United States Court of Appeals for the Federal Circuit

ABBVIE INC. AND
ABBVIE BIOTECHNOLOGY LIMITED,
Plaintiffs-Appellees,

v.

THE MATHILDA AND TERENCE KENNEDY INSTITUTE OF RHEUMATOLOGY TRUST,
Defendant-Appellant.

2013-1545

Appeal from the United States District Court for the Southern District of New York in No. 11-CV-2541, Judge Paul A. Crotty.

Decided: August 21, 2014

MARK A. PERRY, Gibson, Dunn & Crutcher LLP, of Washington, DC, argued for defendant-appellant. With him on the brief were WAYNE M. BARSKY and TIMOTHY P. BEST, of Los Angeles, California. Of counsel on the brief were JOHN P. WHITE, NORMAN H. ZIVIN and ROBERT T. MALDONADO, Cooper & Dunham LLP, of New York, New York.

MICHAEL A. MORIN, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for

plaintiffs-appellees. With him on the brief were DAVID P. FRAZIER, CASEY L. DWYER and CORA R. HOLT.

Before DYK, WALLACH, and CHEN, *Circuit Judges.*

DYK, *Circuit Judge.*

The Mathilda and Terrance Kennedy Institute of Rheumatology Trust (Kennedy) owns U.S. Patent Nos. 7,846,442 (the '442 patent) and 6,270,766 (the '766 patent). Both patents are directed towards methods of treating rheumatoid arthritis by co-administering two drugs. AbbVie, Inc. and AbbVie Biotechnology Ltd. (collectively, AbbVie) are licensees of the '766 patent but not the '442 patent. In 2011, AbbVie sued Kennedy in the Southern District of New York for a declaratory judgment that the '442 patent was invalid under the doctrine of obviousness-type double patenting because the '442 patent was not patentably distinct from the '766 patent. We agree with AbbVie that the '442 patent would have been obvious in light of the '766 patent. Accordingly, we affirm the district court's finding of invalidity.

BACKGROUND

Rheumatoid arthritis is an autoimmune disease that causes painful joint inflammation. If left untreated, this disease can result in bone destruction and lead to potentially life-threatening complications. Although there is no cure for rheumatoid arthritis, scientists have developed a number of treatments that help abate this disease. The patents at issue in this appeal cover a very popular and effective treatment for rheumatoid arthritis: combination therapy of a disease-modifying antirheumatic drug and an antibody.

Kennedy secured two patents on this combination therapy—the '766 and '442 patents. The first (the '766 patent) expired on October 8, 2012, while the second (the

'422 patent) does not expire until August 21, 2018. The question here is whether the '442 patent is invalid for obviousness-type double patenting. Some background of the two patents is essential to understanding the double patenting issue.

Prior to the advent of this combination therapy, patients were treated with disease-modifying antirheumatic drugs, such as methotrexate. However, in the 1980s, researchers began to study the use of antibodies in the treatment of rheumatoid arthritis. Antibodies are the proteins that the immune system uses to identify and neutralize foreign bodies such as viruses and bacteria. During this period, the named inventors of the '766 and '422 patents discovered that a protein called Tumor Necrosis Factor Alpha (TNFα) is partially responsible for the inflammation rheumatoid arthritis causes. This discovery led the inventors to research antibodies that block the TNFα protein. In September 1994, the inventors began a study of rheumatoid arthritis patients whose disease had not responded completely to treatment with methotrexate. The inventors gave those patients an anti-TNFα antibody, either alone or in combination with methotrexate treatment. This study, known as the T-14 study, formed the basis of the '766 and '442 patents and demonstrated the utility of the method claimed in the patents. The T-14 study revealed that rheumatoid arthritis patients better responded to anti-TNFα antibodies when they were administered in conjunction with methotrexate as compared to the response observed when either of the drugs was administered alone.

Titled "Anti-TNF Antibodies and Methotrexate in the Treatment of Arthritis and Crohn's Disease," the '766 patent application was filed on August 1, 1996, and claimed priority to a date of October 8, 1992. The specification clarifies that the invention

> is also based on the unexpected and dramatic discovery that a multiple dose regimen of . . . an [anti-TNF] antibody, *when administered adjunctively with methotrexate* to an individual suffering from a TNF-mediated disease[,] produces a highly beneficial or synergistic clinical response for a significantly longer duration *compared to that obtained with a single or multiple dose regimen of the antagonist administered alone or that obtained with methotrexate administered alone*.

'766 Patent col. 2 ll. 39-48 (emphases added).

The '766 patent then claims a method of co-administering the anti-TNFα antibody and methotrexate. Independent claim 8 is representative: "A method of treating rheumatoid arthritis in an individual in need thereof comprising co-administering methotrexate and an [anti-TNFα] antibody or an antigen-binding fragment thereof to the individual, in therapeutically effective amounts." '766 Patent col. 35 ll. 59-63.

Claims 9 through 14 depend, either directly or indirectly, on claim 8, adding additional limitations to the method of treating rheumatoid arthritis set forth in claim 8. '766 Patent col. 35 l. 64 to col. 36 l. 51. For example, claim 9 recites "[a] method of claim 8 wherein the [anti-TNFα] antibody or antigen-binding fragment is administered in a series of doses separated by intervals of days or weeks." '766 Patent col. 35 ll. 64-67. The '766 patent issued on August 7, 2001, and expired on October 8, 2012.

