United States Court of Appeals for the Federal Circuit

BEST MEDICAL INTERNATIONAL, INC.,
Appellant

v.

ELEKTA INC.,
Appellee

2021-2099, 2021-2100

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2020-00071, IPR2020-00072, IPR2020-00970, IPR2020-00971.

OPINION ISSUED: August 26, 2022
OPINION MODIFIED: August 29, 2022

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Before HUGHES, LINN, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

This is an obviousness case where the disputed level of skill in the art impacted the Patent Trial and Appeal Board's unpatentability determination in two inter partes reviews. In its final written decisions addressing various claims of U.S. Patent No. 6,393,096, the Board found that a person having ordinary skill in the art would have had formal computer programming experience. Petitioner Elekta Inc.'s expert had that experience; Patent Owner Best Medical International Inc.'s (BMI) did not. The Board accordingly discounted BMI's expert testimony and determined Elekta had proven that challenged claims 1, 43, 44, and 46 were unpatentable as obvious.

BMI appeals the Board's unpatentability determinations. Prior to filing this appeal, BMI finally canceled claim 1 during an ex parte reexamination. Because there is no longer a case or controversy regarding the patentability of claim 1, we dismiss-in-part BMI's appeal for lack of jurisdiction and therefore do not reach the merits of the Board's unpatentability determination for claim 1. For claims 43, 44, and 46, substantial evidence supports the Board's findings regarding the level of skill in the art and each of the remaining *Graham* factors. We therefore affirm the Board's unpatentability determination for those claims.

BACKGROUND

I

The '096 patent is generally directed to a method and apparatus for conformal radiation therapy of tumors using a pre-determined radiation dose. '096 patent, Abstract; *id.* at col. 1 ll. 10–12.

Tumors are three-dimensional and typically irregularly shaped. To account for the three-dimensionality, the gantry of a radiation machine—which houses the radiation beam—rotates around a patient to irradiate the tumor

from different angles. The gantry uses a multileaf collimator to narrow the radiation beam and conform it to the shape of the tumor. According to the written description, collimator leaves "can be programmed to follow the spatial contour of the tumor" by moving the leaves "individually into and out of the path of the radiation beam," "thus block[ing] the transmission of radiation to tissue disposed outside the tumor's spatial outline." *Id.* at col. 1 ll. 35–49.

The '096 patent purports to improve upon prior art approaches to radiation therapy by computing an optimal radiation beam arrangement that maximizes radiation of a tumor while minimizing radiation of healthy tissue. According to the written description, the "optimal beam arrangement is arrived at by computationally increasing the proposed beam weight [or beam intensity] iteratively, incorporating cost functions to ensure that an iterative change in the beam weight would not result in unacceptable exposure to the volumes of tissue or other structures being subjected to the proposed [radiation] dose." *Id.* at col. 5 ll. 39–44. The "dose distribution resulting from the proposed beam selection is compared to a . . . desired[] dose for the tumor volume and surrounding tissue structures." *Id.* at col. 5 ll. 44–47. The written description explains that if a change in the proposed beam weight (i.e., intensity) results in a radiation dose that more closely matches the desired prescription than the previous beam weight, the proposed beam weight is accepted. *Id.* at col. 5 ll. 47–49. Claim 43 is representative of the claims on appeal and recites:

> 43. A method of determining an optimized radiation beam arrangement for applying radiation to at least one tumor target volume while minimizing radiation to at least one structure volume in a patient, comprising the steps of:

> distinguishing each of the at least one tumor target volume and each of the at least one structure volume by target or structure type;
>
> determining desired partial volume data for each of the at least one target volume and structure volume associated with a desired dose prescription;
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> entering the desired partial volume data into a computer;
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> providing a user with a range of values to indicate the importance of objects to be irradiated;
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> providing the user with a range of conformality control factors; and
>
> using the computer to computationally calculate an optimized radiation beam arrangement.

Id. at col. 21 l. 19–col. 22 l. 10.

