

# Delaware Law Weekly

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## District Court Ruling Paves Way for Generic Drug

By Elizabeth Bennett  
Of the DLW

District Judge Sue L. Robinson ruled in favor of the defendants in the case *In re '318 Patent Infringement Litigation*, stating that a patent for the Alzheimer's disease drug Razadyne could not be both non-obvious and enabled.

The decision hinged on the lack of hard experimentation data for the patent, according to the Aug. 27 opinion from the U.S. District Court for the District of Delaware.

Enablement is a patent requirement in the U.S. Code which says: "The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same," as quoted in the opinion.

The '318 patent in question relied too heavily on the prior art to fulfill its enablement requirement, the opinion said.

Given that Robinson rejected the defendants' argument that the prior art rendered the patent invalid because of obviousness, she ruled that the same prior art could not enable the patent.

The plaintiffs are Synaptech Inc. and Ortho-McNeil Neurologics, a division of Ortho-McNeil-Janssen Pharmaceuticals Inc., a subsidiary of Johnson & Johnson. The defendants in the consolidated litigation are Barr Laboratories Inc. and Alphapharm Pty Ltd.

The day following Robinson's decision Barr announced it had received approval from the Food and Drug Administration for its generic version of Razadyne and that it intended to launch the drug immediately. The FDA had placed a 30-month stay on the application, triggered by the infringement suit that was filed in 2005.

Ortho-McNeil intends to appeal Robinson's ruling.

"We will appeal because we believe we are entitled to damages for at-risk launches," said a spokesperson for the company. She explained that the launch of the generic drugs would be "at-risk" because the appeals court could reverse the ruling and uphold the patent.

Ortho-McNeil-Janssen licenses the '318 patent, owned by Synaptech. The patent is due to expire in December, but even that short period of time could implicate substantial amounts of money.

Barr stated in its announcement that Razadyne tablets had annual sales of about \$102 million for the 12 months ending in June 2008. According to the opinion, the drug has "grossed over \$912 million over the first five years of its sales."

In her opinion, Robinson also denied the plaintiffs motion for a temporary

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## DuPont Corporate Counsel Takes On National Leadership Role

By Elizabeth Bennett  
Of the DLW

Ramona E. Romero traveled to Los Angeles to be sworn in Sept. 6 as the new president of the Hispanic National Bar Association at its 33rd annual convention, capping off more than a decade with the organization.

As corporate counsel for logistics and energy at E.I. du Pont de Nemours & Co., Romero is responsible for legal oversight of transportation, distribution and supply-chain management services and energy resources totaling billions of dollars each year. She also oversees related litigation.

As president of the HNBA, she will represent the interests of about 25,000 Hispanic American attorneys, judges and law professors.

The 46-year-old Romero's life is a classic American story. She and her mother came to New York City from the Dominican

Republic when she was 11 years old. Her mother worked in a handbag factory, and Romero learned to speak English while attending public schools. Eventually, she attended Barnard College of Columbia University and Harvard Law School.

After 10 years at Crowell & Mooring in Washington, D.C., where she handled complex commercial litigation and

antitrust matters, Romero made the move to DuPont in 1998.

She decided to move in-house because DuPont was seeking someone with her precise experience and because she had met a Philadelphian she would later marry. The couple now lives in a suburb of

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Philadelphia and has two daughters.

Before her current position with DuPont, Romero managed its much-lauded outside counsel and supplier partnering program. In that role, she had a great opportunity to demonstrate a commitment to diversity, and she volunteered to lead such projects as the DuPont Legal Minority Job Fair, the DuPont Minority Counsel Network Conference and the DuPont Diverse Legal Supplier Program. She is also co-founder of the Dominican American National Roundtable, the first effort to empower Dominican Americans nationally.

Early on in her career, she joined the Hispanic Bar Association of the District of Columbia, rising to be its president in 1997.

After her move to the Delaware area, Romero served as the regional president for HNBA from 2000 to 2001 and again from 2004 to 2006.

In fact, Romero recruited the president of the Delaware Hispanic Bar Association, Rafael X. Zahralddin-Aravena of Elliott Greenleaf in Wilmington, to serve as HNBA regional president. She is also a member of the local organization, which just got started this year.

Romero called the HNBA "the national voice of the Hispanic legal community," before describing its dual mission.

"First, we help advance Hispanics in the law and we provide a community for Hispanics in the law, for those in the pipeline and for those who are already lawyers," Romero said. "We also have a very clear mission to serve the Hispanic community through nonpartisan advocacy."

Jimmie V. Reyna, a partner and director of the international trade and customs practice group for Williams Mullen in Washington, D.C., was finishing his term as president of the HNBA around the same time Romero was chosen by the membership as president-elect. He explained that these elections are hardly a given.

"Three quarters of our officer positions are contested," Reyna said. He explained that the membership examines formal candidates' statements as well as personal histories.

Reyna, who has known Romero for about six years, said he is proud and excited to see her serve as president. He called her successful legal career her No. 1 qualification.

"We want people to be our national

leaders who have excelled as lawyers," Reyna said.

Second, Reyna said voters examine the candidates' record of work in the Hispanic community, particularly within the HNBA. Romero is entering her sixth term on the organization's board of governors.

"During her service on the board she proved to be a giver, an effective participant and a leader who could put her ideas across," Reyna said. "When it came time to roll up her sleeves, she would do that."

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*'We understand the need for the {United States} to protect its borders, but we also believe you cannot ignore the plight and needs of the 12 million-plus people who live and work in this country.'*

— Ramona E. Romero

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When he was president of the HNBA, he appointed Romero as the 2007 chairwoman of its Legislative Day, when members travel to Capitol Hill to address legal issues that affect the Hispanic community.

"She did a wonderful job," Reyna said.

Romero took on that responsibility while she was the HNBA's vice president for external affairs. She also served as chairwoman of the HNBA's Task Force on Comprehensive Immigration Reform in 2007.

"We understand the need for the [United States] to protect its borders, but we also believe you cannot ignore the plight and needs of the 12 million-plus people who live and work in this country," Romero said. "That's why we have embraced comprehensive immigration reform that includes a path to citizenship for immigrant workers."

While the most recent legislation failed, the HNBA will continue to advocate for its community. To that end, Romero has articulated an ambitious agenda for her year as president under the theme, "Opening doors through collaboration."

One element is vigorous promotion of Hispanic candidates for various appointments. Called the Hispanic Appointments Project, Romero said the effort will be led by a Republican and a Democrat to

identify prospective candidates for executive and judicial appointments.

"That is, we want to identify potential Latino U.S. attorneys, assistant attorneys general, general counsels of federal agencies — all of the executive appointments made by the president, in addition to the bench," she said.

The HNBA is also launching Project SAFE at its convention, which stands for safe and fair elections, Romero said.

"We are part of a larger, nonpartisan voter protection coalition," she said. "Hispanics in the past have experienced a number of obstacles when exercising their right to vote."

The project will gather lawyers and others to serve as election watchers and to staff a hotline for election protection issues.

"It's a big part of our fall agenda," Romero said.

A business development "boot camp" is also on that agenda, Romero added.

"Minority lawyers often don't get the training they need to develop their business and become rainmakers," she said, adding that this issue goes to the root of diversity in the legal field because, like any business, a firm's decisions are driven by economic factors.

"The other thing I'm doing is launching a presidential Commission on the Status of Latinas in the Legal Profession. Latinas are more underrepresented than any other minority group. We want to understand the obstacles Latinas face and develop and recommend solutions."

This last item illustrates the intersection of Romero's work advocating for the Latino community with her work promoting women in the profession.

Romero, among other things, has served on the advisory council of the National Association of Minority and Women-Owned Firms. Through her work with DuPont's preferred legal services providers, as well as with NAMWOLF, Romero got to know Ellisa Habbart, co-founder of the Delaware Counsel Group in Wilmington, who is also active in promoting the cause of women in the law.

Habbart said she thinks Romero has what it takes to be a successful advocate.

"She brings to the table a tremendous combination of smarts and confidence. She believes what she believes. She's a straight shooter and she won't be afraid to do what she can to promote those beliefs," Habbart said, adding, "She is one of the most delightful people in my world." •