Supreme Court of the United States

RETRACTABLE TECHNOLOGIES, INC. AND THOMAS J. SHAW,

Cross-Respondents,

v.

BECTON, DICKINSON AND COMPANY,

Cross-Petitioner.

ON CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR CONDITIONAL CROSS-PETITIONER

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INTRODUCTION

RTI's arguments for denying BD's conditional cross-petition only serve to highlight the reasons for denying RTI's own petition. The claim construction issues on which RTI urges the Court to deny review are no more case-specific than the issue on which RTI seeks review. All involve the application of settled legal principles—applied in Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc), cert. denied, 546 U.S. 1170 (2006), and previously praised by RTI for providing "certainty and consistency in claim construction" (RTI Reh'g Pet. 6)—to specific patent claims. RTI may disagree with the conclusion that the Federal Circuit reached when it applied those principles to the "body" limitation, just as BD believes that the Federal Circuit erred when it ruled for RTI on the "lodging," "retainer member," and "cutting" issues. But none of these issues warrants review. BD therefore agrees with RTI that the conditional cross-petition should be denied—not because it is less worthy of review than RTI's petition, but because it presents the same unworthy issues as RTI's petition.

If the Court were to grant RTI's petition, however, it should also grant BD's conditional cross-petition. Despite RTI's denials, the issues in the two petitions are closely intertwined and should, in fairness, be considered together. The claim construction issues in the cross-petition provide an alternative ground for affirmance of the judgment, and RTI's position on those issues is in tension with its new position on the "body" limitation. The Court should not consider any of the case-specific claim construction issues in the case, but if it decides to review one, it should review them all.

ARGUMENT

I. THE ISSUES RAISED IN BD'S CONDITIONAL CROSS-PETITION ARE NO MORE CASE-SPECIFIC THAN THE ISSUE RAISED IN RTI'S PETITION

RTI attempts to distinguish its petition from BD's conditional cross-petition on the ground that "the crosspetition does not even assert, let alone demonstrate, that the Federal Circuit's holdings reflect a divergence from this Court's precedents or an intra-circuit conflict." RTI Opp. 2. With respect, RTI has missed the point. BD did not argue that there is a conflict in authority because there is none—on any of the limitations. As demonstrated in BD's brief in opposition to RTI's petition, there is a broad consensus on the Federal Circuit and in this Court's precedents that claims must be read in light of the specification. BD Br. in Opp. in No. 11-1154 ("BD Opp.") 9-11; see also, e.g., United States v. Adams, 383 U.S. 39, 49 (1966); Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940); *Phillips*, 415 F.3d at 1313, 1315, 1316; RTI Pet. App. in No. 11-1154 ("RTI App.") 33a (Rader, C.J., dissenting in part) ("Certainly, the claims do not stand alone and must be read in light of the specifications."); RTI App. 94a (Moore, J., dissenting from denial of reh'g en banc) ("Of course the claims are to be construed in the context of the entire patent, including the specification."). There is also a broad consensus that it is improper to import limitations from the specification into the claims. BD Opp. 11-12. RTI's and BD's disagreement is simply over how these general rules apply to specific claim limitations in RTI's patents.

"While that task may present difficulties in some cases," the Federal Circuit's balanced approach to claim construction recognizes that "attempting to resolve

that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification." Phillips, 415 F.3d at 1323-1324. RTI strips away that context when it argues that differing case-specific outcomes represent a split of authority. RTI Pet. in No. 11-1154 ("RTI Pet.") 11-12 & n.6. BD could have done the same, but its "split" would have been just as illuso-The point of BD's conditional crossrv as RTI's. petition is not that this case presents multiple issues that independently merit review, but that to the extent the Court decides to review the one case-specific claim construction issue on which RTI lost, it should also review the three related claim construction issues on which RTI prevailed.

RTI also misses the mark when it tries to distinguish its petition on the ground that it "raises broad legal issues of general applicability" because it "asks the Court to clarify the interplay between a patent's claims and its specification in determining claim meaning." RTI Opp. 5. The issues presented in BD's conditional cross-petition also involve "the interplay between a patent's claims and its specification." The only difference is that, on those limitations, RTI took a different position on that "interplay." For example, RTI insisted that "[t]he court must always read the claims in view of the full specification." RTI C.A. Br. 32 (internal quotation marks omitted). RTI also argued that "[t]he scope of claims may be restricted by arguments made during the prosecution history to distinguish the invention from prior art references." Id. 62. And having stretched the "[t]he doctrine of claim differentiation" to support its reading of "body," RTI turned

around and argued that "[t]he doctrine is only a presumption that can be overcome by arguments made during prosecution" and "only requires there be a difference in scope between the claims." *Id.* 63.