After the issuance of the '766 patent, the inventors obtained a second patent, the '442 patent, on the method of treatment described therein. Although Kennedy admits that the claims of the '442 patent are encompassed by those of the '766 patent, Kennedy argued that the claims of the '442 patent were separately patentable.

The '442 patent application was filed on September 12, 2005, and claimed priority to the date the '766 patent was filed: August 1, 1996. The specification of the '442 patent is identical to that of the '766 patent. Independent claim 1 of the '442 patent is representative:

> 1. A method of treating an individual suffering from rheumatoid arthritis whose active disease is incompletely controlled despite already receiving methotrexate comprising adjunctively administering with methotrexate therapy a different composition comprising an anti-human [TNFα] antibody or a human [TNFα] binding fragment thereof to the individual, wherein the anti-human [TNFα] or fragment thereof (a) binds to an epitope on human [TNFα], (b) inhibits binding of human [TNFα] to human [TNFα] cell surface receptors and (c) is administered at a dosage of 0.01-100 mg/kg, and wherein such administration reduces or eliminates signs and symptoms associated with rheumatoid arthritis.

'442 Patent col. 35 ll. 2-15. The remaining claims are similar. Unlike the '766 patent, which is directed towards all "individual[s] in need" of rheumatoid arthritis treatment, '766 Patent col. 35 ll. 35-36, the '442 patent claims treatment of a more specific patient group: individuals with "active disease." '442 Patent col. 35 l. 3. The claim language is also different in that the '442 patent references "adjunctively administering" the two drugs, '442 Patent col. 35 l. 5, whereas the '766 patent refers to "co-administering" the two drugs. '766 Patent col. 35 l. 36. The '442 patent issued on December 7, 2010, and expires on August 21, 2018—six years after the expiration of the '766 patent. Both the '766 and '442 patents were assigned to Kennedy.

On December 23, 2002, AbbVie[1] sought and obtained a license to the '766 patent. Thereafter, AbbVie obtained FDA approval to sell Humira, an anti-TNFα antibody, for use either alone or in combination with methotrexate to treat rheumatoid arthritis. AbbVie paid Kennedy over $100 million in royalties for AbbVie's sale of Humira in the United States. Once the '442 patent issued in 2010, Kennedy demanded that AbbVie secure an additional license for that patent in order to continue sales of Humira.

Unwilling to pay further royalties for the right to sell the same product, AbbVie filed this action in the district court on April 13, 2011. AbbVie sought a declaratory judgment that claims of the '442 patent were invalid over the '766 patent for obviousness-type double patenting. After a bench trial, the district court ruled that claims 1-7, 13, 14, and 17-20 of the '442 patent (all of the claims that are the subject of the declaratory judgment action) were invalid over claims 8-14 of the '766 patent. While Kennedy conceded that the '766 patent encompasses the same inventive subject matter as the '442 patent (*i.e.*, that the '766 patent is a dominant patent), Kennedy contended that the '442 patent was nonetheless patentable over the '766 patent. Kennedy argued that the '766 patent claims a "broad genus" of methods for treating rheumatoid arthritis, whereas the '442 patent claims a "narrower species" of those treatment methods with unexpected results. Appellant's Br. 4.

As the first step of the obviousness-type double patenting inquiry, the district court construed the claims of the patents and rejected Kennedy's proposed construc-

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[1] AbbVie was previously known as Abbott Biotechnology Ltd. and then AbbVie Biotechnology Ltd. For simplicity, we refer to this party as AbbVie.

tions of the terms "co-administering," as it is used in the '766 patent, and "active disease," as it is used in the '442 patent. Kennedy argued that the word "co-administering" should be construed to cover not only the administration of methotrexate and the antibody together, but also a scenario in which a patient receives methotrexate alone, is taken off methotrexate, and then receives the antibody alone. The district court rejected Kennedy's proposed claim construction and instead construed the term "co-administering" as follows:

> a person of ordinary skill in the art would understand "co-administration" . . . to encompass three possibilities for the order of administration of the methotrexate and anti-TNFα antibody . . . : (1) treatment with methotrexate and antibody is started at approximately the same time ("concomitantly"); (2) treatment with methotrexate is begun first and treatment with antibody is then added ("adjunctively") to ongoing and continuing methotrexate treatment; or (3) treatment with antibody is begun first and treatment with methotrexate is then added ("adjunctively") to ongoing and continuing antibody treatment.

J.A. 85-86 ¶ 317. The court then construed the word "adjunctively," as it is used in the '442 patent, "to mean a method of administration of methotrexate and an anti-TNFα antibody in which therapy with an anti-TNFα antibody (or fragment thereof) is added to ongoing methotrexate treatment." J.A. 91 ¶ 338. Thus, the district court found that the '442 patent's "adjunctive" administration is one of the three forms of "co-administration" covered by the '766 patent.

