**Nos. 18-1976, -2023**

**UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

---

GLAXOSMITHKLINE LLC and
SMITHKLINE BEECHAM (CORK) LIMITED,
*Plaintiffs-Appellants,*

v.

TEVA PHARMACEUTICALS USA, INC.,
*Defendant-Cross-Appellant.*

---

Appeal from the U.S. District Court for the District of Delaware
(Stark, C.J.) No. 1:14-cv-00878-LPS-CJB

---

# CORRECTED BRIEF OF *AMICI CURIAE* FIFTY-SEVEN LAW, ECONOMICS, BUSINESS, HEALTH, AND MEDICINE PROFESSORS IN SUPPORT OF CROSS-APPELLANT'S PETITION FOR REHEARING EN BANC

---

Matthew J. Dowd
Robert J. Scheffel
Dowd Scheffel PLLC
1717 Pennsylvania Ave., NW
Suite 1025
Washington, D.C. 20006
(202) 559-9175
mdowd@dowdscheffel.com
rscheffel@dowdscheffel.com

Michael A. Carrier
Distinguished Professor
Rutgers Law School
217 North Fifth Street
Camden, NJ 08102
(856) 225-6380
mcarrier@law.rutgers.edu

# UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## CERTIFICATE OF INTEREST

**Case Number** Nos. 18-1976, -2023

**Short Case Caption** GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.

**Filing Party/Entity** Amici Curiae Fifty-Seven Law, Economics, Business, Health, and Medicine Professors

**Instructions:** Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 12/22/2020

Signature: /s/ Michael A. Carrier

Name: Michael A. Carrier

| **1. Represented Entities.** Fed. Cir. R. 47.4(a)(1). | **2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2). | **3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3). |
|---|---|---|
| Provide the full names of all entities represented by undersigned counsel in this case. | Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.<br><br>☑ None/Not Applicable | Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.<br><br>☑ None/Not Applicable |
| See Attached Addendum A | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

☑ Additional pages attached

**4. Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

| | | |
|---|---|---|
| Michael A. Carrier, Rutgers Law School | | |
| Matthew J. Dowd, Dowd Scheffel PLLC | | |
| Robert J. Scheffel, Dowd Scheffel PLLC | | |

**5. Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

| | | |
|---|---|---|
| | | |
| | | |
| | | |

**6. Organizational Victims and Bankruptcy Cases**. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

| | | |
|---|---|---|
| | | |
| | | |

# Addendum A
## List of Academic Signatories*

Professor Margo A. Bagley
Emory University School of Law

Professor Ann Bartow
University of New Hampshire School of Law

Professor Jeremy Bock
Tulane University Law School

Professor Irene Calboli
Texas A&M University School of Law

Professor Michael A. Carrier
Rutgers Law School

Professor Bernard Chao
University of Denver Sturm College of Law

Professor Thomas Cheng
Faculty of Law
The University of Hong Kong

Professor Andrew Chin
School of Law
University of North Carolina

Professor Jorge L. Contreras
S.J. Quinney College of Law
University of Utah

---

* The brief presents the views of the individual signers. Institutions are listed for identification purposes only.

Professor Joshua Davis
University of San Francisco School of Law

Professor Stacey L. Dogan
Boston University School of Law

Professor Stacie B. Dusetzina
School of Medicine
Vanderbilt University

Professor Samuel F. Ernst
Golden Gate University

Professor Harry First
NYU School of Law

Professor Michal Gal
Faculty of Law
University of Haifa

Professor William Gallagher
Golden Gate University School of Law

Professor Shubha Ghosh
College of Law
Syracuse University

Professor Yaniv Heled
Georgia State University College of Law

Professor Tim Holbrook
Emory University School of Law

Professor Erik Hovenkamp
USC Gould School of Law

Professor Eileen M. Kane
Penn State Law

Professor Ariel Katz
Faculty of Law
University of Toronto

Professor Aaron S. Kesselheim
Harvard Medical School

Professor John B. Kirkwood
Seattle University School of Law

Professor Mark A. Lemley
Stanford Law School

Professor Christopher R. Leslie
School of Law
University of California – Irvine

Professor Yvette Joy Liebesman
Saint Louis University School of Law

Professor Lee Ann Wheelis Lockridge
Louisiana State University Law Center

Professor Phillip R. Malone
Stanford Law School

Professor Duncan Matthews
Queen Mary University of London

Emeritus Adjunct Professor Stephen M. Maurer
University of California at Berkeley

