No. 20-1037

United States Court Of Appeals
for the Federal Circuit

IMMUNEX CORPORATION, AMGEN MANUFACTURING, LIMITED, HOFFMANN-LA ROCHE INC.,

Plaintiffs/Appellants,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH,

Defendants/Appellees,

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, NO. 2:16-CV-01118-CCC-MF. THE HONORABLE CLAIRE C. CECCHI

BRIEF OF AMICUS CURIAE SAMSUNG BIOEPIS CO., LTD., IN SUPPORT OF APPELLANTS AND REVERSAL

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November 15, 2019

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

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Immunex Corporation, et al. **v.** Sandoz Inc., et al.

Case No. 20-1037

CERTIFICATE OF INTEREST

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

Samsung Bioepis Co., Ltd.

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
Samsung Bioepis Co., Ltd.	None	Biogen Inc.
		Samsung BioLogics Co., Ltd.
		(Samsung BioLogics owned by Samsung Elecs Co, and Samsung C&T)

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:

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FORM 9. Certificate of Interest **Form 9**
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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 Corp. v. Samsung Bioepis Co., Ltd., Case No. 2:19-cv-11755 (D.N.J.)

11/15/2019
Date

/s/ Elizabeth M. Flanagan
Signature of counsel

Please Note: All questions must be answered

Elizabeth M. Flanagan
Printed name of counsel

cc: counsel of record

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STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus Samsung Bioepis Co., Ltd. ("Bioepis") is a biopharmaceutical company dedicated to unlocking the potential of biosimilar medicines and transforming the way biologic therapies are brought to patients. Bioepis has developed a biosimilar candidate, SB4, to Appellee Immunex's biologic etanercept sold under the trade name ENBREL®. Bioepis's SB4 is the first biosimilar to have been sold anywhere in the world. SB4 has been approved for use in Korea, the European Union, Australia, Canada, Brazil, Switzerland, Israel, New Zealand, and, most recently, the United States. In April 2019, Appellees filed suit against Bioepis, asserting infringement of the same patents at issue in this appeal. *Immunex Corp. v. Samsung Bioepis Co., Ltd.*, Case No. 2:19-cv-11755 (D.N.J.).

Standards for obviousness law are an important consideration in the biologic/biosimilar industry. The standards in that industry should be the same as in the small molecule/generic pharmaceutical industry. A product like ENBREL®, for which Appellees have already enjoyed over 20 years of market exclusivity, should not be protected from further competition by a broad patent that covers any use for the claimed fusion protein, but is saved from obviousness by a narrow view of what might invalidate such a claim.

Bioepis believes that the district court committed legal error in its obviousness analysis by viewing the goal of creating a therapeutic agent as the only motivation for a skilled artisan to create the fusion protein claimed in the '182 patent and to develop the

method of making it claimed in the '522 patent. The asserted claims do not require that the claimed fusion protein act as a therapeutic agent. Indeed, they do not ascribe any particular use to it at all. The only functionality the claims require is that the fusion protein bind to a particular target, tumor necrosis factor (TNF). But the district court ignored this. For purposes of its obviousness analysis, the district court erroneously read into the asserted claims a therapeutic use requirement. This impermissibly placed an artificial constraint on the question of whether a skilled artisan would have been motivated to achieve the claimed inventions.

When the question of motivation is framed properly according to precedent from both the Supreme Court and this Court, and is based on the plain reach of the claims, the conclusion that the asserted claims are obvious must follow. Both the prior art and the asserted patents themselves disclose numerous reasons, separate and apart from potential therapeutic use, that would have caused skilled artisans to make the claimed inventions. The district court ignored those motivations because of its singular focus on therapeutic use, allowing hindsight knowledge of what etanercept is *now* known for—its therapeutic effect as proven by Immunex years after Roche filed these patents—to drive its analysis. That is error.

Accordingly, Bioepis urges this Court to correct the district court's errors and reverse the district court's judgment in order to make clear that the standards for obviousness are no different for biologic compositions than they are for any other claimed chemical entity.

