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Brief for the Coalition Against Patent Abuse as Amicus Curiae in Support No Party

Charles Duan

Nos. 19-1434, -1452, and -1458

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA, *Petitioner*,

v.

ARTHREX, INC., ET AL.

SMITH & NEPHEW, INC. AND ARTHROCARE CORP., *Petitioners*,

v.

ARTHREX, INC. AND THE UNITED STATES OF AMERICA.

ARTHREX, INC., *Petitioner*,

v.

SMITH & NEPHEW, INC., ARTHROCARE CORP., AND THE UNITED STATES OF AMERICA.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF THE COALITION AGAINST PATENT ABUSE AS *AMICUS CURIAE* IN SUPPORT OF NO PARTY

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INTEREST OF *AMICUS CURIAE*

The Coalition Against Patent Abuse[1] is a coalition of healthcare providers, consumer groups, patient advocacy organizations, free market advocates, employers, and others fighting abuses of the patent system that can extend government-granted monopolies that illegitimately keep drug prices high for years, or even decades. CAPA produces research and analysis on patents and drug costs aimed at educating lawmakers and policy experts on issues vital to American health care.[2]

SUMMARY OF ARGUMENT

Perhaps unexpectedly, a case on the constitutionality of the Patent Trial and Appeal Board has major significance to the pressing policy crisis of drug prices in the United States. Erroneously issued patents monopolize medical therapies, making them unaffordable or inaccessible to numerous Americans. The inter partes review proceedings that the Board conducts have repeatedly and successfully overcome such patents, enabling competition and dramatically lowering prices. This Court should ensure the continued viability of the Board and of inter

[1]Pursuant to Supreme Court Rule 37.3(a), all parties received appropriate notice of this brief and granted blanket consent for the filing of briefs of *amici curiae*. Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than *amicus*, its members, or its counsel, made a monetary contribution to the preparation or submission of this brief.

[2]A list of CAPA members may be found on the website https://www.capanow.org/. Opinions expressed herein reflect the views of the coalition but not necessarily those of the individual members.

partes review, by preserving the Board's objectivity and independence from executive branch political influence.

1. In the eight years that it has been in effect, inter partes review and related patent challenge proceedings have proven effective in overcoming abuse of patents that improperly block competition, raise prices, and stifle future innovation. That critical role is plainly observable in the context of drug patents, where infirmities in patent examination allow pharmaceutical firms to obtain questionable patents that wrongly block generic competition and cost Americans hundreds of millions of dollars every year. Inter partes review has successfully distinguished patents representing genuine innovation from those that serve largely to preserve pharmaceutical monopoly profits without concomitant public benefit.

Case studies of key inter partes reviews on drug patents reveal the effectiveness and value of those proceedings and the Board that conducts them. The case studies show that patents declared erroneous in those proceedings are manifestly uninventive "secondary" patents designed to extend monopoly prices beyond the congressionally specified patent term. They show that cancellation of those patents can lower drug prices by 98%, because they enable multiple competitors, even ones beyond the firms bringing the patent challenges, to compete vigorously on prices. And they show why the Board has proven to be an effective venue for such challenges: because the administrative patent judges on the Board have the qualifications to understand complex technological facts in patent cases and apply patent law to those facts objectively, such that judicial review affirms the Board over 80% of the time.

2. Impartiality is key to why the Board succeeds. Congress structured the Board to conduct inter partes reviews impartially based on the law, largely free of political pressures from powerful lobbies such as the pharmaceutical industry. Indeed, members of this Court have already vigorously denounced attempts by the Director of the U.S. Patent and Trademark Office to manipulate the Board's outcomes through a practice called "panel stacking."

Yet as important as impartiality is to fair adjudication, the Federal Circuit read the Appointments Clause to encourage—even *require*—executive power to meddle with Board decisions on patentability. The Constitution does not demand that level of political influence. Indeed, heavyhanded Director oversight of the Board is superfluous given that the Board's patentability decisions, being almost entirely matters of law, are already rigorously reviewed by the federal judiciary.

Impartiality and objectivity of the Board should lead this Court to approve the structure that Congress designed. In the alternative, should this Court find that some structural remedy is required, that remedy should impose minimal political interference upon the Board, to ensure that its decisions on patentability remain credible, reliable, and impartial. Furthermore, the Court should disapprove the Federal Circuit's improper remanding of all pending decisions, which wastefully unsettles expectations of competitive drug companies and patients who depend on them. In a case with widespread implications for the health of all Americans, this Court should apply to inter partes review that classic principle of medicine: first, do no harm.

ARGUMENT

I. The Patent Trial and Appeal Board Has Proven Its Merit in Reviewing Patents That Wrongfully Raise Drug Prices and Harm American Consumers

When it created the Patent Trial and Appeal Board in 2011 to adjudicate inter partes review proceedings, Congress hoped to overcome serious and systematic flaws in the American patent system that enabled wrongfully issued patents to block competition and injure the American public.[3] In the context of pharmaceutical patents,[4] the Board and inter partes review have been invaluable to approaching the United States drug pricing crisis.

Skyrocketing drug prices today certainly merit the term "crisis." Eight in ten surveyed Americans describe the cost of prescription drugs as "unreasonable,"[5] and the "rising price of prescription drugs was an important factor" to a majority of voters of all parties.[6] Unaf-

[3] *See* H.R. Rep. No. 112-98, at 46–48 (2011); Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 Fed. Cir. B.J. 539, 600–02 (2012).

[4] For simplicity, this brief throughout uses the terms "pharmaceuticals" and "drugs" to refer to the broad class of chemical therapeutic medicines, and "generics" to refer to subsequent competitive products that are roughly market substitutes. In industry parlance, those terms refer only to small-molecule products, while large-molecule therapeutics are analogously designated "biologics" and "biosimilars"; the differences are immaterial to this case.

[5] *See* Ashley Kirzinger et al., *KFF Health Tracking Poll—February 2019: Prescription Drugs*, Kaiser Fam. Found. (Mar. 1, 2019), *available online*. Locations of authorities available online are shown in the Table of Authorities.

