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WAS ALLERGAN'S PATENT-HOUSING AGREEMENT IN EXCHANGE FOR SOVEREIGN IMMUNITY A "SHAM TO SUBVERT THE EXISTING INTELLECTUAL PROPERTY SYSTEM?"

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Allergan plc was fighting to protect its patents from potential infringers and to delay generic knockoffs in order to maintain its monopoly on Restasis, an eye medication generating in excess of \$1.2 billion dollars annually. The Saint Regis Mohawk tribe was not generating enough revenue from its casino to support its \$50 million annual budget. The tribe proposed to hold Allergan's patents in exchange for millions of dollars and the use of the tribe's sovereign immunity to prevent inter partes reviews by the Patent Trial and Appeal Board. While Allergan argues that such an agreement "protect[s] our property against a system that exposes us to double jeopardy," others see it as "a sham to subvert the existing intellectual property system."

Allergan plc² ("Allergan") holds several patents³ for its prescription dry-eye medication Restasis.⁴ In 2015, Allergan sued Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA Inc., and Akorn Inc., (the "Generic Manufacturers"), for patent infringement following their filings of

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² Allergan plc, headquartered in Dublin, Ireland, is a global pharmaceutical company and a leader in what is referred to in the industry as Growth Pharma. *See Company Profile*, ALLERGAN, <https://www.allergan.com/about/company-profile> (last visited Sep. 28, 2018). It develops, manufactures, and commercializes branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world. *See id.*

³ The relevant patents are U.S. Patent Numbers 8,685,930; 8,629,111; 8,642,556; 8,633,162; 8,648,048; and 9,248,191, all expiring in 2024. Findings of Fact and Conclusions of Law at 23, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-01455-WCB (E.D. Tex. 2017).

⁴ Restasis is an ophthalmic formulation of cyclosporine, an eye drop treatment that helps dry eyes produce tears. RESTASIS, <https://www.restasis.com> (last visited Nov. 10, 2018). Allergan reported \$318.2 million in sales of Restasis in the second quarter of 2018, its second-biggest seller behind Botox. *See Press Release*, Allergan, Allergan Reports Strong Second Quarter 2018 Results Including GAAP Net Revenues of \$4.1 Billion (July 26, 2018).

abbreviated new drug applications (“ANDAs”) for generic versions of the branded drug.⁵ The Generic Manufacturers then petitioned for inter partes review⁶ (“IPR”) of those patents to the United States Patent and Trademark Office (“USPTO”).⁷ The Generic Manufacturers were seeking to invalidate the Restasis patents through the USPTO’s Patent Trial and Appeal Board (“PTAB”), which would open the door for generic versions of the drug.⁸ When a branded pharmaceutical drug is protected by a patent, the patent owner has exclusive rights to that drug, thereby preventing competitors from producing generics to compete with it.⁹ Therefore, the price of the branded drug remains high, and the pharmaceutical company effectively has a market monopoly on that drug.¹⁰ However, pharmaceutical companies are finding it difficult to maintain sales and profits amidst efforts to drive down drug prices through the fast-track, less expensive legal IPR process of attacks on drug patents.¹¹

Allergan, in an effort to shield the patents from inter partes reviews by the PTAB, transferred the patents to the Saint Regis Mohawk tribe (the “Tribe”), a community of 13,000 living

⁵ See *St. Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F.3d 1322, 1325 (Fed Cir. 2018).

⁶ Inter partes review is a trial proceeding conducted to review the patentability of one or more claims in a patent. See also *Inter Partes Review*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/patents-application-process/appealing-patent-decisions/trials/inter-partes-review> (last visited Nov. 10, 2018). This process started in 2011 pursuant to the Leahy-Smith America Invents Act for the purpose of objecting to a granted patent based on a prior art. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, Stat. 284 (2011).

⁷ See *St. Regis Mohawk Tribe*, 896 F.3d at 1325.

