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DePaul Journal of Art, Technology & Intellectual Property Law

Volume 34
Issue 1 *Spring 2024*

Article 2

Innovation at a Crossroads: The Supreme Court's Influence on Pharmaceuticals, Trade Policies, and Public Health

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INNOVATION AT A CROSSROADS: THE SUPREME COURT'S INFLUENCE ON PHARMACEUTICALS, TRADE POLICIES, AND PUBLIC HEALTH

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I. INTRODUCTION

The intricate interplay between pharmaceutical patents, generic drugs, and the overarching healthcare landscape in the United States has long captured the attention of legal scholars, policymakers, and the public. At the heart of this multifaceted discourse lies the profound influence of the Supreme Court of the United States. This essay embarks on a comprehensive exploration of the historical aspect of the Supreme Court's engagement with pharmaceutical drugs and patents, delving into its far-reaching impact on healthcare within the nation's borders and across international boundaries.

Part I serves as the introduction and provides a roadmap for this essay.

Part II delves into the Supreme Court's approach to pharmaceutical patent cases, with a primary focus on the pivotal *FTC v. Actavis* decision. This landmark case serves as a quintessential example of how the Supreme Court assesses and adjudicates pharmaceutical patent cases, shedding light on its shifting perspective regarding patents, their impact on drug accessibility and innovation, and the enduring implications of its decisions.

Part III discusses the profound impact of the Supreme Court's decisions on the national healthcare landscape. Through a careful examination of *Actavis*, this essay will explore how the Court's decision has influenced healthcare policies, pricing

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structures, and the availability of life-saving medications. This section illuminates the far-reaching implications of the Court's decisions on the daily lives of Americans and the broader healthcare ecosystem.

Part IV explores the ongoing legal battle of *Moderna v. Pfizer*, where intellectual property rights surrounding COVID-19 vaccines are being fiercely contested. This case holds immense public health implications, and its outcome could significantly impact the accessibility, innovation, and ethical dimensions of vaccine distribution.

Part V investigates the intricate interplay between intellectual property rights, trade policies, and global public health. Examining the role of United States trade policies, particularly the Special 301 Report, and their historical challenges to public health priorities; this essay reflects on the lessons learned from past pandemics and how they highlight the need for more flexible approaches that prioritize global well-being over trade interests.

Part VI of this essay analyzes the IP waiver, which was targeted towards TRIPS Agreement sections to enable global access to essential pandemic-related products. While supported by nations like the United States and the European Union, the IP waiver was ultimately denied.

Part VII focuses on a proposal that offers an alternative to the IP waiver—the deferral program.

Part VIII concludes that it is imperative that the United States endorse the deferral program mentioned in part VII and actively contribute to ensuring that other countries gain access to essential medications and resources. By doing so, the United States can play a pivotal role in promoting global health equity and addressing the urgent needs of vulnerable populations.

This essay navigates through the complex and intertwined dimensions of intellectual property, trade policies, and public health, illuminating the crucial need to find a harmonious balance that safeguards innovation while ensuring universal access to life-saving medications, particularly in extraordinary circumstances like a global pandemic. The ultimate question is whether the safeguards surrounding intellectual property can adapt to these extraordinary times and transition into a collaborative force that bolsters public health rather than impedes it.

II. *FTC V. ACTAVIS, INC.*, 570 U.S. 136 (2013)

FTC v. Actavis revolves[1] around the contentious issue of reverse payment settlements within the pharmaceutical industry. These settlements arise when a brand-name drug manufacturer, who holds a patent, offers financial incentives to generic drug manufacturers, effectively paying them to delay the introduction of their generic drugs into the market.[2] The primary concern is whether these reverse payment agreements violate antitrust laws by hindering competition in the marketplace.[3] In this case, the Federal Trade Commission (FTC) challenged a specific reverse payment settlement between the brand-name drug manufacturer Solvay Pharmaceuticals and several generic drug manufacturers, including Watson Pharmaceuticals (now known as Actavis, Inc.).[4] Solvay held a patent for a testosterone-replacement drug called AndroGel, set to expire in 2020.[5] In 2003, Actavis filed an abbreviated new drug application (ANDA) to produce a generic version of AndroGel, asserting that Solvay's patent was either invalid or not infringed.[6] This act by Actavis triggered a patent infringement lawsuit by Solvay.[7] In 2006, the companies settled their dispute.[8] The settlement terms required Actavis to delay the launch of its generic AndroGel until 2015.[9] In exchange, Solvay agreed to pay Actavis an annual sum of a millions of dollars.[10] The FTC viewed this settlement with skepticism, asserting that the reverse payment was merely a tactic to maintain the drug's high prices and hinder competition.[11]

[1] 570 U.S. 136, 141 (2013).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id*. at 144.
[6] *Id.* at 144.
[7] *Actavis*, 570 U.S at 145.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*

The FTC initiated a complaint against the pharmaceutical companies, alleging that the settlement they reached was problematic.[12] The FTC contended that respondents violated §5 of the Federal Trade Commission Act, 15 U.S.C. §45, by agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years."[13] The FTC believed that these business promotion agreements were essentially payments to prevent Watson, Par, and Paddock from selling generic AndroGel before August 31, 2015.[14] This was viewed as an antitrust violation because, without these payments, Solvay would likely have lost its infringement actions or settled for an earlier release date for generic AndroGel.[15] The FTC contended that in either scenario, Watson, Par, and Paddock would have introduced generic AndroGel to the market before August 31, 2015, significantly reducing its price due to increased competition.[16] Contrarily, the manufacturers moved to dismiss these claims for failure to state a claim for where relief could be granted.[17] The district court agreed with the manufacturers and dismissed the case, the FTC then appealed.[18]

The Eleventh Circuit affirmed, holding that reverse payment agreements should typically receive antitrust immunity.[19] This stance was rooted in a broader legal policy that favors dispute resolution through settlements.[20] The Eleventh Circuit believed that such agreements encourage settlements and circumvent the need for protracted and expensive patent litigation, aligning with the general principle favoring the resolution of disputes through amicable means.[21] The FTC then appealed and the Supreme Court granted cert.[22]

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[12] *Id.*
[13] *Actavis*, 570 U.S at 145.
[14] In re AndroGel Antitrust Litig., 687 F. Supp. 2d 1371, 1376 (N.D. Ga. 2010).
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Actavis*, 570 U.S at 146.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*

The Supreme Court took a different stance, expressing concern over the genuinely adverse effects reverse payment settlements can have on competition.[23] These settlements, according to the Court, allow patent holders to sustain high prices for their products.[24] The Court reasoned that this does not serve the best interests of consumers.[25] While settlements allowing generic challengers to enter the market encourages competition, payments designed to delay their entry are viewed as counter to consumers' interests.[26] The Court noted that a substantial, unexplained reverse payment, is an indicator that the patent holder has doubts about the patent's validity and aims to maintain high prices.[27] In essence, the size of the reverse payment can serve as a practical proxy for assessing the patent's strength.[28] The Court declined to presume that reverse payment settlements are inherently unlawful.[29] Instead, it advocated for evaluating each case individually using the "rule-of-reason" approach.[30] The "rule of reason" approach is intended to determine whether, on balance, a practice is reasonably likely to be anticompetitive or competitively harmless.[31] In this manner, the Court aimed to strike a balance between encouraging settlements and safeguarding competition, especially in the pharmaceutical sector.[32] The Supreme Court reversed and remanded the case for further proceedings consistent with its opinion.[33]

The Supreme Court's decision in this case marked a significant departure from the Eleventh Circuit's stance, which offered near-automatic antitrust immunity to reverse payment settlements. Instead, the Court established that such agreements should be subject to scrutiny via the "rule-of-reason" approach, with each case evaluated on its merits. The Court emphasized the

[23] *Id.* at 154.
[24] *Actavis*, 570 U.S. at 154.
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.* at 158.
[29] *Id.* at 158-159.
[30] *Actavis*, 570 U.S. at 159.
[31] *Id.* at 174.
[32] *Id.*
[33] *Id.* at 160.

importance of ensuring the FTC's opportunity to prove its antitrust claim, allowing for a more detailed assessment of their legality.

III. *ACTAVIS* AND ITS IMPACT ON THE NATIONAL HEALTHCARE LANDSCAPE

The impact of the Supreme Court's decision in *Actavis* has been substantial, particularly in the realm of reverse-payment cases involving pharmaceutical patent settlements.[34] This landmark case has led to the resurgence of antitrust litigation with over 30 separate cases filed or revived since the *Actavis* ruling.[35] This part will examine the impact in terms of reverse-payment case law, pharmaceutical pricing litigation, the subsequent developments on product-hopping cases, and pharmaceutical manufacturer pricing practices.

A. Reverse-Payment Case Law under Actavis

The *Actavis* decision marked a pivotal shift in the legal landscape for reverse-payment claims.[36] Prior to *Actavis*, there was a circuit split on what test to apply to determine whether a settlement agreement violated antitrust law.[37] The Federal, Second, and Eleventh Circuits applied the "scope of the patent" approach.[38] According to this perspective, such agreements were not considered anticompetitive if the settlement's effects aligned with the exclusionary potential outlined in the patent.[39] These Circuits maintained that the legality of the settlement hinged on the agreement staying within the patent's scope, free from sham

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[34] Adam Acosta et al., *FTC v Actavis and pricing practices spearhead rise in US pharmaceutical antitrust cases*, White & Case LLP (Aug. 25, 2023), https://globalcompetitionreview.com/review/the-antitrust-review-of-the-americas/2024/article/ftc-v-actavis-and-pricing-practices-spearhead-rise-in-us-pharmaceutical-antitrust-cases.

[35] *Id.*

[36] *Id.*

[37] Loeb & Loeb LLP, *U.S. Supreme Court Argument on "Reverse Payments" Suggests Potential for Compromise Holding Not Advocated by FTC or Pharmaceuticals Industry* (Apr. 2013), https://www.loeb.com/en/insights/publications/2013/04/us-supreme-court-argument-on-reverse-payments-su__.

[38] *Id.*

[39] *Id.*

litigation or fraudulent patent acquisition.[40] In contrast, the Third and Sixth Circuits employed the "quick look rule of reason" test.[41] This test introduced a rebuttable presumption that reverse payment agreements constituted an unreasonable restraint of trade.[42] The Third Circuit clarified that this presumption could be challenged by demonstrating either an alternative purpose for the payment or a competitive advantage associated with the payment.[43] In its place, the *Actavis* decision introduced a middle-ground approach, requiring the FTC to prove the anticompetitive nature of the payments similar to other "rule-of-reason" cases.[44] This ruling was of paramount significance as it allowed innovators to offer financial settlement considerations to generic companies, extending beyond early entry.[45]

Following *Actavis*, courts grappled with the question of how plaintiffs should plead their cases.[46] Some courts concluded that reverse payments could encompass non-cash transfers of value, such as no-authorized generic (no-AG) agreements, co-promotion deals, licensing, and more.[47] This interpretation stressed that plaintiffs needed to provide sufficient information to estimate the value of these non-cash transfers.[48] Courts notably became stricter in dismissing cases that relied on mere labels and conclusions without a robust factual basis.[49]

The *Actavis* decision introduced questions regarding the application of its principles at the summary judgment stage.[50] Numerous cases centered on whether business agreements executed alongside patent settlements were "large and unjustified."[51] Courts examined various aspects, including the fairness of compensation, the necessity of services, unusual terms

[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] Loeb & Loeb, *supra* note 37.
[44] Acosta, *supra* note 34.
[45] *See id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *See id.*
[50] Acosta, *supra* note 34.
[51] *Id.*

in agreements, and the link between the agreements and patent settlements.[52] Recent summary judgment decisions have varied; some decisions allowed reverse-payment claims to proceed to trial when there were disputed factual issues, particularly concerning whether the settlement caused a delay in generic entry.[53] Others concentrated on causation, denying summary judgment when plaintiffs presented sufficient evidence to support that the settlement in question directly caused harm to competition.[54] *Actavis* cleared the way for several reverse-payment cases to proceed to full trials.[55] The first post-*Actavis* trial was *In re Nexium*, which resulted in a jury finding for the defendants, emphasizing that the reverse payment did not cause a delay in generic entry.[56]

B. Actavis' Impact on Pharmaceutical Pricing Litigation and Exclusionary Conduct

The Supreme Court's decision in *Actavis* not only had a profound impact on reverse-payment cases but also resonated across the broader landscape of antitrust litigation in the pharmaceutical industry.[57] This part explores the effects of *Actavis* on pharmaceutical pricing litigation and challenges to potentially exclusionary conduct in the industry.

1. Pharmaceutical Pricing Litigation

Pharmaceutical pricing litigation has remained a dynamic and contentious area of antitrust law, featuring a spectrum of cases addressing various practices, including rebate arrangements and their impact on competition.[58] Notably, these cases have often examined whether manufacturers employed these strategies to unlawfully exclude competing drugs from payer coverage.[59]

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[52] *Id.*
[53] *See id.*
[54] *See id.*
[55] *Id.*
[56] Acosta, *supra* note 34.
[57] *Id.*
[58] *Id.*
[59] *Id.*

A key development post-*Actavis* is the legal treatment of exclusionary formulary contracting schemes.[60] In a significant case decided in July 2022, the United States Court of Appeals for the Tenth Circuit upheld the summary judgment dismissal of antitrust claims that revolved around a manufacturer's alleged use of conditional rebate contracts for EpiPen.[61] The plaintiff claimed these contracts were employed to block its competing Auvi-Q product from formulary coverage.[62] The Tenth Circuit ruled against the plaintiff, finding that these rebate agreements did not substantially foreclose Auvi-Q from the market.[63] The Tenth Circuit deemed the defendant's conduct as normal competition, emphasizing that such rebate agreements were short and easily terminable, and the defendant's exclusivity offers encouraged price competition.[64] This decision underscored that plaintiffs had to demonstrate substantial foreclosure and coercion to establish an antitrust violation.[65]

Additionally, several other cases have brought contracting practices in the pharmaceutical industry into antitrust scrutiny.[66] In one instance, consumers challenged a manufacturer's list pricing and rebating practices in April 2023.[67] The consumers contended that the manufacturer artificially inflated the list price to pay out higher rebates to pharmacy benefit managers (PBMs) in exchange for preferred formulary positions.[68] These practices were alleged to violate state consumer-protection laws on the grounds of being unfair and unconscionable.[69]

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[60] *Id.*
[61] *Id.* (citing In re EpiPen Epinephrine Injection, Mkt Sales Pracs & Antitrust Litig, No. 21-3005, 2022 US App Lexis 20998 (10th Cir. 29 July 2022)).
[62] *In re EpiPen Epinephrine Injection*, No. 21-3005, 2022 US App Lexis 20998 at 61.
[63] *Id.* at 70.
[64] *Id.*
[65] *See* Acosta, *supra* note 34.
[66] *Id.*
[67] *Id.* (citing Class Action Compl, Camargo v. Abbvie, Inc, No. 23-cv-02589 (ND Ill 25 April 2023)).
[68] *Id.*
[69] *Id.*

Furthermore, the role of PBMs in formulary management has also been a focal point.[70] In another suit, the Attorney General of Ohio brought legal action against some of the largest PBMs in the United States, alleging that they colluded to fix drug prices and engaged in a "pay to play" rebate scheme that coerced manufacturers to increase drug prices.[71] The suit further claimed that PBMs exploited market power through industry consolidation to extract both monopoly profits and monopsony profits.[72] Additionally, the suit alleged that PBMs used their market dominance to engage in "spread pricing" practices, which adversely affected pharmacies.[73]

In the aftermath of *Actavis*, the pharmaceutical industry has witnessed an increased focus on pharmaceutical pricing litigation and challenges to exclusionary conduct. The *Actavis* decision has had a profound influence on how these cases are argued and adjudicated. Moreover, novel legal theories and creative applications of statutes have and continue to emerge, further complicating the legal landscape in pharmaceutical antitrust litigation. This legal environment, marked by evolving jurisprudence and novel legal strategies, continues to shape the pharmaceutical industry's competitive landscape.

C. Actavis' Impact on Pharmaceutical Manufacturer Pricing Practices and the Broader Pharmaceutical Industry

1. Federal Inflation Reduction Act

One of the significant legislative changes following *Actavis* was the passage of the Inflation Reduction Act (IRA).[74] This legislation, pushed by the Biden administration, introduces several drug pricing components, including enabling the Department of Health and Human Services (HHS) to negotiate drug prices under Medicare, imposing mandatory rebates on certain Medicare drugs

[70] *Id.*
[71] Acosta, *supra* note 34 (citing Compl for Disgorgement, Injunctive Relief, and Declaratory Judgment, Ohio v Ascent Health Servs LLC, No. 23 CV H 03 0179 (Ohio Ct Common Pleas 27 March 2023).
[72] *Id.*
[73] *Id.*
[74] *Id.*

with price increases greater than the rate of inflation, and capping annual out-of-pocket costs for prescription drugs under Medicare.[75] These changes aim to address concerns about rising drug prices and improve access to affordable medication.[76] However, they have also raised concerns in the pharmaceutical industry about potential impacts on innovation, particularly for small-molecule drugs.[77] Small-molecule drugs are compounds that fall within the molecular weight range of 0.1 to 1.0 kDA and are derived from natural sources such as bacteria, fungi, and plants.[78] Small-molecule drugs use biochemical processes to address and prevent various diseases.[79] Small-molecule drugs make up 90% of the pharmaceutical drug market and include over-the-counter medications like aspirin.[80] The law has led to legal challenges from industry stakeholders, primarily based on concerns about the negotiation process and its consequences for the industry's competitive landscape.[81]

For example, Merck & Co., is the first pharmaceutical company to sue the United States government in federal court over the IRA.[82] In its submission, Merck contends that the Medicare negotiation program is not a genuine negotiation process but is, in fact, akin to extortion.[83] Merck asserts that this program infringes upon its constitutional rights, specifically alleging a violation of the Fifth Amendment by constituting an unconstitutional taking

[75] *Id.*
[76] *Id.*
[77] Acosta, *supra* note 34.
[78] Veronica Salib, *Comparing Small Molecule and Biologics Drug Development Challenges*, (May 9, 2023), https://pharmanewsintel.com/news/key-differences-in-small-molecule-biologics-drug-development#:~:text=For%20example%2C%20many%20common%20over,classified%20as%20small%2Dmolecule%20drugs.
[79] *Id.*
[80] *Id.*
[81] Acosta, *supra* note 34.
[82] *Id.* (citing Merck & Co., Inc. v. Becerra et al. (D.D.C. 2023) (No. 1:23-cv-01615)).
[83] Brianne M. Kingery et al., *Merck Sues Federal Government Over Medicare Drug Price Negotiation Program*, (Jun. 7, 2023, 12:00 AM), https://www.knobbe.com/blog/merck-sues-federal-government-over-medicare-drug-price-negotiation-program.

without just compensation.[84] Merck argues that the penalties associated with non-compliance with the Medicare negotiation program would coerce drug manufacturers into selling their patented products at government-determined prices.[85] Merck foresees substantial financial penalties, ranging from tens of millions to hundreds of millions of dollars per day, for refusing to negotiate the price of its diabetes drug, Januvia, under the proposed program.[86]

Merck also contends that the Medicare negotiation program infringes upon its First Amendment right to free speech by compelling the company to enter into pricing agreements.[87] According to Merck, the program forces drug manufacturers to communicate their agreement with the determined price and convey that the price is fair.[88] Additionally, Merck and other pharmaceutical companies, argue that the proposed Medicare pricing scheme could lead to a reduction in drug development research programs due to anticipated revenue losses resulting from reduced drug prices.[89] Merck's highly successful drug, Keytruda, a cancer immunotherapy, is expected to be subject to Medicare drug pricing negotiations in the future, potentially facing reduced pricing starting in 2028.[90] Given that Keytruda constitutes a significant portion of Merck's sales, with over $20 billion in revenue last year and an expected increase to $30 billion in sales by 2026, the impact on the company's financial landscape could be substantial.[91]

2. Other Federal Legislation and Regulation

Apart from the IRA, other legislative proposals have been introduced at the federal level to address antitrust and patent enforcement related to pharmaceuticals.[92] One notable set of bills,

[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Id.*
[89] Kingery, *supra* note 83.
[90] *Id.*
[91] *Id.*
[92] Acosta, *supra* note 33.

resembling previous legislative attempts, emerged in the Senate in 2023.[93] These bills, having passed through the Senate Judiciary Committee earlier in the year and advancing to the Senate floor for voting, propose several key changes in antitrust and patent enforcement.[94] These bills aim to prevent anti-competitive practices such as reverse-payment patent settlements, product-hopping, and sham petitioning.[95] The bills also include provisions to create inter-agency task forces to encourage information-sharing between agencies, promoting more robust enforcement of pharmaceutical industry regulations.[96]

3. State Legislation

States continue to be active in regulating drug pricing.[97] In 2022, states deliberated over 290 bills aimed at curbing drug prices, resulting in the enactment of more than 30 of these measures.[98] The first half of 2023 saw the introduction of over 300 state drug-related laws, with some extending beyond mere reporting requirements to implement various forms of price control.[99]

For instance, in May 2023, Minnesota approved the bill: Commerce and Consumer Protection Omnibus Bill, Senate File 2744 (SF 2744).[100] SF 2744, effective as of May 24, 2024, aims to curb the rising drug costs, with a particular focus on the activities of generic drug manufacturers.[101] One of the aspects of SF 2744 is its prohibition on "excessive price increases" imposed by drug manufacturers, including generic drug manufacturers, on the sale of generic or off-patent drugs in the state.[102] An increase is deemed

[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] Acosta, *supra* note 33.
[99] *Id.*
[100] Sophia R. Gaulkin et. Al., *Price Limits, Affordability Boards, Penalties, Oh My: Minnesota Enacts Sweeping Drug Pricing Reforms*, (Jun. 16, 2023), https://www.thefdalawblog.com/2023/06/price-limits-affordability-boards-penalties-oh-my-minnesota-enacts-sweeping-drug-pricing-reforms/.
[101] *Id.*
[102] *Id.*

excessive if it surpasses $30 for a 30-day supply, adjusted for inflation, and exceeds either 15% of the wholesale acquisition cost (WAC) over the previous calendar year or 40% of the WAC over the preceding 3 years.[103] Manufacturers may face compelled restitution to consumers, civil fines up to $10,000 per day, and potential legal actions.[104] The thresholds for violating the excessive price increase prohibition are set below those triggering generic drug price increase reporting requirements to the state, creating additional challenges for manufacturers.[105]

SF 2744 also establishes a Prescription Drug Affordability Board, accompanied by an 18-member stakeholder advisory council, both tasked with addressing drug cost issues.[106] The Board is mandated to identify specific prescription drug products based on criteria such as price increases, WAC thresholds, and potential affordability challenges.[107] Identified drugs, along with related price information, will be made publicly available, except for proprietary or trade-secret information.[108] The Board may initiate a cost review of identified drugs to assess their impact on the state's healthcare system or patients.[109] If an affordability challenge is determined, the Board can establish an upper payment limit for the drug, affecting all purchases and payer reimbursements in the state.[110] Before the passing of this law, there was opposition from various groups, including pharmaceutical trade organizations, clinical oncology societies, and taxpayer advocacy groups.[111] The law may face constitutional challenges, such as Commerce Clause and vagueness issues, akin to those encountered by a similar law, HB 631, in Maryland back in 2018.[112]

Actavis has left an indelible mark on pharmaceutical pricing practices in the United States, with far-reaching

[103] *Id.*
[104] *Id.*
[105] *Id.*
[106] Gaulkin, *supra* note 100.
[107] *Id.*
[108] *Id.*
[109] *Id.*
[110] *Id.*
[111] *Id.*
[112] Gaulkin, *supra* note 100.

implications for the industry. This case has sparked various changes in the pharmaceutical sector, leading to increased scrutiny. These shifts are manifesting through legislative, regulatory, and legal actions. The reverberations of *Actavis* are evolving swiftly, necessitating vigilant observation by stakeholders in the pharmaceutical arena. As previously demonstrated, *Actavis* serves as a testament to how a court's ruling on a patent case can have a significant impact, reshaping the landscape of pharmaceutical patent disputes and their implications for competition and consumer interests.

Drawing from this precedent, this essay will now explore a pending United States case, *Moderna v. Pfizer*, which further highlights the enduring significance of judicial decisions in the pharmaceutical realm. The *Moderna v. Pfizer* case amplifies the importance of understanding the intricate dynamics of patent law, competition, and consumer interests in the pharmaceutical sector. Consequently, it serves as a catalyst for shaping the trajectory of the industry's practices and policies, accentuating the broader ramifications of court decisions in this critical domain.

IV. ***MODERNATX, INC. V. PFIZER INC.*, 1:22-cv-11378, (D. MASS.)**

The *Moderna v. Pfizer* case surrounding the COVID-19 vaccine is a complex legal battle that raises significant concerns for the public in the United States and around the world. Moderna's complaint alleges that Pfizer and BioNTech infringed on its mRNA technology patents, focusing on key patents related to lipid nanoparticles and mRNA encoding for coronavirus spike proteins.[113] This legal dispute has far-reaching implications for public health and innovation.

First and foremost, the outcome of this case could affect the availability and accessibility of COVID-19 vaccines.[114] Moderna's mRNA technology played a crucial role in the rapid development of its COVID-19 vaccine, and it has the potential to

[113] *ModernaTX, Inc. v. Pfizer Inc.*, 1:22-cv-11378, (D. Mass.)
[114] Francis Brefo, *POOLING PATENTS FOR PANDEMIC PROGRESS: MRNA VACCINES AND THE BROADER CONTEXT OF MODERNATX INC V. PFIZER INC.*, 33 DePaul J. Art, Tech. & Intell. Prop. L. 21, 52 (2023).

influence the next generation of vaccines as well.[115] If Moderna succeeds in its claims against Pfizer and BioNTech, it could result in substantial monetary damages.[116] However, more importantly, it could stifle innovation by limiting the availability of this crucial technology to other vaccine developers.[117] This may lead to a lack of competition in the market, which could result in higher prices and reduced access to vaccines for the public.[118]

Moderna's patent pledge in October 2020, which promised not to enforce its COVID-19-related patents during the pandemic, was perceived as prioritizing public health over profits.[119] However, their subsequent decision to retract this pledge and seek royalties from Pfizer and BioNTech, except for sales to the United States government and low- and middle-income countries, has raised ethical concerns.[120] The public perception is that Moderna may be putting its financial interests ahead of public health.[121] This can damage the trust that people have in pharmaceutical companies, particularly during a global health crisis.[122]

The case also highlights the legal complexities of patent pledges and their enforceability.[123] Moderna's decision to revoke its pledge, even after relying on it for a considerable period, raises questions about the legal obligations associated with such promises.[124] The reliance of market actors on patent pledges for investment and innovation can be substantial.[125] If Moderna is allowed to backtrack on its commitment, it may encourage other companies to falsely make similar pledges in the future, assuring that they will not be held accountable later.[126]

As of the composition of this essay, Moderna has filed response briefs on December 7th and 8th, 2023, in response to

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[115] *Id.* at 23.
[116] *Id.* at 32.
[117] *Id.*
[118] *Id.*
[119] *Id.* at 33.
[120] Brefo, *supra* note 114, at 33.
[121] *Id.* at 37.
[122] *Id.*
[123] *Id.* at 34.
[124] *Id.* at 35.
[125] *Id.*
[126] Brefo, *supra* note 114, at 35.

inter partes review (IPR) petitions by Pfizer and BioNTech.[127] Moderna has invoked the *Fintiv* precedent, arguing that the Patent Trial and Appeal Board (PTAB) should deny the petitions.[128] Moderna contends that the IPR petitions raise the same invalidity arguments already presented in the ongoing patent infringement suit against Pfizer and BioNTech in Massachusetts.[129] Citing the *Fintiv* standard, which allows the PTAB to decline reviews when parallel infringement litigation is well-advanced, Moderna asserts that the board should reject the petitions due to overlapping issues and the risk of double-dipping.[130] Moderna further argues that the district court trial is anticipated to conclude around October 2024, ahead of the PTAB's final decisions in March 2025, rendering the IPR unnecessary.[131] Moderna asserts that Pfizer's failure to forgo identical invalidity challenges in the district court supports denying the petitions under the *Fintiv* precedent.[132] The PTAB is expected to decide on the institution of reviews for Moderna's patents by March 2024.[133]

Overall, *Pfizer* demonstrates the potential negative consequences of legal battles over pharmaceutical patents during a public health crisis. It raises concerns about innovation, access to vaccines, and the ethical behavior of pharmaceutical companies, with the court's decisions in this case set to have a profound impact on how the pharmaceutical industry approaches patent disputes and pledges. These implications are not limited to the United States but carry significant weight for public health worldwide.

V. BALANCING TRADE POLICIES AND PUBLIC HEALTH: A HISTORICAL PERSPECTIVE

[127] Ryan Davis, *Moderna Says Pfizer COVID Vax Patent Challenges Fail Fintiv*, LAW360, (Dec. 11, 2023, 7:23 PM), https://www.law360.com/lifesciences/articles/1775945/moderna-says-pfizer-covid-vax-patent-challenges-fail-fintiv.
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *Id.*
[132] *Id.*
[133] Davis, *supra* note 127.

Part V delves into the intricate relationship between intellectual property rights, trade policies, and public health, a complex and often contentious interplay. In the context of the United States, these issues are outlined in the Trade Act of 1974, Section 301, and further exemplified by the annual Special 301 Report.[134] This part examines how United States trade policies, including the Special 301 Report, have historically posed challenges to public health priorities, particularly in terms of access to essential medications. The consequences of these actions are far-reaching, affecting not only domestic but also global contexts.

Moreover, it is evident from historical and recent events, notably the COVID-19 pandemic, that the current safeguards in place are insufficient. The pandemic starkly highlighted the deficiencies in the existing framework, underscoring how public health concerns can be compromised. The past has seen instances where trade policies and intellectual property rights have impeded access to life-saving medicines. The lessons from history and the glaring challenges posed by the COVID-19 pandemic shed light on the need for more comprehensive and flexible approaches that prioritize global public health over trade interests.

A. United States Trade Policies and the Special 301 Report

The Trade Act of 1974, specifically Section 301, grants the United States Trade Representative (USTR) unilateral authority to identify and pursue countries that are believed to inadequately protect intellectual property rights or provide equitable market access to United States industries reliant on intellectual property protection.[135] The USTR releases the Special 301 Report annually, pinpointing countries with deficient intellectual property policies, with a particular focus on pharmaceutical patent protection.[136] Once identified, the USTR employs direct and indirect pressures, such as trade negotiations and preference systems, to promote policy changes that benefit United States intellectual property

[134] Michael Palmedo et al., *The U.S. Posture on Global Access to Medication & The Case for Change*, 11 Indian J. Intell. Prop. L. 76, 88 (2020).
[135] *Id.* at 80.
[136] *Id.*

holders within these countries.[137] These changes often involve amendments to laws, regulatory exclusivities, or directives on the implementation of specific regulations, typically aligning with the USTR's expectations but not always considering local contexts.[138]

B. TRIPS Flexibilities and the United States Approach

To understand the impact of United States trade policies, it is essential to recognize the significance of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities during public health crises. These flexibilities allow countries to prevent intellectual property from becoming a barrier to public health by prioritizing access to healthcare and other public interests over intellectual property rights.[139] Article 31 of the TRIPS Agreement, for instance, permits governments to issue compulsory licenses, enabling generic companies to produce patented products under certain conditions, typically involving royalty payments to patent holders.[140] Other flexibilities include price controls for pharmaceuticals and the importation of generic drugs from other countries.[141]

C. Unilateral Actions and Global Public Health

The United States' unilateral actions, driven by trade policies and the Special 301 Report, have consistently posed challenges to global public health.[142] It is notable that the United States has historically opposed the fair use of TRIPS-based flexibilities during outbreaks of infectious diseases like HIV, AIDS, and SARS.[143] These flexibilities are essential to ensure that intellectual property does not hinder access to life-saving medications.[144] However, the United States has often disregarded multilateral systems and resorted to the powers granted by the Trade Act to pursue its interests, to the detriment of global public health.[145]

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[137] *Id.*at 81.
[138] *Id.*
[139] *Id.*
[140] Palmedo, *supra* note 134, at 78.
[141] *Id.*
[142] *Id.* at 80.
[143] *Id.*
[144] *Id.* at 78.
[145] *Id.* at 80.

One example of the historical stance of the United States involves the Orphan Drug Act of 1983, which aims to encourage research for diseases that affect a small number of patients, 200,000 or less.[146] The act provides special status to drugs treating such "orphan diseases," granting them market exclusivity.[147] However, significant concerns were raised when the United States Food and Drug Administration (FDA) granted Gilead's drug, Remdesivir, orphan drug status for COVID-19 treatment.[148] This designation provides an additional seven years of market exclusivity, primarily intended for drugs treating rare conditions with limited market incentives for innovation and research.[149] In this case, it appeared that the FDA's actions were disconnected from the reality of the COVID-19 pandemic, which was affecting a vast number of patients.[150] At the time Remdesivir was designated as an orphan drug, the United States was recording 3,000 new COVID-19 cases daily.[151]

The intersection of trade policies, intellectual property rights, and global public health is a complex issue with profound implications. The United States' approach, as illustrated by the Special 301 Report and unilateral actions, has historically challenged access to essential medications worldwide. The disregard for TRIPS-based flexibilities, exemplified by the handling of the COVID-19 pandemic, raises questions about the prioritization of public health in the face of trade interests. Balancing intellectual property protection and access to medicines remains a significant challenge, and global cooperation is crucial to ensure that public health prevails over commercial interests.

