How Public Opinion Polls Expand the Conversation on *GSK v. Teva* and Skinny Labeling

By Gretchen Miller & Kevin Boully, Ph.D.
October 14, 2021

"The legal standing of skinny labeling is far from settled. Attempts to keep the *Teva* decision narrow and maintain space for the policy preferences canonized by the Hatch-Waxman Act appear consistent with at least some of what we know about public opinion."

The Federal Circuit's recent majority opinion and Chief Judge Prost's dissenting opinion in the *GlaxoSmithKline LLC v. Teva Pharmaceuticals* "skinny labeling" case has raised eyebrows and piqued interest beyond the usual circles. The decision's result is a lower bar for finding induced infringement—a win for brand-name companies. While the jury found infringement against Teva's skinny labeled carvedilol, a congestive heart failure drug, we could not help but wonder if the American public sees the issue more like the majority Federal Circuit opinion or more like the dissenting opinion of Chief Judge Prost? How do Americans view "skinny labeling," and how might those opinions intersect with future findings of the evolving law? Will jurors see the stronger position of brand companies as something to uphold or does the consumer benefit of generics foster a different preference? We discuss the legal perspectives and national surveys on skinny labeling and patent protections to expand the conversation.

A Narrow Opinion with Broad Implications

About 55% of Americans take prescription medication, and consumers choose between name-brand and generic options. Persuasion Strategies' 2020 National Juror Survey shows about 43% of Americans prefer generic drugs over name-brands. The Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act was intended to promote affordable drug options by allowing generic drug companies to seek Food and Drug Administration (FDA) approval before the brand-name drug patents expire. The law is straightforward. If a brand drug company has a patent on one of a drug's uses, it tells the FDA which use is patented and the exact label language that is covered by its patents. This gives the brand company legal monopoly on that use. The FDA permits a generic version of that drug if the manufacturer "carves out" such use from its drug label – in other words, the language that the brand drug company identified. The practice is known as "skinny labeling."

In *GSK v. Teva*, the drug at issue was used to treat congestive heart failure (CHF) and left ventricular dysfunction (LVD). GSK's patent covered CHF. Teva's label and product insert did not include CHF but cited the same clinical studies and related information that GSK used for its drug. The Federal Circuit's majority sided with a patent-owning GSK, and the dissent sided with the generic Teva. The divided court is a case study of the divided public.

Skinny labeling is such a critical part of public policy that counsel for GSK was careful not to attack it, and the Federal Circuit went through great lengths to clarify that this "narrow, case-specific review of substantial evidence does not upset the careful balance struck by the Hatch-

Waxman Act regarding section viii carve-outs." Op. at 10-11. During oral argument, GSK counsel argued that this was "not a true skinny label case" but rather a "partial label" because "every limitation of the asserted claims can be found in the indication that Teva left on its label at all times." (Juanita Brooks, Feb. 2021 oral argument). Yet, holding a generic liable for using a skinny label prompted broad criticism. In a sharp dissent, Chief Judge Prost wrote, "far from being a disagreement among reasonable minds about the individual facts, this case signals that our law on this issue has gone awry."

This case is part of a broader, evolving issue and two things are clear: (1) induced infringement will be easier to find and (2) a "subset label" may start to determine whether the patent holder will prevail.

Induced Infringement Is Easier to Find

In pharmaceutical cases, the act of direct infringement (treating a condition, administering a drug) is usually performed by the patient or health care provider. Accordingly, the question is often whether a drug manufacturer is liable for inducing infringement. To prove induced infringement a patent owner must show the accused infringer actively encouraged infringement, knowing that the acts they induced constituted patent infringement, and their encouraging acts actually resulted in direct patent infringement. Courts ask whether a defendant's instructions teach an infringing use "such that we are willing to infer from those instructions an affirmative intent to infringe." *AstraZeneca v. Apotex*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Courts also ask whether there is an "**inevitable progression**" to practice the claimed method. *Grunenthal Gmbh v. Alkem Labs*., 919 F.3d 1333 (Fed. Cir. 2019). The first test focuses on the actions of the accused infringer, while the second focuses on a comparison of the claims to the drug label.

In this case, some (including Judge Prost) contend that the evidence of inducement—i.e., that Teva had culpable intent to encourage infringement **and** that its skinny label or press releases caused doctors' prescribing practices—was "thin to nonexistent." Dissent Op. at 2. But a jury found Teva liable all the same. The Federal Circuit's majority ultimately agreed with the jury.

The court reasoned that GSK "presented extensive expert testimony along with Teva's marketing efforts, catalogs, press releases, and testimony from Teva's own witnesses, showing that Teva encouraged carvedilol sales *for* CHF (the patented use) despite its attempted carve-out. This is evidence supporting the jury's finding that Teva induced infringement." Op. at 27. Accordingly, the majority held that a jury could infer an affirmative intent to infringe.

