United States Court of Appeals
for the First Circuit

No. 17-1714

UNITED FOOD AND COMMERCIAL WORKERS UNIONS AND EMPLOYERS MIDWEST HEALTH BENEFITS FUND, on behalf of themselves and others similarly situated; LABORERS HEALTH AND WELFARE TRUST FUND FOR NORTHERN CALIFORNIA, on behalf of themselves and others similarly situated; AFSCME HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated; MINNESOTA LABORERS HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated; PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of themselves and others similarly situated; LOUISIANA HEALTH SERVICE AND INDEMNITY COMPANY, d/b/a BLUE CROSS AND BLUE SHIELD OF LOUISIANA, on behalf of themselves and others similarly situated,

Plaintiffs-Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION; NOVARTIS CORPORATION; NOVARTIS AG,

Defendants-Appellees.

No. 17-1776

RXDN, INC., on behalf of themselves and others similarly situated,

Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION; NOVARTIS CORPORATION; NOVARTIS AG,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Massachusetts

Civil Action Nos. 15-12732-ADB, 15-13461-ADB, 15-13724-ADB, 15-13725-ADB, 15-13726-ADB, 16-12399-ADB

PLAINTIFFS-APPELLANTS' PETITON FOR PANEL REHEARING

Thomas M. Sobol
Kristen A. Johnson
Hannah W. Brennan
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142

Counsel for End Payer Purchaser Appellants

John D. Radice
RADICE LAW FIRM, P.C.
34 Sunset Blvd
Long Beach, NJ 08008

Noah Rosmarin
ADKINS, KELSTON & ZAVEZ, P.C.
90 Canal Street, Suite 500
Boston, MA 02114

Counsel for Direct Purchaser Appellants

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

This case addresses the pleading requirements for suits alleging a company's acquisition and assertion of pharmaceutical patents violates federal competition laws. In affirming dismissal of allegations that Novartis (i) misrepresented to the Patent and Trademark Office (PTO) facts about the polymorphic properties of imatinib mesylate and (ii) used the ensuing patent to delay generic competition, the Opinion conflicts with black letter patent law. The Panel also misapprehends the implications of a prior ruling by the Patent and Trademark Appeal Board (the Board). The resulting Opinion – while at times ostensibly limited to the facts of the case – creates new legal barriers for meritorious antitrust lawsuits.

First, patent law – expressed in many Federal Circuit cases including *In re Soni*[1] and *In re Mayne*[2] – provides that a patent applicant's assertion that a property of his claimed invention is "surprising" or "unexpected" is substantive *evidence* before the PTO used to overcome a prima facie case of obviousness. The Opinion, however, holds that an assertion of "surprising" attributes may not be factual but rather "merely a legal assertion" of non-obviousness that cannot amount to a material representation.

[1] 54 F.3d 746, 750 (Fed. Cir. 1995).

[2] 104 F.3d 1339, 1343 (Fed. Cir. 1997).

Second, patent law – expressed by the Federal Circuit including *KangaROOS U.S.A., Inc. v. Caldor, Inc.*,[3] and found in 37 C.F.R. § 1.56 – provides that a patent examiner's failure to detect misrepresentations does not excuse the applicant from the consequences of his fraud. The Opinion, however, imposes on examiners a duty to uncover even fraudulently *withheld* facts, and uses an examiner's failure to do so to immunize an applicant's misconduct.

Third, patent law – expressed by the Supreme Court in *United States v. Ross*,[4] and the Federal Circuit in *Connell v. Sears, Roebuck & Co.*[5] – provides that the presumption of patent validity is not substantive proof of material facts; it allocates the standard of proof and burden of persuasion. The Opinion, however, elevates this legal presumption to a form of evidence that can, in the context Federal Rule of Civil Procedure 12(b)(6), be used to contradict detailed allegations that the disclosure of withheld facts during full federal court litigation would objectively result in declaring a patent invalid.

Finally, the Board's decision to reverse and remand the examiner's initial rejection of Novartis's '051 patent application (as anticipated or obvious over the original imatinib compound patent) was merely a procedural ruling that would play

[3] 778 F.2d 1571, 1575-76 (Fed. Cir. 1985).

[4] 92 U.S. 281, 285 (1875).

