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Honorable Pauline Newman, Randall R. Rader, and Sharon Prost
United States Circuit Judges
United States Court of Appeals for the Federal Circuit
717 Madison Place, NW
Washington DC 20439

Re: Integra LifeSciences I, Ltd. v. Merck KGaA, Nos. 02-1052, -1065

Your Honors:

As counsel representing Merck KGaA in the above-captioned matter, I write to suggest that the Court might benefit from additional briefing to address an issue that was not addressed in the parties' briefs but that dominated oral argument. Specifically, a panel member suggested remanding this case to the District Court with instructions to determine whether the accused experiments are excluded from the scope of the FDA exemption because they involved the use of research tools.

We continue to believe that such a ruling would be improper, for all the reasons mentioned in oral argument and more. First, the Supreme Court held that Integra "never argued the RGD peptides were used at Scripps as research tools, *and it is apparent from the record that they were not.*" 125 S. Ct. at 2382 n.7 [S74 n.7] (emphasis added). In fact, when the Supreme Court asked about the issue of research tools at oral argument, Integra's counsel explicitly renounced any intention to defend the judgment on the basis of a research-tool carveout, because Integra had made no such argument at any previous stage in the litigation. Second, the contemplated remand would violate the Supreme Court's direction to this Court to review "the evidence *presented at trial* . . . under the standards set forth in the jury instruction, which we believe to be consistent with, if less detailed then, the construction of § 271(e)(1) that we adopt." *Id.* at 2384 [S76] (emphasis added). The trial court did not instruct the jury on any such research tool carveout. Third, as the Supreme Court implied in the footnote 7 referred to during oral argument, Integra simply cannot defend the verdict on a basis it never advanced below (or, for that matter, in this Court).

No doubt, this is why Integra itself did not argue in its brief on remand (or in its earlier briefing before this Court or the Supreme Court) that the judgment could be salvaged on the basis of a research tool carveout. And because Integra never made the argument, this Court has not had the benefit of any briefing on the issue. If this Court is nevertheless inclined to

base its disposition on a research tool carveout—the existence and precise contours of which are of enormous importance to the pharmaceutical and biotech industries—it should do so only with the benefit of full briefing and argument. If given the opportunity to brief the issue, Merck would make the following points:

First, Integra had every opportunity, and every reason, to raise such a carveout at trial, if consonant with its strategy. The Supreme Court's opinion did not break new ground in holding that any information that could reasonably support an IND could qualify for the FDA exemption. It simply restored what the bar, industry, and lower courts understood the law to be before this Court's earlier decision in this case—and to what Merck argued the law was throughout the proceedings, without any disagreement from Integra. Integra deliberately chose to forego any argument about research tools for strategic reasons, fully aware that royalties for infringement of a research tool would be far less than the royalties on the ultimate commercial product. Integra waived the issue, and is certainly not entitled to a new evidentiary hearing, much less a new jury trial, on an issue it strategically declined to address.

Second, even if there were a research tool carveout, it could not possibly apply to the experiments at issue here. Assuming it were appropriate to apply the label "research tool" to a drug that is used as a control against which to measure the activity of another drug candidate, that use could not be excluded from the FDA exemption. How do we know? That is exactly how bioequivalency studies are done for generics, and there is no doubt that these sorts of tests fall squarely within the FDA exemption. Similarly, the testing of a known drug candidate against a purified receptor could not fall outside the FDA exemption, because it is absolutely essential to prove to the FDA beyond doubt that the drug candidate does, indeed, bind to the receptor that is believed to be the target, and not to some other receptor that may control other bodily functions.

For these reasons, if this Court is entertaining a remand to the District Court to apply some version of a research tool carveout, the Court would benefit from briefing on whether such a carveout exists, and what its scope might be.

Thank you for your consideration in this matter.

Respectfully submitted,

MPT

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