Pursuant to Federal Rule of Appellate Procedure 29(a)(2) and Federal Circuit Rule 29, all parties have consented to Bioepis filing this brief. No counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the amicus curiae or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

ARGUMENT

I. The District Court Improperly Framed the Obviousness Analysis

A. The Asserted Claims Define a Fusion Protein and Methods for Its Production, and Say Nothing about Its Intended Use

The asserted claims of the '182 patent cover a particular fusion protein made up of (a) a portion of the p75 TNF receptor; and (b) a portion of an IgG1 immunoglobulin. Beyond defining this composition, the plain language of the claims merely require that the fusion protein bind a particular target, TNF. Appx12717-18. The asserted claims of the '522 patent cover production of the particular fusion protein using biotechnology techniques. Appx12765-66.

The focus of the patents' disclosures is on proteins (including in the form of fusion proteins) that bind TNF. *See, e.g.*, Appx12698. The patents suggest utilities for these TNF binding proteins, including the claimed fusion protein, in line with this function. For example, the '182 patent teaches that they can be used to purify TNF and detect TNF agonists and antagonists according to known procedures. Appx12702 (at 10:6–9). It also states that they "can be used as diagnostics for the detection of TNF

in serum or other body fluids" through known techniques. *Id.* (at 10:1–3). In addition to these two uses that depend on binding TNF, the '182 patent teaches that the TNF-binding proteins can be used "as antigens to produce polyclonal and monoclonal antibodies" through known techniques, and provides an example of how to do that. *Id.* (at 9:56–58); Appx12749 (Ex. 3). The '522 patent repeats these non-therapeutic uses. *See, e.g.*, Appx12747.

The patents do not teach the use of the claimed fusion proteins as therapeutic agents. They do not disclose any embodiments of fusion proteins for therapeutic use, any examples or data relating to fusion proteins for therapeutic use, or any methodology for assessing therapeutic use of any fusion protein.

The particular fusion protein covered by the claims is now known by the name etanercept, and is the active ingredient in Immunex's multi-use ENBREL® biologic agent. As a therapeutic agent, "Etanercept works by binding to and neutralizing excess TNF in patients with rheumatoid arthritis, thereby reducing the auto-immune inflammatory response." Appx6. But none of this was described in Roche's priority application filed in 1990. *See* Appx7. Indeed, the word "etanercept" appears nowhere in the specifications of the asserted patents.

Both the claims and specifications are clear: there is no foundation for viewing the claims as limited to "etanercept" or ENBREL® as opposed to simply the claimed composition of matter—a fusion protein, and the patent itself discloses several non-therapeutic uses for the fusion protein. Yet, in describing the "scientific background

of the claimed invention" and providing the framework for its validity analysis, the district court incorrectly imported into the claims the hindsight knowledge of Immunex's separate development of etanercept and commercialization of ENBREL®, as well as the purported motivations of the Roche inventors. Appx3-5. This infected the court's obviousness analysis and resulted in error.

B. The District Court Required Proof of Motivation to Create a Therapeutic Agent

The obviousness inquiry before the district court turned on the issue of motivation. Rather than assess whether there was a motivation to achieve the *claimed invention*—a fusion protein that binds TNF, the district court assessed "whether it would have been obvious to a POSA to create *etanercept*." Appx29 (emphasis added). In framing the issue this way the district court wrongly presupposed Defendants must establish a motivation to create the claimed fusion protein *as a treatment for inflammation*, which is the proven utility etanercept is known to have today, even though the claims do not mandate such a showing.

The district court first considered whether a skilled artisan would have been motivated to select the p75 TNFR component, and its entire analysis in this regard restrictively focused on what would have motivated someone who was looking to treat an autoimmune disorder. Appx32-33. It then considered the motivation to both select the IgG1 component and fuse it with the p75 TNFR component, and in this regard cabined its analysis to the pros and cons of how that may affect the body's immune

response, thus including administration of the fusion protein to humans as a necessary part of the obviousness calculus. Appx34-46. Along the way, the district court also rejected Defendants' proffered alternative motivations—extended in vivo half life, ease of purification, and enhanced TNF binding[1]—because it had already determined that a skilled artisan would have been concerned about inflammatory response and would not have used a fusion protein to "treat auto-immune diseases." Appx41. *See also* Appx45 (rejecting motivation related to improved bioproduction in favor of inflammatory concerns).