The district court also rejected Kennedy's proposed construction of the phrase "active disease." Kennedy advocated that "active disease," as used in the '442 patent, should be limited to particularly sick patients. The

district court rejected Kennedy's restricted definition and construed the term to reach all patients suffering from rheumatoid arthritis and requiring treatment.

After construing the disputed claim terms of the '766 and '442 patents, the district court turned to the next step of the obviousness-type double patenting inquiry and compared the claims of the two patents. With respect to the terms "co-administration" and "adjunctive," the court found that "[i]n light of the limited universe of treatment methods within the genus of co-administration defined by claims 8 through 14 of the '766 patent, a person of ordinary skill in the art would have envisaged the species of adjunctive administration defined by claims 1 and 2 of the '442 patent." J.A. 93 ¶ 349. Regarding the phrase "active disease" the court found that "a person of ordinary skill in the art would not consider there to be a substantial difference between the patient populations identified by claim 8 of the '766 patent and claim 1 of the '442 patent." J.A. 95 ¶ 354. As a result, the district court found that the '442 patent covered the exact same invention as the '766 patent and held that asserted claims of the '442 patent were invalid over the asserted claims of the '766 patent for obviousness-type double patenting. The district court entered a partial final judgment pursuant to Rule 54(b) in favor of AbbVie, and Kennedy appealed. Fed. R. Civ. P. 54(b).

We have jurisdiction pursuant to 28 U.S.C. §§ 1292(c) and 1295(a)(1). Invalidity must be proven by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'Ship*, 131 S. Ct. 2238, 2242 (2011); *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1349 (Fed. Cir. 2001). While the ultimate conclusion that a patent is invalid under the doctrine of obviousness-type double patenting is reviewed de novo, the underlying factual determinations—including the existence of secondary factors such as unexpected results—are reviewed for clear error. *Eli Lilly*

& Co. v. Teva Parenteral Meds., Inc., 689 F.3d 1368, 1376 (Fed. Cir. 2012). Claim construction is a question of law that we review de novo. *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 744 F.3d 1272, 1286 (Fed. Cir. 2014) (en banc); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (en banc).

DISCUSSION

I

While often described as a court-created doctrine, obviousness-type double patenting is grounded in the text of the Patent Act. *See In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985); *see also Boehringer Ingelheim Int'l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1346 (Fed. Cir. 2010); *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). Section 101 reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, . . . may obtain *a* patent therefor." 35 U.S.C. § 101 (emphasis added). Thus, § 101 forbids an individual from obtaining more than one patent on the same invention, *i.e.*, double patenting. As this court has explained, "a rejection based upon double patenting of the obviousness type" is "grounded in public policy (a policy reflected in the patent statute)." *Longi*, 759 F.2d at 892 (emphasis removed).

The courts have recognized this principle since the inception of our patent laws. In 1819, Justice Story explained,

> It cannot be, that a patentee can have in use at the same time two valid patents for the same invention; and if he can successively take out at different times new patents for the same invention, he may perpetuate his exclusive right during a century . . . . If this proceeding could obtain countenance, it would completely destroy the whole consideration derived by the public for the grant

> of the patent, [] the right to use the invention at the expiration of the term specified in the original grant.

Odiorne v. Amesbury Nail Factory, 18 F. Cas. 578, 579 (C.C.D. Mass. 1819). The Supreme Court has reaffirmed the prohibition on double patenting on multiple occasions. *See Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896) ("It is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted."); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 197-98 (1894); *Suffolk Co. v. Hayden*, 70 U.S. (3 Wall.) 315, 319 (1865). As this court recently reminded, "[t]he bar against double patenting was created to preserve that bargained-for right held by the public." *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1212 (Fed. Cir. 2014); *see also Boehringer*, 592 F.3d at 1346; *Longi*, 759 F.2d at 892; *In re Robeson*, 331 F.2d 610, 614 (CCPA 1964). The ban on double patenting ensures that the public gets the benefit of the invention after the original period of monopoly expires.

Despite the "longstanding" recognition of the "prohibition against double patenting," *Gilead*, 753 F.3d at 1212, Kennedy argues that the statutory and policy rationales underlying the obviousness-type double patenting doctrine no longer exist and the doctrine should be discarded. More specifically, Kennedy contends that the Uruguay Round Agreement Act (URAA), Pub. L. 103-465, 108 Stat. 4809, effective June 8, 1995, and its implementation of a 20-year period of patent protection that runs from a patent's earliest claimed priority date, eliminated the need for the obviousness-type double patenting doctrine.

Kennedy views the purpose of this doctrine narrowly: "The ODP doctrine developed to curb abuses, made possi-

ble by continuation practice" wherein "[n]either the Examiner nor a patent challenger could assert prior art arising between the filing date of the continuation application and an earlier claimed priority date." Appellant's Br. 20. This practice—where "the use of continuation applications to claim previously disclosed but unclaimed features of an invention many years after the filing of the original patent application," *Ricoh Co., Ltd. v. Nashua Corp.*, 185 F.3d 884, No. 97-1344, slip op. at *3 n.3 (Fed. Cir. Feb. 18, 1999)—is known as submarine patenting. Now that the patent term is measured from the earliest claimed priority date, as opposed to the date of issuance, Kennedy contends that the submarine patent problem no longer exists and that the URAA amendment vitiated the policy basis for the doctrine of obviousness-type double patenting.

