

Alert | Intellectual Property Litigation

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Solicitor General Provides Views of the United States on Section viii Carve-Outs, Induced Patent Infringement in *GSK v. Teva*

On October 3, 2022, the U.S. Supreme Court invited the Solicitor General to weigh in with the views of the United States on the U.S. Court of Appeals for the Federal Circuit’s decision in *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021). At issue in this patent case is the law concerning “section viii” carve-outs by a generic manufacturer which omit from the proposed label patented methods of use or indications so long as the omissions do not render the proposed drug less safe or effective. Following a jury verdict of infringement that was overturned by the district court’s Judgment as a Matter of Law, the Federal Circuit reversed in a 2-1 decision ruling that Teva’s carve out of the patented indication from its label for a generic version of Coreg® (carvedilol) induced doctors to infringe of GlaxoSmithKline’s (GSK) method-of-use patent.

On March 29, 2023, the Solicitor General’s [brief](#) took the position that the Supreme Court “should grant [Teva’s] petition for a writ of certiorari and reverse the judgment of the court of appeals.” The Solicitor General explained that the Federal Circuit erred when deciding Teva induced doctors to infringe GSK’s method-of-use patent because “[t]he carved-out labeling did not reflect [Teva’s] unencumbered choice, but instead was driven by FDA regulatory requirements and GSK’s own identification of the indication that should be excised.” According to the Solicitor General, most of the evidence—“marketing efforts, catalogs, [and] press releases”—relied on by the Federal Circuit in finding induced infringement “showed only that ‘the literature [Teva] provided to doctors told them to read labels and to prescribe according to

them.” But “[a]bsent independent evidence that [Teva] understood its carved-out labeling to encompass patented uses, proof that [Teva] expected and encouraged doctors to rely on the labeling cannot support an inference of intent to induce infringement.” The Solicitor General went on to state that: “[t]he decision below is incorrect. No reasonable jury could have concluded that the carved-out labeling for [Teva’s] generic carvedilol from 2007-2011 was itself evidence of intent to induce infringement.” Recognizing the potential significant and longstanding impact this case could have on the pharmaceutical industry, the Solicitor General further indicated that “[u]ncertainty about the section viii pathway is likely to deter generic manufacturers from invoking that mechanism, thereby threatening the availability of lower-cost generic drugs, in contravention of the statutory design.” The Solicitor General concluded “[t]he question presented warrants further review. If allowed to stand, the decision below threatens significant harm to competition and to consumers.”

The Supreme Court’s determination on whether to grant certiorari will be closely watched and much anticipated by the pharmaceutical industry.

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