This list of excerpts from the district court's opinion starkly illustrates these points:

- ". . . a POSA would have been discouraged from using TNFR as a treatment option." Appx32.
- "Additionally, a POSA in 1990 would have considered cytokines to be 'poor therapeutic targets' and therefore TNFR would not have been an obvious choice." Appx33.
- ". . . a POSA would not have considered any individual cytokine to be a good therapeutic target . . . ." Appx33.
- ". . . a POSA would have looked to a different cytokine, called IL-1, to treat inflammatory diseases . . . ." Appx 33.

[1] *See, e.g.*, Trial Tr. (9/11 PM) at 90:5-6, 18-19, 91:10-12 (Sandoz expert discussing the motivations of adding IgG_1 to aid in purification of TNFR and using IgG_1 to increase the half-life of TNFR); Trial Tr. (9/20 PM) at 42:21-24, 43:1-7 (Immunex expert admitting to prior art that discusses the use of receptor-IgG fusion proteins for purification and increased half-life).

- ". . . a POSA deciding to select TNFR to treat pro-inflammatory diseases would have likely used p55 . . . ." Appx33.

- "Against this backdrop, a POSA studying auto-immune diseases would have avoided Ig because the inflammatory immune response elicited by Ig fusion proteins was extremely undesirable." Appx34-35.

- ". . . would have taught a POSA to look away from Ig fusion proteins as a potential treatment option for auto-immune disorders." Appx35.

- "Based on these prior references, a POSA would have refrained from using Ig fusion proteins for anti-inflammatory treatments . . . ." Appx36.

- ". . . a POSA looking to treat an autoimmune condition, such as rheumatoid arthritis, would have been dissuaded from combining TNFR with IgG1." Appx40.

- "It is not obvious that a POSA would have selected this idea as a possible solution for patients with pro-inflammatory conditions . . . ." Appx41.

- "Among these possibilities was combining p75 with PEG, which as mentioned above was a widely used and FDA approved non-Ig construct." Appx43.

- "Based on this finding, a POSA seeking new therapies for auto-immune disorders would not have been motivated to remove the CH1 domain . . . ." Appx45.

As can be seen, the requirement that there must have been a motivation to create a therapeutic agent to treat autoimmune diseases and curb inflammation permeated the district court's obviousness analysis.

The unduly stringent motivation requirement the district court employed—though wrong—is not entirely of its own making. Plaintiffs called for it by setting up the therapeutic agent strawman in opposing Defendants' obviousness argument. This led the district court astray because Plaintiffs' arguments focused on the research

motivations driving the inventors, and the allegedly surprising characteristics of the ultimate commercial embodiment of the asserted claims—etanercept/ENBREL®. But the former is improper, and the latter does not recognize the actual scope of the claims.

II. The District Court Wrongly Concluded Non-Obviousness By Committing Legal Error

A. The Proper Obviousness Inquiry Focuses on the Invention *Claimed* and Whether There Was *Any* Motivation to Make It

In contrast to the district court's obviousness analysis that turned entirely on an unclaimed feature, the correct obviousness inquiry examines whether the *claimed invention* would have been obvious to a person of skill in the art at the time of the invention. *See Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 973 (Fed. Cir. 2014) (explaining that a claim is obvious if a skilled artisan "would have been motivated to combine the teachings of the prior art references to *achieve the claimed invention*, and that the skilled artisan would have had a reasonable expectation of success in doing so") (quoting *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)) (emphasis added).

It is improper to rely on unclaimed features to support a finding of non-obviousness. *See Senju Pharm. Co. v. Lupin Ltd.*, 780 F.3d 1337, 1346-47 (Fed. Cir. 2015) (affirming judgment of obviousness and rejecting appellant's non-obviousness arguments that were based on something that was "not a limitation of [the asserted] claims [] and, therefore, is not relevant to the obviousness determination"); *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292-93 (Fed. Cir. 2013) (rejecting non-obviousness

analysis relying on unclaimed features because "the person of ordinary skill need only have a reasonable expectation of developing the claimed invention").

The motivation to combine analysis thus must focus on the claimed invention, and is not otherwise limited in reach. Indeed, as this Court has long recognized, motivation "may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006). The motivation need not be the same motivation that the inventors had (or purportedly had, in this case), nor the motivation to make the ultimate commercial product that is encompassed by the claims. *See In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006) ("[T]he skilled artisan need not be motivated to combine [the prior art] for the same reason contemplated by [the inventor].").