But this argument ignores another crucial purpose of the doctrine: It is designed to prevent an inventor from securing a second, later expiring patent for the same invention. *See Miller*, 151 U.S. at 197-98; *Singer*, 163 U.S. at 185. That problem still exists. Patents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO. *See* 35 U.S.C. § 154(b) (patent term adjustments); *In re Berg*, 140 F.3d 1428, 1430 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 1048-49 (Fed. Cir. 1993). So too where, as here, the applicant chooses to file separate applications for overlapping subject matter and to claim different priority dates for the applications, the separate patents will have different expiration dates since the patent term is measured from the claimed priority date.[2] When such situations arise, the doctrine of obvi-

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[2] Here, Kennedy claimed a priority date of October 8, 1992 (the filing date of an earlier application), for the

ousness-type double patenting ensures that a particular invention (and obvious variants thereof) does not receive an undue patent term extension. *See Berg*, 140 F.3d at 1432, 1435; *Goodman*, 11 F.3d at 1052-53; *In re Braat*, 937 F.2d 589, 592 (Fed. Cir. 1991).

Although this court has recognized that the doctrine of obviousness-type double patenting is less significant in post-URAA patent disputes, we have also recognized its continued importance. For example, in *In re Fallaux*, we recognized "that the unjustified patent term extension justification for obviousness-type double patenting" may have "limited force in . . . many double patenting rejections today, in no small part because of the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing." 564 F.3d 1313, 1318 (Fed. Cir. 2009).[3]

'766 patent. For the '442 patent, Kennedy claimed a later priority date, August 1, 1996 (the filing date of the application that issued as the '766 patent), so that the '442 patent would expire after the '766 patent.

[3] *See also Boehringer*, 592 F.3d at 1346 ("The doctrine of obviousness-type double patenting is an important check on improper extension of patent rights through the use of divisional and continuation applications, at least for patents issued from applications filed prior to the amendment of 35 U.S.C. § 154 to create twenty-year terms running from the date of the earliest related application."); 3A Donald S. Chisum, Chisum on Patents § 9.01 ("[T]he 1994 Uruguay Round Agreements Act . . . alters the scenarios raising double patenting concerns, but it does not alter the fundamental policies against issuing multiple patents for the same claimed invention or for obvious variations of the same invention.").

At the same time, the continued importance of the doctrine of obviousness-type double patenting where two patents have different expiration dates was recently reaffirmed by this court in *Gilead*. In *Gilead,* we held that a later-issued, but earlier-expiring patent could qualify as a double patenting reference, and thus invalidate an earlier-issued, but later expiring patent. 753 F.3d at 1217. Because both the reference and later expiring patents in *Gilead* issued after the 1995 URAA amendment, *id.* at 1209, *Gilead* implicitly assumed the continued vitality of the obviousness-type double patenting doctrine. *See id.* at 1212. We now make explicit what was implicit in *Gilead*: the doctrine of obviousness-type double patenting continues to apply where two patents that claim the same invention have different expiration dates. We hold that Kennedy is not entitled to an extra six years of monopoly solely because it filed a separate application unless the two inventions are patentably distinct.

II

We now turn to the question of whether the doctrine applies here. The obviousness-type double patenting analysis involves two steps: "First, the court 'construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences.' Second, the court 'determines whether those differences render the claims patentably distinct.'" *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1385 (Fed. Cir. 2010) (alteration in original) (quoting *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1363 (Fed. Cir. 2008)). "'A later claim that is not patentably distinct from,' i.e., 'is obvious over[ ] or anticipated by,' an earlier claim is invalid for obviousness-type double patenting." *Id.* at 1385 (alteration in original) (quoting *Eli Lilly*, 251 F.3d at 968).

A. Claim Construction

1. Co-Administration

We begin with Kennedy's claim construction arguments. Through claim construction, Kennedy attempts to enlarge the scope of the '766 patent while narrowing that of the '442 patent. First, Kennedy urges that the district court erred in limiting the term "co-administering"[4] in the '766 patent to three modes of administration. The district court construed "co-administering" to mean that treatment with the antibody can be: (1) started at approximately the same time as treatment with methotrexate (concomitant administration); (2) added after treatment with the methotrexate has already begun (adjunctive administration); or (3) begun first, with the methotrexate treatment later added (adjunctive administration). Kennedy argues that this definition erroneously excludes a fourth form of co-administration: administration of the antibody alone after discontinuing the administration of methotrexate.

