

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

SINAN TAS,
Appellant

v.

**PHILIP A. BEACHY, MICHAEL K. COOPER,
JEFFREY A. PORTER, JAMES K. CHEN, ANSSI
JUSSI NIKOLAI TAIPALE,**
Appellees

2015-1175

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in Nos. 105,926,
105,949.

Decided: September 29, 2015

SINAN TAS, Bor, Turkey, pro se.

OLIVER ASHE, JR., Ashe, P.C., Reston, VA, for appel-
lees. Also represented by BRION P. HEANEY, Millen, White,
Zelano & Branigan PC, Arlington, VA.

Before PROST, *Chief Judge*, NEWMAN, and CHEN,
Circuit Judges.

PER CURIAM.

This case involves Interference Nos. 105,926 and 105,949 (the '926 and '949 interferences, respectively).¹ The subject matter of the interferences relates to a method of treating humans that have a specific type of cancer, a basal carcinoma cell (BCC) tumor, with a compound called cyclopamine, as well as acceptable cyclopamine alternatives. BCC tumors form when a signaling pathway used by cells for initiating apoptosis (programmed cell death) mutates, resulting in the uncontrolled proliferation of cells. The relevant signaling pathway here is the Hedgehog/Smoothened (Hh/Smo) cell signaling pathway and involves two proteins: Hedgehog (Hh) and Smoothened (Smo). Cyclopamine takes advantage of the Hh/Smo signaling pathway to initiate apoptosis, which inhibits the BCCs from proliferating.

This dispute arose when Dr. Sinan Taş and his co-inventor added claims to the application that became U.S. Patent No. 7,893,078 (the '078 patent). These claims recited “cyclopamine *or another compound that selectively inhibits Hedgehog/Smoothened signaling.*” See J.A. 4379–80 (emphasis added). Philip Beachy and four other inventors (collectively, Beachy) then filed two patent applications that claimed and purportedly also described the subject matter claimed in the '078 patent: U.S. Patent Application Nos. 13/363,934 and 13/364,121 (the '934

¹ The America Invents Act (AIA), Pub. L. No. 112-29, eliminated interference proceedings. Because the applications and patents at issue in this case were filed before March 16, 2013, we apply the pre-AIA 35 U.S.C. § 135.

and '121 applications, respectively).² The United States Patent and Trademark Office (USPTO) Patent Trial and Appeal Board (PTAB) initiated two interferences to determine whether Taş or Beachy first invented the relevant subject matter, and consolidated the proceedings.

The interferences contain one Count each, numbered Count 2 in the '949 interference and Count 3 in the '926 interference. There is no Count 1. The PTAB designated all claims of the '078 patent (claims 1–23) and all pending claims of the '121 application (claims 201–213) as corresponding to Count 2, and all claims of the '078 patent and all pending claims of the '934 application (claims 101–112 and 114–127) as corresponding to Count 3.

For both interferences, the PTAB declared Beachy the Senior Party and Taş the Junior Party because it accorded (1) the '078 patent the benefit of International Application No. PCT/TR01/00027, filed July 2, 2001, (2) the '934 application the benefit of four prior applications, including U.S. Patent Application No. 09/668,076 (the '076 application), filed October 13, 2000, and (3) the '121 application the benefit of four prior applications, including U.S. Patent Application Nos. 09/708,964 (the '964 application), filed November 8, 2000, and 09/685,244 (the '244 application), filed October 10, 2000.

Taş admitted that he cannot prove an actual date of invention prior to the July 2, 2001, priority date. *See* J.A. 861 (Taş's Preliminary Statement stating that "Taş [relies] for its earliest constructive reduction to practice on PCT/TR01/00027, filed on 02 July 2001."); 37 C.F.R. §

² For the purposes of these interferences, Johns Hopkins University School of Medicine and Genentech, Inc. are the real parties in interest in the '934 and '121 applications. The PTAB below and the parties on appeal refer to the appellee as Beachy, and we do the same.

1.629(a) (“A party shall be strictly held to any date alleged in the preliminary statement.”). Taş instead argues, for the ’949 interference, that no interference-in-fact exists between the ’078 patent and the ’121 application. Taş also attacks the written description and enablement support of the priority applications to both Beachy applications, which, if successful, would give the Beachy applications a priority date later than the ’078 patent. *See Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993) (Noting that the earlier-filed priority application must satisfy section 112, paragraph 1.).

We affirm the PTAB’s determination that an interference-in-fact exists between Taş’s ’078 patent and Beachy’s ’121 application. We also affirm the PTAB’s determination that both the Counts and all the pending claims of the ’121 and ’934 applications are sufficiently described and enabled by the Beachy priority applications.