VI. UNLOCKING GLOBAL ACCESS: INTELLECTUAL PROPERTY WAIVER DEBATE AMID THE COVID-19 CRISIS

Amid the global COVID-19 crisis, the urgency to address access to essential pandemic-related products, particularly in

[146] Palmedo, *supra* note 134, at 78-79.
[147] *Id.*
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*

resource-constrained nations, underscored the need for a more flexible approach to intellectual property rights. This need led to the proposal of the Intellectual Property waiver (IP waiver), which specifically targeted sections of the TRIPS Agreement. The proposed IP waiver, specifically focused on sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement, which aimed to eliminate barriers and facilitate global-scale production of essential vaccines, therapeutics, and diagnostics.[152] Despite receiving initial support from the United States and the European Union, the proposal for a waiver was ultimately rejected due to debates over its specifics and potential consequences.[153]

Although the IP waiver was ultimately denied, it still brought to the forefront the need for a paradigm shift in the global approach to intellectual property in the pharmaceutical sector. This part will explore the IP waiver, the benefits it offered, and the opposition it faced that ultimately led to its denial.

A. Legal Basis for the Waiver

The legal foundation for the IP waiver resided in Article IX(3) of the TRIPS Agreement,[154] which grants Member Countries the ability to seek a waiver from specific World Trade Organization (WTO) agreement provisions.[155] However, securing a waiver would have required a consensus decision, with a minimum of a 3/4 majority approving the request.[156] Decisions granting a waiver would have had to cite exceptional circumstances, outline the terms and conditions of the waiver, while also including the date of termination.[157] This waiver mechanism was not without precedent and has been utilized in the past, such as with the Doha Declaration for public health.[158]

The adoption of the Doha Declaration in 2001 marked a milestone achievement for developing nations, acknowledging the profound impact of public health challenges faced by many of

[152] Srividhya Ragavan, *Waive IP Rights & Save Lives*, 231 SouthViews, 1, 10 (Nov. 2021), https://scholarship.law.tamu.edu/facscholar/1784/.
[153] *Id.* at 2.
[154] *Id*.
[155] *Id.*
[156] *Id.*
[157] *Id.*
[158] Ragavan, *supra* note 152, at 3.

them.[159] Under the TRIPS Agreement, WTO members possess the authority to issue compulsory licenses in accordance with their domestic legislation, granting third parties the ability to utilize intellectual property rights without the consent of the right holders.[160] The Doha Declaration not only affirmed this right but also provided clarity on its scope.[161] Before the Doha Declaration, TRIPS regulations stipulated that the authorized use of patented technology should primarily be directed towards the domestic market unless addressing anti-competitive practices.[162] However, the Doha Declaration acknowledged that this constraint could hinder the effective implementation of compulsory licensing, particularly for countries lacking pharmaceutical manufacturing capabilities.[163] To address this limitation, in 2005, WTO members collectively decided to legally amend the TRIPS Agreement.[164] This amendment introduced a new and distinctive form of compulsory license specifically designed for the export of medicines to countries facing critical needs.[165]

The impact of the Doha Declaration extends beyond its initial adoption. International and non-governmental organizations have extensively utilized the Doha Declaration in their analyses and advocacy efforts pertaining to access to medicines, leveraging its principles to underscore the importance of addressing barriers to treatment.[166] Moreover, the declaration has served as a foundational reference for policy actions undertaken at both

[159] Carlos Correa et al., *The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Health* 8, 31 (Dec. 20, 2011), https://www.undp.org/sites/g/files/zskgke326/files/publications/Discussion_Paper_Doha_Declaration_Public_Health.pdf.
[160] World Trade Organization, *TRIPS and public health*, https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm#:~:text=Adoption%20of%20the%20Doha%20Declaration,about%20its%20effect%20on%20prices (last visited Mar. 2, 2024).
[161] *Id.*
[162] *Id.*
[163] *Id.*
[164] *Id.*
[165] *Id.*
[166] Correa, *supra* note 159, at 18.

national and regional levels, particularly in the realm of formulating strategies to enhance access to medicines.[167]

B. Waiver vs. Compulsory Licenses

A critical advantage of the IP waiver proposal was its efficiency when compared to compulsory licensing, the alternative approach under existing TRIPS provisions.[168] Compulsory licensing empowers a government to authorize domestic companies to manufacture more affordable alternatives to patented drugs owned by foreign pharmaceutical companies.[169] These local companies can then produce and distribute these drugs within the country, paying a fair royalty on their sales to the foreign drug companies.[170] This practice enhances market competition, leading to substantial reductions in drug prices.[171] Additionally, parallel importing enables countries to import inexpensive generic versions of drugs without seeking approval from the original patent holders.[172]

Compulsory licenses often face resistance from influential nations and can be perceived as a violation of intellectual property rights, making them less effective in practice.[173] While certain nations are constrained by limitations in bilateral relationships, as seen in free-trade agreements containing provisions that restrict the application of compulsory licenses, it is crucial to note that numerous countries, despite lacking legal constraints, refrain from utilizing compulsory licensing.[174] This hesitation often stems from concerns about potential trade retaliation and the intricate process involved in implementing compulsory licenses.[175] Big pharmaceutical companies, especially in the United States and the

[167] *Id.*
[168] *Id.*
[169] Kavaljit Singh, *ANTHRAX, DRUG TRANSNATIONALS, AND TRIPS*, FPIF (Apr. 1, 2002), https://fpif.org/anthrax_drug_transnationals_and_trips/.
[170] *Id.*
[171] *Id.*
[172] *Id.*
[173] Hilary Wong, *The case for compulsory licensing during COVID-19*, National Library of Medicine (May 15, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/#R9.
[174] *Id.*
[175] *Id.*

European Union, have historically opposed compulsory licensing.[176]

A notable instance illustrating this opposition unfolded during the anthrax attacks in the United States in October 2001, with the focus on Ciprofloxacin, an antibiotic patented by the German company Bayer AG (Bayer) until December 9, 2003.[177] The TRIPS agreement restricted other companies from producing generic versions of Cipro in the United States during this period, allowing exceptions only in extraordinary circumstances like compulsory licensing and parallel importing.[178] As the anthrax scare drove up demand, the retail price of Cipro soared, rendering it financially out of reach for many Americans.[179] Despite the escalating need, Bayer, facing challenges in meeting the demand promptly, offered only a fraction of the required supply.[180] Critics contended that, in the midst of a public health crisis, the United States government should have overridden Bayer's patent with a compulsory license, permitting the production of generic versions by approved manufacturers.[181] This approach could have ensured a timely and cost-effective supply of the drug within 60 days.[182] The IP waiver aimed to eliminate these hurdles and allow for a smoother pathway to increased production of vaccines and treatments.[183]