⁸ See *id.* In early 2017, the PTAB invalidated some of the patents held by Abbvie Inc. on its \$16 billion immunosuppressant Humira, opening the door for low-cost generic competition for the country’s best-selling drug. See Jan Wolfe, *U.S. tribal patent deal could have big impact on generic drug market*, REUTERS, (Sept. 11, 2017, 3:36 PM), <https://www.reuters.com/article/us-allergan-patents-mohawk/u-s-tribal-patent-deal-could-have-big-impact-on-generic-drug-market-idUSKCN>.

⁹ Srividhya Ragavan, *The Drug Debate: Data Exclusivity is the New Way to Delay Generics*, 50 CONN. L. REV. ONLINE 1, 7 (2018) (noting that even absent a patent, the drug developer may still enjoy a period of exclusivity).

¹⁰ Eric E. Johnson, *The Case for Eliminating Patent Law’s Inequitable Conduct Defense*, 117 COLUM. L. REV. 1, 3-4 (2017).

¹¹ Joe Mullin, *Drug Company Hands Patents Off to Native American Tribe to Avoid Challenge*, ARS TECHNICA, (Sept. 13, 2017, 8:40 AM), <https://arstechnica.com/tech-policy/2017/09/how-a-native-american-tribe-ended-up-owning-six-key-patents-on-an-eye-drug/> (noting that invalidating a patent by using an IPR can cost a challenger a few hundred thousand dollars, which while expensive, is a bargain compared to the millions it can cost to invalidate a patent in federal district court); see also J. Jonas Anderson and Peter S. Menell, *Restoring the Fact/Law Distinction in Patent Claim Construction*, 109 NW. U. L. REV. 187, 189 (2015) (noting that bench trials are associated with increased litigation costs, “[f]or much of patent law’s history, patent litigators have preferred bench trials”); Gillian K. Hadfield, *What’s Different about Law?* 86 U. CHI. L. REV. 19, 23 (2018) (“Modern courts are effectively out of reach for the vast majority of the population—even the relatively well-off.”).

on the border of New York and Canada,¹² hoping that its sovereign immunity¹³ would shield the patents from those inter partes challenges.¹⁴ Allergan’s legal theory stemmed from a PTAB decision involving the University of Florida Research Foundation Inc. (“UFRF”), the patent licensing arm of the University of Florida (“UF”).¹⁵ UFRF owned a patent related to health care computer information systems that managed physiologic and treatment data.¹⁶ UF sued Covidien LP,¹⁷ a patent licensee, in 2015 for breach of their license agreement due to Covidien’s failure to pay royalties.¹⁸ Covidien counterclaimed, arguing that it did not infringe on the patent license because the products at issue were not covered by the patent.¹⁹ UF successfully argued that the patent challenges raised by Covidien should be dismissed because UF, as an arm of the state of Florida, should be granted sovereign immunity.²⁰ Given that case and others, the Tribe’s general counsel, Dale White, argued

¹² See Katie Thomas, *How to Protect a Drug Patent? Give It to a Native American Tribe*, THE NEW YORK TIMES, (Sept. 8, 2017), <https://www.nytimes.com/2017/09/08/health/allergan-patent-tribe.html>.

¹³ See Okla. Tax Comm’n v. Potawatomi Tribe, 498 U.S. 505, 509 (1991) (discussing how as “domestic dependent nations,” Indian tribes possess “inherent sovereign immunity,” and suits against them are generally barred “absent a clear waiver by the tribe or congressional abrogation”); see also Joseph Patterson, *The Native American Struggle Between Economic Growth and Cultural, Religious, and Environmental Protection: A Corporate Solution*, 92 NOTRE DAME L. REV., 140, 144 (2017) (“[T]he United States Constitution does in fact ‘contemplate the existence of Indian nations’ and Native American sovereignty . . .”).