[5] 722 F.2d 1542, 1549 (Fed. Cir. 1983).

no role in later infringement litigation testing the patent's validity. The Opinion, however, mistakenly treats this procedural ruling as substantive evidence to contradict detailed facts alleging an objective likelihood that the '051 patent would be held invalid by a court once all facts were disclosed about the crystal.

Standing alone, this case is important. But the Opinion also affects pending and future cases seeking to hold drug patent applicants accountable for procuring and asserting fraudulently-obtained patents. The Opinion appears to adopt new law that even when a plaintiff can prove the underlying patent would be held invalid as obvious or anticipated – pharmaceutical companies cannot be held liable for prosecuting sham infringement lawsuits based on those bogus patents. As for patent practice, the Opinion articulates rules of patent law that conflict with long-established precedent, creating confusion about the principles of fair play in acquiring pharmaceutical patents. These misapprehensions of law are troubling because the crux of the Opinion's reasoning rests on law or positions the parties did not advance.

Under Federal Rule of Civil Procedure 40, the purchasers respectfully request that the Panel rehear the case.

II. ARGUMENT

A. The Opinion conflicts with the basic tenant of patent law that an applicant's assertion that a property of his claimed invention is "surprising" or "unexpected" is a substantive fact used to overcome a prima facie case of obviousness.

To overcome prima facie obviousness, patent applicants frequently assert – as a factual matter – that a property of their claimed inventions is "surprising" or "unexpected."[6] This is especially true in the pharmaceutical field, where inventors often claim that a feature of their chemical compound, such as a salt or crystalline form, is surprising or unexpected.[7] When pharmaceutical companies assert that their inventions are surprising or unexpected, the Federal Circuit consistently treats the assertions as *factual*.[8] The question of whether an invention possesses a surprising or unexpected feature is an evidentiary matter.

Before the PTO, Novartis represented as fact that the β-crystalline form of imatinib mesylate was a "[n]ew crystalline form."[9] It stated it had "*now* been

---

[6] *See, e.g.*, *Soni*, 54 F.3d at 750; *Mayne*, 104 F.3d at 1343.

[7] *See, e.g.*, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1369-70 (Fed. Cir. 2007); *Abbvie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1380 (Fed. Cir. 2014); *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 501 F.3d 1263, 1269 (Fed. Cir. 2007).

[8] *See, e.g.*, *In re Corkill*, 771 F.2d 1496, 1501 (Fed. Cir. 1985) ("A greater than expected result is an *evidentiary factor* . . . ." (citing *United States v. Adams*, 383 U.S. 39, 51-52 (1966) (unless otherwise noted, emphasis herein is added))); *In re Klosak*, 455 F.2d 1077, 1080 (C.C.P.A. 1972) ("The fact that an invention provides results which would not have been expected . . . is strong evidence . . . .").

[9] JA-000369; *see also* JA-000373, 391.

surprisingly found . . . *under certain conditions* [to] be found in the methanesulfonate salt of this compound, . . . which has very advantageous properties."[10] And it represented the crystal had not been "prepared" previously.[11] Novartis's application then spent many pages distinguishing the attributes of the "new" β-crystal form from the ostensibly prior, α-form.[12]

The complaint details, however, that Novartis's predecessor made or found the β-crystal form *a decade earlier*, that imatinib mesylate *naturally converts* to that form (or else can be converted through simple lab work), and that the crystal form was used for years in clinical tests. The complaint alleges Novartis withheld these facts.

The Opinion, however, finds "Novartis's characterization of the existence of the crystalline form of that salt as 'surprising'" to be nothing "more than an assertion of non-obviousness" which "is implicit in any patent application."[13] This

---

[10] JA-000372; *see also* JA-000388, 501 (repeating "under certain conditions").

[11] JA-000434.

[12] JA-000372-7, 388-405.

[13] Op. 20. The Opinion's footnote 8 – ruling that the "new" representations were inadequately raised – misapprehends the record. The purchasers repeatedly made this allegation in their complaints. JA-000079 (¶184) (noting that Novartis's patent application described the β-crystal as new, "even though employing a non-needle crystalline form was an obvious choice that had been in use . . . [since] 1993"); JA-000098 (¶270); JA-000080 (¶¶189-92); JA-00081 (¶¶196-97); JA-000096 (¶263); JA-000098 (¶270); JA-0000102 (¶291). They then advanced this point to oppose Novartis's motion to dismiss (which the district court recognized, ADD-029-030). *See, e.g.*, Pls. Opp'n to Defs.' Mot. to Dismiss at 5, Civ. A. No.