The Supreme Court made this flexible motivation inquiry clear in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), where it rejected a "rigid approach" to the analysis of motivation. The Court explained that, "[i]n determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls." *Id.* at 419. Instead, "the problem motivating the patentee may be only one of many addressed by the patent's subject matter." *Id.* at 420. In *KSR*, the Supreme Court reversed this Court's judgment of non-obviousness because this Court erred by "holding that courts and patent examiners should look only to the problem the patentee was trying to solve." *Id.* "Under the correct analysis, *any need or*

problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* (emphasis added). The proper motivation analysis thus broadly considers whether those skilled in the art had *any* reason to make the claimed invention, regardless of whether that reason is the same one that drove the patentee to make it or ultimately makes it commercially successful.

This Court has applied that broad, flexible standard many times to reverse obviousness conclusions reached by wrongly restricting the motivation analyses to only one potential reason to make the claimed invention. This holds equally true in cases implicating pharmaceutical subject matter. *See, e.g.*, *Nalpropion Pharms., Inc. v. Actavis Labs., Inc.*, 934 F.3d 1344, 1354 (Fed. Cir. 2019) (reversing judgment of non-obviousness of claims directed to a composition that combined two different drugs for weight loss because both drugs were known to have some weight loss effect and there was no requirement that a skilled artisan be motivated by potential FDA approval); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1365 (Fed. Cir. 2012) (finding the district court had erred in "its refusal to look at any motivation beyond that articulated by the patent"); *Allergan*, 726 F.3d at 1292 ("Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications."); *see also Bayer Pharma AG v. Watson Labs., Inc.*, 874 F.3d 1316, 1324 (Fed. Cir. 2017) (reversing finding of non-obviousness where

the district court's motivation analysis "focused too heavily" on single issue of commercial product availability).

B. Under the Analysis Dictated by the Supreme Court and this Court's Precedent, the Asserted Claims Are Obvious

The district court's obviousness analysis here does exactly what the law set forth above says *not* to do. It includes an unclaimed feature in the analysis—that the claimed fusion protein be useful as a therapeutic agent, and it limits the analysis of motivation to combine to whether there would have been a motivation to create a therapeutic agent, ignoring all other possible motivations for making the claimed fusion protein. This is reversible error.

Under the proper analysis, grounded in the actual claimed invention and examining all the potential motivations for making that invention, the claims are obvious.

This Court reversed a finding of non-obviousness under similar facts in *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286 (Fed. Cir. 2013), a Hatch-Waxman case. There, the district court found claims directed to a two-drug formulation non-obvious. *Id.* at 1291. Allergan sold an FDA-approved ophthalmic formulation, Combigan®, that embodied those claims. Combigan® had reduced dosing compared to the prior art, from three to two times daily, without loss of efficacy, but the claims did not contain limitations related to the formulation's dosing regimen or efficacy. *Id.* at 1289. The district court found no motivation to combine the two drugs into one composition because (1) the

FDA did not view patient compliance—which increases as the number of doses decreases—as a factor for approval of a drug, and (2) a skilled artisan would not have had a motivation to make a product if it could not get FDA approval. *Id.* at 1291.

This Court reversed, holding that "[t]here is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval." *Id.* at 1292. Instead, "[m]otivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications." *Id.* Nor should motivation be limited to making the specific, approved commercial product, when the claims were broader, because the skilled artisan "need only have a reasonable expectation of success in *developing the claimed invention*." *Id.* (emphasis added). Because the record contained evidence of motivations to make the claimed combination of drugs besides seeking and obtaining FDA approval for it, the formulation claims were obvious. *Id.* In contrast, this Court upheld non-obviousness of one method claim that specifically recited the dose reduction without loss of efficacy. *Id.* at 1294.