Professor Stephen McJohn
Suffolk University Law School

Professor Michael J. Meurer
Boston University School of Law

Emeritus Professor of Economics Roger Noll
Stanford University

Professor Tyler T. Ochoa
Santa Clara University School of Law

Professor Jennifer D. Oliva
Seton Hall University School of Law

Professor Barack Orbach
James E. Rogers College of Law
University of Arizona

Former Professor Luigi Palombi
University of Sydney

Professor Jordan Paradise
Loyola University Chicago School of Law

Professor Srividhya Ragavan
School of Law
Texas A&M University

Professor Zia Rahman
Department of Microbiology and Immunology
Penn State University College of Medicine

Professor Arti K. Rai
Duke Law School

Professor Ana Santos Rutschman
Saint Louis University School of Law

Professor Rachel E. Sachs
Washington University School of Law

Professor William M. Sage
Professor of Law and Medicine
The University of Texas at Austin

Professor Christopher L. Sagers
Cleveland-Marshall College of Law

Professor Catherine Sandoval
Santa Clara University School of Law

Professor Josh Sarnoff
DePaul University College of Law

Professor Ameet Sarpatwari
Harvard Medical School

Professor Kurt Saunders
California State University, Northridge

Professor Steven Semeraro
Thomas Jefferson Law School

Visiting Professor David A. Simon
The George Washington University Law School

Visiting Scholar Michael Sinha
Northeastern University School of Law

Adjunct Professor Jennifer Sturiale
Georgetown University Law Center

Professor H.H.B. Vedder
Faculty of Law
University of Groningen

Professor Liza Vertinsky
Emory Law School

Professor Melissa Feeney Wasserman
School of Law
The University of Texas at Austin

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page(s)**

**Cases**

**Statutes**



**Other Authorities**

## INTEREST OF *AMICI CURIAE*

*Amici curiae* are professors of law, economics, business, health, and medicine. A list of signatories is attached as Addendum A. Their sole interest in this case is to ensure that patent law develops in a way that serves the public interest and public health by promoting competition.[1]

## SUMMARY OF THE ARGUMENT

"Skinny labels" have a funny name. But that is all that is funny about them.

When a drug can be used to treat multiple conditions, a generic can "carve out" the patented indications from its label. The resulting "skinny label" allows the generic to launch its product for uses not covered by a patent. The panel majority in this case held, contrary to the regulatory regime and this Court's precedent, that this long-recognized practice of skinny labeling could form the basis for induced infringement.

The panel held Teva liable for inducing patent infringement even though, as Chief Judge Prost explained, the company "did everything

[1] No party's counsel authored this brief in whole or in part, and no party, party's counsel, or any other person has contributed money intended to fund the preparation or submission of this brief. All parties consent to the filing of this brief.

right." Dissent 8, 33. In particular, the dissent worried that the panel ruling renders the "'content' of Teva's skinny label alone . . . sufficient to prove induced infringement—even though Teva's skinny label did not encourage, promote, recommend, *or even suggest* the patented method." *Id.* at 3 (emphasis in original). Given the importance of skinny labels and their potential "nullification," *id.* at 4, by the panel decision, this Court should grant en banc review to make clear that skinny labels like Teva's do not induce infringement.

## ARGUMENT

The pharmaceutical industry is unique in the extent to which the regulatory regime explicitly recognizes the roles of innovation and competition. This carefully crafted regime cannot work if the provisions fostering generic entry are undermined. In allowing generics to enter the market on unpatented indications, without being subject to infringement lawsuits and an automatic 30-month stay of FDA approval, skinny labeling plays an indispensable role in expediting generic entry and bringing more affordable medicines to consumers. The panel decision threatens this balance by allowing brand companies to improperly block

the marketing of generic drugs for indications no longer covered by patents, thus reducing generic competition.