ruling conflicts with long-accepted patent law and practice under 35 U.S.C. § 103.[14] A representation of "new," "surprising" results is not, as the Opinion writes, a "bare assertion that an invention is not obvious." Instead, it is a factual assertion specifically inserted to avoid an obviousness rejection – one that an examiner is primed to accept at face value.[15] And the Panel's corollary ruling – that a representation of surprising results "is not in and of itself a material misrepresentation for purposes of *Walker Process*" – conflicts with accepted patent

---

15-12732-ADB, ECF No. 120 (D. Mass. June 9, 2016) (Pls.' Opp'n) ("Novartis intentionally . . . misrepresented that the non-needle form of the compound was a recent, 'surprising' discovery . . . ."); *id.* at 28 (the "β-crystal form could be, and had been years earlier, easily made."); JA-000250-51 (the district court asking "Is your claim that they already knew about it a long time ago, or was it inherent in the original, whatever you want to call it, compound?" to which the purchasers responded, "Both of those things"); JA-000263. And they urged this point on appeal. *See, e.g.*, Appellee Br. 13-14 ("The purchasers allege . . . the β-crystal form was the *exact same compound* Ciba-Geigy had formulated in the early 1990s, patented, tested, and then described in published articles. . . . Novartis put a new name – the 'β-crystal form' – on an old characteristic – a non-needle crystal.'"); *id.* at 70 ("Novartis's supposed discovery of a β-crystalline form of imatinib mesylate [also] could not have been 'surprising' in 2000 (when it submitted its second patent application) because Novartis (and its predecessors) had been testing and investigating the β-crystal version for seven years, since at least 1993"); Appellant Reply 38 ("[I]t was not an accident that the words "new" and "surprisingly" appeared in the patent specification. Novartis had actual knowledge that these statements were false . . . .").

[14] *See supra* note 8.

[15] *Id.*

law. The issuance of many patents, particularly in the area of pharmaceuticals, turns on representations that a particular formulation was surprising.[16]

Nor can the conflict with other patent law be avoided by narrowing the Panel's ruling to Novartis's specific use of the term "surprising" in the '051 patent application. Novartis's representations in its '051 application are no less detailed than those other pharmaceutical companies routinely include in their patents when they claim it was "surprising" or "unexpected" to create or discover a particular crystal form.[17]

Novartis was not merely asserting the non-obviousness of its patent; it was making a *factual* representation to the PTO that its formation of β-crystal and the properties of that crystal were surprising. Novartis used the word "surprising" to invoke a long line of precedent enabling a patentee to overcome a prima facie case

---

[16] *See supra* note 7.

[17] *See, e.g.*, U.S. Patent No. 6,002,011 at col. 2, l. 11-23 (the inventors "discovered to everybody's *surprise* that the desired desolvation can be easily achieved"; "suspending and stirring the [monoethanolate monohydrate] crystals . . . *unexpectedly* causes a transformation of said solvate crystals into substantially solvent-free crystals."); *see Takeda Pharm. Co., v. Handa Pharms., LLC*, No. C-11-00840-JCS, 2013 WL 9853725, at *28, *31, *38 (N.D. Cal. Oct. 17, 2013) (finding that the prior art, including '011 patent and others re crystallization of lansoprazole, "would not have given rise to a reasonable expectation of success as to" obtaining a crystal form of *dex*lansoprazole.); *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 877-79 (E.D.N.C. 1993) (applicant who prosecuted patent for a crystal form of ranitidine submitted a declaration stating that crystal form 2 "can most satisfactorily be prepared and isolated . . . . This is surprising . . . ."), *aff'd*, 52 F.3d 1043 (Fed. Cir. 1995).

of obviousness.[18] And like many other applications, the "surprising" or "unexpected" representations here are coupled with (i) references to a "new" crystal and (ii) repeated contrasts to an ostensibly earlier, less functional form.

Novartis did not argue before this Court that its representations of "surprise" were mere legal argument. As a result, the litigants did not present these issues – including evidence of common pharmaceutical patent practice – to the Panel.