Similarly, here, the district court improperly limited the motivation inquiry by looking only at whether a skilled artisan would have been motivated to make a fusion protein as a therapeutic agent. *See, e.g.*, Appx36 ("Based on these prior references, a POSA would have refrained from using Ig fusion proteins for anti-inflammatory *treatments*.") (emphasis added); Appx45 ("Based on this finding, a POSA *seeking new therapies for auto-immune disorders* would not have been motivated to remove the CH1

domain.") (emphasis added). But, just as the formulation claims in *Allergan* did not specify the FDA-approved, commercial product, Plaintiffs' claims do not specify that the claimed fusion protein must function as a therapeutic agent, let alone for treating autoimmune diseases. *See* Section I.A. Indeed, the asserted patents do not *teach* using it as a therapeutic agent. And, as in *Allergan*, there were reasons to make the claimed composition apart from as a therapeutic agent, reasons that the district court failed to properly consider because of its erroneous focus on making a therapeutic agent. *See, e.g.*, Appx12702 (at 9:55-58, 10:1-3, 10:6-9); Trial Tr. (9/11 PM) at 90:5-6, 18-19, 91:10-12; Trial Tr. (9/20 PM) at 42:21-24, 43:1-7; *see also* Appx41 (rejecting alternate motivations of extended in vivo half-life, ease of purification, and enhanced TNF binding based on its focus on use of the protein "to treat auto-immune diseases").

There is another reason why the district court's dismissal of those alternate motivations, based on its finding that a skilled artisan would have avoided using Ig because of potential inflammatory immune response (*e.g.*, Appx34-35), is problematic. Just because there may be a rationale to not make a combination, that does not negate all other potential reasons for doing so. This Court has explained that "a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." *Medichem, S.A. v. Rolabo, S.L,* 437 F.3d 1157, 1165 (Fed. Cir. 2006).

The district court's faulty reasoning in finding non-obviousness mirrors the analysis this Court rejected in *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1365

(Fed. Cir. 2012), another Hatch-Waxman case. There, the asserted claims covered a method for treating allergic eye disease by stabilizing cells by topically applying a therapeutic amount of certain drug. *Id.* at 1364. The prior art disclosed use of a similar drug formulation in guinea pigs as an antihistamine, and the district court found guinea pig models were sufficiently predictive of human activity. *Id.* at 1368. But that prior art did not speak to stabilizing the relevant cells. *Id.* The district court concluded non-obviousness based on its finding that a skilled artisan would not have been motivated to use the prior art formulation in human eyes because it was not known that it would stabilize the relevant cells, and this Court reversed because of the improperly limited motivation inquiry. *Id.* at 1368-69.

Specifically, this Court found that the district court in *Alcon* had erred in "its refusal to look at any motivation beyond that articulated by the patent." *Id.* at 1368. The single motivation the district court focused on was "not the only motivation to arrive at the claimed invention." *Id.* at 1369. Instead, a person of skill in the art would have been motivated to use the prior art formulation for another reason—"to treat human eye allergies as claimed for its established antihistaminic activity." *Id.* Thus, the district court in *Alcon* erred in finding the claims non-obvious because of its improper focus on only one possible motivation to make the claimed invention. There, as here, the district court's analysis was incorrect because of "its refusal to look at any motivation beyond" the single one that it focused on, which was "not the only motivation to arrive at the claimed invention." *Id.* at 1368-69.

Thus, just as in *Allergan* and *Alcon*, the finding of non-obviousness here should be reversed because of the district court's flawed and erroneous analysis on motivation to combine.

CONCLUSION

Both the Supreme Court's and this Court's precedent dictate that the obviousness analysis must focus on the claimed invention and take a flexible approach in assessing whether there were any motivations to make it, without limiting the analysis to any one particular motivation. Those standards have long been applied to patents in the small-molecule pharmaceutical field, and it is critical that they be applied the same way to patents in the field of biologics. But the district court here failed to do so. Instead, the court improperly considered development of a therapeutic agent as the sole possible motivation for a skilled artisan to make the claimed invention, despite the fact that no such limitation exists in the asserted claims, and that the prior art and asserted patents disclosed numerous non-therapeutic uses for the claimed TNFR-IgG1 fusion protein. Amicus Bioepis thus respectfully requests that this error be corrected and the district court's judgment be reversed, thereby confirming that the existing legal standards for obviousness apply equally to biologic-related claims.

Dated: November 15, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE AND FILING

I hereby certify that I electronically filed the foregoing document with the Clerk of the Court of the United States Court of Appeal for the Federal Circuit by using the Court's CM/ECF filing system.

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CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B)(ii). The relevant portions of the brief, including all footnotes, contain 3,838 words as determined by Microsoft Word.

Dated: November 15, 2019

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