¹⁴ Allergan, Inc. v. Teva Pharms. USA, Inc., No. 15-01455, 2017 U.S. Dist. LEXIS 136445, at *6, *10 (E.D. Tex. Aug. 25, 2017). The idea for the deal was not Allergan’s. Sy Mukherjee, *Botox Maker Allergan’s CEO Defends Selling Drug Patents to Native American Tribe to Thwart Rivals*, FORTUNE (Sep. 9, 2017), http://fortune.com/2017/09/09/allergan-drug-patents-native-american/?utm_source=emailshare&utm_medium=email&utm_campaign=email-share-article&utm_content=20181111. Allergan was approached by counsel for the tribe which was trying to expand its revenue through patent-housing. *Id.*

¹⁵ See Jared Manse, *University Patents Now Immune To Inter Partes Review: Will Business Come Calling?*, THOMPSON COBURN LLP, (Mar. 7, 2017), <https://www.thompsoncoburn.com/insights/publications/item/2018-07-17/university-patents-now-immune-to-inter-partes-review-will-business-come-calling>.

¹⁶ *Id.*

¹⁷ Covidien, an Irish-headquartered global healthcare products company and manufacturer of medical devices and supplies, was purchased by Medtronic plc, one of the world’s largest medical equipment companies in January, 2015. Press Release, Medtronic, Medtronic Completes Acquisition of Covidien, (January 26, 2015).

¹⁸ Manse, *supra* note 15.

¹⁹ *Id.*

²⁰ Covidien LP v. Univ. of Fla. Research Found., Inc. No. IPR2016-01274, at 3 (P.T.A.B. Jan. 25, 2017) (holding that UFRF is entitled to Eleventh Amendment immunity “as an arm of the state of Florida”); see also NeoChord, Inc. v. Univ. of Md., Balt., No. IPR2016-00208, at 2 (P.T.A.B. May 23, 2017) (holding that the University of Maryland was entitled to Eleventh Amendment immunity).

that “Indian tribes have sovereignty that is stronger than states,” thus suggesting that Allergan might have a strong case.²¹

Allergan paid the Tribe \$13.75 million plus promised royalties to take ownership of the patents so it could claim tribal sovereign immunity as grounds to dismiss the IPRs.²² The Tribe would then license the rights to all FDA-approved uses of the patents back to Allergan for an estimated \$15 million per year in royalties.²³ This was arguably a creative way for Allergan to insulate its patents from PTAB review and for the Tribe to generate revenue.²⁴ However, not everyone saw it that way. According to Denise Bradley, a spokeswoman for challenger Teva Pharmaceuticals, the deal is “a new and unusual way for a company to try to delay access to high-quality and affordable generic alternatives.”²⁵ The PTAB invited amicus briefs on the matter and received fifteen such briefs, almost evenly split on the issue.²⁶

Allergan and others who filed amicus briefs asserted that PTAB reviews are flawed and unfair to patent owners.²⁷ The brand-name drug industry has long opposed the PTAB process, which was created in 2011 to streamline patent challenges by allowing them to be decided by the administrative panel.²⁸ However, Allergan sees that as a form of double jeopardy since the patents are subject to federal litigation as well as challenges using the IPR process.²⁹ Allergan CEO, Brent Saunders, said, “We’re not trying to artificially extend these patents, we’re just trying to protect our

²¹ See Thomas, *supra* note 22. *But see* *Kiowa Tribe of Okla. v. Mfg. Techs., Inc.*, 523 U.S. 751, 756 (1998) (stating that “[i]mmunity possessed by Indian Tribes is not co-extensive with that of the States”).

²² See Thomas, *supra* note 22.

²³ *Id.*

²⁴ *Id.* (noting that while the tribe operates a casino near the reservation, it “has many unmet needs,” and “wants to be self-reliant” according to Dale White, general counsel for the tribe). This was the first pharmaceutical deal for the tribe, but it already owned technology patents. *Id.*

²⁵ *Id.*

²⁶ Kevin E. Noonan, *Amicus Briefs Filed in Mohawk Tribe’s Motion to Dismiss IPRs*, PATENT DOCS, (Jan. 28, 2018), <http://www.patentdocs.org/2018/01/amicus-briefs-filed-in-mohawk-tribes-motion-to-dismiss-iprs.html>.

²⁷ *Id.*

²⁸ Mukherjee, *supra* note 14; *see also* 35 U.S.C. §§ 311 - 316 (2011) (outlining the inter partes review process).