[6] Coal. Against Patent Abuse & Morning Consult, Reforming the Patent System 1 (Nov. 2020), *available online*.

fordability has harmed Americans, with nearly a third of surveyed adults reported not taking medicines as prescribed because of costs, and 29% of them reportedly became sicker as a result.[7] Indeed, researchers attribute between 112,000 and 125,000 deaths a year to patients who fail to take necessary medications because they cannot afford them.[8]

The most straightforward approach to overcoming this drug pricing problem is competition.[9] Having multiple firms selling a drug can cut prices tremendously—over 95% in some cases, a U.S. Food and Drug Administration study finds.[10] The Government Accountability Office similarly concludes that generics cost on average 75% less than the brand-name equivalent, and substitution of generic drugs between 1999 and 2010 saved Americans more than $1 trillion.[11] Because patents by definition are government-granted privileges to escape competition, multiple surveys find that Americans overwhelmingly

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[7] *See* Kirzinger et al., *supra* note 5.

[8] *See* Xcenda AmerisourceBergen, Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report 13 tbl.6 (2020), *available online*; Ass'n for Accessible Meds., Generic Drug Access & Savings in the U.S. 26 (2017), *available online*.

[9] *See* U.S. Gov't Accountability Office, GAO-18-40, Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals 47–50 (Nov. 2017), *available online* (citing studies).

[10] Ryan Conrad & Randall Lutter, U.S. Food & Drug Admin., Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices 3 (Dec. 2019), *available online*.

[11] *See* Letter from John E. Dicken, U.S. Gov't Accountability Office, to Orrin G. Hatch, U.S. Senate, *GAO-12-371R: Savings from Generic Drug Use* (Jan. 31, 2012), *available online*.

blame pharmaceutical patents and the firms that hold them for the unreasonable costs of drugs.[12]

Inter partes reviews conducted by the Board have played a key role in stemming these harms. The case studies that follow were gathered by correlating drug patent inter partes review outcomes where all patent claims were canceled, against Medicaid and other data on drug prices.[13] Several key features of the Board emerge from this study, pointing to inter partes review being a strong mechanism for overcoming the ongoing problems of skyrocketing drug prices.

1. Most obviously, the effect of inter partes review on questionable drug patents is to lower prices—often dramatically. Cancellation of erroneous patents on a drug opens the door to generic competition, and that competition brings prices down on average 75%, saving American consumers over $100 billion a year according to the Government Accountability Office.[14] The case studies repeatedly show competition following rapidly after a Board decision in inter partes review, with almost immediate savings of up to 93%.

2. Monopoly drug prices might be tolerable if the patents backing those prices represented genuine innovation, but the patents that the Board has declared

[12]*See* Coal. Against Patent Abuse & Morning Consult, *supra* note 6, at 1; Kirzinger et al., *supra* note 5.

[13]Specifically, this analysis uses National Average Drug Acquisition Cost (NADAC) weekly reference data, which is based on monthly pharmacy surveys and other data. *See* Ctrs. for Medicare & Medicaid Servs., Methodology for Calcul ating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs 20 (Nov. 2013), *available online*.

[14]*See* Dicken, *supra* note 11; U.S. Gov't Accountability Office, *supra* note 9, at 47–50.

erroneous do not. Instead, the case studies reflect bald manipulation of the patent system to extend monopoly control over drugs that ought to be open to competition.[15] The challenged patents involve mere combinations of well-known drugs, predictable dosage adjustments, and trivial modifications to drug delivery. These "inventions" offered insignificant benefits or even caused harm, in one case being the centerpiece of a drug company's fraudulent scheme that led to a $1.7 billion fine.

These "follow-on" or "secondary" patents, so called because they are directed not to the active ingredient of a drug but to uses or formulations,[16] regularly fail in litigation against generics[17] and are often described as as "weak" or "less solid" even by the very companies ob-

[15]By contrast, there is no evidence of the Board being overbearing on legitimately issued patents. A study of inter partes reviews between 2012 and 2017 found that only 7 out of 198 challenged drug patents were directed to active ingredients, with only 2 such challenges successful in canceling all disputed patent claims. *See* Jonathan J. Darrow et al., *The Generic Drug Industry Embraces a Faster, Cheaper Pathway for Challenging Patents*, 17 APPLIED HEALTH ECON. & HEALTH POL'Y 47, 51 (2018). Moreover, while there were some initial concerns about abuse of inter partes review to manipulate drug companies' stock prices, those practices were apparently "a complete failure" and now are largely "all but over." Matthew Bultman, *Hedge Fund Drug Patent Challenges in Doubt After Bass' Test*, LAW360 (Mar. 31, 2017), *available online*.

[16]On secondary patents, see generally KEVIN T. RICHARDS ET AL., CONG. RESEARCH SERV., REPORT NO. R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 9, 16–19 (Feb. 11, 2020), *available online*.

[17]*See, e.g.*, C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013); COMPETITION DIR.-GEN., EUROPEAN COMM'N, PHARMACEUTICAL SECTOR INQUIRY: FINAL REPORT para. 501, at 191 (July 8, 2009), *available online*.

taining them.[18] Nevertheless, the number of secondary patents is large and growing,[19] with pharmaceutical firms acknowledging that those patents have the intended purpose of "extending the term of the existing compound patent."[20]

3. Why the Board is especially important in overcoming improper secondary drug patents is another insight to be gleaned from these case studies. Members of the Board are required to have "competent legal knowledge and scientific ability,"[21] and that expertise has proven valuable to the correct disposition of drug patent cases that can involve difficult scientific facts. On at least one occasion the appellate court praised the Board for providing "ample" evidence in support of its conclusions; the fact that the Board is affirmed on appeal more frequently than the district courts further confirms its competence.[22]

4. The case studies further show that the outcome of inter partes review is not just that the challenger may enter the market, but that other generic manufacturers

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[18] COMPETITION DIR.-GEN., EUROPEAN COMM'N, *supra* note 17, para. 504, at 192 (quoting pharmaceutical firm); *see* C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 644 (2011).

[19] *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 630 & tbl.6 (2018); Hemphill & Sampat, *supra* note 18, at 619; Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE No. e49470, 4 tbl.1 (2012), *available online*.

[20] COMPETITION DIR.-GEN., EUROPEAN COMM'N, *supra* note 17, para. 526, at 196 (quoting pharmaceutical firm).

