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# 'We took Ravgen head-on': How we won zero-damages and others didn't

Michael Summersgill and his co-counsel at WilmerHale secured more favourable outcomes for their clients than others in a series of lawsuits brought by Ravgen over pre-natal screening tests, he tells Sarah Speight.

Picture the scene. Multiple cases are brought by one plaintiff against several defendants, in the same jurisdictions, involving identical patents and very similar facts.

Why, then, would the outcome vary so dramatically that one client has settled for zero money, where others have been stung for hundreds of millions of dollars?

The answer, according to Boston-based Michael Summersgill—a partner and first-chair trial lawyer at WilmerHale—lies in how the cases are defended.

Summersgill and his co-counsel have achieved successful outcomes for clients sued by Maryland, US-based biotech firm Ravgen, which develops non-invasive prenatal genetic screening technology.

Despite being small in size, the firm has aggressively litigated its patents directed to non-invasive prenatal testing (NIPT) testing.

In 2020, Ravgen filed eight lawsuits against other companies (according to WilmerHale, virtually the entire NIPT industry): Labcorp, Myriad, Illumina, PerkinElmer, Quest Diagnostics, Natera, Roche's Ariosa Diagnostics, and Biora Therapeutics.

All eight lawsuits were filed in the same two jurisdictions (Western District of Texas and the District of Delaware).

Ravgen asserted the same two patents (US patent numbers 7,727,720 and 7,332,277), and made similar infringement allegations directed to the same blood collection tubes supplied to each of the defendants by the same third party.

Some of those cases have seen large awards and settlements. The first to go to trial was against Labcorp in September 2022, which resulted in a \$373 million win for Ravgen (not quite the \$800 million-odd that it had wanted, though).

Ravgen has settled related lawsuits for varying sums, including Myriad (\$34 million), and Illumina.

Meanwhile, according to WilmerHale, its clients have fared better.

In October 2022, immediately after WilmerHale client Quest won summary judgment on a release defence and persuaded the judge to schedule an inequitable conduct trial ahead of the jury trial, Ravgen's case against Quest was resolved on confidential terms.

In January this year, although a US jury found that Natera's prenatal screening technology infringed a patent held by Ravgen, awarding damages of \$57 million, the jury rejected Ravgen's wilfulness allegations. The damages awarded were a fraction of the \$1.2 billion Ravgen could have sought as wilfulness damages.

(Shortly after this outcome, Ravgen's trial lead, Kerri-Ann Limbeek of Desmarais, told *LSIPR* that Ravgen planned to appeal. No appeal has been filed yet and post-trial motions are still pending.)

More recently, in September, Ravgen and WilmerHale client Roche settled shortly after the court's tentative ruling in Roche's favour cut the potential damages to less than \$3 million —a small fraction of Ravgen's damages claim.

And WilmerHale secured a zero-money dismissal with prejudice for Biora—this being the biggest contrast with LabCorp's multimillion damages bill.

In an interview with *LSIPR*, Summersgill, who led the cases against Ravgen for Quest, Natera and Biora, and coordinated with his partners on Roche, explains how they achieved the outcomes they did.

#### LSIPR: How exactly did WilmerHale secure these outcomes for its clients?

Michael Summersgill: It takes a great team and a lot of creative lawyering.

First, we came up with arguments that the other defendants didn't; the release argument is a good example of that. In the Quest case, after a robust fact investigation, we developed an argument that—because of a provision in a licence agreement between Ravgen and another company—Ravgen had released claims for past infringement against companies like Quest and others.

It was a release argument that no other defendant had uncovered [even though] the others had that same potential defence. We then prevailed on it in the Quest and Biora cases.

Second, what wins these complicated cases at trial is the trial narrative. We developed a strong narrative in each of these cases, that was supported by the facts and the evidence, and that I think showed why our clients should win.

