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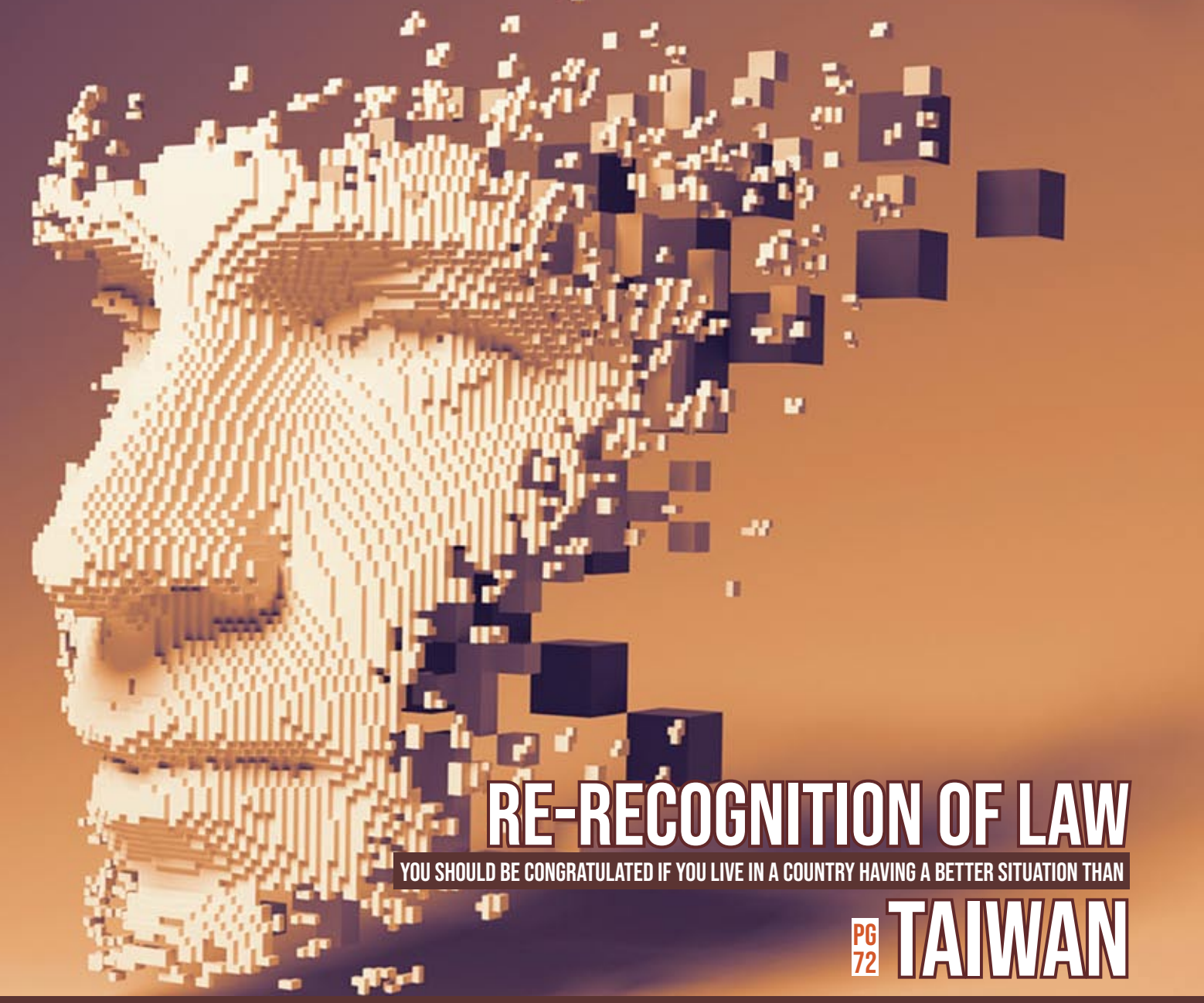

RE-RECOGNITION OF LAW

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TAIWAN

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WILL SECTION viii CARVE-OUTS SURVIVE GSK V. TEVA?

Although the initial decision in the case raised serious problems for the viability of these carve-outs to avoid patent infringement, after re-argument, it appears that the Court may avoid this issue by focusing more narrowly on the unique facts of this case

On February 23, 2021, the United States Court of Appeals for the Federal Circuit heard re-argument in GSK v. Teva, a significant case that the pharmaceutical industry and legal practitioners are following because of its potential implications for "Section viii" labeling carve-outs for generic drugs (also known as "skinny labels"). Although the initial decision in the case raised serious problems for the viability of these carve-outs to avoid patent infringement, after re-argument, it appears that the Court may avoid this issue by focusing more narrowly on the unique facts of this case.

GSK v. Teva arises from litigation in the District of Delaware relating to GSK's Coreg® product (carvedilol). GSK listed two patents in the Orange Book, U.S. Patent No. 4,503,067, relating to treatment of hypertension, and U.S. Patent No. 5,760,069, relating to treatment of congestive heart failure ("CHF"). Teva filed a Paragraph IV certification over the '069 patent, and in 2007, following expiration of the '067 patent, launched its generic. Teva's label in 2007 stated that the product was approved for treatment of left ventricular dysfunction following myocardial infarction ("LVD-MI") and hypertension, but carved out the CHF indication under 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii"). At launch, Teva also announced that its generic drug was AB-rated to Coreg® in the Orange Book despite this carve-out. In 2011, FDA required Teva to amend its label to introduce CHF as an approved indication.