[21] *See* 35 U.S.C. § 6(a).

[22] *See* Jason Rantanen et al., *Federal Circuit Statistics Update—September 2020*, PATENTLY-O (Sept. 15, 2020), *available online*.

may do so as well. In several cases, cancellation of patents by inter partes review opened the door to market competition by third party competitors uninvolved in the proceeding. This is critical for lowering drug prices because savings from generic entry are sharply related to the number of competitors. Per the FDA study, a single generic brings prices down by about 39%, while six or more competitors drops prices by 95% on average.[23] Where inter partes review has enabled multiple generic competitors to enter the market, it has especially contributed to solving this American crisis.

A. Alzheimer's Disease

Inter partes review over an Alzheimer's disease treatment patent demonstrates the value of that proceeding's use of skilled, specialized adjudicators to overcome patents of little technological value. Although use of rivastigmine to treat moderate dementia diseases was discovered in the 1980s,[24] pharmaceutical company Novartis in 1998 sought patents on delivery of that drug through a transdermal patch applied to the skin, which it sold under the name Exelon Patch.[25] The thrust of those patents was the combination of rivastigmine with an antioxidant in a transdermal patch, where rivastigmine alone in a patch was old knowledge and thus unpatentable.

In the inter partes review *Novartis AG v. Noven Pharmaceuticals Inc.*, the Board found the combination

[23] *See* Conrad & Lutter, *supra* note 10, at 2–3 & fig.

[24] *See In re Rivastigmine Patent Litig.*, No. 1:05-md-1551, at 3–4 (S.D.N.Y. Sept. 22, 2005) (noting filing of patent application on the chemical).

[25] *See* U.S. Patent No. 6,316,023 (issued Nov. 13, 2001); U.S. Patent No. 6,335,031 (issued Jan. 1, 2002).

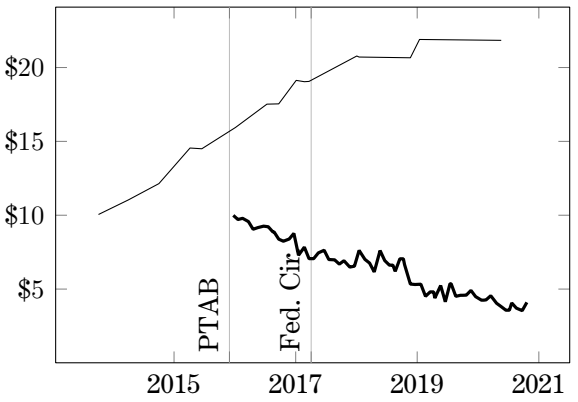

Figure 1: Brand and generic prices of rivastigmine 13.3mg (Exelon) patch.

obvious, and the Federal Circuit affirmed.[26] Since basic scientific principles taught that rivastigmine would degrade absent an antioxidant, the Board and the Court of Appeals agreed that one with ordinary skill in organic chemistry would have come up with the same combination, rendering the patent in error.[27] Generic entry followed quickly, reducing prices by up to 75%.

Two years earlier, a district court had reached a seemingly opposite conclusion, refusing to deem the same patents invalid.[28] That result, though odd, in fact exhibits a strong advantage of inter partes review. The district court admitted difficulty in understanding the expert opinions, conceding that "both arguments seem logical" and finding itself forced to "resolv[e] this dispute based

[26] *See* 853 F.3d 1289, 1291 (Fed. Cir. 2017).

[27] *See id.* at 1295–96.

[28] *See Novartis Pharm. Corp. v. Par Pharm., Inc.*, 48 F. Supp. 3d 733, 736 (D. Del. 2015), *aff'd sub nom. Novartis Pharm. Corp. v. Watson Labs., Inc.*, 611 F. App'x 988 (Fed. Cir. 2015) (nonprecedential).

on credibility" rather than scientific reasoning.[29] The Federal Circuit's own ambivalence about that result is perhaps reflected in the court's designation of its opinion as nonprecedential.[30]

That hesitancy contrasts starkly with the appeals court's confidence in the scientific accuracy of the inter partes review decision. There, the Federal Circuit praised the Board for citing "[a]mple record evidence from scholarly sources."[31] It further distinguished the contrary district court result on the grounds that the Board had a better-developed factual record—likely because the parties were willing to present the expert Board with scientific facts that would have been too technical for the district court.[32] Specialized expertise thus led the Board, and the reviewing Article III appeals court, to receive a richer presentation of scientific facts from which to reach a better-reasoned result.

B. Opioid Addiction

In 2008, British pharmaceutical firm Reckitt Benckiser reaped over $540 million on its blockbuster opioid addiction treatment buprenorphine/naloxone, sold under the brand name Suboxone.[33] But it stood to lose that revenue stream when the company's federal regulatory exclusivity expired in 2009, opening the drug

[29] *See id.* at 757.

[30] *See Novartis Pharm.*, 611 F. App'x 988.

[31] *See Novartis AG*, 853 F.3d at 1295.

[32] *See id.* at 1293–94.

[33] *See* Reckitt Benckiser Grp. PLC, Annual Report and Financial Statements 2008, at 20 (Mar. 2009) (applying currency exchange rate of 1.6).

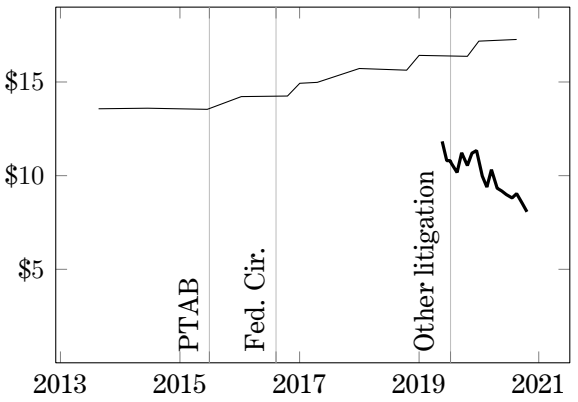

Figure 2: Brand and generic prices of buprenorphine 12mg/naloxone 3mg (Suboxone) sublingual film.

to generic competition.[34] In an effort to maintain its monopoly position, Reckitt Benckiser devised a scheme to switch buprenorphine patients from a tablet-form medicine to a "sublingual film" designed to dissolve under the tongue; patents on the latter formulation would have prevented generic entry through at least 2023.[35] Despite no evidence that the latter formulation was an improvement and indeed some indications that it was more dangerous to children, Reckitt Benckiser and its corporate successor Indivior propounded numerous false advertisements and studies claiming that the sublingual film was safer for households with children.[36]

[34]*See id.* at 18; Rebecca L. Haffajee & Richard G. Frank, *Generic Drug Policy and Suboxone to Treat Opioid Use Disorder*, 47 J.L. MED. & ETHICS 43, 44 (2019).