The '766 patent's specification confirms the correctness of the district court's claim construction. The specification never uses the term "co-administering" to refer to patients who only received the antibody after discontinuing treatment with methotrexate. The specification makes clear that the invention described in the claims is limited to concomitant and adjunctive use. The specification outlines several possible modes of co-administration: "TNF antagonists can be administered prior to, simulta-

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[4] Claim 8 of the '766 patent reads: "A method of treating rheumatoid arthritis in an individual in need thereof comprising co-administering methotrexate and an [anti-TNFα] antibody or an antigen-binding fragment thereof to the individual, in therapeutically effective amounts." '766 Patent col. 35 ll. 59-63.

neously with (in the same or different compositions) or sequentially with the administration of methotrexate. For example, TNF antagonists can be administered as adjunctive and/or concomitant therapy to methotrexate therapy." '766 Patent col. 18 ll. 58-62. "Concomitant" therapy involves starting the two drugs at the same time and then continuing their administration together; "adjunctive" therapy involves starting one of the drugs after the other and then continuing their administration together. The specification concludes that "[t]he present invention relates to the discovery that tumor necrosis factor antagonists can be administered to patients suffering from a TNF-mediated disease as adjunctive and/or concomitant therapy to methotrexate therapy, with good to excellent alleviation of the signs and symptoms of the disease." '766 Patent col. 4 ll. 31-36. This discussion in the specification shows that "co-administering" encompasses treatment with the antibody that can be started before, after, or at the same time as treatment with methotrexate, as long as two drugs are administered together. The specification nowhere suggests that the invention includes administration of the antibody alone after discontinuing treatment with methotrexate.

The specification's discussion of the three examples it provides similarly confirms the district court's claim construction. None of the examples discusses the discontinuation of methotrexate as a form of co-administration or as part of the invention. The first example describes the T-14 study. To qualify for entry into the T-14 study, patients must have received weekly methotrexate treatment for at least six months. Upon enrollment into the study, the patients were "stabilized" on a fixed weekly dose of methotrexate for the first four weeks. After this first, equalizing month, the patients were organized into three separate groups that received three different treatment regimens—three different modes of antibody admin-

istration. The week the patients began to receive the differing treatment regimens was called "week zero" because it marked the beginning of the trial period. The three distinct treatment regimens, or modes of anti-body administration, were: (1) patients who received methotrexate as a tablet and infusions of a placebo instead of the anti-TNFα antibody (the "control" group), (2) patients who received methotrexate as a tablet and infusions of the anti-TNFα antibody throughout the trial ("MTX+" group), and (3) patients who received a placebo tablet instead of methotrexate and infusions of the anti-TNFα antibody throughout the trial (the "anti-TNFα antibody alone" or "MTX-" group). In the T-14 study, as in the specification's other examples, the therapy that the non-placebo, non-control patients received was "adjunctive" co-administration.[5] The specification discusses the MTX- treatment group and recognized that this group manifested some limited benefits as compared to the MTX+ group,[6] but never suggests that this group received the

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[5] In other words, the antibody treatment was added onto the methotrexate therapy: the patients were already receiving methotrexate and then began taking the antibody in addition. None of the examples discusses a scenario in which patient received "concomitant" co-administration—where treatment with methotrexate and the antibody are begun at the exact same time. Nevertheless, the specifications of the '766 patent and '442 patent discuss concomitant administration of the two drugs as a type of "co-administration."

[6] At trial, multiple experts attributed this result to a "carry-over" effect that the patients' prior treatment with methotrexate caused. All the patients in the T-14 study had received weekly methotrexate for at least six months prior to the trial and were then "stabilized" on a

adjunctive or concomitant therapy that is within the invention of the '766 patent's claims.

To the contrary, the specification of the '766 patent points to the outcomes experienced by the MTX+ group, as compared to those the MTX- and control groups experienced, in order to show that "co-administration" produces "a highly beneficial or synergistic clinical response." '766 Patent col. 31 l. 39; *see* '766 Patent col. 29 ll. 3-10. It was only through a *comparison* of the MTX+ group to the MTX- group (which the specification refers to as the group receiving the antibody "without methotrexate," '766 Patent col. 29 ll. 8-9) that the specification concludes that "treatment with a multiple dose regimen of [the antibody] as adjunctive and/or concomitant therapy to methotrexate therapy, in [rheumatoid arthritis] patients whose disease is incompletely controlled by methotrexate, produces a highly beneficial or synergistic clinical response that can be sustained through 26 weeks." '766 Patent col. 31 ll. 35-40. Put simply, the specification compares the better outcomes that the group treated with both drugs experienced to the poorer results obtained in the groups that received no methotrexate or no antibody after week zero to support its conclusion that "co-administration"—administration of both drugs at the same time—is a superior method of rheumatoid arthritis treatment. Co-administration cannot include patients who discontinued methotrexate as Kennedy contends.

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fixed weekly dose of methotrexate for the first four weeks of the study.

The specification does not discuss this carry-over effect or suggest that the MTX- group received a form of co-administration. As discussed in the text, the specification highlights the superior results that the MTX+ group experienced in order to prove that "co-administration" is a beneficial therapy.

Nevertheless, Kennedy argues that the principle of claim differentiation counsels in favor of reading claim 8 to encompass embodiments where *single* doses of either the antibody *or* methotrexate are delivered to patients. Claim 8 reads "[a] method of treating rheumatoid arthritis in an individual in need thereof comprising co-administering methotrexate and an [anti-TNFα] antibody or an antigen-binding fragment thereof to the individual, in therapeutically effective amounts," '766 Patent col. 35 ll. 59-63, while claim 9 reads "[a] method of claim 8 wherein the [anti-TNFα] antibody or antigen-binding fragment is administered *in a series of doses separated by intervals of days or weeks*." '766 Patent col. 35 ll. 64-67 (emphasis added). Kennedy contends that "[a] comparison of claim 8 to its dependent claim 9 demonstrates that the only additional limitation is that the anti-TNFα antibody must be administered 'in a series of doses separated by intervals of days or weeks.'" Appellant's Br. 37. Kennedy relies on this difference to support its argument that the administration of the antibody after discontinuation of methotrexate treatment is covered.