II

Varian Medical Systems, Inc. filed two IPR petitions, one challenging claims 1 and 18 of the '096 patent (IPR2020-00071) and the other challenging claims 43, 44, and 46 (IPR2020-00072). The Board instituted review in both IPRs on May 1, 2020. Soon thereafter, Elekta filed copycat petitions requesting institution and joinder to Varian's instituted IPR proceedings. The Board granted institution on June 24, 2020 (IPR2020-00971 and IPR2020-00970) and joined Elekta as a party to Varian's proceedings.[1]

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[1] Varian withdrew from this appeal on April 22, 2022. Because of this procedural posture, certain filings were made only in the Varian IPR proceedings, and thus we cite to those proceedings when needed.

While these IPRs were underway, a parallel ex parte reexamination (initiated by Varian in December 2019) was ongoing. That reexamination included review of claims 1 and 18. In August 2020 (after institution of the IPRs), the Examiner in the reexamination rejected claim 1 based on statutory and obviousness-type double patenting. Rather than arguing the merits of the Examiner's rejection, BMI canceled claim 1 "without prejudice or disclaimer" in November 2020. Mot. to Dismiss Appeal, Ex. I at 10, *Best Med. Int'l Inc. v. Elekta Inc.*, No. 21-2099 (Fed. Cir. Aug. 16, 2021), ECF No. 17. The Examiner noted BMI's cancelation of claim 1 in their final rejection on February 10, 2021. *Id.* Ex. J.

Meanwhile, the Board issued its final written decisions in the IPRs in April 2021. *See Varian Med. Sys., Inc. v. Best Med. Int'l, Inc.*, No. IPR2020-00071, 2021 WL 1599184 (P.T.A.B. Apr. 23, 2021) (*'071 Final Written Decision*); *Varian Med. Sys., Inc. v. Best Med. Int'l, Inc.*, No. IPR2020-00072, 2021 WL 1595724 (P.T.A.B. Apr. 23, 2021) (*'072 Final Written Decision*). In the '071 IPR, the Board noted that BMI canceled claim 1 during reexamination but concluded that claim 1 had "not yet been canceled by any final action" because BMI had "not filed a statutory disclaimer of claim 1." *'071 Final Written Decision*, 2021 WL 1599184, at *2. The Board therefore considered the merits of Elekta's patentability challenge for claim 1. *See id.* The Board determined that Elekta had proven that claim 1 was unpatentable as obvious but had not done so for claim 18. *Id.* at *25. In the '072 IPR, the Board determined that Elekta had proven that claims 43, 44, and 46 were

unpatentable as obvious over Carol-1995[2] and Viggars.[3] *See '072 Final Written Decision*, 2021 WL 1595724, at *19–20.

BMI filed a notice of appeal of the Examiner's rejection in the reexamination with the Board on June 9, 2021. BMI filed its notices of appeal of each of the Board's final written decisions with this court on June 25, 2021. We have jurisdiction over final Board decisions under 28 U.S.C. § 1295(a)(4)(A). As discussed below, BMI does not have standing to invoke that jurisdiction regarding the Board's unpatentability determination for claim 1. We do have jurisdiction to consider the merits of the Board's unpatentability determination for claims 43, 44, and 46.

DISCUSSION

I

We begin with the threshold question of jurisdiction. BMI argues that the Board lacked authority to consider claim 1's patentability because that claim was canceled before the Board issued its final written decision, rendering the patentability question moot. BMI therefore asks for *Munsingwear* vacatur of the Board's unpatentability determination. The Supreme Court's decision in *United States v. Munsingwear, Inc.* "directs courts to vacate the underlying decision in certain appeals that have become moot during their pendency, 'clear[ing] the path for future relitigation.'" *Apple Inc. v. Qualcomm Inc.*, 17 F.4th 1131, 1136 (Fed. Cir. 2021) (*Apple II*) (alteration in original)

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[2] Mark P. Carol, *Peacock™: A System for Planning and Rotational Delivery of Intensity-Modulated Fields*, 6 Int'l J. Imaging Sys. & Tech. 56 (1995).

[3] David A. Viggars et al., *The Objective Evaluation of Alternative Treatment Plans III: The Quantitative Analysis of Dose Volume Histograms*, 23 Int'l J. of Radiation Oncology • Biology • Physics 419 (1992).

(quoting 340 U.S. 36, 40 (1950)). For the reasons below, we cannot say that the Board erred in addressing patentability. We also hold that *Munsingwear* vacatur is inapplicable here because this appeal did not become moot during the pendency of the appeal. Rather, the "mooting" event—claim 1 being finally canceled—occurred before BMI filed its notice of appeal. We therefore agree with Elekta that BMI lacks standing to appeal the Board's unpatentability determination.

We first address whether the Board had the authority to issue a final written decision determining the patentability of claim 1. At the time the Board issued its final written decision, BMI had canceled claim 1 during reexamination but did so "without prejudice or disclaimer." Mot. to Dismiss Appeal, Ex. I at 10 (emphasis added). As the Board correctly noted, claim 1 had not been finally canceled at that point (e.g., BMI had not filed a statutory disclaimer of the patent claim under 35 U.S.C. § 253(a)) and so it remained part of the proceeding. *See '071 Final Written Decision*, 2021 WL 1599184, at *2. In *SAS Institute, Inc. v. Iancu*, the Supreme Court held that the Board in its final written decision "must address every claim the petitioner has challenged." 138 S. Ct. 1348, 1354 (2018) (citing 35 U.S.C. § 318(a)). In view of *SAS*, the Board reasonably concluded that it was required to address patentability of claim 1 absent any final cancelation. *See* J.A. 227 (Hr'g Tr. 115:16–24) ("Under *SAS* we still have to issue a ruling on that claim unless it's actually disclaimed or if, for example, Patent Owner requests adverse judgment on that claim."). We cannot say that the Board erred in addressing claim 1's patentability under these circumstances.

We next consider Elekta's argument that BMI lacks standing to appeal the Board's unpatentability determination. As a federal court, we are limited to deciding "Cases" and "Controversies." U.S. Const. art. III, § 2. Standing to sue (and appeal) "is a doctrine rooted in the traditional understanding" of Article III's case or controversy

requirement. *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). "[T]he standing requirement kicks in when a party seeks review in a federal court." *Apple II*, 17 F.4th at 1136 (cleaned up). To satisfy Article III's standing requirement, the appellant must establish (1) an injury in fact (2) that is fairly traceable to the appellee's challenged conduct and (3) is "likely to be redressed by a favorable judicial decision." *Spokeo,* 578 U.S. at 338. The alleged injury must be "'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 339 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). During oral argument on appeal, BMI conceded that: (1) it canceled claim 1 by filing a notice of appeal from the ex parte reexamination before the Board without challenging the double patenting rejections of claim 1 and (2) the cancelation was final. Oral Arg. at 6:40–8:58, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=21-2099_05062022.mp3. BMI does not dispute that this occurred before BMI filed its notice of appeal in this court. In other words, BMI admits that it finally canceled claim 1 prior to filing its notice of appeal in this case. As a result, there was no case or controversy regarding claim 1's patentability at that time. BMI therefore lacks standing to appeal the Board's patentability determination for claim 1, and we lack jurisdiction over this part of BMI's appeal.

BMI nonetheless argues that it suffered an injury in fact based on alleged collateral estoppel effects resulting from the Board's unpatentability determination for claim 1 sufficient to confer us with Article III jurisdiction. Appellant's Br. 2–4. BMI specifically points to a statement made by the Examiner during reexamination of one of BMI's other patents (U.S. Patent No. 6,038,283) as support for its alleged injury. There, the Examiner stated that they were "essentially bound by the [B]oard's reasoning" in the '071 IPR for certain issues regarding the obviousness of claim 1. Opp. to Appellee's Mot. to Dismiss, Ex. V at 4, *Best Med. Int'l, Inc. v. Elekta Inc.*, No. 21-2099 (Fed. Cir.