Furthermore, the IP waiver covered a broader spectrum of intellectual property rights, including copyrights, trade secrets, and industrial designs, which may have impeded local manufacturing and distribution.[184] While compulsory licenses primarily address patents, the waiver provided a more comprehensive solution.[185]

C. Export of COVID Vaccines

[176] Ragavan, *supra* note 152, at 3.
[177] Singh, *supra* note 169.
[178] *Id.*
[179] *Id.*
[180] *Id.*
[181] *Id.*
[182] *Id.*
[183] Ragavan, *supra* note 152, at 2.
[184] *Id.* at 6-7.
[185] *Id.*

The IP waiver would have facilitated the export of COVID-19 vaccines by removing the cumbersome restrictions outlined in Article 31(*bis*) of TRIPS.[186] Article 31(*bis*) imposes conditions on both exporting and importing WTO Members, making the process complex and time-consuming.[187] For developing countries, navigating this process can be challenging, as it involves extensive administrative procedures and international regulations.[188]

The IP waiver could have simplified the export process, by enabling local production and distribution while avoiding export-related delays.[189] The IP waiver aligned with the objectives of the TRIPS Agreement to ensure equitable access to essential medications and technology transfer.[190]

D. Price Benefit

Another significant advantage of the IP waiver was its ability to address pricing issues more effectively.[191] As of now, negotiating affordable prices for patented products can be burdensome.[192] The IP waiver could have empowered governments to intervene and reduce costs, as high-volume sales can offset any potential loss of monopoly pricing.[193] This approach has been demonstrated in cases where compulsory licenses led to increased sales and profits for pharmaceutical companies, as more people could afford the medication.[194]

E. Innovation Using Public Funds

Many pharmaceutical companies have developed COVID-19 vaccines with substantial public funding.[195] The extensive use of public funds raises questions about the justification for private intellectual property rights over these life-saving medications.[196]

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[186] *Id.* at 5.
[187] *Id.*
[188] *Id.* at 5.
[189] Ragavan, *supra* note 152, at 5.
[190] *Id.*
[191] *Id.* at 7.
[192] *Id.*
[193] *Id.*
[194] *Id.*
[195] Ragavan, *supra* note 152, at 8.
[196] *Id.*

The IP waiver acknowledged the significant role of public investment and promoted the sharing of research outcomes to benefit the global community.[197]

F. Opposition of the IP Waiver

Despite the strong arguments that were in favor of the proposed IP waiver, there were several compelling counterarguments put forward by those who opposed it or questioned its necessity, expediency, or effectiveness.[198] First, many of the issues related to the insufficient supply of vaccines and essential medical products during the COVID-19 pandemic were due to factors such as limited manufacturing capacity, shortages of raw materials, logistical challenges, and weaknesses in public health infrastructure.[199] These issues were not directly related to intellectual property and innovation.[200] Even with the IP waiver, it was uncertain whether it would have quickly resolved these underlying problems.[201] Second, the development of various medical products and technologies relies on different incentive structures, which the IP waiver might have disrupted.[202] The incentives needed for COVID-19 vaccines differ from those for therapeutic treatments or medical equipment.[203] Adjustments to intellectual property frameworks can either encourage or hinder innovation depending on the context.[204] Third, the adoption of the IP waiver could have set a precedent for altering intellectual property rights during future global crises, potentially undermining the stability and predictability of the intellectual property system.[205] Fourth, due to the consensus-based nature of WTO negotiations, it would have taken considerable time to reach a

[197] *Id.*
[198] Yu, Peter K., *Deferring Intellectual Property Rights in Pandemic Times*. Hastings Law Journal, Vol. 74, 489, 550 https://ssrn.com/abstract=4062300 (Last modified Mar. 15, 2023).
[199] *Id.* at 505.
[200] *Id.*
[201] *Id.*
[202] *Id.*
[203] *Id.*
[204] Yu, *supra* note 198, at 505.
[205] *Id.* at 507.

compromise on the IP waiver's adoption.[206] This delay might have rendered it ineffective in addressing the current pandemic. Fifth, even if the IP waiver were swiftly adopted, countries would have needed to enact or amend laws to implement it, which could have been complicated with existing intellectual property obligations in trade and investment agreements.[207] Sixth, adoption of the IP waiver might have required concessions and compromises from developed countries, raising questions about its overall impact on trade negotiations.[208] Seventh, the one-size-fits-all approach inherent in the TRIPS Agreement and TRIPS-plus agreements was mirrored by the IP waiver.[209] However, countries vary in their experiences, needs, and capabilities, making a uniform approach problematic.[210] Finally, least developed countries, often associated with the IP waiver, had limited immediate use for it unless the pandemic endured for an extended period.[211] Many already had extended transition periods for patent protections.[212] Therefore, the IP waiver's benefits would primarily be in their ability to import health products and technologies from other WTO members, including developing countries with manufacturing capacity.[213]

The debate that surrounded the IP waiver went beyond the immediate response to the COVID-19 pandemic.[214] It called for a paradigm shift in the global approach to intellectual property in the pharmaceutical sector.[215] A broader and more comprehensive framework, akin to a Public Health Treaty, is needed to address access, equity, and innovation.[216] Such a treaty should encompass the goals of both the WTO and the World Health Organization (WHO) to ensure that global trade aligns with public health objectives.[217] The IP waiver was a compelling idea aimed at

[206] *Id.*
[207] *Id.* at 508.
[208] *Id.* at 509.
[209] *Id.*
[210] Yu, *supra* note 198, at 509.
[211] *Id.* at 510.
[212] *Id.*
[213] *Id.*
[214] Ragavan, *supra* note 152, at 9.
[215] *Id.*
[216] *Id.*
[217] *Id.*

addressing the urgent need for equitable access to vaccines and treatments. Unfortunately, the promising IP waiver proposal was denied, facing opposition and skepticism. However, it has paved the way for an alternative approach – the deferral program proposal.