But claim 9 says nothing about the discontinuation of the methotrexate. Its administration is assumed to be ongoing with the single or multiple doses of the antibody. The plain text of the '766 patent's specification and claims supports the district court's claim construction of "co-administering." *See also* J.A. 86-87 ¶ 319-21 (the district court also explained that the inventors' testimony at trial supported this construction of the term "co-administering"). Accordingly, the district court correctly interpreted "co-administration."

2. Active Disease

Kennedy also contests the district court's construction of the term "active disease," as used in the '442 patent.[7] Kennedy contends that the '442 patent "explicitly defines" the term "active disease" to mean "'the presence of six or more swollen joints plus at least three of four secondary criteria (duration of morning stiffness ≧45 minutes; ≧6 tender or painful joints; erythrocyte sedimentation rate (ESR) ≧28 mm/hour; C-reactive protein (CRP) ≧20 mg/l[)].'" Appellant's Br. 32 (quoting '442 Patent col. 20 ll. 35-39). In support of this argument, Kennedy points to the '442 patent's description of the T-14 study's patient population:

> One hundred one (101) patients . . . who had . . . active disease (according to the criteria of the American College of Rheumatology) . . . were enrolled in the trial. Active disease was defined by the presence of six or more swollen joints plus at least three of four secondary criteria (duration of morning stiffness ≧45 minutes; ≧6 tender or painful joints; erythrocyte sedimentation rate (ESR) ≧28 mm/hour; C-reactive protein (CRP) ≧20 mg/l.

'442 Patent col. 20 ll. 29-39.

Kennedy relies on the prosecution history of the '442 patent to support its desired claim construction argument. The examiner originally rejected the '442 patent for indefiniteness, in part, because Kennedy did not sufficiently define the term "active disease." In its response to

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[7] Claim 1 of the '442 patent states: "A method of treating an individual suffering from rheumatoid arthritis whose active disease is incompletely controlled despite already receiving methotrexate . . . ." '442 Patent col. 35 ll. 2-4.

the examiner's rejection, Kennedy stated that "active disease" is "defined by" the portion of the specification quoted above referring to the T-14 study. J.A. 5955. Thereafter, the examiner allowed the '442 patent's claims: "Given that [the] claimed methods are drawn to treating . . . patients who have already failed to respond to methotrexate or *whose active disease* has been incompletely controlled by previous treatment with methotrexate; the claimed methods of treating rheumatoid arthritis . . . due to unexpected results . . . are deemed to be an unobvious species." J.A. 6007 (emphasis added). Kennedy argues that this prosecution history reveals that its more specific definition of active disease, in accordance with the definition set forth in the portion of the specification describing the T-14 study, was critical to the examiner's allowance of the '442 patent claims.

AbbVie, on the other hand, contends that the quoted portion of the '442 specification does not provide a single definition of active disease, but rather sets forth *two* definitions. Accordingly, AbbVie argues that the inventors cannot be viewed as having acted as their own lexicographers. *See Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1355 (Fed. Cir. 2003) ("Because the specification provides two alternative definitions for the term at issue, the specification does not define the claim term."). Under such circumstances, AbbVie contends that the standard definition of active disease—"patients with continuing signs and symptoms of rheumatoid arthritis," J.A. 92 ¶ 345—should apply here. This standard definition includes individuals in need of rheumatoid arthritis treatment, the definition used in the '766 patent.

We assume, without deciding, that Kennedy's proposed construction of "active disease" was correct. The consequence is the genus claimed in the '766 patent (treating all patients in need thereof) is broader than the species claimed in the '442 patent (treating patients with

"active disease," *i.e.*, particularly sick patients). Thus, assuming Kennedy's construction of the term "active disease" is correct, we must decide whether a patent that claims to treat a subset of patients with more severe rheumatoid arthritis (the '442 patent) is an obvious variant of a patent that claims treatment of rheumatoid arthritis patients generally (the '766 patent).

B. Obviousness

We thus turn to the second step of the obviousness-type double patenting analysis: "whether the differences in subject matter between the claims" of the '766 and '442 patents render their claims "patentably distinct" because the '442 patent applies to patients with active disease.[8]

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[8] We note that Kennedy does not contend that under the district court's claim construction of the term "co-administering," the '442 patent is patentably distinct from the '766 patent because it claims "adjunctive" therapy alone. In other words, Kennedy does not contend that the '442 patent is a separately patentable species of the '766 patent because it only claims "adjunctive" co-administration and not "concomitant" co-administration.