I

“An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.” 37 C.F.R. 41.203(a); *see Eli Lilly v. Bd. of Regents of Univ. of Washington*, 334 F.3d 1264, 1267 (Fed. Cir. 2003). Once the PTAB declares an interference, the party claiming that an interference-in-fact does not exist bears the burden of persuasion. *Case v. CPC Int’l, Inc.*, 730 F.2d 745, 750 (Fed. Cir. 1984).

Count 3 contains two alternatives. *See* J.A. 8–9. The first alternative, based in large measure on claims 15 and 20 of Taş’s ’078 patent, recites a medicament comprising cyclopamine that “causes decrease of size or disappearance of the tumor.” The second alternative, based in large measure on claims 115–116 of Beachy’s ’934 application, recites a medicament comprising cyclopamine that “inhibits tumor cell proliferation.” In the ’949 interference, Taş filed a preliminary motion in which he argued that the

two alternatives are not the same, and thus no interference-in-fact exists, because inhibiting proliferation of a tumor is not the same as causing the decrease of size or disappearance of the tumor. The PTAB first correctly noted that it must compare the *claims* of the patent and application at issue, not the alternatives of a Count, to determine whether an interference-in-fact exists. *See* 37 C.F.R. § 41.203(a). The PTAB nevertheless proceeded to decide the merits of Taş’s argument because it determined that Taş’s motion “essentially has compared” claims 15 and 20 of the ’078 patent to claim 201 of the ’121 application.

In response to Taş’s motion, the PTAB pointed out that the claims also require the medicament comprising cyclopamine to “induce apoptosis” in a BCC tumor. The PTAB found that when apoptosis takes place in a BCC tumor, the results recited in both Count 3 alternatives occur: the tumor decreases in size and possibly disappears, and the tumor cells stop proliferating. The PTAB thus held that an interference-in-fact exists because the claims recite consistent result limitations that are a consequence of apoptosis having taken place.

On appeal, Taş argues that the PTAB improperly construed the “inhibits tumor cell proliferation” limitation when the PTAB stated that “[i]f proliferation is inhibited, then the tumor does not grow.” Taş Opening Br. at 41 (quoting J.A. 17). Taş contends that the “inhibits tumor cell proliferation” limitation can also be met if the tumor grows at a slower pace. But even under his proposed construction, Taş does not dispute that inhibiting tumor cell proliferation is a result of apoptosis in a BCC tumor. Accordingly, the PTAB’s determination that the claims recite consistent result limitations that are a consequence of apoptosis having taken place remains unchallenged. We therefore affirm the PTAB’s declaration that an interference-in-fact exists between claims 15 and 20 of the

'078 patent and claim 201 of the '121 application, as well as the other claims unchallenged on appeal.

II

Prior to the AIA, the person who first conceived and reduced the invention to practice was generally considered to be the first inventor. *See* 35 U.S.C. § 102(g) (2006). Under this regime, the filing of a patent application serves as constructive reduction to practice of the subject matter disclosed therein. *Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998). When a party to an interference seeks the benefit of an earlier-filed U.S. patent application, the earlier application must contain a written description of the subject matter of the interference Count, and must meet the enablement requirement. *Id.*

In both interferences, Taş filed preliminary motions challenging the written description and enablement support for both Counts and the pending claims of the Beachy applications. In one preliminary motion, Taş argued that the '076 priority application does not provide written description or enablement support for five limitations of Count 3. In another preliminary motion, Taş argued that the '244 and '964 priority applications do not provide written description or enablement for five limitations of Count 2. And, in yet another preliminary motion, Taş argued that the pending claims of the '121 and '934 applications are unpatentable because ten limitations lack written description in the respective specifications of those applications.³

To satisfy the written description requirement, the specification must sufficiently describe the claimed inven-

³ Taş also argued to the PTAB that the pending claims of the '121 and '934 applications are unpatentable as indefinite. The PTAB denied Taş's indefiniteness challenge. Taş does not appeal the PTAB's denial.

tion to a person skilled in the art and show that the inventor actually invented the claimed invention. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Whether a specification provides written support for a claim is a question of fact. *Id.* To satisfy the enablement requirement, the specification must describe the manner of making and using the invention “in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . .” 35 U.S.C. § 112 ¶ 1; see *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322 (Fed. Cir. 2005). Whether a specification enables a claim is a question of law based on underlying factual findings. *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988). We review the PTAB’s enablement determination de novo, and its factual findings for substantial evidence. *In re Gartside*, 203 F.3d 1305, 1313 (Fed. Cir. 2000); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991).