[35]*See* Haffajee & Frank, *supra* note 34, at 45.

[36]*See* Plea Agreement at Exh. B, paras. 18–26, at 5–8, *United States v. Indivior Sols., Inc.*, No. 1:19-cr-16 (W.D. Va. July 27, 2020) (Doc. No. 427-5).

In July of 2020, Indivior pleaded guilty to fraud and agreed to a $290 million fine, following a $1.4 billion settlement by Reckitt Benckiser.[37] But the scheme was successful in its legacy: Most buprenorphine users switched to the film formulation, and Indivior discontinued its own sales of the tablet.[38] Undoing the fraud, then, required undoing the patents that monopolized the film formulation, and inter partes review was the tool to do so. In the 2015 proceeding *BioDelivery Sciences International, Inc. v. RB Pharmaceuticals Ltd.*, the Board found error in one of Indivior's key patents on the sublingual film; the Court of Appeals affirmed.[39]

In combination with other litigation on Indivior's other patents,[40] the inter partes review decision opened the door to generic competition on Suboxone film as of 2019. At least thirteen generics are now approved for sale, and prices have dropped about 50% compared to the peak brand price. Inter partes review created tremendous patient savings by enabling competition, despite a patent holder's brazen efforts to stifle it.

C. Insulin

Glargine is a modern formulation of insulin that releases itself slowly into the bloodstream, reducing the

[37] *See id.* at 3 tbl.; Press Release, U.S. Dep't of Justice, *Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History* (July 11, 2019), *available online*.

[38] *See* Haffajee & Frank, *supra* note 34, at 46, 48–49.

[39] *See* No. IPR2014-00325, slip op. at 2 (P.T.A.B. June 30, 2015) (final written decision), *aff'd without opinion*, 667 F. App'x 997 (Fed. Cir. 2016).

[40] *See Indivior Inc. v. Dr. Reddy's Labs., SA*, 930 F.3d 1325, 1330–31 (Fed. Cir. 2019).

number of injections needed. Sanofi's patents on its glargine product, Lantus, were declared erroneous in 2019.[41] But generic entry was not immediately possible because Sanofi also held patents on the SoloStar injector pen device in which it distributed Lantus; regulatory approval required an equivalent generic injector.[42] To enable generic competition on glargine, then, several generic manufacturers sought inter partes review against Sanofi's SoloStar injector pen patents.[43]

Challenges to the SoloStar patents revealed how little innovation the product accounted for. The supposedly novel injector pen was strikingly similar to the many other insulin injectors earlier on the market, with only the minor changes to features such as screw threads that the Board deemed obvious to one of ordinary skill in mechanical engineering.[44] In an effort to overcome this outcome, Sanofi contended that the SoloStar had performed superiorly in the market compared to other insulin pens, but the evidence before the Board proved almost the opposite: The Board credited testimony that the SoloStar was "not recognized as an unusually good

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[41] *Sanofi-Aventis Deutschland GmbH v. Mylan Pharm. Inc.*, No. 2012-1368, -1369, slip op. at 20 (Fed. Cir. Nov. 19, 2019) (nonprecedential).

[42] On the use of device patents to block generic drug competition, see Reed F. Beall & Aaron S. Kesselheim, *Tertiary Patenting on Drug–Device Combination Products in the United States*, 36 NATURE BIOTECHNOLOGY 142, 143 (2018).

[43] *See Mylan Pharm. Inc. v. Sanofi-Aventis Deutschland GmbH*, No. IPR2018-01678, at 2 (P.T.A.B. May 29, 2020) (final written decision), *appeal filed*, No. 20-1871 (Fed. Cir. June 10, 2020).

[44] *See, e.g.*, *id.* at 34 (finding that "one of ordinary skill in the art would have reasonably expected the modified parts to perform the same function as before").

pen" and was "in a statistical tie" with a competitor.[45] Market demand for the SoloStar appeared to be driven by consumer preference not for the device but for the glargine inside it.[46]

The apparent lack of valuable innovation in the SoloStar pen is consistent with the view, also posited in an antitrust case that the First Circuit recently allowed to proceed, that the SoloStar patents were no more than an "effective extension of Sanofi's monopoly."[47] Subsequent generic entry confirms that view: After successful inter partes reviews, Mylan received approval for and announced plans to launch a generic glargine injector pen, at a list price of $147.98 for five pens compared to $425.31 for the Lantus SoloStar.[48]

Notably, Mylan announced this 65% price cut while Federal Circuit appeals were pending on the SoloStar patents; the company stated it was "confident" that the appeals "will not affect commercialization."[49] That confidence reflects an ongoing recognition that the Board's inter partes review decisions are of such high quality—the Federal Circuit fully affirms the Board in 80% of appeals[50]—that pharmaceutical manufacturers are willing to stake millions in potential damages on at-risk launches based on those decisions.

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[45] *Id.* at 87–88.

[46] *See id.* at 87, 103–05.

[47] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 2 (1st Cir. 2020).

[48] *See* Press Release, Mylan N.V., *Mylan and Biocon Biologics Announce Launch of Semglee (insulin glargine injection) in the U.S. to Expand Access for Patients Living with Diabetes* (Aug. 31, 2020), *available online*; SANOFI-AVENTIS U.S. LLC, HOW MUCH SHOULD I EXPECT TO PAY FOR LANTUS? (Oct. 2019), *available online*.

[49] *See* Mylan N.V., *supra* note 48.

[50] *See* Rantanen et al., *supra* note 22.