The Opinion's treatment of *Purdue Pharma L.P. v. Endo Pharms. Inc.*[19] is problematic for patent law. The plaintiffs presented *Purdue* as simply "one [] case" where the word "surprising" in the context of a patent prosecution can be a material factual misstatement.[20] The Opinion notes that in *Purdue*, "the applicant, by consistently representing to the Patent Office that the effects were a 'surprising discovery,' was clearly representing that the alleged effects were 'based on the results of clinical studies,' when that was not in fact true."[21] To distinguish *Purdue*, the Opinion says that, in the present appeal, the "representation at issue in Novartis's application concerns only the existence of the salt's crystalline form; it

[18] Of course, the complaint alleges Novartis knew the β-crystalline form was not surprising: conversion is either inherent or else achieved through simple laboratory techniques.

[19] 438 F.3d 1123 (Fed. Cir. 2006).

[20] Appellant Br. 71-72.

[21] Op. 22.

does not concern the form's 'effects.'"[22] For the Opinion, if an applicant's misrepresentations relate to a surprising ability to achieve a particular formulation but not its effects, "use of the word 'surprising' gives rise to no similarly misleading implication."[23]

This conflicts with patent law. Inventiveness due to surprising findings, particularly in the area of chemical arts, is not limited to showing novel effects, but spans a great many inventive possibilities, including compounds, formulations, uses, salts, and crystals, where the surprising feature is the creation of the item, not its functions.[24] While the Opinion's treatment of *Purdue* suggests otherwise, patent applicants do not get a free pass to misrepresent surprising structural results so long as they do not falsify the form's effects. While *Purdue* did involve some different facts from those here, *Purdue* underscores that statements of "surprise" appear in patent prosecutions as statements of fact to avoid obviousness rejections.

---

[22] *Id.*

[23] *Id*.

[24] *See* Irah H. Donner, *Patent Prosecution: Law, Practice, and Procedure* 3281-317 (9th ed. 2015); Shashank Upadhye, *Generic Pharmaceutical Patent and FDA Law* 14-27 (2013).

B. The Opinion conflicts with the basic patent law tenet that a patent examiner's failure to detect a misrepresentation does not excuse the patent applicant's fraud.

A patent examiner's inability or failure to detect a patent applicant's misrepresentation of fact does not excuse the patent applicant's misconduct. Under 37 C.F.R. § 1.56, patent applicants have a "duty to disclose to the [PTO] *all* information known to that individual to be material to patentability . . . ."[25] This duty is critical because patent examination is an ex parte, *non-adversarial*, proceeding. Congress and the PTO set up the patent examination process such that the patent examiner relies on the applicant to apprise her of information relevant to patentability. As the Supreme Court put it, the examiner "must rely upon [patent applicants'] integrity."[26] The Federal Circuit in *KangaROOS* explicitly *rejected* the argument that "it is neither fair nor correct to penalize the applicant if the examiner failed to carry out [his] responsibility."[27] Instead, if the elements of fraud are met, "lapse on the part of the examiner does not excuse the applicant."[28]

---

[25] 37 C.F.R. § 1.56 (a) (2000).

[26] *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949); *see also Transweb, LLC v. 3M Innovative Props. Co.*, 16 F. Supp. 3d 385 (D.N.J. 2014). ("The PTO depends on [patent applicants'] honest and forthcoming disclosure of material prior art references of which they are aware . . . ."), *aff'd*, 812 F.3d 1295 (Fed. Cir. 2016).

[27] 778 F. 2d. at 1576.

[28] *Id.*

The Opinion, however, holds that the complaint fails to allege material misrepresentations or omissions because the patent examiner was "free to assess" Novartis's statements "in light of the prior art . . . available to the examiner."[29] To do so, the Opinion invokes a line of patent case law – as set forth in *Akzo N.V. v. U.S. International Trade Commission*[30] – that the parties did not address before either the district court or this Court.

To be sure, *Akzo* stands for the proposition that if the patent applicant makes prior art available to the patent examiner, the applicant's subsequent arguments to the examiner about the import of those references ought not to be treated (in later proceedings as a form of material misrepresentation).[31] The logic is clear: the examiner has the disputed prior art in front of her, so attorney argument from the patent applicant is unlikely to mislead her. The examiner can decide whether the applicant's argument is persuasive.

The situation is entirely different when the applicant *misrepresents facts* about the unexpected properties of an invention, and when the applicant *withholds facts* about the invention's discovery from the examiner. In those situations, the

[29] Op. 21.

[30] 808 F.2d 1471, 1482 (Fed. Cir. 1986).