Aug. 26, 2021), ECF No. 18. But even if the Examiner were bound by the Board's findings and conclusions, we fail to see why BMI could not challenge the Examiner's findings and conclusions in the '283 patent reexamination proceedings in an appeal to this court. Indeed, we know of no cases that would apply collateral estoppel in these circumstances, nor has BMI cited any. *See SkyHawke Techs., LLC v. Deca Int'l Corp.*, 828 F.3d 1373, 1376 (Fed. Cir. 2016) (explaining that non-appealable issues and judgments are without preclusive effect (collecting cases)).

Regardless, "the potential for collateral consequences" is insufficient, on its own, to confer standing upon BMI. *Hyosung TNS Inc. v. Int'l Trade Comm'n*, 926 F.3d 1353, 1358–59 (Fed. Cir. 2019) (concerning mootness); *see also Apple Inc. v. Qualcomm Inc.*, 992 F.3d 1378, 1385 (Fed. Cir. 2021) (*Apple I*) (concluding that the harm an IPR petitioner "may face from estoppel" under 35 U.S.C. § 315(e) "is insufficient to provide standing"); *Ala. Mun. Distribs. Grp. v. FERC*, 312 F.3d 470, 474 (D.C. Cir. 2002) ("But in fact it seems inescapable that neither standing nor ripeness could properly grow out of a harm predicated on a potential collateral estoppel effect."). Accordingly, we conclude that this alleged collateral injury cannot support Article III standing. We therefore dismiss BMI's appeal regarding claim 1 for lack of standing.

II

There is no dispute that BMI has standing to appeal the Board's determination that claims 43, 44, and 46 would have been obvious. We thus proceed to the merits. We review the Board's ultimate conclusion of obviousness de novo and its underlying findings of fact for substantial evidence. *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 160 (Fed. Cir. 2021).

On appeal, BMI challenges the Board's findings regarding the level of skill in the art, motivation to combine, and reasonable expectation of success, as well as the

Board's claim construction. We address each of BMI's arguments below.

A

We begin with BMI's challenge to the Board's finding that a person of ordinary skill in the art would have had "formal computer programming experience, i.e., designing and writing underlying computer code." *See '072 Final Written Decision*, 2021 WL 1595724, at *7. BMI's expert, Mr. Daniel Chase, does not have the requisite computer programming experience. The Board therefore considered but discounted Mr. Chase's testimony in its obviousness analysis. *See, e.g., id.* at *17. The Board's finding regarding the level of skill in the art is a question of fact that we review for substantial evidence. *See Innovention Toys, LLC v. MGA Ent., Inc.*, 637 F.3d 1314, 1323 (Fed. Cir. 2011).

We have previously identified a non-exhaustive list of factors that may guide the fact finder in finding the appropriate level of skill in the art. These factors include: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (quoting *Env't Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983)). The patent's purpose can also be informative. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1362–63 (Fed. Cir. 2006).

Before the Board, the parties presented little evidence relating to these factors. In advocating for formal computer programming experience, Elekta relied principally on its expert Dr. Kenneth Gall's declaration. Dr. Gall opined that a person of ordinary skill in the art would have had "two or more years of experience in . . . computer

programming associated with treatment plan optimization." Gall Decl. ¶ 16.[4] He expanded on this in his reply declaration, opining that computer programming experience is "necessary to be able to understand and implement the inventions disclosed and claimed in the '096 patent and the teachings of the asserted prior art." Gall Reply Decl. ¶ 5.[5] He also noted that his opinion as to the appropriate level of skill in the art was supported by the fact that "[a]ll of the named inventors of the '096 patent were well-versed in writing computer programs for treatment planning software." *Id.* ¶ 11 (citing Carol Dep. 106:25–107:12[6]).