If RTI were genuinely interested in "clarify[ing] the interplay between a patent's claims and its specification" (RTI Opp. 5), it would welcome the opportunity to address the full range of claim construction issues in this case, including those on which it was on the other side of the issue it now presents. Its resistance shows that RTI is not seeking resolution of a dispute of principle regarding the rules of claim construction, but rather mere review of the application of those principles to the one claim construction ruling on which RTI did not prevail.

II. ALL THE CLAIM CONSTRUCTION ISSUES IN THE CASE ARE INTERTWINED

A. If The Court Reviews The Construction Of "Body," It Should Also Review The Construction Of "Lodging"

As demonstrated in BD's conditional cross-petition, there is a clear tension between RTI's proposed approach to interpreting "body" and RTI's reliance on the specification and prosecution history to narrow the "lodging" limitation. BD Cond. Cross-Pet. 25-28. On "body," RTI emphasized the absence of an express limitation excluding multi-piece bodies, relied on a tenuous claim differentiation argument, and argued that the specification and prosecution history should not be considered. See id. On "lodging," RTI ignored the absence of an express "locking" limitation, gave no weight to a more powerful claim differentiation argument, and argued that the specification and prosecution history narrow the meaning of the claim. See id.

RTI makes no attempt to reconcile its two positions. Nor does it deny that, under BD's construction of "lodging," claim 25 of the '077 patent would be invalid regardless of how "body" is construed. RTI instead tries to avoid the issue by arguing that BD waived the right to a proper construction of "lodging," leaving only a factual dispute regarding what the prior art disclosed. But that is incorrect.

BD argued to both the district court and the Federal Circuit that, under the proper construction of "lodging," claim 25 of the '077 patent is invalid. See, e.g., A1480¹ ("The implicit claim construction argument underlying this contention—that the claim excludes devices in which the thumb cap is locked in place—is clearly wrong."); BD C.A. Br. 63 ("Because the claim construction underlying RTI's argument is incorrect, the district court erred by denying BD's motion for JMOL with respect to claim 25."). Neither court held that the point was waived. To the contrary, the Federal Circuit held that BD had preserved all aspects of its invalidity argument: "Because BD did not waive its invalidity arguments, we address each of BD's arguments below." RTI App. 24a. The court then adopted RTI's position that the prosecution history narrows the meaning of the term "lodging." Compare id. 26a ("during prosecution ... inventor Shaw argued that Pressly, instead of disclosing a thumb cap that lodges into the back end of the open barrel, 'requires locking of the plunger"), with RTI C.A. Br. 62 ("The scope of claims may be restricted by arguments made during the prosecution history to distinguish the invention from prior art references.... [The inventor's] response distin-

¹ "A____" refers to the Court of Appeals Appendix.

guished Pressly because it required a conventional locking mechanism.").

RTI's attempt to recast the "lodging" issue as a factual dispute fails. Before trial, both parties agreed that "lodging" did not need to be construed because the jury could give the term its plain and ordinary meaning. At trial, however, RTI's expert attempted to distinguish the prior art on the ground that "the other prior art devices had a locking mechanism." A2608. This did not lead to a "factual dispute" (RTI Opp. 3) regarding what the *prior art* did or did not disclose. Rather, it triggered a dispute as to what claim 25 did or did not cover—specifically, whether, as RTI implied, the claim excluded devices in which the thumb cap is locked in addition to being lodged. That is a claim construction issue, and BD argued that it should be resolved by the court. See A1480. In response, RTI did not suggest to the district court that BD was advancing a new claim construction argument or that any such argument had been waived. See A1550-1556. Indeed, as the party advocating a narrowing construction that deviates from the plain meaning of "lodging," it was RTI's burden to raise the issue before trial. If there was any waiver, it was RTI's.

Accordingly, there is no obstacle to this Court considering the "lodging" issue if it grants RTI's petition. The issue is dispositive on the '077 patent, and, as RTI has made no attempt to deny, RTI's position on "lodging" cannot be reconciled with the position RTI takes in its own petition. The "body" and "lodging" issues should therefore be considered together or, more appropriately, not at all.

B. If The Court Reviews The Construction Of "Body," It Should Also Review The "Retainer Member" And "Cutting" Rulings

RTI does not dispute that, if BD prevails on either the "retainer member" or "cutting" issue, it would compel affirmance on the '224 patent, moot the construction of "body" in that patent, and require reversal of the infringement judgment on the 1 mL Integra. See BD Cond. Cross-Pet. 30-31, 36. RTI nonetheless argues that if this Court grants its petition, it should not consider these related issues. RTI's reasons for distinguishing its petition do not withstand scrutiny.

Aside from the arguments discussed above (*supra*, pp. 2-3), RTI's principal ground for distinguishing its petition rests on the convenient (and incorrect) assumption that the issue on which it petitions involves a deviation from the plain meaning of the claims, while on every other issue "the claims and specification are in harmony and support" its position. RTI Opp. 6. As discussed in BD's brief in opposition, the term "body" is a general term with multiple meanings, not a single plain meaning that can be ascertained independent of context. BD Opp. 16.