VII. THE DEFERRAL PROGRAM PROPOSAL

This part will propose an alternative to the IP waiver: the deferral program. The deferral program is a proposal that combines suspension and extension of intellectual property rights.[218] Under the deferral program, the suspension of intellectual property rights initiates when a triggering event occurs.[219] The triggering event may be defined as a Phase 6 pandemic, following the WHO's framework, which involves sustained community-level outbreaks across multiple regions and countries.[220] During such a major public health crisis, rights holders would temporarily lose their ability to exploit their intellectual property rights, a scenario akin to the initial months of the COVID-19 pandemic when economies worldwide came to a standstill.[221] The rationale for this suspension is that during a Phase 6 pandemic, massive public health challenges justify a deferral of intellectual property rights, as rights holders are not able to fully utilize these rights in the open market.[222]

As the global pandemic subsides, economies recover, and the triggering event subsides, the suspension is lifted.[223] Intellectual property protection is reinstated, with additional years added to the original term of protection.[224] A crucial aspect of the extension mechanism is the provision of a limited grace period, typically one year.[225] The extension model, similar to the Hatch-Waxman Act, aims to fairly compensate rights holders for the period of suspension.[226] The mechanism recognizes that rights holders

[218] Yu, *supra* note 198, at 533.
[219] *Id.* at 534.
[220] *Id.*
[221] *Id.*
[222] *Id.*
[223] *Id.*
[224] Yu, *supra* note 198, at 534.
[225] *Id.*
[226] *Id.* at 535.

should regain their intellectual property rights once the crisis passes, thereby addressing concerns of fairness and equity.[227]

A. Strengths of the Deferral Proposal

The primary strength of the deferral proposal lies in its ability to serve as a middle ground between the demands of the IP waiver's supporters and opponents.[228] Unlike its predecessors, this proposal is uniquely positioned to provide a more balanced compromise.[229]

For proponents of the TRIPS waiver, the deferral proposal is an appealing choice because it recognizes and addresses concerns regarding global inequities perpetuated by the existing international intellectual property system.[230] Just like the IP waiver, the deferral proposal starts by suspending relevant intellectual property rights during a health crisis.[231] However, the critical distinction is that it seeks to compensate rights holders by extending their rights that would have been suspended during the pandemic.[232]

Additionally, the deferral proposal responds to the concerns of the IP waiver's opponents who fear that the suspension of intellectual property rights could diminish incentives for research and development.[233] The extension component of the deferral scheme ensures that rights holders are duly compensated for the losses incurred during such suspensions, thereby preserving incentives for crucial medical advancements.[234]

The deferral proposal also helps tackle some of the implementation challenges associated with regulatory takings, expropriation of foreign investments, and issues related to fair and equitable treatment.[235] By offering post-pandemic extensions, it reduces the risk of investor-state disputes and what is known as

[227] *Id.*
[228] *Id.* at 543.
[229] *Id.*
[230] Yu, *supra* note 198, at 544.
[231] *Id.*
[232] *Id.*
[233] *Id.* at 545.
[234] *Id.*
[235] *Id.*

"regulatory chill," which could undermine a country's ability to regulate harmful activities.[236]

The deferral proposal can work in harmony with other initiatives, including the TRIPS waiver.[237] It provides policymakers with more options and can enhance negotiation strategies, potentially increasing the likelihood of finding mutually acceptable solutions.[238]

At the international level, the proposal raises questions about whether patent protection can be deferred or interrupted under extraordinary circumstances.[239] This ambiguity could be advantageous, especially during a public health crisis, as it may not necessarily violate the TRIPS Agreement.[240]

B. Limitations of the Deferral Proposal

While the deferral proposal boasts several merits, it is not without its share of limitations. The proposal may not be suitable for all forms of intellectual property rights.[241] While it works well for rights with defined terms of protection like copyrights, industrial designs, and patents, it is less effective for rights with undefined or indefinite terms, such as trade secrets and trademarks.[242] Trademark protection did not significantly hinder access to health products during the COVID-19 pandemic.[243] Some challenging disputes will persist, including disagreements over the definition of the pandemic's end, the continuation of innovations initiated during the pandemic, allocation of rights, and remuneration arrangements.[244] These complex cases may require litigation for resolution.[245] Implementing the deferral proposal involves legislative changes in many countries, which can be time-

[236] Yu, *supra* note 198, at 545.
[237] *Id.*
[238] *Id.*
[239] *Id.*
[240] *Id.*
[241] *Id.* at 546.
[242] Yu, *supra* note 198, at 546.
[243] *Id.* at 548.
[244] *Id.*
[245] *Id.*

consuming.[246] However, it is likely to encounter less resistance from rights holders compared to the TRIPS waiver.[247]

The intellectual property deferral proposal represents a compelling alternative for addressing global health crises while preserving incentives for innovation. The deferral proposal's ability to balance the concerns of proponents and opponents, coupled with its capacity to complement existing initiatives, makes it a viable policy option. However, it is not without limitations, especially regarding its applicability to certain types of intellectual property and the challenge of resolving complex disputes. The success of this proposal will depend on how well it is implemented and the extent to which it can accommodate the diverse interests of stakeholders.

VIII. CONCLUSION

In conclusion, the Supreme Court's decisions in pharmaceutical cases exert a profound and wide-ranging influence on the pharmaceutical industry, both within the United States and on a global scale. At the national level, exemplified by the *FTC v. Actavis* case, these decisions not only spark a surge in legal challenges and innovations in legal strategies but also hold the power to shape legislative changes. The substantial impact of the United States court system on pharmaceutical industry-related legislation is a source of significant concern, particularly amplified during pandemics.

Presently, the pending United States case, *Moderna v. Pfizer*, elicits apprehension regarding its potential ramifications on vaccine availability and research opportunities. *Pfizer* brings to light historical United States opposition to the fair application of TRIPS-based flexibilities during infectious disease outbreaks such as HIV, AIDS, and SARS. These flexibilities are paramount in ensuring that intellectual property rights do not impede access to life-saving medications. Unfortunately, the United States has frequently circumvented multilateral frameworks, resorting to the authority conferred by the Trade Act to advance its interests at the expense of global public health.

[246] *Id.* at 549.
[247] *Id.*

The discourse surrounding the IP waiver, which initially emerged as a promising solution during the COVID-19 pandemic, went beyond the immediate response to the crisis. The IP waiver was a compelling idea aimed at addressing the urgent need for equitable access to vaccines and treatments. Unfortunately, this promising IP waiver proposal was denied, facing opposition and skepticism. However, it has paved the way for an alternative approach – the deferral program.

The deferral program stands as a compelling alternative that builds upon the strengths of the IP waiver while addressing its limitations. It considers the need for equitable access, the preservation of incentives for research and development, and the resolution of implementation challenges. The deferral program offers a balanced approach, acknowledging the global public health imperative while safeguarding intellectual property rights. It represents a significant step toward a more comprehensive framework, akin to a Public Health Treaty, that can better align the objectives of international trade and public health, even in the absence of the IP waiver's immediate implementation. For more affluent countries like the United States, embracing the deferral program is not only a responsible step but also a humane one. Embracing the deferral program is a way to show solidarity with the rest of the world and a recognition of their global role in ensuring health and well-being.