[31] *Id.*

examiner is free to accept the representations as true and does not investigate the existence of facts withheld from her.

The complaint here alleges the patent examiner did not have all the necessary information before her. It alleges Novartis failed to disclose, as was its duty, that it produced the β-crystalline form of imatinib mesylate in the early 1990s, either through simple laboratory techniques or else through inherent conversion. The *Akzo* presupposition – that all relevant prior art was before the examiner – does not apply. The Board and the examiner were entitled to rely on Novartis's representation of "surprise" as truthful, to assume Novartis complied with its duty of disclosure.

By invoking the *Akzo* line of cases to excuse affirmative misstatements of fact and concealment of information critical to patentability, the Opinion conflicts with patent law that does not excuse factual misconduct before the PTO.

C. The Opinion conflicts with the basic patent law principle that the presumption of patent validity is not a form of substantive proof.

Legal presumptions do not supply evidence of substantive facts.[32] This rule applies equally to the presumption of patent validity. As the Federal Circuit has consistently explained, the presumption is not *proof* of the patent's validity.[33]

---

[32] *United States v. Ross*, 92 U.S. 281, 285 (1875).

[33] *See Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983); *Morton Grove Pharm., Inc. v. Par Pharm. Co.*, No. 04-cv-7007, 2006 WL 850873, at *11 (N.D. Ill. March 28, 2006); *see also* Kristen Dietly, *Lightening the Load:*

The Opinion, however, uses the presumption of patent validity to hold that the complaint inadequately pled objective baselessness. According to the Panel, it is "against [the] background" of the presumption of invalidity that the Panel could not see "how on this record plaintiffs can satisfy the 'objectively baseless'" prong of *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* (*PREI*).[34]

This substantive use of a procedural presumption is particularly problematic in the Rule 12(b)(6) context. The complaint pleads that in federal patent litigation, with all facts of the β-crystal disclosed, the factfinder would conclude imatinib mesylate inherently converts to the β-crystalline form (or else can be converted through routine procedures). Once accepted as true, the allegations show it was highly improbable that Novartis's patent would have withstood a validity challenge in federal court, rendering the sham claim viable. Rather than assume the truth of those subsidiary facts under Rule 12(b)(6), the Opinion uses the presumption of validity to vitiate them, even though, in the underlying patent infringement litigation the presumption would serve no substantive evidentiary purpose.

Whether the Burden of Proof for Overcoming a Patent's Presumption of Validity Should Be Lowered, 78 Fordham L. Rev. 2615, 2628-29 (2010).

[34] 508 U.S. 49 (1993).

The Opinion's use of the presumption also misapprehends the proper *PRE* analysis. Under *PREI*, the issue is not whether the patent was nonobvious before the PTO (on the facts provided to it by the applicant). Instead, the issue is whether before a court, after full patent litigation proceedings, there was a realistic potential the factfinder would uphold the patent's validity. Sham litigation analysis presumes the factfinder has all relevant evidence – here, that Novartis concealed that imatinib mesylate inherently converts to the β-crystalline form (or converts through routine procedures). Since the allegations presumed to be true show the patent was procured by fraud, the presumption of validity cannot rebut the allegations.

D. The Opinion misapprehends the import of the Board ruling in two vital respects.

At two critical junctures, the Opinion misapprehends the import of the Board's decision to reverse and remand the examiner's original rejection of Novartis's '051 patent application as anticipated or obvious over the original imatinib compound patent.

The Board reversed the examiner's initial rejection based on procedural shortcuts taken by the examiner. As to anticipation, the examiner failed to provide "some evidence or scientific reasoning" before she required Novartis to prove the

β-crystal is not an inherent feature of imatinib mesylate.[35] In so holding, the Board expressed no opinion as to whether the β-crystal is actually an inherent feature of imatinib mesylate.[36] As to obviousness, the Board faulted the examiner for invoking a *per se* rule of obviousness.[37] In so holding, the Board said nothing about the new polymorphic form's patentability.

The Opinion misapprehends the import of the Board decision. First, the ruling uses the Board's decision as substantive evidence of a prior determination of obviousness, stating "in light of the fact that the [PTO] issued the patent following the Board's earlier ruling reversing the patent examiner's rulings as to anticipation and obviousness" it could not see how the complaint could allege objective baselessness.[38] But the Board's procedural ruling was not a decision on the merits of the application; it would play no role at all in later court proceedings over the validity of the patent. Thus, it cannot serve as evidence of non-obviousness—either in the trial of the underlying patent litigation or in the assessment of the pleadings of this antitrust case. Nor does the examiner's ultimate grant of the patent provide evidence of non-obviousness to counter the allegations here, just as that grant

[35] ADD-044.