Teva waited to introduce its product until September 2007, after GSK's patent on the chemical compound had expired. Between that time and April 2011 (when the FDA required Teva to amend its label to match GSK's label), Teva carved out the "indication and prescribing information for treatment of congestive heart failure." Op. 6. Teva amended its proposed label to omit the then-patented indication, and the FDA's final approval of Teva's generic application resulted in a skinny label that was only indicated for hypertension and post-myocardial infarction with left ventricular dysfunction—neither of which was covered by any patent in force. Dissent 9. It is hard to see how such a carefully designed skinny label can induce infringement. It is harder to see how the majority can conclude it does so without even mentioning skinny labels.

As Chief Judge Prost points out, the panel opinion raises multiple questions about whether causation can be shown based on Teva's press releases, product catalogs, and AB rating. *Id.* at 21–32. This brief focuses solely on the skinny-label issue, highlighting the potential

decimation of a valuable path for generics to enter the market for unpatented methods of treatment.

## I. Generic Competition Is Central To The Regulatory Regime

Generic competition is an essential element of the finely-tuned regulatory regime governing the pharmaceutical industry. In 1984, Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act ("Hatch-Waxman Act"). In doing so, the legislature crafted a delicate balance fostering both generic competition and brand-firm innovation.

### A. The Regime Fosters Generic Competition

The drafters of the Hatch-Waxman Act sought to ensure the provision of "low-cost, generic drugs for millions of Americans." 130 Cong. Rec. 24,427 (1984) (statement of Rep. Henry Waxman). Generic competition would save consumers, as well as the federal and state governments, millions of dollars each year. And it would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." *Id.*; *see also* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 42 (2009) ("*Unsettling Settlements*").

One tool of the Hatch-Waxman Act that promotes generic competition is the establishment of the FDA-based exception to infringement, which allowed generics to experiment on the drug during the patent term to facilitate FDA testing. 35 U.S.C. § 271(e)(1). In addition, Congress dispensed with the requirement that generics needed to independently prove safety and efficacy, allowing them to rely on the brand's clinical studies. 21 U.S.C. § 355(j). The legislature also encouraged generics to challenge invalid or noninfringed patents by creating a 180-day period of marketing exclusivity for the first generic firm to do so. *Id.* § 355(j)(5)(B)(iv).

Finally, Congress allowed generic firms to "carve out" patented uses from their labels, fostering competition only on unprotected indications. Section 355(j)(2)(A)(viii) provides that, for "a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection," the applicant must provide "a statement that the method of use patent does not claim such a use." 21 U.S.C. § 355(j)(2)(A)(viii). As the Supreme Court has explained, the section viii route allows a generic manufacturer to "market the drug for one or more methods of use not covered by the brand's patents." *Caraco Pharm.*

*Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 406 (2012). And it "is designed to speed the introduction of low-cost generic drugs to market." *Id.* at 405.

### B. The Regime Fosters Brand-Firm Innovation

In addition to promoting generic competition, the Hatch-Waxman Act sought to increase brand-firm innovation. In the decades before the Act, the number of new chemical entities entering human testing fell 81 percent, and new drug compounds and dosage forms also decreased, in part due to a significant decline in the period between FDA approval and patent expiration. Carrier, *Unsettling Settlements*, *supra*, at 43–44.

To foster brand-firm innovation, the Hatch-Waxman Act made several changes. It authorized patent-term extensions, with the current extension amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. 35 U.S.C. § 156(c), (g)(6). It provided for market exclusivity periods not based on patents, such as a four- or five-year period for a company offering a drug with a new active ingredient. 21 U.S.C. § 355(j)(5)(F)(ii). And it granted to patent holders an automatic 30-month stay of FDA approval, ensuring

that—even without obtaining a preliminary injunction—brand firms will not face generic competition for a period of time. *Id.* § 355(j)(5)(B)(iii).