Substantial evidence “means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Our review of factual findings for substantial evidence examines the record as a whole, taking into account evidence that supports the PTAB’s position as well as that evidence detracting from the PTAB’s conclusion. *Gartside*, 203 F.3d at 1312. “[T]he possibility of drawing two inconsistent conclusions from the evidence” will not render the PTAB’s findings unsupported by substantial evidence. See *Consolo v. Fed. Mar. Comm’n*, 383 U.S. 607, 620 (1966). If the evidence in record will support several reasonable but contradictory conclusions, we will not find the PTAB’s decision unsupported by substantial evidence simply because the PTAB chose one conclusion over another plausible alternative. *In re Jolley*, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

A

As a preliminary matter, we note that the PTAB credited and relied on, to some extent, the testimony of Beachy's expert, Dr. Curran, for many of its findings. Taş argues that the PTAB's acceptance of Dr. Curran's testimony was in error because Dr. Curran is not a physician, and the subject matter requires the expertise of a physician. Taş also argues that Dr. Curran's testimony is not reliable because certain publications contradict Dr. Curran's testimony. Beachy responds by listing Dr. Curran's qualifications and pointing out that Taş failed to object to Dr. Curran's testimony in accordance with PTAB rules.

The PTAB addressed Taş's challenge to Dr. Curran in its decision on rehearing. The PTAB noted that Taş failed to challenge Dr. Curran's qualifications in any of the motions it decided, and the issue could not be raised for the first time on rehearing. Because Taş's challenge to Dr. Curran was not properly raised below, we will not consider it on appeal.

B

On appeal, Taş first takes issue with the following sentence from the '076 and '964 applications: "For instance, the subject compounds can be utilized to cause such transformed cells to become either post-mitotic or apoptotic." '076 application, 38:9–12; '964 application, 36:11–14. Taş argues that a person skilled in the art would not believe this sentence is true, and the sentence therefore does not provide written description or enablement support.

First, Taş argues that a person skilled in the art would not believe this sentence because the "subject compounds" in the applications (*e.g.*, cyclopamine) are Hh

antagonists, but this sentence was “plagiarized”⁴ from an earlier patent that discussed the opposite, Hh *agonists*. The PTAB dismissed this argument because Taş cited no legal authority to suggest that the alleged act of plagiarism is at all relevant to the written description or enablement analysis. On appeal, Taş argues that the alleged act of plagiarism is relevant because a person skilled in the art, knowing the content of the earlier patent and presuming the earlier patent to be correct, would not believe the sentence-at-issue in the applications. We understand Taş’s argument to not be about the alleged act of plagiarism itself, for which he still provides no legal authority, but rather to be about what a person skilled in the art would understand the applications to teach. On this point, Taş contends that a person skilled in the art would believe the earlier patent over the applications because prior art references do not corroborate the statement made in the applications. The PTAB heard arguments from both sides about what the applications teach a person skilled in the art, favored Beachy’s evidence over Taş’s, and credited the plain disclosure of the applications. After reviewing the record, we find that the PTAB’s findings are supported by substantial evidence.

Taş next argues that a person skilled in the art would not believe that cyclopamine can be used to cause the relevant cells to become apoptotic because figure 4A in the same applications contradicts this result. Taş describes

⁴ On appeal, Taş elevates its “plagiarism” allegations to also include accusations that the inventors intentionally deceived the USPTO, engaged in fraud upon the USPTO, and violated 37 C.F.R. § 1.56(a), which is the duty of the inventor to disclose to the USPTO information material to patentability. Taş waived these allegations by failing to raise them below, and we find no merit to the allegations.

figure 4A as showing tumor cells treated with cyclopamine at various dose levels in which microscopically visible cell death was not observed. Because apoptosis is a form of cell death detectable by microscopic examination, Taş argues that figure 4A expressly teaches against using a sufficient dose of cyclopamine to cause the relevant cells to become apoptotic. Again, the PTAB heard arguments from both sides and credited the testimony of Beachy's expert that the applications teach a person skilled in the art that cyclopamine could be administered in doses sufficient to induce apoptosis in BCCs. Applying this Court's guidance in *Ariad Pharm.*, 598 F.3d at 1352, the PTAB also determined that a working example of a particular dose level resulting in measurable cell death was not necessary to adequately describe or enable an embodiment within the scope of Count 3. The PTAB correctly applied the law, and its findings are supported by substantial evidence.