[36] ADD-043-44.

[37] ADD-044-45.

[38] Op. 27.

would play no evidentiary role in patent litigation contesting the validity of the patent.

Second, the Opinion overlooks the import the Board's decision has in conclusively demonstrating that Novartis's "surprising" representation was material. The Board reversed the examiner's rejection precisely because Novartis claimed "surprise" in the creation of the β-crystal. Indeed, the Board quoted *that specific representation* back to the examiner – in explaining her procedural, burden-shifting error – as the basis for holding the applicant had asserted facts sufficient to state a case of non-obviousness. No clearer case of material misrepresentation can be pled.

Finally, the Opinion appears to make new law based on a misapprehension of the absence of conflicting law. The decision states that "the plaintiffs have not identified a single precedent that permitted an antitrust 'sham' litigation claim to go forward based on an allegation that the infringement litigation was objectively baseless because the underlying patent was alleged to be invalid due to anticipation or obviousness."[39] But that is not the case. *Multiple* courts have permitted "sham" theories to go forward based on allegations the infringement litigation was

[39] Op. 30.

objectively baseless due to obviousness of the underlying patents.[40] The purchasers cited these cases in their opening appellate brief and/or before the district court.[41]

The Opinion's sweeping ruling that future antitrust plaintiffs cannot adequately plead sham based on manifestly obvious or anticipated patents misapprehends the state of the law. It misapplies the non-substantive presumption of validity. And it overlooks that the *PREI* analysis looks to what would happen in a court after full discovery, not to what did happen before the PTO in an *ex parte* proceeding where the applicant misrepresented facts and omitted materially dispositive information.

III. CONCLUSION

We respectfully request rehearing.

Dated: September 14, 2018

Respectfully submitted,

/s/ Thomas M. Sobol
Thomas M. Sobol (BBO #471770)

---

[40] *See In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 345, 348-49 (D.R.I. 2017) (upholding sham theory based, in part, on invalidity due to obviousness); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-MD-2343, 2013 WL 2181185, at *18 (E.D. Tenn. May 20, 2013) (invalidity due to anticipation and obviousness); *In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, 2014 WL 4988410, at *10-11 (D.N.J. Oct. 6, 2014) (denying motion to dismiss as to the plaintiffs' *Walker Process* claims and, inferentially, their sham litigation based, in part, on the invalidity of method-of-use claims (*see* Direct Purchaser Class Plaintiffs' Second Amended Consolidated Class Action Complaint and Jury Demand ¶ 259, *In re Effexor XR Antitrust Litig.*, 3:11-cv-05479, ECF No. 287 (D.N.J. Oct. 23, 2013))).

[41] *See* Appellant Br. 47; Pls.' Opp'n 18 n.115.

Kristen A. Johnson (BBO #1153285)
Hannah W. Brennan (BBO #1181216)
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Tel.: (617) 482-3700
Fax: (617) 482-3003
tom@hbsslaw.com
hannahb@hbsslaw.com

Counsel for the End Payer Purchaser Appellants

John D. Radice (BBO #1148856)
RADICE LAW FIRM, P.C.
34 Sunset Blvd
Long Beach, NJ 08008
Tel.: (646) 245-8502
Fax: (609) 385-0745
jradice@radicelawfirm.com

Noah Rosmarin (BBO #630632)
ADKINS, KELSTON & ZAVEZ, P.C.
90 Canal Street, Suite 500
Boston, MA 02114
Tel.: (617) 367-1040
Fax: (617) 742-8280
nrosmarin@akzlaw.com

Counsel for the Direct Purchaser Appellant

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 40, the appellants certify that the foregoing consolidated brief is in 14-point Times New Roman proportional font and contains 3,890 words. It is thus in compliance with the type-volume limitation set forth in Federal Rule of Appellate Procedure 40 and First Circuit Local Rule 40.

CERTIFICATE OF SERVICE

I hereby certify that, on this date, the foregoing document was served by filing it on the court's CM/ECF system and additionally via electronic mail to all counsel of record.

Dated: September 14, 2018

/s/ Thomas M. Sobol
Thomas M. