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Litigators of the Week: Morgan Lewis IP Aces Save Babies' Lives—and Taxpayers Money

By Jenna Greene
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Our Litigators of the Week are Morgan, Lewis & Bockius partners Sanjay Murthy, Mike Abernathy and Will Peterson.

They prevailed before the U.S. Court of Appeals for the Federal Circuit in a hard-fought battle that opens the door to generic competition to a pricey name-brand drug that saves newborn babies who can't breathe.

The Aug. 27 appellate decision breaks new ground. It's the first time so-called method of treatment claims have been held invalid under Section 101 of the Patent Act. The decision stands to give other generic challengers a powerful new line of attack against pharmaceutical companies that use such claims to evergreen their products.

The Morgan Lewis trio discussed the case with Lit Daily.

Lit Daily: Who is your client and what was at stake?

Mike Abernathy: We represented Praxair Inc. and Praxair Distribution Inc., drug manufacturer of nitric oxide gas inhalation and its delivery device. Praxair has since merged with Linde and is now the world's largest industrial gas company.

Fifty percent of nitric oxide sales are to the US government through Medicaid. The cost for treatment of a single patient using the branded drug INOMAX can reach $18,000.

Nitric oxide is used to treat persistent pulmonary hypertension of the newborn (PPHN), a life-threatening condition where the baby does not change over from fetal to normal newborn circulation. Blood is forced away from the lungs due to high blood pressure in the arteries that go to the lungs. This decreases the body's supply of oxygen. Babies with this condition present as "blue," and it is a fatal condition, if left untreated.

L-R: William R. Peterson, Sanjay K. Murthy and Michael J. Abernathy of Morgan, Lewis & Bockius.

Inhaled nitric oxide acts by dilating the blood vessels in the lungs, which then allows the baby to breathe normally.

But the prohibitive cost had forced some hospitals to either curtail their use of the product or to use dangerous alternatives to try to treat infants suffering from hypoxic respiratory failure.

The generic being developed by Praxair will bring down this cost, making the life-saving drug more accessible to neonates born with the debilitating condition, while saving the U.S. government significant money.

Tell us about your opponent.

Sanjay Murthy: Mallinckrodt is a specialty pharmaceutical company with its U.S. operations based in St. Louis. They offer both branded and generic pharmaceutical products, including INOMAX.

Mallinckrodt was represented by a team of 15 lawyers including Wilmer Hale's Seth Waxman, the former solicitor general of the United States, on appeal. At trial, the company was represented by Latham & Watkins's global chair of intellectual property, Ken Schuler.

Will Peterson: Mallinckrodt was very well-served by its counsel, who did an excellent job defending its positions.

When and how did you get involved in the case?

Mike Abernathy: We (Sanjay and I) became involved in the case in 2012, prior to joining Morgan Lewis, following Praxair's unsuccessful search for counsel with extensive ANDA and medical device experience. We are among only a handful of lawyers with considerable experience trying both medical devices and pharma type of matters.

Despite the size of the inhaled nitric oxide market, no other competitors were willing to take on Mallinckrodt's expansive patent estate to bring a generic product to market. Several global companies considered challenging Mallinckrodt but ultimately did not.

Praxair/Linde was the only company to seek authorization to make a generic product in the United States. Ultimately, this was the largest IP litigation matter in Praxair's history.

Will Peterson: I became involved in 2017, after the judgment at the trial level. Since joining Morgan Lewis, I have worked closely with Mike, Sanjay, and other members of Morgan Lewis's intellectual property practice on a number of Federal Circuit appeals.

Because my background is a general appellate practice, in intellectual property appeals I rely heavily on Julie Goldemberg, a senior associate who served as a law clerk at the Federal Circuit. This case was no exception. Mike and Sanjay recognize the value of appellate specialists in defending important judgments and asked Julie and me to join the team.

What were some of the most challenging parts of the case for you?

Sanjay Murthy: There were several challenging points throughout the case. Our client had attempted to challenge all of Mallinckrodt's patents through inter partes review proceedings at the Patent Office. Unfortunately, the team lost all but one of those challenges at the PTO.

In addition, the FDA took a very long time reviewing Praxair's ANDA filing and forced it to change its drug label on several occasions. This made the district court litigation more challenging.

Finally, when we changed firms near the end of discovery, Mallinckrodt filed a motion for disqualification. The motion was ultimately unsuccessful but extremely costly and time consuming to defend.

Another challenging aspect was trying a case involving several patents related to many different types of technology, and a number of complex regulatory issues because INOMAX was treated as a drug/device combination product by FDA.

The Morgan Lewis team had to retain four technical experts (two M.D.s and two PhDs), as well as an FDA regulatory expert to handle all of these issues.

What was your overarching theme in litigating the case?

Mike Abernathy: Our overarching theme was that Mallinckrodt's 11 patents were not the product of true innovation, but rather were created to unlawfully extend their patent monopoly on inhaled nitric oxide gas, which was supposed to end in 2013.

Will Peterson: Before the Federal Circuit, we emphasized that the patents did not claim a method of treatment but instead claimed not treating a selected subset of patients. Under the claimed methods, every patient who received treatment received exactly the same treatment that the patient previously would have received.

We were gratified to see this distinction reflected in the Federal Circuit's opinion, which recognized that the claim "does no more than add an instruction

to withhold [INOMAX] treatment from the identified patients[.]"

Did you make any unconventional strategic choices?

Sanjay Murthy: The largest risk we took was asserting invalidity for method of treatment claims under Section 101. At the time we did this, no one to our knowledge, had successfully invalidated claims on that ground. We faced skepticism from at least one judge that looked at the issue during the pendency of the case.

But we made 101 the focus of the trial and our cross examination of plaintiff's lead inventor (which I handled) and expert witness (which Mike handled). This tag team strategy caught plaintiff somewhat off guard.

Rather than prepare their witnesses for an attack on Section 101, plaintiff's counsel had apparently focused their efforts on our inequitable conduct and prior art-based defenses, which he had highlighted in his opening. In this way, we hid the ball on our best defense and our gamble paid off.

Tell us about the Federal Circuit decision. It's the first time so-called method of treatment claims have been held invalid under Section 101 of the Patent Act. Why is this significant?

Sanjay Murthy: Before our case, there were several decisions that suggested that method of treatment claims would always pass muster under Section 101 of the Patent Act. Our decision confirms that some method of treatment claims may be vulnerable to attack under Section 101.

This is significant because method of treatment claims are often barriers to entry for generic pharmaceutical products in the United States. The Praxair decision will prevent brand pharmaceutical companies from obtaining patents that are merely natural phenomenon and thus could wrongfully extend patent monopolies. By extension, the Praxair decision should help bring the cost of prescription drugs down by weeding out non-meritorious patents.

Will Peterson: Legally, the key to the decision is that the label "method of treatment" does not allow a patentee to evade general principles of patent eligibility.

Mallinckrodt's strategy was to rely on cases holding method-of-treatment claims to be eligible for patent protection. What we had to do in response was convince the Federal Circuit to look past the "method of treatment" label. The decision should not be read as casting doubt on the patentability of novel methods of treatment, but the patentee must actually invent a method of treatment to be eligible for patent protection.

As the panel majority recognized, what Mallinckrodt labeled a "method of treatment" (non-treatment of certain patients) was not the sort of inventive method of treatment that the Federal Circuit had found eligible for patent protection in previous decisions.

How do you see the case affecting the industry?

Sanjay Murthy: The Federal Circuit upheld Judge Sleet's rulings of invalidity and non-infringement, which paves the way for the introduction of the first-ever generic competition in the nearly $500 million-a-year inhaled nitric oxide market.

The United States is the only country in the world where generic nitric oxide is not available. The cost of the product was so high that respiratory therapists were experimenting with potentially dangerous workarounds to save money

This decision will give access to a lot of patients that desperately need it. More broadly, pharmaceutical companies routinely use method of treatment claims to evergreen their products. This decision will give patent challengers a powerful tool to invalidate suspect method of treatment claims under Section 101.

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