### C. The Regime is Balanced

The Act's drafters emphasized the equilibrium between competition and innovation at the heart of the Hatch-Waxman Act. Representative Henry Waxman underscored the "fundamental balance of the bill," 130 Cong. Rec. 24,425 (1984), and the Energy and Commerce Committee explained that allowing early generic challenges "fairly balanced" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent. H.R. Rep. No. 98-857, pt. 1, at 28 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2661. Similarly, the Judiciary Committee concluded that it "has merely done what the Congress has traditionally done" in IP law: "balance the need to stimulate innovation against the goal of furthering the public interest." H.R. Rep. No. 98-857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714.

### D. The Panel Neglected the Regime and Generic Competition

In finding that the long-authorized and well-trodden path to generic entry through skinny labels can lead to infringement, the majority

opinion does not consider the regulatory framework. Section viii statements serve as a microcosm of the framework's balance, expediting generic entry for non-patented uses while specifically disclaiming patented uses, thereby not harming innovation.

The majority opinion does not address the legislative history or aspects of the regulatory regime—both of which evince Congress's goal to promote generic competition. *See* Michael A. Carrier, *The Federal Circuit Reverses a Judgment Upholding "Skinny Labels,"* e-Competitions (forthcoming Dec. 2020) (*"Skinny Labels"*).[2] Even though this is an essential element of the Hatch-Waxman Act, the majority did not seem to recognize that its ruling could decimate the practice of skinny labeling. In fact, the panel did not "even discuss the statutory framework permitting skinny labeling." Paul Dietze et al., *Fed. Circ. Ruling Is Troubling For Generic Drug Manufacturers*, Law360 (Oct. 21, 2020).[3] Chief Judge Prost understood that the majority's holding "is no small matter," as "it nullifies Congress's statutory provision for skinny labels"

[2] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3740745.

[3] https://www.law360.com/articles/1320956/fed-circ-ruling-is-troubling-for-generic-drug-manufacturers.

and "slow[s], rather than speed[s], the introduction of low-cost generics." Dissent 3.

Relatedly, the panel neglected to consider the unique advantages offered by section viii statements. *See* Carrier, *Skinny Labels*, *supra*, at 5. For generics seeking to enter while a drug is covered by a patent, there are two options. The first possible route is a "Paragraph IV" certification, which allows a generic to certify that the patent "is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). But this route has disadvantages. The brand firm, just by filing a lawsuit and no matter how weak the patent is, can obtain an automatic 30-month stay of FDA approval. *Id.* § 355(j)(5)(B)(iii); *see also* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1386–87 (2013) (finding that patent holders win only 32% of cases involving secondary patents covering "ancillary aspects of drug innovation"). And the generic has to wait until the 30-month stay expires before getting final FDA approval to enter the market. Even then, to market its less expensive drug, the generic would often have to "launch at risk" because the lengthy and expensive patent litigation often extends beyond the 30-month stay. Launching at risk exposes the generic to potentially

substantial lost-profit damages, in particular because the brand product sells at a much higher price than the generic. *See Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (noting the "risk" of Paragraph IV certification, which is accompanied by "the hazard of sparking costly litigation"); Peter Loftus, *Pfizer, Takeda to Get $2.15 Billion Settlement*, Wall Street Journal (June 12, 2013) (reporting settlement for infringement from at-risk launch of generic Protonix).

In contrast, the section viii route provides unique advantages to generic firms and the public. Because a section viii statement does not require the same notification to patent holders as does a Paragraph IV certification, litigation is "not usually triggered." Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* § 26:11 (2020). In addition, drug applications based on a section viii statement are not subject to the 30-month stay, ensuring faster FDA final approval so generics can enter the market more quickly. For that reason, the D.C. Circuit recognized that section viii is "an attractive route for generic manufacturers." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (quotation omitted).

In short, the panel neglects the importance of generic competition and careful balance of the pharmaceutical regime.

## II. The Panel Misapplied This Court's Precedent

Previous decisions of this Court underscored the importance of skinny labels and how, in nearly every imaginable scenario, they are not likely to induce infringement. The panel majority issued a contrary ruling to these decisions and instead cited precedent involving different settings and different areas of law.