Kennedy does contend, however, that the '442 patent is non-obvious over the '766 patent because the '442 patent claims are narrower than those of the '766 patent in that the '442 patent refers to a reduction in the "signs and symptoms associated with rheumatoid arthritis." '442 Patent col. 35 ll. 13-15. Kennedy asserts that the reduction in both the "signs and symptoms" of the disease was an unexpected result. At oral argument, Kennedy explained that "signs" of the disease are indicators that are measured in the laboratory, such as inhibition of the biological activity of TNFα, whereas "symptoms" are observable patient outcomes, such as a renewed ability to walk. Kennedy then argued that the claims of the '766 patent only require a reduction in the *signs* of the dis-

Amgen Inc. v. F. Hoffman–La Roche Ltd, 580 F.3d 1340, 1361 (Fed. Cir. 2009); *see Eli Lilly & Co.*, 689 F.3d at 1377; *Sun*, 611 F.3d at 1385. As we clarified in *Eli Lilly* and *Amgen*, in this respect, the law of obviousness-type double patenting looks to the law of obviousness generally. As we further explained in *Amgen*, "[t]his part of the obviousness-type double patenting analysis is analogous to an obviousness analysis under 35 U.S.C. § 103." *Amgen*, 580 F.3d at 1361; *Eli Lilly*, 689 F.3d at 1377; *see also Longi*, 759 F.2d at 896. Indeed, Kennedy admits that "the second step of the [obviousness-type double patenting] analysis is analogous to an inquiry into the obviousness of a claim under 35 U.S.C. § 103." Appellant's Br. 44 (citing *Longi*, 759 F.2d at 892 n.4). Thus, if the later expiring patent is "merely an obvious variation of an invention disclosed and claimed in the [reference] patent," the later expiring patent is invalid for obviousness-type double patenting. *In re Vogel*, 422 F.2d 438, 441 (CCPA

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ease—inhibition of the biological activity of the TNFα protein—whereas the T-14 study shows that the '442 patent led to a reduction in both the signs *and* symptoms of the disease.

Although the '766 patent may not have specifically claimed to "reduce[] or eliminate[] [the] signs and symptoms associated with rheumatoid arthritis," '442 Patent col. 35 ll. 14-15, the '766 patent's specification demonstrates that this outcome was a known result of the patent's claimed method. According to the '766 patent's specification, "[t]he present invention is based on the discovery that treatment of patients suffering from [rheumatoid arthritis] with [an anti-TNF antibody] . . . *as adjunctive and/or concomitant therapy to methotrexate therapy* produces a rapid and sustained reduction in the clinical *signs and symptoms* of the disease." '766 Patent col. 2 ll. 33-39 (emphases added).

1970). But "the nonclaim portion of the earlier patent ordinarily does not qualify as prior art against the patentee." *Eli Lilly*, 689 F.3d at 1379.

To be sure, obviousness is not demonstrated merely by showing that an earlier expiring patent dominates a later expiring patent. Nor do we think that the district court here relied on any such principle. It is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus. *See Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1270 (Fed. Cir. 2003); *In re Kaplan*, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986); *In re Sarett*, 327 F.2d 1005, 1014 (CCPA 1964); 3A Donald S. Chisum, Chisum on Patents § 9.03[2][b][ii].

But not every species of a patented genus is separately patentable. First, when a "genus is so limited that a person of ordinary skill in the art can 'at once envisage each member of this limited class,' . . . a reference describing the genus anticipates every species within the genus." *In re Gleave*, 560 F.3d 1331, 1337-38 (Fed. Cir. 2009) (quoting *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006), and citing *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005)); *see also Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001) ("[T]he disclosure of a small genus may anticipate the species of that genus even if the species are not themselves recited."). For example, in *Pfizer, Inc. v. Apotex, Inc.*, we invalidated a patent on a species belonging to a previously patented genus. 480 F.3d 1348, 1361 (Fed. Cir. 2007). As we explained, "this is not the case where there are 'numerous parameters' to try." *Id.* at 1363. Because prior art references "provide[d] ample motivation to narrow the [a previously patented] genus of . . . pharmaceutically-acceptable anions to a few," *id.* at 1366, we concluded that the species at issue in this case was unpatentable. *Id.* at

1372. We clarified that "the outcome of this case need not rest heavily on the size of the genus . . . disclosed by [a prior art reference] because clear and convincing evidence establishes that . . . one of ordinary skill in the art would have favorably considered [the species patent at issue]." *Id.* at 1363. In *In re Petering*, the court similarly found that certain species claims were unpatentable over a prior patent on their genus:

> It is our opinion that one skilled in this art would, on reading the [prior] patent, *at once envisage each member of this limited class,* even though this skilled person might not at once define in his mind the formal boundaries of the class as we have done here. . . . [W]e think that one with ordinary skill in this art, with. . . [the reference genus patent] before him, *would also have before him those subspecies*.

301 F.2d 676, 681-82 (CCPA 1962) (emphases added). Thus, species are unpatentable when prior art disclosures describe the genus containing those species such that a person of ordinary skill in the art would be able to envision every member of the class. Here, we think it is clear that a reader of the '766 patent could have easily envisioned a species limited to sicker patients. The district court was correct in concluding that the species of the '442 patent was not patentably distinct from the genus of the '766 patent.

