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Plead It or Lose It: Prior Art and Expert Evidence

Expert evidence and prior art (*e.g.*, earlier publications showing the invention was already known) drive nearly every patent dispute. A recent trilogy of interlocutory decisions from the Federal Court shows the pleadings and the burden of proof decide which of that evidence reaches the trial judge. For parties attacking validity, the message is blunt: plead it or lose it.

Salix Pharmaceuticals, Inc. (Salix) brought an action against Sandoz Canada Inc. (Sandoz) under the *Patented Medicines (Notice of Compliance) Regulations* concerning the antibiotic rifaximin. After discovery, Sandoz proposed extensive amendments to its defence and counterclaim, including new invalidity grounds and additional prior art references. Cautioned by the Court that a contested amendment motion would likely jeopardize the trial date, Sandoz chose not to formally move to amend and instead made only the amendments Salix accepted.

Sandoz' expert reports still relied on much of the material it had left out of its pleading. Three pre-trial motions followed:

1. **Salix' motion to strike expert evidence.** Salix largely succeeded in striking portions of Sandoz' expert reports.
2. **Sandoz' responding motion to strike expert evidence.** The Court dismissed Sandoz' retaliatory motion against Salix' responding reports, describing it as "tit for tat."
3. **Sandoz' motion for leave to file reply expert evidence.** The Court granted leave, but only in part.

We focus on the first two decisions, which together define each party's pleading obligations.

Prior Art & The Pleadings

Expert opinion evidence is admissible only if it meets four threshold requirements:

- Relevance
- Necessity
- The absence of any exclusionary rule
- A properly qualified expert

Salix' motion turned on relevance alone. The question was whether Sandoz' experts could rely on 18 documents that did not appear in its pleading.

Sandoz divided the challenged documents into six different categories:

1. Not prior art *per se*, but evidence
2. Documents produced by Salix
3. Non-controversial background
4. Documents relating to examples in the patent
5. The expert's papers
6. "One cite among many"

The Court was largely unpersuaded. The "labels" provided to the documents were irrelevant: any document used to support an invalidity attack, including art relied on as common general knowledge for obviousness, must be grounded in the pleading. It made no difference that Salix had produced some of the documents; at the threshold stage, the question is relevance, not prejudice. And if the art was truly non-controversial or merely cumulative, the Court asked why Sandoz needed to add it at all. Parties should be narrowing their case as trial approaches, not expanding it.

Why "Tit for Tat" Failed

Sandoz' own motion to strike expert evidence tried to turn the tables, seeking to exclude 40 pieces of prior art from Salix' expert reports that it said Salix had not pleaded. The Court dismissed the motion in its entirety, finding the "tit for tat" argument rested on a misinterpretation of affirmative defences and a misapplication of the law. As the party alleging obviousness, Sandoz had the positive duty to plead the art it put in play.

The result is an intentional imbalance between the two sides. The party attacking validity bears the burden and must plead the art on which it relies, including prior art it relies on as common general knowledge to support an obviousness allegation. The patentee (patent owner) need not lead primary evidence on issues where the defendant bears the burden and need not plead the art it uses to respond.

Abandoned Grounds Stay Abandoned

Salix also sought to strike evidence supporting an overbreadth theory that Sandoz had not pleaded: that the inventor had not actually made and tested the claimed subject-matter. That theory had first appeared in Sandoz' proposed amendments but fell away when Sandoz chose not to pursue the amendment over Salix' objection.

Sandoz' pleading did allege overbreadth but particularized it by reference to what the patent disclosed, not what the inventor did. This made the challenged expert evidence irrelevant and inadmissible. The Court also accepted Salix' further objection that opinions in Sandoz' expert report concerning patent claims no longer in dispute were inadmissible.

No Amendment Through The Back Door

As a fallback, Sandoz asked the Court to treat its materials responding to Salix' strike motion as a request to amend. The Court declined for three reasons:

1. No amendment motion or further draft pleading was before it.
2. Salix' expert strike motion raised different issues, a different test, and a different burden.
3. Sandoz remained free to seek an amendment to support the excluded evidence, but it had to bring a formal motion to do so.

Reply: The Defendant's Safety Valve

The third decision shows the pleading asymmetry has limits. Sandoz sought leave to file reply expert reports, including one from a new expert who had not given evidence in chief. Applying the two-step test for the admissibility of reply evidence (Is the evidence genuinely responsive? Could its relevance have been anticipated?), the Court allowed some of the proposed reply but struck passages that merely restated disagreement or bolstered previous evidence.

In short, patentees may respond freely and rely on unpleaded art, but a defendant may be permitted reply on genuinely new grounds, even through a new expert.

Key Takeaways

The recent trilogy offers several practical lessons for parties preparing their pleadings and expert evidence:

- **Plead everything your experts rely on for invalidity.** A defendant attacking a patent's validity must identify in its pleading the prior art and common general-knowledge documents it relies on for obviousness. Calling a document background, non-controversial, or a supplementary citation will not save it, and neither will the absence of prejudice.
- **The pleading burden follows the legal burden.** The duty to plead prior art rests on the party alleging invalidity. A patentee's responding experts may engage with the

pleaded art and cite additional unpleaded art in response.

- **Responsive evidence is not a new issue.** Evidence that answers the opposing expert or the pleaded art need not be separately pleaded, and it is not holding back evidence for a later stage to gain an advantage where the responding party was not required to, and did not, lead that evidence in chief.
- **Abandoned invalidity grounds cannot be revived through experts.** The material facts pleaded define the scope of a ground of invalidity. An expert cannot advance a different factual theory omitted from the operative pleading.
- **Keep expert evidence focused on the issues in dispute.** Opinions concerning claims no longer at issue are inadmissible. The Court also cautioned against relying on additional references that merely support propositions already established by pleaded prior art, emphasizing that parties should narrow, not expand, their cases as trial approaches.
- **An expert's publications can establish expertise, not invalidity.** Experts may cite their own papers to establish their qualifications, as the *Federal Courts Rules* and the Expert Code of Conduct contemplate. They may not rely on those papers as unpleaded prior art.
- **Amend by motion and do it early.** An opposing party's evidentiary motion is no substitute for a motion to amend. If the other side opposes an amendment, bring a formal motion ideally before the trial date is at risk.
- **Object early and consistently.** Salix' consistent objections to Sandoz' expert evidence distinguished this case from *Georgetown*, where unpleaded art survived after both sides' experts had engaged with it.
- **Reply remains available for the genuinely unanticipated.** A defendant surprised by responding evidence can seek leave to reply, even through a new expert. The Court will not permit reply that merely restates or bolsters earlier evidence.