The majority, as Chief Judge Prost pointed out, Dissent 19–20, did not discuss relevant precedent holding that skinny labels do not induce infringement. For example, in *Warner-Lambert Co. v. Apotex Corp.*, this Court held that "the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use," as the generic application "does not induce anyone to perform the unapproved acts required to infringe." 316 F.3d 1348, 1364–65 (Fed. Cir. 2003). And in *Takeda Pharmaceuticals U.S.A. Inc. v. West-Ward Pharmaceutical Corp.*, this Court explained that "vague label language cannot be combined with speculation about how physicians may

act to find inducement" and held that to induce infringement of a patented method, a "label must encourage, recommend, or promote infringement." 785 F.3d 625, 631–32 (Fed. Cir. 2015).

According to the majority, "[p]recedent has recognized that the content of the product label is evidence of inducement to infringe." Op. 16. But the cases it cited arise in different settings, with none involving skinny labels. The majority first cited *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.* for the point that "[t]he contents of the label itself may permit the inference of specific intent to encourage, recommend, or promote infringement." Op. 16 (quoting 887 F.3d 1117, 1129 (Fed. Cir. 2018)). But that sentence comes at the end of a discussion in *Vanda* about "active steps taken to encourage direct infringement," a "proposed label [that] instructs users to perform the patented method," and a label that "encourage[s], recommend[s], or promote[s] infringement." 887 F.3d at 1129 (citations omitted).

The panel also cited *Sanofi v. Watson Laboratories Inc.* for the point that "[t]he content of the label in this case permits the inference of specific intent to encourage the infringing use." Op. 16 (quoting 875 F.3d 636, 646 (Fed. Cir. 2017)). But the *Sanofi* case did not involve a section

viii statement, and the precedent it relied on also involved dissimilar scenarios. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059 (Fed. Cir. 2010) (noting that "[the generic] was aware of and certainly concerned about the potential infringement problem posed by its label, but nevertheless decided to proceed with the label" (quotation omitted)); *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1369 (Fed. Cir. 2017) (noting that "the product labeling includes repeated instructions" that "are unambiguous on their face and encourage or recommend infringement"). None of these cases presents facts similar to a skinny label that disclaimed patented uses.

Even further afield was the majority's citation of precedent from "causation in tort liability." Op. 16–17 (citing *Tinnus Enters., LLC v. Telebrands Corp.,* 846 F.3d 1190, 1204 (Fed. Cir. 2017) (instruction manuals), and *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006) (instructions)). The observation that instruction manuals and instructions can form the basis for induced infringement is not surprising. But unlike the instruction manuals, the skinny label specifically lacks any instruction to infringe. In addition,

the tort cases cited by the majority have nothing to do with skinny labels, let alone generic conduct or the pharmaceutical industry.

* * *

The panel's decision is far-reaching and exceptionally important. As Chief Judge Prost explained, a finding of inducement based on Teva's skinny label "invites a claim of inducement for almost any generic that legally enters the market with a skinny label." Dissent 18–19 (emphases omitted). Such a "nullification," *id.* at 4, of a 35-year-old law that has been an indispensable path for generics to enter the market contradicts this Court's decisions giving effect to skinny labels and threatens to sow uncertainty for generics, undermine the balance at the heart of the Hatch-Waxman pharmaceutical regime, and increase the costs of drugs for millions of Americans.

## III. Conclusion

For these reasons, the Court should grant the petition for rehearing.

Date: December 22, 2020

Respectfully submitted,

By: */s/ Michael A. Carrier*
Michael A. Carrier
Distinguished Professor
Rutgers Law School
217 North Fifth Street
Camden, New Jersey 08102
(856) 225-6380
mcarrier@law.rutgers.edu

Matthew J. Dowd
Robert J. Scheffel
Dowd Scheffel PLLC
1717 Pennsylvania Avenue, NW
Suite 1025
Washington, D.C. 20006
(202) 559-9175
mdowd@dowdscheffel.com
rscheffel@dowdscheffel.com

*Counsel for Amici Curiae Fifty-Seven Law, Economics, Business, Health, and Medicine Professors*

# Addendum A
## List of Academic Signatories*

Professor Margo A. Bagley
Emory University School of Law

Professor Ann Bartow
University of New Hampshire School of Law

Professor Jeremy Bock
Tulane University Law School

Professor Irene Calboli
Texas A&M University School of Law

Professor Michael A. Carrier
Rutgers Law School

Professor Bernard Chao
University of Denver Sturm College of Law

Professor Thomas Cheng
Faculty of Law
The University of Hong Kong

Professor Andrew Chin
School of Law
University of North Carolina

Professor Jorge L. Contreras
S.J. Quinney College of Law
University of Utah

---

* The brief presents the views of the individual signers. Institutions are listed for identification purposes only.