For example, for Natera, we developed a straightforward but compelling narrative: Natera and Ravgen were founded around the same time to try to solve the same problem of developing a better prenatal diagnostic test; Natera developed a test that is over 99.9% accurate and that revolutionised prenatal diagnostics; Ravgen made big claims about its test but independent scientists concluded that it didn't work as claimed so Ravgen failed in the market; and now Ravgen is trying to accomplish here in court what it couldn't accomplish out in the market.

Third, we brought in witnesses to support that narrative that others didn't. The best example of that is Dr Wolfgang Holzgreve, one of the leading researchers and scientists in this field who had evaluated Ravgen's claims long before any litigation and concluded Ravgen's test didn't work as claimed. He was very compelling to the jury.

Fourth, every case has its own challenging facts and documents. Some defendants run from the challenging facts and documents. That doesn't work. We embraced them, we took them head on, and we put them into the relevant context.

We showed the jury how they ultimately didn't support what Ravgen was saying about them. Credibility is everything. And if you run from bad facts, you lose credibility.

Finally, trial requires great execution on the fly under the toughest of circumstances. We've tried many cases against very talented lawyers; that experience gives our teams an edge in terms of execution.

One of the comments that we frequently get from clients after trials, whatever the result, is that they've never seen teams execute at trial quite the way we do. We have great and very demanding clients, so that is the highest praise we could receive.

### LSIPR: But why shouldn't Ravgen, which could be argued as a 'David' against many 'Goliaths', enforce its rights?

**MS:** Patents are an important part of innovation. But when patents are misapplied—and patents that never should have been granted in the first place are misapplied—they harm innovation.

So why shouldn't Ravgen enforce its patents? Because their method, according to their own research, missed one out of three genetic abnormalities. That's a big issue.

The only way that Ravgen got the patent [granted] was by claiming they had achieved unexpected results—that by using formaldehyde, they were able to obtain as much as 10 times more foetal DNA than prior methods. They made these big claims to the patent office.

But the leading experts independently tested Ravgen's method and concluded it didn't work as claimed. Ravgen knew about those tests but never disclosed them to the patent office.

Companies like Quest, Natera, Biora and Roche are developing innovative medical tests and other products that are changing patients' lives for the better. They are the real innovators.

Cases like Ravgen's, where they're asserting a patent that shouldn't have been allowed in the first place, are a tax on innovation.

## LSIPR: Ravgen said it will oppose any appeal from Natera on the finding of infringement. What is your response to that?

**MS:** We think we have a strong appeal on the issue of infringement. The Ravgen patent requires using formaldehyde to preserve a sample. We presented testing evidence that there were only trace amounts of formaldehyde—less than naturally occurs in human blood—in the blood collection tubes at issue and that that trace amount had no impact on the sample.

Ravgen's expert admitted, on the public record, that they hadn't performed any testing that showed otherwise.

We also have a uniquely strong inequitable conduct argument—that Ravgen committed fraud on the patent office. Strong inequitable conduct claims are rare; this is the strongest one I've seen in over 28 years of doing this.

#### LSIPR: How did you secure the zero-money settlement for Biora?

**MS:** We filed a summary judgment motion similar to the one we prevailed on in the Quest case, arguing that Biora was released under the same licence agreement for the same reason.

As reflected in the publicly available transcript, after hearing our argument on the motion in Delaware, US District Court Judge Hall issued a tentative ruling from the bench granting our motion, which would have eliminated all of Ravgen's damages claim against Biora.

A few weeks later, the parties filed a stipulation stating that Ravgen was dismissing its claims with prejudice, and that Biora was not paying any amount to Ravgen.

Michael Summersgill is a partner at WilmerHale. His co-counsel on the cases mentioned above were partners Robert (Bob) Gunther (who led the Roche case), Amanda Major, Arthur Coviello, and counsel Harry Hanson.

<u>https://www.lifesciencesipreview.com/americas/we-took-ravgen-head-on-how-we-won-zero-damages-and-others-didnt</u>