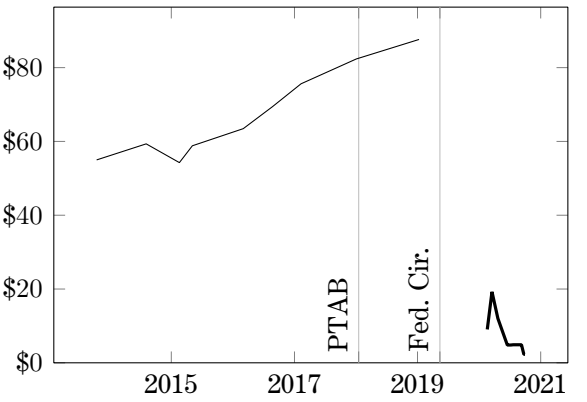

Figure 3: Brand and generic prices of abiraterone acetate 250mg (Zytiga).

D. Prostate Cancer

Abiraterone acetate, used to treat prostate cancer, has been known since at least 1994, and patents on the compound expired about 2014.[51] Janssen Biotech markets and holds patents to a formulation called Zytiga, in which abiraterone is prescribed for use in combination with "a therapeutically effective amount of prednisone," a well-known steroid.[52]

In inter partes review, the Board deemed the combination patent erroneously obvious, and the Federal Circuit agreed in view of evidence that both abiraterone and prednisone were "individually considered promising prostate cancer treatments," and ordinary scientists had no reason to doubt that the two treatments would be

[51] *See Abiraterone Acetate*, 10 Drugs R & D 261 (2010); *A New Way to Treat Prostate Cancer: The Story of Abiraterone*, Inst. Cancer Res. (May 26, 2011), *available online*.

[52] *See BTG Int'l Ltd. v. Amneal Pharm. LLC*, 923 F.3d 1063, 1066–67 (Fed. Cir. 2019).

more effective together.[53] Indeed, evidence before the Board showed that combining steroids with other anti-cancer treatments was not just "common practice" but indeed "the standard regimen" at the time that Janssen's patent was applied for.[54]

Upon the Federal Circuit's conclusion that this obvious combination was unpatentable, generic competitors entered at a price of $2–19 per dose, compared to $88 for the brand. Inter partes review thus enabled almost 98% savings on a drug that the World Health Organization lists as one of the "essential medicines for priority diseases" that constitute "minimum medicine needs for a basic health-care system."[55]

E. Ulcerative Colitis

Mesalamine treats certain gastrointestinal disease that affects about a million Americans. While mesalamine was well-known and studied as early as the 1970s,[56] the firm Dr. Falk Pharma held a patent on an extended-release capsule formulation marketed as Apriso.[57] The patent was directed neither to mesalamine nor to the capsule formulation alone, both of which were old and

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[53] *Id.* at 1074.

[54] *Id.* at 1074–75.

[55] *See* World Health Org., Model List of Essential Medicines 32 (21st ed. 2019), *available online*.

[56] *See* A.K. Azad Khan et al., *An Experiment to Determine the Active Therapeutic Moiety of Suphasalazine*, 310 Lancet 892 (1977); John Mayberry, *The History of 5-ASA Compounds and Their Use in Ulcerative Colitis—Trailblazing Discoveries in Gastroenterology*, 22 J. Gastrointestinal & Liver Diseases 375, 376 (2013).

[57] *See* U.S. Patent No. 8,865,688 (issued Oct. 21, 2014).

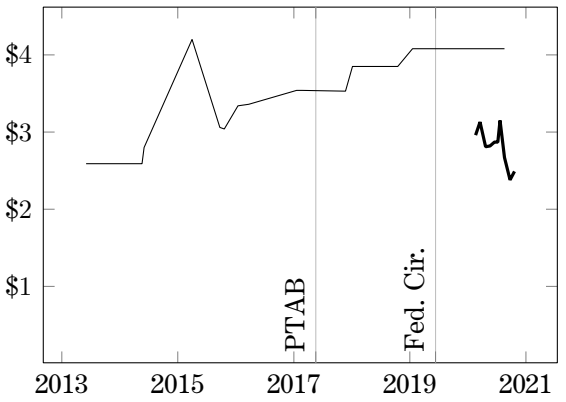

Figure 4: Brand and generic prices of mesalamine 0.375g (Apriso) extended release capsule.

well-known, but rather to the practice of administering those capsules without food or antacids.[58]

In an inter partes review proceeding affirmed on appeal, the Board deemed the patent obvious. Regarding taking the drug without antacids, the Board concluded that doing so would have been obvious to any ordinary scientist, who would have known that antacids decrease stomach acidity (hence the name) and thus would undermine the capsule's acidity-dependent coating.[59] The Board found administration without food an even less compelling "innovation." Citing a decades-old academic paper on how food-triggered digestive processes affect drug absorption, the Board concluded that an ordinary

[58] *See id.* col. 34, ll. 15, 19–20.

[59] *See GeneriCo, LLC v. Dr. Falk Pharma GmbH*, No. IPR2016-00297, at 26–27 (P.T.A.B. May 19, 2017) (final written decision), *aff'd*, No. 17-2312 (Fed. Cir. June 12, 2019) (nonprecedential).

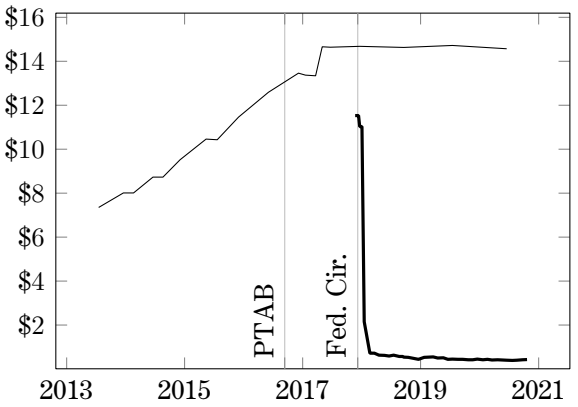

Figure 5: Brand and generic prices of prasugrel 10mg (Effient).

researcher would have known that "a drug intended for the colon should be administered without food."[60]

Generic entry occurred about October 2019, and in the short time up to now, prices have come 42% down.