²⁹ Mukherjee, *supra* note 14.

property against a system that exposes us to double jeopardy.”³⁰ The stock market reacted favorably to the Allergan deal with a 2.5% increase in the price of Allergan stock on the day of the announcement of the deal.³¹ Philip Johnson, principal at Johnson-IP Strategy & Policy Consulting, focused on the IPRs themselves, echoing Allergan’s assertion that there are problems with the IPR proceedings.³² “If we are successful in [fixing IPRs], patentees would not need to assign their patents to sovereigns, as there will be nothing to be gained by doing so.”³³ However, others were not impressed with the agreement between Allergan and the Tribe.

Congressional Opposition

“It is unacceptable, however, for private actors like Allergan, to do an end-run around IPR by making use of a third-party’s sovereign immunity, solely for a strategic advantage,” said the New York, Democratic Congressman Jerrold Nadler.³⁴ “Such behavior makes a mockery of congressional authority and of the rule of law,” continued Nadler.³⁵ A group of senators sent a letter to Allergan CEO Brent Saunders accusing Allergan of a “blatant effort to further Allergan’s market monopoly on Restasis”³⁶ and asserting that “it is difficult to conceive of Allergan’s transaction as anything other than a sham to subvert the existing intellectual property system.”³⁷ In addition, in a letter to the Senate Judiciary Committee, four senators asserted that the agreement was a “blatantly anti-competitive attempt” to protect Allergan’s patents and pricing.³⁸

Other industry opinions

³⁰ *Id.*

³¹ *Id.*

³² *Hearing on Sovereign Immunity and the Intellectual Property System Before the Subcomm. On Courts, Intellectual Property and the Internet*, 115th Cong. (2017) (statement of Philip S. Johnson).

³³ *Id.* at 3.

³⁴ *Hearing on Sovereign Immunity and the Intellectual Property System Before the Subcomm. On Courts, Intellectual Property and the Internet*, 115th Cong. (2017) (opening statement by Rep. Jerrold Nadler).

³⁵ *Id.*

³⁶ *Senator Hassan and Colleagues to Allergan CEO: Monopoly Keeps Price of Drug High, Limits Competition*, MAGGIE HASSAN, U.S. SEN. FOR N.H., (Nov. 7, 2017), <https://www.hassan.senate.gov/news/press-releases/senator-hassan-and-colleagues-to-allergan-ceo-monopoly-keeps-price-of-drug-high-limits-competition>.

³⁷ *Id.*

³⁸ Letter from Sens. Maggie Hassan, Sherrod Brown, Bob Casey, and Richard Blumenthal to Sens. Charles Grassley and Dianne Feinstein (Sept. 27, 2017).

In addition to the outcry from Congress, there were others who were not in favor of using the Tribe's sovereign immunity to shield commercial patents that were not even developed by the Tribe.³⁹ Christopher Mohr, general counsel for the Software and Information Industry Association, testified before the House subcommittee on intellectual property, arguing that sovereign immunity did not belong in the US intellectual property system.⁴⁰ Reading from his prepared notes, he explained, “[W]hen [sovereign entities] commercially exploit those federally-created rights, the law should require them to play by the same sets of rules as any other commercial participant.”⁴¹ William Jay, of Goodwin Procter LLP, spoke for the Association for Accessible Medicines when urging Congress to consider legislation abrogating tribal immunity in inter partes reviews and testified that “[n]o one has the right to hold onto a patent that isn’t innovative; certainly no one should be able to shield such a patent from review while using it to preserve a monopoly and charge higher prices to patients and the public.”⁴²

Derek Lowe, a blogger on the pharma industry, wrote that it “does not seem like a good way to run an intellectual property system” to tell a pharmaceutical company “[t]he validity of your patents is subject to review, unless you pay off some Indian tribe.”⁴³ And, he suggests that this move by Allergan not only looks bad for Allergan, but others in the drug industry as well.⁴⁴ Given the unprecedented structure of this deal, its impact on the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, is unclear.⁴⁵ The Act was adopted by Congress to streamline generic drug approvals and patent litigation involving generic

³⁹ See *Hearing on Sovereign Immunity and the Intellectual Property System Before the Subcomm. On Courts, Intellectual Property and the Internet*, 115th Cong. (2017) (statement of Christopher A. Mohr).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Hearing on Sovereign Immunity and the Intellectual Property System Before the Subcomm. On Courts, Intellectual Property and the Internet*, 115th Cong. (2017) (statement of William Jay).