C

Taş also takes issue with the following sentence from the '076 and '964 applications: “An ‘effective amount’ of a subject compound, with respect to the subject method of treatment, refers to an amount of the antagonist in a preparation which, when applied as part of a desired dosage regimen brings about, e.g., a change in the rate of cell proliferation and/or the state of differentiation of a cell and/or rate of survival of a cell according to clinically acceptable standards for the disorder to be treated or the cosmetic purpose.” '076 application, 10:8–15 (emphasis added); '964 application, 12:22–29. According to Taş, the inventors did not have possession of this subject matter because the sentence does not specify which cells it is referring to, or whether the change is an increase or a decrease in the rate of proliferation, the state of differentiation, or the rate of survival.

The claims and Counts at issue here involve the administration of cyclopamine to treat humans having BCC tumors, which requires a sufficient dose of cyclopamine to induce apoptosis and cause a decrease of size or disappearance of the tumor. The PTAB found that the applications sufficiently described those claims and Counts, and the PTAB's findings are supported by substantial evidence.

D

Taş next argues that some teachings of the '076 and '964 applications are not enabling because they are "inoperative in entire categories," such as treating injuries of nervous system and immunology affected diseases, and enhancing regeneration of tissue and organs. The claims and Counts at issue here, however, only involve the administration of cyclopamine to treat humans having a BCC tumor. The teachings Taş complained of are for embodiments not covered by the claims and Counts and are therefore irrelevant to whether the applications enable the claims and Counts.

E

Taş also argues that the disclosure of human cancers in the '076 and '964 applications does not provide written description or enablement support for the Counts or claims at issue. According to Taş, the applications must describe the actual treatment of a human because (1) Hh/Smo signaling was known to be necessary for non-BCC cells required for human life, (2) effective doses of cyclopamine was known to kill a high proportion of adults, (3) the vast majority of cancer chemotherapy tested in laboratory animals was known to fail in treating cancer in humans, and (4) tumor cells were known to have greater Hh/Smo signaling than normal cells, so inhibiting the signaling would cause normal cells to succumb before the tumor cells. In response, Beachy points to evidence in front of the PTAB that teaches Hh signaling is inactive in

most adult tissues and cyclopamine was known to have no adverse effects in humans.

The PTAB correctly stated that the written description and enablement requirements do not demand as a matter of law actual examples or an actual reduction to practice. *See Eli Lilly*, 598 F.3d at 1352; *Wands*, 858 F.2d at 735. The PTAB found that the description in the priority applications of methods by which cyclopamine may be administered, appropriate and effective dosages, how the subject medicament works within the cancerous cell, and a spectrum of conditions against which administration of the cyclopamine may be effective sufficiently described the subject matter to a person skilled in the art, and enabled such a person to make and use the invention without undue experimentation. After considering all the arguments and the record, we see no reason to disturb that finding.

F

In a final attack on the teachings of the '076 and '964 applications, Taş argues that the descriptions of mice grafted with foreign tumor cells does not provide written description or enablement support because (1) the amount of cyclopamine applied to each mouse is not specified, (2) the volume of the tumor grafts is not described, (3) the described change in the size of the graft might be from a spontaneous change instead of from a reaction to the cyclopamine, and (4) the induction of apoptosis in the tumor grafts is not described. These are the same arguments Taş presented to the PTAB. *See J.A.* 36–37, 46. The PTAB considered Taş's arguments and evidence, teachings from the applications, and the testimony from Beachy's expert, Dr. Curran, that a person skilled in the art would have known that the administration of a sufficient amount of cyclopamine to a human to inhibit Hh signaling in the tumor would also result in a decrease in tumor size. Substantial evidence therefore supports the

PTAB decision that Taş failed to meet its burden of showing that the '076 and '964 applications do not provide written description or enablement support.

III

Beachy also filed preliminary motions in the interference proceedings below, asking the PTAB to find the claims of Taş's '078 patent invalid as lacking written description, lacking enablement, and being indefinite. The PTAB granted one of Beachy's motions as to the lack of written description for claims 2–20 and 23, and another of Beachy's motions as to the lack of written description for claim 7. Taş appeals. Because claims 1–23 of the '078 patent are unpatentable to Taş under 35 U.S.C. § 102(g) based on Beachy's prior invention of Counts 2 and 3, we do not need to reach whether claims 2–20 and 23 are also invalid under 35 U.S.C. § 112.

* * *

We have considered all other arguments and find them without merit.

We therefore affirm the PTAB's denial of Taş's preliminary motions regarding no interference-in-fact and lack of written description and enablement for the Counts of the '926 and '949 interferences and the claims of the '121 and '934 applications. With respect to these issues, the PTAB correctly applied the law, and its findings are supported by substantial evidence.

AFFIRMED

No costs.