge-CH2-CH3 region of an IgG heavy chain," by illustrating the use of "a cDNA fragment that encodes the extracellular region of a TNF-binding protein, and describ[ing] the process generally using a p55 TNFR as an illustration." (Appx20 (citing expert testimony).)

Nevertheless, Sandoz contends that there were no "blaze marks" leading to the Ig portion or to the fusion, without confronting the fact that, again, the court found the opposite. (Br. 58–59.) Sandoz ignores the court's finding about deposited vectors, and discounts Example 11 because it refers to p55 instead of p75. (Br. 59.) But Sandoz never established that the "recipe" applies only to p55. To the contrary, even the inventor testimony Sandoz cites, which the court credited (Appx20), establishes that an artisan following the Example 11 "recipe" and using the extracellular portion of p75 would "get . . . etanercept." (Appx4845.) And, again, there is no doubt that the specification teaches use of both p75 and IgG1: p75 is one of just *two* receptors that are "especially"

preferred, and IgG1 is one of just two antibodies "particular[ly]" suggested for a fusion protein.[17] (Appx12699(4:5–9); Appx12700(5:61).)

Sandoz chastises the court for purportedly relying on the "claims themselves" to provide written description support. (Br. 59–60.) Sandoz mischaracterizes the opinion. The court expressly recognized that "the specification must 'reasonably convey . . . possession of the claimed subject matter.'" (Appx11 (quoting *Ariad Pharm. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)).) The court also recognized that it is necessary to refer to the "claims," because "the level of detail required . . . varies depending on the nature and scope of the claims" (Appx11)—the written description "analysis compares the claims with the invention disclosed in the specification." *Ariad*, 598 F.3d at 1348. The claims define the invention the inventor must have possessed, and the specification demonstrates that possession, which is

[17] Sandoz relies on *Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), but it is inapposite. There, this Court analyzed the written description requirement applied to claims directed to a genus. *See id.* at 1163–65. Here, the Roche claims are directed to a particular fusion protein, and the district court found that the specification adequately discloses the claimed fusion protein and how to produce it. (Appx13–24.)

what the district court said here. (Appx11, Appx21, Appx21–22.)[18] Most fundamentally, Sandoz does not—because it cannot—point to any finding that rested on the issued claims rather than the specification.

III. The Court Properly Rejected Sandoz's Obviousness Defense.

The court's extensive findings fully support its conclusion of non-obviousness. (Appx28–59.) Sandoz's obviousness appeal leaves most of these findings unchallenged, targeting only two issues: motivation to combine and some (but not all) objective indicia. But as the court concluded, the combination of a portion of p75 with the hinge-CH2-CH3 of IgG1 went against conventional wisdom; there was no motivation to combine the two unrelated proteins; and the objective indicia point to a breakthrough invention.

A. The Findings Regarding Motivation Were Not Erroneous.

It was Sandoz's burden to prove a motivation to combine the references to arrive at the claimed inventions. *See, e.g.*, *Millennium*

[18] Moreover, the *original* claims "are part of the specification and can provide written description support for later issued claims," *ScriptPro, LLC v. Innovation Assocs., Inc.*, 833 F.3d 1336, 1339 (Fed. Cir. 2016), and here the application included claims that would cover a p75-IGg1 fusion protein (*e.g.*, Appx25129 (claim 19, which relates to a fusion of a TNF-binding protein and IgG1 or IgG3)).

Pharm., Inc. v. Sandoz Inc., 862 F.3d 1356, 1364 (Fed. Cir. 2017). To attempt to do so, Sandoz focused on a *therapeutic* goal, arguing that "the prior art encouraged constructing a TNF receptor-IgG1 fusion protein and suggested using such proteins to treat an autoimmune disease." (Appx60196 (emphasis omitted); *see also* Appx60197 ("drug therapy . . . for regulating the immune activities"); Appx60200–60201 (arguing prior art recommended use "to treat human inflammatory diseases"); Appx60095–60096.) Immunex argued that a person of skill would *not* have used part of an antibody in an anti-inflammatory therapeutic, due to concerns about "effector functions." (Appx60333.)

This was a straightforward fact dispute. The court weighed the evidence, including the credibility of the witnesses, and rejected Sandoz's position, finding not only that Sandoz failed to show *any reason* a skilled artisan would have been motivated to combine, but also that Immunex's evidence established that "a POSA would have refrained from using Ig fusion proteins for anti-inflammatory treatments" in light of "effector functions." (Appx36–38, Appx42.) Sandoz does not even suggest that this finding was clearly erroneous.

Instead, Sandoz argues that the court committed a "glaring error" by failing to address a supposed motivation to make etanercept to create a "research tool." (Br. 63.) This idea was, charitably, an afterthought below. Sandoz's expert, in the very question-and-answer Sandoz cites, testified that the "the key sentence" in the relevant reference was the one that refers to "therapy" for regulating "immune activities." (Appx4162 (cited at Br. 63).)