For its part, BMI relied principally on Mr. Chase's declaration submitted with its post-institution response.[7] There, Mr. Chase opined that "the requirement of 'two or more years of . . . computer programming associated with treatment plan optimization'" was "inappropriate." Chase Decl. ¶ 86[8] (alteration in original). He provided no explanation as to why this requirement was inappropriate apart from characterizing it as "vague." *See id.*

The Board, faced with competing expert testimony and little supporting evidence from either party, nevertheless endeavored to discern whether a skilled artisan would have had computer programming experience. In doing so, the

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[4] Dr. Gall's declaration is Exhibit 1002 in IPR2020-00072 and IPR2020-00970.

[5] Dr. Gall's reply declaration is Exhibit 1043 in IPR2020-00072.

[6] Dr. Mark Carol is a named inventor of the '096 patent. His deposition transcript is Exhibit 1046 in IPR2020-00072.

[7] All citations to BMI's papers and exhibits are to papers and exhibits filed in IPR2020-00072 to which Elekta's IPR was joined as a party.

[8] Mr. Chase's post-institution declaration is Exhibit 2037 in IPR2020-00072.

Board relied on "the entire trial record," including the patent's teachings as a whole, to conclude that formal computer programming experience was required. *See '072 Final Written Decision*, 2021 WL 1595724, at *5–7. The Board recognized (and it is undisputed) that the claimed invention is implemented on a computer. Indeed, representative claim 43 recites "using the computer to computationally calculate an optimized radiation beam arrangement." '096 patent col. 22 ll. 9–10. And the written description is replete with references to the invention being implemented on a computer. For example, the Board relied on a passage from the written description that explains that the "optimization method may be carried out using . . . a conventional computer or set of computers, and plan optimization software, which utilizes the optimization method of the present invention." *'072 Final Written Decision*, 2021 WL 1595724, at *6 (quoting '096 patent col. 5 l. 54–col. 6 l. 2). The Board, relying on these teachings, was not unreasonable in concluding that a skilled artisan would have had formal computer programming experience.

We are unpersuaded by BMI's argument to the contrary. BMI points to passages in the written description that it contends use the word "program" in the context of "describ[ing] the entry of data into existing treatment planning systems by a clinician," i.e., not coding. Appellant's Br. 58 (citing '096 patent col. 1 ll. 35–43, col. 13 ll. 30–35). But the Board considered and rejected this evidence in coming to its conclusion. *See '072 Final Written Decision*, 2021 WL 1595724, at *7. Even if BMI were correct that these passages detract from the Board's finding regarding the level of skill in the art, we are reviewing the Board's finding on the appropriate level of skill for substantial evidence. *See Innovention*, 637 F.3d at 1323. On such a review, we do not reweigh the evidence but rather ask whether there is "evidence that a reasonable mind might accept as adequate to support a conclusion." *Cleo Inc. v. United States*, 501 F.3d 1291, 1296 (Fed. Cir. 2007). On

this record and in view of the limited and conclusory treatment the parties gave this issue, we cannot say that the Board's conclusion that a skilled artisan would have had formal computer programming experience was unreasonable or unsupported by substantial evidence.[9]

B

BMI's additional arguments for reversal are unpersuasive.

First, BMI challenges the Board's construction of various claim terms, a question of law we review de novo where, as here, it is decided on the intrinsic evidence. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). BMI argues that the claims require that the "desired partial volume data" that is "enter[ed]" into "a computer" must be used by "the computer to computationally calculate an optimized radiation beam arrangement," and that this must be accomplished using a single computer. Appellant's Br. 41. We are not convinced by BMI's argument that the claims require that the recited "computer" in the "entering" step must be the same "computer" in the "using" step and that the prior art fails to disclose this requirement. Based on the plain claim language and written description, we see no error in the Board's determination that the claims broadly allow for a set of computers to perform these steps. *See, e.g.*, '096 patent col. 5 l. 64–col. 6 l. 2 (explaining that the claimed optimization method may be carried out using a "set of computers"). Furthermore, substantial evidence—including the references themselves and expert testimony—supports the Board's finding that

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[9] While not discussed by the Board, we note that named inventor Dr. Carol's deposition testimony supports the Board's conclusion in this regard. *See Daiichi Sankyo*, 501 F.3d at 1256 (explaining that the inventor's educational level can inform the level of skill in the art).

the combined computer-implemented functions of Viggars's treatment evaluation program and Carol-1995's treatment optimization program meet the recited "entering" and "using" steps. *See '072 Final Written Decision*, 2021 WL 1595724, at *12, *14–15.