F. Heart Disease

Prasugrel is an anti–blood clot drug used to treat cardiovascular disease; the brand formulation is Effient. The patent on the drug itself expired in 2017, but Daiichi Sankyo also held later-expiring patents on "methods of using Effient with aspirin," which effectively extended patent protection by six years.[61]

Since aspirin is a blood thinner that also limits blood clots, the Board in inter partes review concluded that the

[60] *See id.* at 36–37.

[61] Eli Lilly & Co., Annual Report (Form 10-K), at 10 (Feb. 21, 2017). Eli Lilly markets Effient in the United States.

combination of aspirin and prasugrel was obvious.[62] Tracing prasugrel's predecessors, the Board found consistent use of aspirin in combination with increasingly powerful anti-clotting agents, and concluded that an ordinary researcher "would have followed the rationale" of that prior art to "select[] the more potent, and preferred ADP-receptor blocking anti-platelet drug, i.e., prasugrel," as the predictable next choice for the combination.[63]

The costs of the improper Effient patent extension were made apparent once generic competitors entered in 2017, at prices 97% below the brand cost.

G. Anemia

Erythropoietin is a biologic compound used in the treatment of anemia. The compound is naturally produced by the kidney and was purified as far back as 1977,[64] but Janssen Pharmaceuticals held a patent reciting a dosing regimen of 5–30 days between doses.[65]

Hospira petitioned for inter partes review on the grounds that the dosing regimen had already been revealed in the same inventor's earlier patent filing from two years earlier; Janssen apparently agreed and directed the Patent Office to cancel the relevant patent claims.[66] Had Hospira not challenged the later-filed patent, Janssen would have enjoyed about two extra

[62] *See Accord Healthcare Inc. v. Daiichi Sankyo Co.*, No. IPR2015-00864, at 22 (P.T.A.B. Sept. 12, 2016) (final written decision), *aff'd without opinion*, 706 F. App'x 679 (Fed. Cir. 2017).

[63] *Id.* at 19.

[64] *See* Takaji Miyake et al., *Purification of Human Erythropoietin*, 252 J. Biological Chemistry 5558 (1977).

[65] U.S. Patent No. 6,746,002 col. 60, l. 6 (issued June 8, 2004).

[66] *Hospira, Inc. v. Janssen Pharm., Inc.*, No. IPR2013-00365, at 2 (P.T.A.B. Oct. 24, 2013).

years of improper patent term. But because inter partes review resulted in cancellation of the patent claims, several erythropoietin biosimilars have now entered the market, saving patients about 57%.[67]

* * *

Inter partes review, as conducted by the Patent Trial and Appeal Board, has played an important role in overcoming patents of little public value that wrongfully force Americans to pay inflated drug prices. The stark cost savings of generic entry that follows from inter partes review reflects the ongoing importance of preserving the Board's ability to conduct such proceedings.

II. The Appointments Clause Should Not Undermine the Impartiality and Objectivity of the Board

In its construction and application of the Appointments Clause, the Federal Circuit failed to account for the value of the Patent Trial and Appeal Board's ability to render objective decisions free of political influence. Doing so disregarded Congressional design, impinged upon the reliability of the American patent system, and was unnecessary under the Constitution.

Unlike the Federal Circuit, this Court should not diminish the Board's impartiality. The most effective way to do so would be to affirm the constitutionality of the Board's present structure, limiting the Director's authority to interpose politics into patentability law decisions to what Congress has provided by statute. Should some structural change be required under the Appointments

[67] *See* Jacob Bell, *Pfizer Launches Biosimilar Version of Amgen's Epogen*, BioPharma Dive (Nov. 14, 2018), *available online*.

Clause, that change should be tailored as narrowly as possible to maintain the Board's objectivity.

A. The Board Is and Ought to Be Structured to Minimize Political Actors' Influence over Patent Decisions

Congress designed the Patent Trial and Appeal Board to be an expert adjudicatory body that could apply patent law impartially to complex scientific information. Ever since Congress first provided for administrative reconsideration of patents in 1980, the rationale has always been that the Patent Office housed "the most expert opinions" that could rigorously apply scientific and technical knowledge to patent law, perhaps more accurately than district court judges and juries without scientific expertise.[68] The modern incarnation of such administrative reconsideration, inter partes review, continues to advance this interest in scientific impartiality. Proceedings are conducted by collegial multi-member panels, which in other contexts are known to apply law more rigorously and in conformance with their superior tribunals compared to single-person adjudicators.[69] And members of the Board must statutorily be "persons of competent legal knowledge and scientific ability."[70]

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[68]H.R. Rep. No. 96-1307, at 4 (1980); *see* Saurabh Vishnubhakat, Arti K. Rai & Jay P. Kesan, *Strategic Decision Making in Dual PTAB and District Court Proceedings*, 31 Berkeley Tech. L.J. 45, 52–55 (2016).

[69]35 U.S.C. § 6(c); *see* Lewis A. Kornhauser & Lawrence G. Sager, *Unpacking the Court*, 96 Yale L.J. 82, 100–02 (1986); Frank B. Cross & Emerson H. Tiller, *Judicial Partisanship and Obedience to Legal Doctrine: Whistleblowing on the Federal Courts of Appeals*, 107 Yale L.J. 2155, 2176 (1998).

[70]35 U.S.C. § 6(a).

To be sure, rogue or incompetent Board members may slip through the cracks, and so the Director maintains several supervisory controls over the Board. The Director decides which inter partes review proceedings to institute,[71] establishes precedential and informative opinions,[72] and issues guidance on the Patent Office's interpretations of law.[73] The Director further has authority to select Board members to decide individual proceedings—a powerful tool for dealing with wayward subordinates.[74] These supervisory powers over the Board are no doubt influential, but they are indirect: They do not enable the Director to change specific outcomes easily or to punish administrative patent judges for those outcomes. The indirectness of these powers further confirms that Congress intended to insulate the Board's individual decisions from direct political pressure.

B. What the Federal Circuit Thought the Appointments Clause Requires, This Court's Justices Have Vigorously Denounced

Turning this adjudicatory objectivity on its head, the Federal Circuit interpreted the Appointments Clause to all but require the Director to have direct political control over the Board's individual decisions.[75] Yet many,

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[71] *See* § 314(b).