Professor Joshua Davis
University of San Francisco School of Law

Professor Stacey L. Dogan
Boston University School of Law

Professor Stacie B. Dusetzina
School of Medicine
Vanderbilt University

Professor Samuel F. Ernst
Golden Gate University

Professor Harry First
NYU School of Law

Professor Michal Gal
Faculty of Law
University of Haifa

Professor William Gallagher
Golden Gate University School of Law

Professor Shubha Ghosh
College of Law
Syracuse University

Professor Yaniv Heled
Georgia State University College of Law

Professor Tim Holbrook
Emory University School of Law

Professor Erik Hovenkamp
USC Gould School of Law

Professor Eileen M. Kane
Penn State Law

Professor Ariel Katz
Faculty of Law
University of Toronto

Professor Aaron S. Kesselheim
Harvard Medical School

Professor John B. Kirkwood
Seattle University School of Law

Professor Mark A. Lemley
Stanford Law School

Professor Christopher R. Leslie
School of Law
University of California – Irvine

Professor Yvette Joy Liebesman
Saint Louis University School of Law

Professor Lee Ann Wheelis Lockridge
Louisiana State University Law Center

Professor Phillip R. Malone
Stanford Law School

Professor Duncan Matthews
Queen Mary University of London

Emeritus Adjunct Professor Stephen M. Maurer
University of California at Berkeley

Professor Stephen McJohn
Suffolk University Law School

Professor Michael J. Meurer
Boston University School of Law

Emeritus Professor of Economics Roger Noll
Stanford University

Professor Tyler T. Ochoa
Santa Clara University School of Law

Professor Jennifer D. Oliva
Seton Hall University School of Law

Professor Barack Orbach
James E. Rogers College of Law
University of Arizona

Former Professor Luigi Palombi
University of Sydney

Professor Jordan Paradise
Loyola University Chicago School of Law

Professor Srividhya Ragavan
School of Law
Texas A&M University

Professor Zia Rahman
Department of Microbiology and Immunology
Penn State University College of Medicine

Professor Arti K. Rai
Duke Law School

Professor Ana Santos Rutschman
Saint Louis University School of Law

Professor Rachel E. Sachs
Washington University School of Law

Professor William M. Sage
Professor of Law and Medicine
The University of Texas at Austin

Professor Christopher L. Sagers
Cleveland-Marshall College of Law

Professor Catherine Sandoval
Santa Clara University School of Law

Professor Josh Sarnoff
DePaul University College of Law

Professor Ameet Sarpatwari
Harvard Medical School

Professor Kurt Saunders
California State University, Northridge

Professor Steven Semeraro
Thomas Jefferson Law School

Visiting Professor David A. Simon
The George Washington University Law School

Visiting Scholar Michael Sinha
Northeastern University School of Law

Adjunct Professor Jennifer Sturiale
Georgetown University Law Center

Professor H.H.B. Vedder
Faculty of Law
University of Groningen

Professor Liza Vertinsky
Emory Law School

Professor Melissa Feeney Wasserman
School of Law
The University of Texas at Austin

**FORM 19. Certificate of Compliance with Type-Volume Limitations** **Form 19**
**July 2020**

# UNITED STATES COURT OF APPEALS
# FOR THE FEDERAL CIRCUIT

## CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

**Case Number:** Nos. 18-1976, -2023

**Short Case Caption:** GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc.

**Instructions:** When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

☑ the filing has been prepared using a proportionally-spaced typeface and includes 2,596 words.

☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.

☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 12/22/2020

Signature: /s/ Michael A. Carrier

Name: Michael A. Carrier