Moreover, RTI does not meaningfully engage with the "plain meaning" of the claims containing the "retainer member" term, which clearly supports BD's construction. RTI does not even acknowledge that claim 1 of the '733 patent separately lists the "needle holder" as a "retractable part" and the "retainer member" as a "nonretractable part," thus indicating that they are two distinct parts. See BD Cond. Cross-Pet. 32 (quoting A179 14:16-30). Further, contrary to RTI's assertion (RTI Opp. 7), the language of claim 43 of the '224 patent supports BD, because its reference to the "continuous

retainer member *surrounding* the inner head" (A202 22:48-49 (emphasis added)) undermines RTI's argument that they can be a single piece. RTI also ignores the references to the two parts being "couple[d]" and "uncouple[d]." A179 14:29, 14:45; A202 22:51. If RTI were serious about giving claim terms their plain and ordinary meaning, it would surely recognize that the term "couple[d]" refers to the relationship between *two* separate parts.

Unable to find support in the claim language, RTI turns to the specification. But its arguments only reinforce how intertwined the issues in this case are. For example, in arguing that the "retainer member" and "needle holder" are not separate pieces, RTI notes that one embodiment refers to "welding" the pieces together. RTI Opp. 8. According to RTI, this means "the 'retainer member' and 'needle holder' are one piece welded together." Id. During the prosecution of the patent, however, RTI tried to distinguish its invention from the prior art precisely by arguing that a prior art reference did not show a one-piece barrel, but rather two pieces welded together. See A3685 (Pressly "is not 'made of' a one-piece barrel because needle assembly (9) is fixed to barrel (5) by ultrasonic welding means."). RTI cannot have it both ways.

RTI's argument regarding the summary of the invention also fails. RTI does not and cannot dispute that its own summary of the invention states that the retainer member is one part of a "two part head." A193 3:63-64. It further states that the "retainer member" and "inner head" are held "with a friction force" (A193 4:3-5) or that "the *two part head* of the needle holder comprises the separable retainer member being tack welded to the inner head of the needle holder" (A193 4:11-13 (emphasis added)). Thus, even when there is

welding, RTI still describes the retainer member and needle holder as separate parts. RTI dismisses these statements because the beginning of the paragraph states "[i]n one embodiment." RTI Opp. 8 (quoting A193 3:63). RTI fails to recognize, however, that the term "retainer member" is a coined term that appears only in the description of that particular embodiment and the claims that correspond to it. The definition of "retainer member" in the summary of the invention therefore controls that term's meaning and cannot be discounted as applying merely to one embodiment of a broader invention; there is no broader "retainer member" invention.

The "cutting" issue similarly involves the "interplay" between specification and claim language, namely the situations in which a court should find "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." RTI App. 19a. If there was any error, it was that the Federal Circuit set the bar for disclaimer too high. RTI does not deny that its specification "characteriz[ed] the disclosed retractable mechanism as 'rel[ying] entirely on clamping force or friction." RTI Opp. 10. It instead argues that the specification in effect takes back this disclaimer when it states that in one embodiment a "weld is 'ruptured, fractured or otherwise separated." Id. What RTI fails to appreciate is that this separation, which is incidental to the release of the *frictional* force that holds the needle, is not the same as cutting a single piece into two to release the entirely mechanical force that keeps the needle in the projecting position. See BD Cond. Cross-Pet. 37.

More broadly, it is telling that RTI does not engage with the Federal Circuit's recognition that clear claim language can be narrowed only if the specification "contain[ed] 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." RTI App. 19a. This language shows that the Federal Circuit already applies the rule that RTI urges (see RTI Pet. 21) when confronted with what it actually believes to be clear claim language. RTI's petition for certiorari merely faults the Federal Circuit for not invoking the same disclaimer rule with respect to the "body" limitation. RTI Opp. 10. But that does not mean that the Federal Circuit rejects RTI's rule categorically as a matter of law; it simply means that the Federal Circuit did not believe that "plain language" can govern when the language is not plain, as is the case with "body." This demonstrates, once again, that disagreements among parties or judges on such issues are not disagreements over legal principles, but over the application of principles to particular, case-specific, highly technical patent claims.

BD respectfully submits that, if this Court wishes to "clarify the interplay between a patent's claims and its specification in determining claim meaning" as RTI urges (RTI Opp. 5), such an effort would be undermined if the Court were to address only a single limitation in this case, while leaving standing interpretations of other similarly-situated or indistinguishable terms. The Court would also be deprived of the added perspective that comes from addressing multiple claim limitations, rather than one limitation viewed in isolation. Accordingly, if the Court grants RTI's petition, it should also grant BD's cross-petition. The better course, however, is to deny both.

CONCLUSION

RTI's petition for a writ of certiorari (No. 11-1154) should be denied. If it is granted, however, this conditional cross-petition should also be granted.

Respectfully submitted.

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June 2012