BMI also argues that the claimed "conformality control factors" are "mathematically defined parameter[s]" and the Board's reliance on Carol-1995 as teaching this limitation is therefore erroneous. Appellant's Br. 43–44. We are not persuaded, because nothing in the plain language limits the claims to "mathematically defined parameters." While BMI cites to a passage from the written description describing a specific embodiment that supports its proposed construction, *see* '096 patent col. 14 ll. 42–52, we do not "limit[] claims to a preferred embodiment," *Comaper Corp. v. Antec, Inc.*, 596 F.3d 1343, 1348 (Fed. Cir. 2010). We therefore see no error in the Board's determination that the claims encompass conformality control factors like Carol-1995's table angles and thickness of treatment slice. *See '072 Final Written Decision*, 2021 WL 1595724, at *14.

BMI next argues that the Board's finding that Carol-1995 teaches "providing a user with a range of values to indicate the importance of objects to be irradiated" is unsupported by substantial evidence. Appellant's Br. 45–46. We disagree. As the Board recognized, Carol-1995 explicitly states that a user has "direct control over . . . aggressiveness," which "influences the relative importance of delivering the prescribed dose to the complete target versus sparing avoidance and sensitive structures (relative values of 'WeightI' and 'WeightJ')." J.A. 3655; *see also '072 Final Written Decision*, 2021 WL 1595724, at *13 (citing same). And the Board credited Dr. Gall's testimony that a skilled artisan would have therefore "found it obvious that a range of relative values for WeightI and WeightJ could be provided to the user to indicate the importance of objects to be irradiated." *'072 Final Written Decision*, 2021 WL 1595724, at *13 (quoting J.A. 3378 (Gall Decl. ¶ 92)).

Substantial evidence thus supports the Board's finding that Carol-1995 suggests this limitation.

Finally, BMI challenges the Board's findings as to whether there would have been a motivation to combine Carol-1995 with Viggars and whether a skilled artisan would have had a reasonable expectation of success in doing so, both factual questions that we review for substantial evidence. *Strathclyde*, 17 F.4th at 160. We have considered BMI's arguments and are unpersuaded. The Board relied on the teachings of the references themselves to support both findings. For example, for motivation to combine, the Board cited Viggars's teaching that its program can be "used to decide, in an objective and systematic way, whether a particular plan is acceptable" as supplying a reason to combine Viggars with Carol-1995's treatment optimization program. *'072 Final Written Decision*, 2021 WL 1595724, at *16 (quoting J.A. 995). And the Board relied on the fact that Viggars's treatment evaluation program had been successfully integrated with a commercial treatment planning system as providing a skilled artisan with a reasonable expectation that she could successfully integrate Viggars's treatment evaluation program with Carol-1995's treatment planning system. *See id.* at *17 (citing J.A. 990). The Board's well-reasoned analysis for both of these *Graham* factors is supported by substantial evidence.

CONCLUSION

We have considered BMI's remaining arguments and find them unpersuasive. For the foregoing reasons, BMI lacks standing to appeal the Board's unpatentability determination for claim 1, and we therefore dismiss that portion of the appeal for lack of jurisdiction. Because substantial evidence supports the Board's finding as to level of skill in the art, as well as each of the other *Graham* factors, and because we discern no error in the Board's claim

constructions, we affirm the Board's determination that claims 43, 44, and 46 are unpatentable as obvious.

AFFIRMED-IN-PART AND DISMISSED-IN-PART

COSTS

No costs.