

THE
AM LAW LITIGATION DAILY

Litigators of the Week:
Clearing the Path for a Potential Generic
Launch of a Blockbuster Heart Failure Drug

By Ross Todd

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Our Litigators of the week are **Gianni Servodidio** and **Rémi Jaffré** of **Jenner & Block** and **Ron Daignault** of **Daignault Iyer**, who represent generic drugmaker MSN Laboratories, which is seeking to launch a generic version of Novartis’s blockbuster heart failure medication Entresto—a drug that generated \$7.8 billion in sales last year.

With Servodidio and Jaffré taking defending against trade dress litigation and Daignault taking the lead in patent litigation, the team secured wins at the Third Circuit and the Federal Circuit over the past week fending off Novartis’s requests for injunctions blocking an MSN Labs generic launch.

Litigation Daily: Who was your client and what was at stake here?

Gianni Servodidio: Our client is MSN Labs, an India- and New Jersey-based company that develops and manufactures high-quality generic drugs. In this case, the drug at issue was MSN’s generic version of Novartis’s Entresto, a blockbuster medication for chronic heart failure that



Courtesy photos

(l-r) Jenner & Block partners Gianni Servodidio and Rémi Jaffré, and Ron Daignault of Daignault Iyer.

had previously been under patent protection for years. MSN had invested significantly to be the first to introduce a generic version of Entresto to the market, which conveys important public benefits. Novartis, on the other hand, wanted to prevent generic entry for as long as possible.

How did these matters come to you and your firms?

Ron Daignault: I have been representing MSN for ten years, and so the Entresto case was one of the matters we were handling. When Novartis filed its trademark and trade dress case against MSN and moved for a preliminary injunction, I

referred MSN to Gianni and the Jenner team. Gianni and I had worked together for years at **Pennie & Edmonds** and for a bit at Jenner, and I knew of Gianni's great work in the trademark area, so it made perfect sense for him and the Jenner team to fend off Novartis's trademark and trade dress claims.

Who all was on the team and how have you divided the work?

Rémi Jaffré: Ron's team handled the patent litigation (including related appeals) and the Jenner team handled the trademark and trade dress litigation (including related appeals). **Adam Unikowsky**, a partner in Jenner's appellate practice, played a significant role on the stay motions and appellate briefing.

For those just getting up to speed, what legal hurdles has your client had to overcome so far to open the door for its generic version of Entresto to get to market?

Daignault: First, MSN had to get final FDA approval for its drug in the face of multiple "citizens petitions" filed by Novartis arguing that MSN's drug was unsafe. The FDA rejected those petitions and approved MSN's drug. Novartis then filed a lawsuit challenging the FDA's approval, which was also rejected by the court. MSN also had to overcome several patent-related obstacles, with Novartis's '659 and '918 patents being the last two patent hurdles MSN had to overcome during this past year, when Novartis filed a preliminary-injunction motion that the Delaware district court denied in August 2024. Thereafter, the Federal Circuit reversed the district court's invalidity decision on the '659 patent. That patent had benefited from a six-month "pediatric exclusivity," which MSN had challenged, but just expired on July 16. For Novartis's other '918 patent, my team

succeeded in proving at a bench trial before Judge Andrews that MSN was not infringing the patent. Finally, MSN had to overcome the trademark and trade dress claims Novartis asserted for the first time early this year. Judge Padin initially entered a preliminary injunction, so the Jenner team had to convince her that was an error, which she eventually recognized by staying the injunction and then reconsidering and denying it entirely.

As Ron said, Judge Padin previously granted Novartis an injunction in the trade dress case before siding with you and your clients. How common are these sorts of trade dress challenges—especially in drugs that differ in size and color by dosage—in the generic space?

Jaffré: Attempts to assert trade dress rights in the appearance of pills are not unheard of, and there is case law in this area going both ways, based on very case-specific considerations. But changes in product-design trade dress law and in the regulatory environment for generics have meant that more recent case law is skeptical of these trade dress challenges. For dosage-coded drugs in particular, the Third Circuit's 2003 decision in the *Shire* case supports the argument that dosage-coding by size and color is functional and thus not protectable as trade dress.

The Federal Circuit and Third Circuit decisions on Novartis's injunction requests clear the path for your client to move forward with its generic launch, but the underlying appeals are ongoing. What comes next in those appeals?

Servodidio: In the appeal from Judge Padin's decision, the Third Circuit already denied Novartis's emergency request for an injunction pending appeal, so now the parties will brief and argue the appeal from the denial of a preliminary injunction in the ordinary course.

Daignault: On the patent side, the parties will now proceed with briefing on Novartis's appeal of MSN's trial win.

What risk does your client face if it launches its generic version of the drug and ultimately loses one of these appeals?

Servodidio: We believe the risk of reversal on appeal is low, not least because the district court decisions at issue are subject to deferential appellate review. That said, it is not uncommon for a generics manufacturer to launch a drug "at risk" of a patent challenge. The risk is that if it loses, it will owe the patent owner damages. In the New Jersey litigation, if MSN loses the pending appeal, a preliminary injunction could be reinstated and MSN may have to redesign its pills pending trial.

What can other generic makers take from what you accomplished here?

Daignault: Almost all other generic Entresto manufacturers settled with Novartis and agreed not to enter the market until late in 2026. But MSN took the fight to Novartis, and now patients will have access to affordable life-changing heart medication over a year earlier than they otherwise would have. The district court's denial of a trade dress injunction on the grounds that color coding and shapes of pills can be functional depending on the facts of the case also has implications that all generic manufacturers should consider as they evaluate the physical appearance of their tablets.

What will you remember most about these matters?

Servodidio: The court gave us only five days to oppose Novartis's motion, which had multiple fact and expert affidavits. The team worked relentlessly over that time to develop a strong record in opposition to the motion, and it paid off as it allowed the court to reconsider her earlier decision based on the record we had assembled.

Jaffré: For me, it will be the day when Judge Padin issued an order saying she was *sua sponte* thinking of reconsidering her preliminary injunction. It is rare for judges to reconsider their prior decisions, and even rarer for them to do it *sua sponte*. Seeing that order was very gratifying, because it showed that the arguments we had made to Judge Padin in favor of a stay of the injunction were really landing with her.

Daignault: I feel like I have been living and breathing the Entresto case every day this past year. Novartis's efforts to block MSN's generic product were non-stop and relentless with ups and downs—beating Novartis's PI motion last August with briefs and technical expert declarations and then a hearing in about a week's time; putting on a great trial in December with my colleagues here at the firm and with **Kevin Warner** at **Rakoczy Molino** that we won; battling it out in the Federal Circuit over the last several months on patent invalidity issues and Novartis's pediatric exclusivity; and then just this week, the Federal Circuit denying Novartis's injunction pending appeal, which is a really gratifying end result.