GSK filed for reissue of the '069 patent, which issued as U.S. Patent No. RE 40,000, and in 2014, GSK sued Teva for infringement of the RE '000 patent. GSK alleged that Teva induced infringement of the

> The Federal Circuit will likely issue its highly anticipated opinion in this case in 2021. Depending on the reasoning set forth in the decision, the issues relating to Section VIII carve-outs may again be raised in a petition for rehearing en banc or in a petition for certiorari at the U.S. Supreme Court.

RE'000 patent both before and after 2011 based on advertising and on the literal label language for treatment of LVD-MI, which it alleged infringed. Teva argued that it had carved out the infringing CHF indication, and that it was compelled by FDA to add CHF to its label, so there was no evidence that Teva caused physicians to prescribe its product for infringing uses.

A jury agreed with GSK in June 2017, awarding $235 million in damages. Teva moved for judgment as a matter of law, arguing that there was no evidence it caused any infringement by physicians before or after the label amendment. GSK argued that Teva's label, advertisements, and other materials were circumstantial evidence of induced infringement.

The District Court found that there was no evidence that any doctor was ever induced to infringe via prescription for CHF by Teva's label, and that any infringement was not due to Teva, and granted judgment as a matter of law in March 2018.

On appeal, the United States Court of Appeals for the Federal Circuit initially reversed this decision in October 2020, in a split decision with Chief Judge Prost dissenting. The majority pointed to Teva's press releases and marketing communications as sufficient circumstantial evidence of induced infringement. In particular, the majority focused on Teva's advertisement of its generic as AB-rated, which it explained would allow physicians to infer that Teva's generic was approved for all of the same uses as Coreg®, including CHF. Chief Judge Prost, in her dissent, wrote that the majority's holding essentially nullified the practice of "skinny label" launches that are permitted under the Hatch-Waxman Amendments.

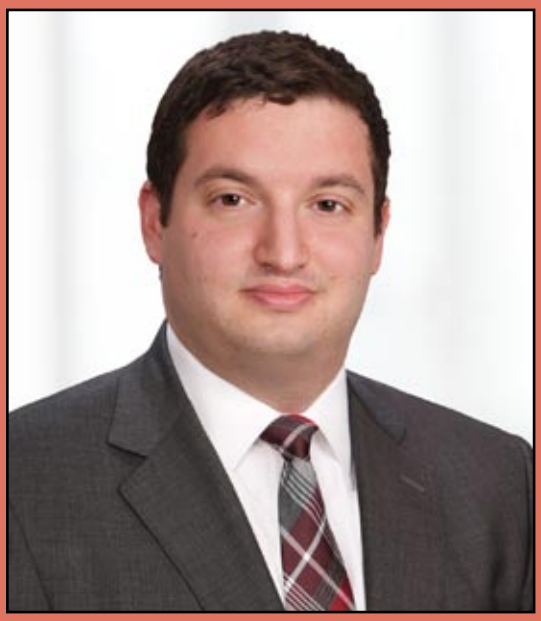
Following the decision, Teva petitioned for rehearing and rehearing en banc. Industry groups, public interest groups, and members of Congress filed amicus curiae briefs both in support of and in opposition to rehearing the case. On February 9, 2021, the Court granted the petition and ordered oral argument focused on the issue of whether the jury had sufficient evidence of induced infringement prior to 2011.

At oral argument on February 23, both the Court and GSK sought to focus the case on evidence other than the AB-rating and advertisement of that rating. GSK's counsel focused on its argument that because LVD-MI was an infringing use, Teva did not actually carve out all patented uses of the RE'000 patent. The Court questioned this, focusing on

an Orange Book use-code that only included CHF. GSK's counsel nevertheless did not concede that the AB-rating, the press releases, and the partial label itself were all evidence of inducement of infringement for treatment CHF.

Teva's counsel began by focusing on Hatch-Waxman's policy of allowing the public to use drugs for unpatented uses, but was questioned by Judge Newman about whether a finding in its favor might deter the research that leads to discovery of newer uses for old drugs. Teva's counsel argued in response that this was not a concern because patent protection would be available if a generic did actually induce infringement of patented uses, which Teva argued it did not do here. Teva's argument ultimately was focused on whether GSK had presented the jury with sufficient expert testimony that LVD-MI infringed, and whether Teva presented any contrary evidence. Teva's counsel pointed to testimony from its own expert, and also argued that the Court could decide as a matter of law whether the label induced infringing uses. Teva argued that if this was a non-infringing use, then the remaining evidence could not support infringement.

Based upon the questions at oral argument, it appears that the Court will first focus on whether GSK presented sufficient evidence that LVD-MI was an infringing use, and thus whether the label induced physicians to infringe via this use. If the Court holds that there was not sufficient evidence, it may once again have to address whether there is evidence of inducing infringement by prescription for CHF based on Teva's press releases and marketing in spite of the Section viii carve-out. In this case, the decision would have significant



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implications for generic drug companies and their ability to satisfy FDA law requirements to get approval for unpatented uses without infringing patents for carved-out, patented uses.

The Federal Circuit will likely issue its highly-anticipated opinion in this case in 2021. Depending on the reasoning set forth in the decision, the issues relating to Section viii carve-outs may again be raised in a petition for rehearing en banc or in a petition for certiorari at the U.S. Supreme Court. One thing is clear: both branded and generic drug companies have a vested interest in the outcome of GSK v. Teva.

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Brian represents clients on a breadth of intellectual property matters, with an emphasis on patent litigation. He has represented clients in disputes before the International Trade Commission, Federal Circuit and U.S. District Courts. Brian's work spans a broad spectrum of technologies, including cathode materials for lithium-ion batteries, RFID technology used in electronic toll collection, networking devices, digital two-way radios, residential HVAC equipment and cellular technology.

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