Moreover, even if Kennedy were to show that not every species could be envisioned from the '766 patent's genus, Kennedy's claim of non-obviousness rests on its contention that the species has unexpected results. A species contained in a previously patented genus may be patentable if the species manifests unexpected properties or produces unexpected results. For example, in *Petering*, the court found that a species was patentable in spite of prior art that claimed its genus because the species had

unexpected properties. 301 F.2d at 683. In *Pfizer, Inc. v. Apotex, Inc.*, on the other hand, we concluded that Pfizer's patent was invalid because Pfizer "failed to prove that the results [associated with the species patent at issue] [we]re unexpected." 480 F.3d at 1371. Kennedy's claim of unexpected results is not supported.

In its brief, Kennedy appeared to admit that it was only able to show that the '442 patent manifested unexpected results if its desired construction of the term "co-administering" were accepted.[9] However, at oral argument, Kennedy more broadly asserted that the '442 patent led to the unexpected result of improving the health of the "hardest-to-treat patients"—the patients with "active disease." We disagree.

To determine whether the '442 patent is directed to a species that yielded unexpected results, we must necessarily look to the '766 patent's disclosures to assess what results were expected at the time the '766 patent application was filed. The demonstration of utility of the '766 patent relies on the T-14 study, the very study that Kennedy now relies on to show that the '442 patent led to unexpected results and merits a separate patent. Indeed, Kennedy's definition of the term "active disease" is taken from the T-14 study. The '766 patent relied on the results obtained in the T-14 study to demonstrate that a combination therapy of methotrexate and anti-TNFα antibody improved the health of the very subset of rheumatoid

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[9] In its brief, Kennedy explained that "[t]he district court refused to credit [Kennedy's evidence of unexpected results] principally because the court's construction of 'co-administering' eliminated the results obtained with the . . . MTX- patients from the analysis, leaving nothing against which to compare the results of the '442 patent's . . . treatment." Appellant's Br. 56; *see also id.* at 63.

arthritis patients that Kennedy now contends show that the method of the '442 patent led to unexpected results. Thus, the '442 patent merely claims the known utility of the '766 patent and does not claim a species with unexpected results.

However, Kennedy argues that the '766 patent's disclosures cannot be used to determine whether the results of the '442 patent were unexpected because this amounts to treating the disclosures of the '766 patent as prior art. It is true that a reference patent's specification cannot be used as prior art in an obviousness-type double patenting analysis. *See Eli Lilly*, 689 F.3d at 1378-79; *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003); *Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1280 (Fed. Cir. 1992). But, it is also well settled that we may look to a reference patent's disclosures of utility to determine the question of obviousness. As our predecessor court concluded, "[i]n considering the question [of obviousness-type double patenting], the patent disclosure may not be used as prior art. *This does not mean that the disclosure may not be used at all.* As pointed out above, in certain instances it may be used . . . as required to answer the . . . question above." *Vogel*, 422 F.2d at 441-42 (internal citations omitted) (emphasis added). Similarly, in *In re Basell Poliolefine Italia S.P.A.*, we clarified that "[w]hile . . . it is impermissible to treat a 'patent disclosure as though it were prior art' in a double patenting inquiry, . . . the disclosure may be used . . . to answer the question whether claims merely define an obvious variation of what is earlier disclosed and claimed." 547 F.3d 1371, 1378-79 (Fed. Cir. 2008) (quoting *Kaplan*, 789 F.2d at 1580).

We have repeatedly approved examination of the disclosed utility of the invention claimed in an earlier patent to address the question of obviousness. As we explained in *Geneva Pharmaceutical, Inc. v. GlaxoSmithKline PLC*,

"[t]he [reference] patent's claim describes a compound, and [the reference patent's] written description discloses a single utility of that compound . . . . The [later expiring] patent claims nothing more than [the reference patent's] disclosed utility as a method of using the [reference patent's] compound. Thus, the claims of the [reference patent] and [later expiring] patents are not patentably distinct." 349 F.3d at 1386.[10]

In *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, we explained that a later expiring patent is not patentably distinct from an earlier expiring patent if it merely claims a disclosed utility of the earlier claimed invention.

> The claims at issue of the [later expiring] patent merely recite methods of administering a "therapeutically-effective amount" of the compositions found in claim 5 of the [earlier expiring] patent. . . . Thus, . . . the [later expiring] patent merely claims a particular use described in the [earlier expiring] patent . . . . The asserted claims of the [later expiring patent] are therefore not patentably distinct over the claims of the [earlier expiring] patent.

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[10] In reaching this conclusion, the court confirmed the policy rationale articulated by our predecessor court in *In re Byck*:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.

48 F.2d 665, 666 (CCPA 1931).

518 F.3d at 1363 (internal footnote omitted). There is no meaningful distinction between examining the disclosed utility of an earlier patent to determine the overall question of obviousness and looking at the disclosed utility of an earlier patent to determine whether the utility of the later patent was unexpected at the time of the earlier patent. Neither involves improper use of the reference patent's specification as prior art.

The '442 patent does not claim a species manifesting unexpected results. The '442 patent would have been obvious over the '766 patent.

CONCLUSION

In sum, we conclude that the '442 patent is invalid for obviousness-type double patenting in light of the '766 patent.

AFFIRMED

Costs to appellee.