Rare $155m jury verdict for a biotech patent

THE CASE:
Baxalta Inc v Bayer HealthCare
US District Court for the District of Delaware
4 February 2019

Complex biotech cases tend to avoid jury trials, but one of Delaware's largest-ever patent damages awards shows how they can be won, explain **Jim Badke**, **Sona De** and **Ching-Lee Fukuda**

On 4 February 2019, after a six-day trial, a Delaware jury found in favour of Bayer HealthCare across the board in a high-stakes biotech patent case against Baxalta's flagship hemophilia drug, Adynovate, a product Baxalta considered to be "critical" to maintaining its competitive position. Bayer had patented an innovative life-saving drug for haemophilia that can be taken less frequently than conventional alternatives.

The jury found all asserted claims of Bayer's patent both infringed by Adynovate and valid. It rejected multiple defences raised by Baxalta, including Baxalta's arguments that the patent was not infringed, was obvious, lacked unexpected results and failed to teach the invention.

The jury then awarded Bayer more than $155m for past infringing manufacture and sales, applying a royalty rate of about 18% of net sales. This outcome is significant both from a liability and damages perspective. The liability issues involved complex aspects of protein chemistry and biotechnology. Although juries decide patent infringement suits, cases involving pharmaceutical drugs are often tried to the bench. This is one of the few biotech patent cases decided by jury, and it involved scientific principles more complex than what juries typically encounter in patent suits.

The damages award is one of the 10 largest patent verdicts in Delaware in the past decade and constitutes the largest biotech patent verdict in that court. Even then, the damages award represents just the two and half years since Adynovate's launch. The additional remedy for future sales of Adynovate, which Baxalta characterised in the evidence as "business critical," will be determined by the court.

The case illustrates how trial presentation of even the most complex issues can be effectively done before a jury.

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Case background

Bayer and Baxalta have been head-to-head competitors in the field of recombinant Factor VIII technology to treat haemophilia for over 25 years. This case is one of five disputes between these parties, with three proceedings pending in Germany, and another in the US set to be tried in May 2020.

Haemophilia is an inherited disease where a patient lacks a blood component necessary for proper blood clotting called Factor VIII. Patients are treated by replacement Factor VIII made in the laboratory, which is typically injected 3-4 times a week. This regimen can cause significant pain, damage to the veins and skin at infusion sites, and extreme inconvenience. These problems often lead to lack of adherence to the treatment regimen, which is required to safeguard the patient against bleeding episodes. Because haemophilia runs in families, multiple children in the same family may require multiple infusions a week. Bayer's invention added a strategically placed polymer to a particular region of Factor VIII that unexpectedly increased how long it lasts in the body, thus reducing the number of infusions by at least one per week, without interrupting its ability to work. This reduction of infusions in every family member afflicted with this disease provides significant relief.

Infringement

At trial, Baxalta attempted to present defences that were contrary to the court's claim constructions, but also its admissions in the case and its own statements to the Food and Drug Administration about Adynovate. One such defence, rejected by the jury, was that Adynovate was not "functionally active" to clot blood. On its face, this was not credible, as Adynovate is a commercially available treatment for haemophilia A. But it also contradicted Baxalta's statements to the FDA, which Bayer's experts repeatedly demonstrated to the jury. Meanwhile, Baxalta's repeated attempts to read requirements into the claims that neither the words of the claims or the claim constructions required, failed to convince the jury that Baxalta did not infringe.

Validity

Baxalta put two validity challenges to the jury: whether the claimed inventions (i) were obvious based on a combination of references and derivation, and (ii) not enabled.

Baxalta's main argument on obviousness stemmed from a history between Bayer and a company named Nektar, Baxalta's research partner for Adynovate. Before working with

Baxalta, Nektar had done work for Bayer in the same field. Baxalta used this history to argue that Bayer derived its patent invention from Nektar back in the day. In an unusual twist, Baxalta's parent company had hired the first named inventor on Bayer's patent and Baxalta brought him to trial to essentially testify against his own patent. Bayer had to cross examine its own inventor to show the jury records explaining that Bayer had the foundation of the invention before the Nektar work. Bayer then used the Nektar work against Baxalta to show that Nektar not only failed to conceive Bayer's invention first, but that this failure only underscored how innovative Bayer's invention actually was.