The dissent saw the case differently. Judge Prost reasoned that Teva, by carving out "everything that GSK said would infringe," was "trying to avoid having its label encourage infringement." She reasoned that one cannot infer that doctors, as a class, rely on a skinny label particularly when every expert cardiologist at trial said they "didn't even read the label to make prescribing decisions." Dissent at 3. What Judge Prost found most troubling was that it seemed that a generic could be found liable simply by describing its product as "equivalent"—in a system that *requires* generic drugs to be equivalent, and in which everyone *understands* that generic drugs are equivalent." Id. If this is so, then in Judge Prost's view "a plaintiff now has to show very little for a jury to speculate as to the rest." Dissent at 3. Can we reconcile Judge Prost's rationale with that of the majority?

Two of the most important filters for jury decision making in patent cases are relevant to the induced infringement question. Persuasion Strategies' 2020 National Juror Survey shows 65% of jury-eligible Americans say getting a patent for an invention is "difficult" and more than 82% rate the USPTO "favorably"—more than any other agency tested. These proportions have been consistent for the last decade. The perceived high-value of a patent, and the strong presumption of validity are strong levers for jurors evaluating the bigger question of whether to support the patent owner even when an alleged infringer is not directly infringing.

The second key filter, jurors' self-interest in consumer benefit, is a key influence when jurors consider induced infringement claims. Around 70% of Americans say the patent process *helps* competition in the marketplace. Jurors question whether the allegedly inducing behavior is ultimately an unfair violation of jurors' faith in aggressive competition or whether it reasonably expands consumer benefits in a way that jurors would not want to curtail. A 2021 survey conducted by Persuasion Strategies shows 67% of Americans who believe doctors should prescribe drugs if they're proven to work *support* skinny labeling, while just 39% who say doctors should only prescribe medications "according to the label" feel the same. Jurors use their common sense to reach a decision that feels to right the balance between fair competition and consumer benefits.

Broad Claim, Subset Label

The key test seems to be whether there is a *broad* claim and a "subset" label. If the accused use is a *subset of* a broader claim – the patent holder will likely win. This is because the subset is almost automatically an "**inevitable progression**" to practice the claimed method (the *Grunenthal* test). In *GSK v. Teva*, the claims were directed to "decreasing mortality caused by congestive heart failure (CHF)." But the accused label was directed to left ventricular dysfunction (LVD) – a *subset* of CHF. The patent holder won. Because the accused label was a

"subset" of the claims, "the patented use was on the generic label at all relevant times and that, therefore, Teva failed to carve out all patented indications." Op. at 10.

Similarly, if a hypothetical claim were directed to "treating eye disease" and an accused label is directed to "treating glaucoma" – a subset of eye disease, it is inevitable that treating glaucoma would also be treating eye disease. The patent holder would be expected to win.

The subset argument is interesting because jurors tend to favor decisions that follow the logic of precedent. If a brand company had the right to a broader category of protection and the medication at issue is a subset, there is an unfairness to treating the subset differently and a fairness to the expectation that it should be treated the same way – an expectation competitors and the brand company's themselves ought to be able to rely upon when making decisions that affect consumers. This may have been part of the original jury's thinking in the infringement finding. This logic, however, is highly dependent on the individual's perception of how the competitive behavior affects consumers and the options they have to access the medical products they need. Again, if the broader claim protection unfairly limits consumer options by barring competition, many Americans are motivated to nullify that protection and increase access by perceiving the subset as independent.

Public Perception of Skinny Labeling

The opinion is a victory for branded companies. Is it a victory for patients, too? Maybe.

If it leads to more specific patents, it leads to what the public would view as fairer and more appropriately enforced patents. This should lead to consumer benefits, something the public can and likely will support. But how does this jibe with trust in the patent system?

To learn what the public thinks of skinny labeling, Persuasion Strategies conducted its 2021 "Skinny Labeling" survey experiment with jury-eligible Americans (see chart below). About 60% support the idea of a generic company choosing ***not*** to label a medication for a use patented by a name-brand competitor. At this level, jurors are likely more concerned about having affordable options and ensuring access to medications than their preference for brand name products. We also examined support if the generic company is skinny labeling to intentionally "avoid legal problems." Given that assumption, support drops to 47%. If the generic company knows the consumers will use the medication for off-label purposes, support drops to 45%. People care about intent, fairness, and transparency and these issues all emerge with skinny labeling and the *Teva* opinion.

When considering whether skinny labeling is fair and legal, 61% said they felt skinny labeling was definitely or probably legal [see below, right column, 31% + 30%], 57% said it was definitely or probably fair to leave an anticipated use off the label [see below, left column, 30% +27%], and half of those polled said they felt it was both fair and legal. People do not necessarily care about how skinny labeling affects brand-name companies, or even how it may or may not influence the role of patents in the pharmaceutical industry. Jurors care about access to medications they need at prices they can afford. Specifically, we found statistical support for the conclusion that people who prefer to buy generic products are much more supportive of skinny labeling than people who prefer name-brand products (72% versus 40%).

The Bottom Line

The legal standing of skinny labeling is far from settled. Attempts to keep the *Teva* decision narrow and maintain space for the policy preferences canonized by the Hatch-Waxman Act appear consistent with at least some of what we know about public opinion. Americans idealize patents and the protections they carry. Americans also want to protect themselves and their options in the marketplace. The balancing act, in jury decisions, and potentially in the Federal Circuit's eyes, is likely to continue.

The authors would like to thank Katerina Oberdieck from Persuasion Strategies for the data research and statistical modeling cited in this piece.

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