Sandoz's focus on therapy made sense. Two of the asserted claims cover pharmaceutical compositions (Appx12717–12718 ('182 patent claims 12 and 36)), not "research tools." And Sandoz's asserted motivations to combine turned on therapeutic benefits: "improving *in vivo* half-life," for example, was important because "[p]atients don't like to be injected all the time." (Appx4181; *see also* Appx558 (emphasizing that activity "in the body" was "the entire purpose").) But half-life concerns that are important for drugs are irrelevant to *in vitro* experiments. (*See* Appx5251 ("half-life" is "very important" for "a drug").)

The district court properly focused on the evidence and factual disputes presented to it, including regarding motivation. In the end,

the court found that the evidence supported Immunex's account of the facts: a skilled artisan would not have selected the components of etanercept or combined them in the specific way to make etanercept. (*See generally* Appx28–59.)

But even if Sandoz *had* emphasized research tools below, it failed to provide meaningful evidence—let alone clear and convincing evidence—to explain why a skilled artisan developing research tools or diagnostics would have been motivated to modify the p75 receptor to arrive at etanercept. The snippets of testimony that Sandoz cites actually support the conclusion that there was no motivation at the time to make etanercept as a research tool. (*See* Br. 63 (citing Appx4161–4162; Appx4832; Appx28349).) In particular, Sandoz's expert Dr. Blobel and Roche inventor Dr. Lesslauer addressed using the p75 TNF receptor *alone* in diagnostic assays or as a research tool. (Appx4161–4162; Appx28349.) Another Roche inventor, Dr. Loetscher, testified that if you had both the receptor and etanercept at the time, either could theoretically be useful in *in vitro* experiments. (Appx4832.) And even if Dr. Loetscher had used both the receptor and the fusion protein in experiments, an inventor's own motivations are irrelevant.

See, e.g., *Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000) ("path that leads an inventor to the invention is . . . irrelevant"). Critically, *no* witness identified any shortcoming in any prior art p75 construct that would have motivated a skilled artisan to modify it to make an improved diagnostic or research tool, let alone make the modifications required to obtain etanercept.

B. The Court's Assessment of the Objective Evidence Was Not Erroneous.

Sandoz closes with a cursory discussion of objective evidence, including the nexus between such evidence and the claimed invention. (Br. 63–65.) But "[q]uestions of nexus are highly fact-dependent," and it is up to "the fact-finder" to determine the objective evidence's "probative value." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). Here, the court concluded that the claims cover the active ingredient in Enbrel and its method of manufacture (Appx52); nexus is appropriately presumed.[19] *Id.* at 1329.

[19] Sandoz's argument regarding "failure of others" (Br. 63–65) is a sleight of hand: Immunex succeeded with *Roche's invention*, and Immunex took a license. (Appx58.)

Sandoz failed to rebut that presumption at trial. (Appx48; Appx52; Appx54.) Sandoz now claims the court erred by not considering "earlier patents claiming etanercept" (Br. 64), without explaining why they matter. The '690 Jacobs patent, in particular, issued from a continuation-in-part filed two years *after* the original Roche applications, and it does not claim etanercept at all. *See supra* Part I.E. Further, Sandoz targets only "certain objective indicia" (Br. 63), implicitly conceding crucial findings regarding unexpected results and licensing.

Finally, Sandoz insists that the court gave insufficient weight to evidence of "simultaneous invention." (Br. 64–65.) The court found that three of the four alleged instances of near-simultaneous invention involved molecules distinct from etanercept; other than the Roche inventors, only Immunex came up with etanercept, *after* Roche's invention. (Appx57–58.) As the court held, the existence of interference practice shows that "near simultaneous invention" by one additional inventor is not dispositive of obviousness; otherwise interference practice would serve no purpose. *Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1460 (Fed. Cir. 1984). And,

as the district court recognized, "unexpected results" can "preclude a finding of obviousness," even when there is near-simultaneous invention. (Appx58.)

Whether objective indicia support a finding of obviousness is ultimately a factual question, "considered in light of all of the circumstances." (*Id.* (quoting *Lindemann*, 730 F.2d at 1460).) Here, having considered all the evidence at trial—including unexpected results, clinical and commercial success, and licensing—the court rejected Sandoz's simultaneous invention arguments and concluded that the objective evidence supported a finding of non-obviousness. (Appx 58.) That finding is entitled to deference, and it is not clearly erroneous.

CONCLUSION

The decision below should be affirmed.

December 13, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit using the CM/ECF system this 13th of December, 2019, and that a copy was served on all counsel of record by the CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Fed. Cir. R. 32(a). The brief contains 13,966 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Fed. Cir. R. 32(b).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

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