Bayer also used expert testimony to defeat these defences. Bayer's cross examination of Baxalta's primary validity expert secured admissions as to the failings of the remaining references that Baxalta used for obviousness. Bayer's own expert then framed the references in easy to understand categories for the jury to explain why they would not be combined. Bayer also showed real-world evidence of non-obviousness through unexpected results. Where past attempts to add polymer reduced Factor VIII activity, Bayer's invention both preserved that activity and extended how long the drug lasts in the body (aka, its half-life). Bayer crossed Baxalta's own experts to show that the actual patent data showed the same level of improvement as Adynovate itself.

Baxlata's enablement argument was that Bayer's patent did not have an example of the specific Factor VIII with polymer that Adynovate uses. Bayer countered this by showing the jury that the law does not require such example and having its expert explain that there is enough information to enable skilled scientists to make what is claimed.

Damages

On the damages front, the court kept the parties hopping when it issued rulings on both parties' *Daubert* motions the Friday before a Monday trial start. The order granted-in-part Bayer's motion to exclude Baxalta's damages expert from testifying about the licences he relied upon, finding them to be non-comparable licences. The order also allowed Bayer's damages expert to testify about the bargaining range for feasible outcomes of the reasonable royalty rate but excluded his testimony as to an exact rate. During trial, the bargaining range was submitted to the jury to determine, based on the facts, the reasonable royalty rate.

On Baxalta's side, Baxalta's expert testified that the reasonable royalty rate should be 1%. Baxalta's own documents, however, referred to Adynovate as its "flagship" product and as "business critical," and revealed that defending Baxalta's business with Adynovate is "an imperative". Baxalta was making 82.5% in gross profits from its sales of Adynovate, and had no non-infringing extended half-life alternative to turn to if it could not obtain a licence from Bayer. Relatedly, Baxalta produced altered profitability numbers long after the close of fact discovery and after receiving Bayer's damages expert report, in an effort to deflate the damages award. Baxalta's altered lower profit numbers were inconsistent with what Baxalta produced during fact discovery and with the testimony of Baxalta's own Rule 30(b)(6) corporate witness on financial topics. The court, on the eve of trial, found this new production to be in "bad faith" but allowed Baxalta to present the additional numbers to the jury. During trial, Bayer's trial team demonstrated to the jury the suspicious timing and inconsistencies of Baxalta's altered profit numbers.

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On Bayer's side, Bayer's expert testified that the reasonable royalty rate should fall within the bargaining range for the two parties between 5.1% and 42.4%. The endpoints were calculated based on what Bayer would have lost by licensing Baxalta, what Baxalta would have gained from the licence, and consideration of the *Georgia-Pacific* factors. For example, Bayer's witnesses testified that, even though Bayer itself does not practise the '520 patent, Bayer spent well over a decade developing the technology claimed in the '520 patent and would never have voluntarily licensed it to a direct competitor.

The facts demonstrated that, for Baxalta, obtaining a licence to the '520 patent was the key to its future success in the haemophilia market. Ultimately, the damages portion of the closing argument concluded with the following: "Why would Bayer license a patent like this to Baxalta for just 1%? That is completely unreasonable to say it's 1% and it's frankly insulting. So we ask you to look at that... and give what is fair to Bayer."

The jury determined that awarding 17.78% of the worldwide net sales revenues of Adynovate is what is fair to Bayer.

Trial presentation

Time management was a challenge where each side was limited to 14 hours to present opening arguments and evidence over five days. The trial involved 18 witnesses, half of which were experts. Fact witnesses included executives from both Bayer and Baxalta and inventors. Given the science and damages, experts included physicians, protein chemists, polymer chemists, and economists. By the last day of trial, Baxalta had very little time left to cross Bayer's final two experts. Bayer avoided this problem by focusing its crosses of Baxalta's experts, which saved time and showcased the key points to undermine their opinions before the jury.

Pulling all the evidence together, along with the law, in a cohesive deliverable message for the jury was key to closing arguments. The authors Badke, De and Fukuda delivered a shared closing argument that weaved together the story of Baxalta's infringement, the innovation of Bayer's patented invention, and the fair amount of damages that the jury was asked to determine.

Authors

Jim Badke, Sona De and Ching-Lee Fukuda lead the IP litigation practice in the New York office of Sidley Austin. They led the Bayer trial team and have tried cases together for over a decade, spanning technologies in the pharmaceutical, biotech, medical device, medtech, software and electronics, and chemical fields.