⁴³ Derek Lowe, *Allergan Pulls A Fast One*, SCIENCE TRANSLATIONAL MEDICINE, (Sept. 11, 2017) <https://blogs.sciencemag.org/pipeline/archives/2017/09/11/allergan-pulls-a-fast-one>.

⁴⁴ *Id.*

⁴⁵ Pub. L. No. 98-417, 98 Stat. 1585 (1984).

drugs.⁴⁶ Instead of the time-consuming and expensive clinical trials endured by proposed new branded drugs, the Hatch-Waxman Act provided an expedited FDA approval process for generic drug applications.⁴⁷ The Act also created a unique patent litigation process triggered by a generic drug company's submission of an ANDA for FDA approval which allows the applicant to rely on safety and efficacy studies in the NDA submitted by the branded applicant.⁴⁸ If Allergan's attempt was successful, not only might that mean that sovereign immunity would bar IPRs, but it might also prevent generic drug companies from independently challenging patent invalidity as permitted by Hatch-Waxman.⁴⁹

The Generic Manufacturers argued that the PTAB is “not adjudicating claims between parties but instead is reconsidering a grant of a government franchise” and that Allergan's attempted use of the Tribe's sovereign immunity is “an impermissible attempt to ‘market an exception’ from the law and non-Indian companies have no legitimate interest in renting tribal immunity to circumvent the law.”⁵⁰ They went on to assert that “[u]nder fundamental ‘principles of fairness and consistency,’ sovereign immunity may not be wielded for ‘tactical advantage’ to enable a sovereign to retain the ‘fruits’ of the patent system while escaping its burdens.”⁵¹

The Decisions

The first blow to Allergan was the loss of its patent infringement claims in the Eastern

⁴⁶ See generally Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 Food & Drug L.J. 187 (1999).

⁴⁷ Findings of Fact and Conclusions of Law at 26, *Allergan, Inc. v. Teva Pharms. USA, Inc.*, No. 2:15-cv-01455-WCB (E.D. Tex. 2017).

⁴⁸ *Id.* at 26-27.

⁴⁹ Rachel Sachs, *Be Very, Very Concerned About What Allergan Just Did*, BILL OF HEALTH, (Sept. 9, 2017), <http://blogs.harvard.edu/billofhealth/2017/09/09/be-very-very-concerned-about-what-allergan-just-did/> (“Recall that the usual posture of a Paragraph IV suit is as follows: a generic drug company has filed a paragraph IV ANDA alleging that the innovator company's patents are invalid (for example). The innovator company then sues the generic for patent infringement, as permitted by the statute. The generic drug company may then counterclaim for invalidity. If they succeed in invalidating the innovator company's patents, then the generic can come to market earlier than anticipated and help bring down drug prices more quickly.”).

⁵⁰ *St. Regis Mohawk Tribe v. Mylan Pharms., Inc.*, 896 F.3d 1322, 1326 (Fed. Cir. 2018).

⁵¹ Brief for Appellees at 23, *St. Regis Mohawk Tribe v. Mylan Pharms. Inc.*, 896 F. 3d 1322 (Fed. Cir. 2018) (citing *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1383-85 (Fed. Cir. 2007)).

District of Texas.⁵² Senior U.S. Circuit Judge William Bryson ruled in favor of the generic drug company defendants finding that the asserted claims in the four patents at issue, which were among the transferred patents, were obvious.⁵³ Allergan’s argument that finding relief for dry eyes without major side effects was not obvious failed.⁵⁴ Judge Bryson pointed out that “Allergan that met that need, not because Allergan was at the forefront of innovation in a competitive setting, but because it had enjoyed a long period of patent protection, which ensured that it would be the only party . . . able to invent and exploit [the relevant] product”⁵⁵ since Allergan had enjoyed patent protection in this area since 1993.⁵⁶ And on the issue of sovereign immunity, the Court said:

Allergan purports to have sold the patents to the Tribe, but in reality it has paid the Tribe to allow Allergan to purchase—or perhaps more precisely, to rent—the Tribe’s sovereign immunity in order to defeat the pending IPR proceedings in the PTO. This is not a situation in which the patentee was entitled to sovereign immunity in the first instance. Rather, Allergan, which does not enjoy sovereign immunity, has invoked the benefits of the patent system and has obtained valuable patent protection for its product, Restasis. But when faced with the possibility that the PTO would determine that those patents should not have been issued, Allergan has sought to prevent the PTO from reconsidering its original issuance decision. What Allergan seeks is the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits through the administrative mechanism for canceling invalid patents. If that ploy succeeds, any patentee facing IPR proceedings would presumably be able to defeat those proceedings by employing the same artifice.⁵⁷

The second blow was dealt on July 20, 2018, when the Federal Circuit ruled against Allergan and the Tribe.⁵⁸ While tribal immunity would apply in a civil lawsuit, IPRs are more like an enforcement action from a federal agency, and therefore Federal Circuit Judge Kimberly A. Moore

⁵² See Findings of Fact and Conclusions of Law, Allergan, Inc. v. Teva Pharms. USA, Inc., No. 15-01455-WCB, 2017 U.S. Dist. LEXIS 136445 (E.D. Tex. Aug. 25, 2017).

⁵³ *Id.* at 135.

⁵⁴ *Id.* at 35.

⁵⁵ *Id.* at 104.

⁵⁶ *Id.* at 102.

⁵⁷ Allergan, Inc. v. Teva Pharm. USA, Inc., No. 15-01455-WCB, 2017 U.S. Dist. LEXIS 170825, at *10 (E.D. Tex. Oct. 16, 2017).

⁵⁸ *St. Regis Mohawk Tribe v. Mylan Pharms., Inc.*, 896 F.3d 1322, 1325 (Fed. Cir. 2018).

wrote, for a three-judge panel, that “we hold that tribal sovereign immunity cannot be asserted in IPRs.”⁵⁹ The court explained that

IPR is neither clearly a judicial proceeding instituted by a private party nor clearly an enforcement action brought by the federal government. It is a ‘hybrid proceeding’ with ‘adjudicatory characteristics’ similar to court proceedings, but in other respects it ‘is less like a judicial proceeding and more like a specialized agency proceeding.’⁶⁰

The court affirmed the PTAB’s authority to conduct an IPR of the patents at issue and decide their validity, without application of sovereign immunity.⁶¹

Judge Moore wrote that “the USPTO is acting as the United States in its role as a superior sovereign to reconsider a prior administrative grant and protect the public interest in keeping patent monopolies ‘within their legitimate scope.’”⁶² In a concurring opinion, Circuit Judge Timothy B. Dyk said the purpose of an IPR is to allow the USPTO to take a second look at an issued patent and fix its mistakes, which is similar to “its reexamination ancestors” preceding IPRs “to which everyone agrees sovereign immunity does not apply.”⁶³

Conclusion

Mylan Pharmaceuticals Inc.’s CEO Heather Bresch said “[t]his win is a victory in our ongoing efforts to stop patent abuses by brand companies and to help drive access to more affordable medicine.”⁶⁴ But if brand companies like Allergan cannot protect their patents, what incentive will there be for them to continue to be innovative and spend hundreds of millions of dollars on clinical trials on which the Generic Manufacturers can rely? Was this really a win for the Generic Manufacturers?

⁵⁹ *Id.* at 1326.

⁶⁰ *Id.* (citing *Cuozzzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2143–44 (2016)).

⁶¹ *Id.* at 1329.

⁶² *Id.* (citing *Cuozzzo*, 136 S. Ct. at 2144).

⁶³ *Id.* at 1335 (Dyk, J., concurring).

⁶⁴ *Mylan Again Defeats Allergan’s Efforts to Deny Patients Access to More Affordable Medicine*, PR NEWSWIRE, (Jul. 20, 2018), <https://www.prnewswire.com/news-releases/mylan-again-defeats-allergans-efforts-to-deny-patients-access-to-more-affordable-medicine-300684412.html>.