[72] *See* Patent Trial & Appeal Bd., Standard Operating Procedure 2 (10th rev. ed. Sept. 20, 2018), *available online*.

[73] *See* 35 U.S.C. § 3(a)(2)(A).

[74] *See* § 6(c).

[75] *See Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1335 (Fed. Cir. 2019) (Pet. App. 22a).

including justices of this Court, have harshly criticized that exact sort of political control over the Board. Were this Court to affirm the Federal Circuit's constitutional interpretation, it would only worsen this problem of political interference.

In 2015, reports began to surface that the Director was "stacking" panels of the Board.[76] By statute, the Director has authority to set the composition of panels of the Board and increase their sizes,[77] and the Patent Office has several times conceded that the Director was adding Board members to panels until the decisions "flipped" to the Director's liking.[78]

These attempts by the Director to change inter partes review outcomes raised multiple concerns. Justice Gorsuch has repeatedly noted that Director power to manipulate inter partes review outcomes "favors those with political clout, the powerful and the popular."[79] Chief Justice Roberts and Justice Kennedy similarly criticized the practice of panel stacking, questioning whether it

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[76] *See* Saurabh Vishnubhakat, *Disguised Patent Policymaking*, 76 WASH. & LEE L. REV. 1667, 1678–80 (2019). A pre–inter partes review example of panel stacking occurred in 1992, relating to rejection of a patent application. *See In re Alappat*, 33 F.3d 1526, 1531 (Fed. Cir. 1994) (en banc).

[77] *See* 35 U.S.C. § 6(c).

[78] *See* Oral Argument at 47:20, *Yissum Research Dev. Co. of the Hebrew Univ. of Jerusalem v. Sony Corp.*, 626 F. App'x 1006 (Fed. Cir. Dec. 7, 2015) (No. 2015-1343) (affirmed without opinion), *reproduced in* Vishnubhakat, *supra* note 76, at 1679–80; *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1015–16 (Fed. Cir. 2017).

[79] *Thryv, Inc. v. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1388 (2020) (Gorsuch, J., dissenting); *see also Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1380 (2018) (Gorsuch, J., dissenting, joined by Roberts, C.J.).

denied due process.[80] Judge Wallach of the Federal Circuit questioned whether panel stacking ran afoul of "fundamental rule of law questions" such as "neutrality of decision makers,"[81] and other commentators have criticized how "the ostensibly neutral and independent adjudicatory process" of inter partes review is now "much more beholden to the agency's political hierarchy" due to panel stacking.[82]

The Federal Circuit's interpretation of the Appointments Clause essentially demands panel stacking to the extreme. The two powers that the Federal Circuit weighed most heavily, direct authority to reverse Board decisions and removal power over administrative patent judges, would have far more influence over patentability outcomes than adding members to panels until the outcome shifts. To the extent that panel stacking sounds improper, there is greater impropriety in what the Federal Circuit thought the Appointments Clause demands.

Given that it is settled that the Board may constitutionally adjudicate patentability disputes,[83] one would think it preferable to make that body as objective and impartial—like Article III judges—as possible. There is no reason to read the Appointments Clause as the

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[80] *See* Transcript of Argument at 32–33, *Oil States*, 138 S. Ct. 1365 (Nov. 27, 2017) (No. 16-712).

[81] *See* Oral Argument at 26:37, *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364 (Fed. Cir. May 4, 2017) (No. 2015-1944, -1945, -1946) (en banc), *reproduced in* Vishnubhakat, *supra* note 76, at 1681.

[82] Vishnubhakat, *supra* note 76, at 1684; *see* Christopher J. Walker & Melissa F. Wasserman, *The New World of Agency Adjudication*, 107 CAL. L. REV. 141, 183 (2019); John M. Golden, *PTO Panel Stacking: Unblessed by the Federal Circuit and Likely Unlawful*, 104 IOWA L. REV. 2447, 2449–50 (2019).

[83] *See Oil States*, 138 S. Ct. at 1379.

Federal Circuit did, demanding the very political capture that this Court has denounced.

C. Courts, Not Political Officers, Supervise Board Decisions That Are Largely Matters of Pure Law

In the general case, the Appointments Clause is "designed to preserve political accountability" through a chain of command, ensuring that agency decisions were consistent with executive policy.[84] With respect to the Board, however, the importance of such oversight is greatly attenuated due to a unique aspect of inter partes review decisions: They are largely matters of law fully supervised by the courts. Direct political control over Board decisions is thus unnecessarily duplicative, and indeed potentially harmful since in some cases the Director could unilaterally strip a right to judicial review.

When it conducts inter partes reviews, the Board makes essentially one final decision:[85] whether a patent is novel under 35 U.S.C. § 102 and nonobvious under 35 U.S.C. § 103. As this Court observed in *Graham v. John Deere Co. of Kansas City*, "the ultimate question of patent validity is one of law," which the courts review de novo.[86] Executive officers enjoy no discretion and receive no deference for their opinions on patentability

[84] *Edmond v. United States*, 520 U.S. 651, 663 (1997); *see Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 498 (2010).

[85] The other major decision during inter partes review, whether to institute review, is made by the Director, who merely sub-delegates that task to the Board. *See* 35 U.S.C. § 314(b).

[86] 383 U.S. 1, 17 (1966) (quoting *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 155 (1950)).

other than to the extent that their experience renders them persuasive.[87]

To be sure, there are underlying facts that inform patentability decisions, but even there the Board's discretion is tightly limited. Since inter partes review must be premised on patents or printed publications,[88] the factual disputes are often confined to written evidence that courts are well familiar with interpreting.[89] Testimonial evidence "cannot be used to prove the proper or legal construction of any instrument of writing,"[90] so a court largely does not defer to the Board's interpretations but rather "proceeds upon its own responsibility, as an arbiter of the law, giving to the patent its true and final character and force."[91] And case-specific factual disputes will generally not reflect upon broader executive policy that needs to be consistent across Board decisions.

Administrative patent judges on the Board are thus distinguishable from other executive branch officials that this Court has considered under its Appointments Clause precedents, because those officials exercised "significant discretion" unreviewable by courts, such that political

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[87] *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1020 (Fed. Cir. 2019); Andrew Michaels, *How Much Deference Courts Owe to USPTO Guidance*, LAW360 (June 20, 2019), *available online*.

[88] *See* 35 U.S.C. § 311(b). Other post-grant patent challenge proceedings may be based on testimonial evidence, but those proceedings are rarer, and nevertheless the ultimate questions are still matters of law.

[89] *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

[90] *Id.* (quoting *Winans v. N.Y. & Erie R.R. Co.*, 62 U.S. (21 How.) 88, 101 (1858)).

[91] *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996).

oversight and consistency across adjudications was of greater importance.[92] The closer analogy is *Morrison v. Olson*, which held that an independent counsel within the Department of Justice was an inferior officer despite enjoying good-cause removal protections and "independent authority" in decisionmaking, much like the Board.[93] In so holding, this Court relied in large part on the fact that the independent counsel lacked discretionary latitude: The authorizing statute "does not include any authority to formulate policy for the Government or the Executive Branch."[94] The Board's patentability decisions similarly do not formulate policy; they simply apply the patent laws, subject to strict supervision by the federal courts.

Given that the Board's patentability decisions are matters of law, it is the judiciary, and in particular the Federal Circuit and this Court where appeals from the Board lie, that is responsible for ensuring the correctness of those decisions. As Justice Alito wrote in *Cuozzo Speed Technologies, LLC v. Lee*, the courts' role over inter partes review is "ensuring that the Office's actions—no less than the patents it reviews—stay within the bounds of the law."[95] Justice Breyer for the Court agreed that were "the agency to act outside its statutory limits . . . [s]uch 'shenanigans' may properly be reviewable" in an Article III court.[96] There is little value in allowing

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[92] *See, e.g., Lucia v. SEC*, 138 S. Ct. 2044, 2048 (2018) (quoting *Freytag v. Commissioner*, 501 U.S. 868, 878 (1991)); *Edmond v. United States*, 520 U.S. 651, 664–65 (1997) (noting limited appellate review over, and thus substantial discretion of, certain military criminal judges).

[93] 487 U.S. 654, 662–63 (1988).

[94] *Id.* at 671.

[95] 136 S. Ct. 2131, 2155–56 (2016).

[96] *Id.* at 2141.

a political appointee, such as the Patent Office Director, to meddle with decisions properly committed to judicial oversight.

Indeed, political influence over patentability determinations could in some situations remove judicial review altogether, thereby usurping Article III review by political action. Appellate review of Board decisions is curiously asymmetric: While a patent owner can always appeal a Board determination of unpatentability, a patent challenger—even a manufacturing company contemplating manufacturing a device that implicates the challenged patent—may lack standing to appeal an adverse decision.[97] Should the Director press the Board to reverse a decision of unpatentability, the patent challenger could effectively be denied judicial review, thereby enabling a political actor to "insulat[e] his favorite firms and process from this process entirely."[98]

Because the correctness of individual Board decisions on patentability is a matter of law, it is the courts that are responsible for oversight of errors in those decisions. Enhanced Director control over those decisions interposes unnecessary and wasteful political influence into the process, and it conflates the properly separate roles of the executive branch and the judiciary.

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[97] *See, e.g., Gen. Elec. Co. v. United Techs. Corp.*, 928 F.3d 1349, 1353–55 (Fed. Cir. 2019); *Consumer Watchdog v. Wis. Alumni Research Found.*, 753 F.3d 1258, 1263 (Fed. Cir. 2014).

[98] *Thryv, Inc. v. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1388 (2020) (Gorsuch, J., dissenting).

D. To Ensure the Board's Impartiality, This Court Should Find It Constitutional or Apply a Minimally Disruptive Remedy

The most straightforward way to avoid undue political influence over patent law determinations is to confirm the constitutionality of the Board as Congress devised it. Board members should be deemed inferior officers subject to the Patent Office Director's political oversight, which Congress crafted to be powerful but not overly compromising of the Board's objectivity.

Should this Court disagree and find some structural change necessary to the Board, then any such remedy should continue to ensure the Board's objectivity and to avoid political meddling that would diminish confidence in the fair application of the patent laws. The Federal Circuit viewed severing the Board's protections from at-will termination to be the "narrowest remedy,"[99] but that remedy has been criticized as a non-transparent practice raising "the possibility of behind-the-scenes pressure" on administrative patent judges.[100] Other, less intrusive options may present themselves, such as enhancing the Director's ability to sit on individual panels or to designate opinions as precedential. These more limited remedies would comport with the preference to "use a scalpel rather than a bulldozer" to remedy constitutional defects.[101]

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[99] *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1338 (Fed. Cir. 2019).

[100] *See The Patent Trial and Appeal Board and the Appointments Clause: Implications of Recent Court Decisions: Hearing Before the H. Comm. on the Judiciary*, 116th Cong. 5 (Nov. 19, 2019) (testimony of Professor Arti Rai), *available online*.

[101] *Seila Law LLC v. Consumer Fin. Prot. Bureau*, 140 S. Ct. 2183, 2210 (2020) (plurality op.).

Furthermore, the Federal Circuit erroneously required all pending cases before it to be remanded for possible rehearing before newly constituted panels. These orders are directly contrary to this Court's precedents on judicial retroactivity.[102] More importantly, those remands ignore the reliance interests that competitive generic companies and patients using generics now have in affordable medicines made possible by successful inter partes reviews.

As the examples of Alzheimer's, diabetes, prostate cancer, heart disease, opioid addiction, and other conditions show, inter partes reviews will likely continue to play a critical role in making medicines affordable and curbing abusive, even fraudulent patent tactics by pharmaceutical monopolists. These important and valuable decisions stem from having a Board that is and is seen to be objective, fair, impartial, and fact-based. The Appointments Clause does not require upending this salutary state of affairs, and there is no reason for this Court to do so.

[102] *See* Andrew C. Michaels, *Retroactivity and Appointments*, 52 LOY. U. CHI. L.J. (forthcoming 2020) (manuscript at 60–61), *available online*.

CONCLUSION

For the foregoing reasons, this Court should ensure that any holding in this case ensures the viability of post-grant patent proceedings to enable a competitive pharmaceutical market, and protect those proceedings from unnecessary political influence.

Respectfully submitted,

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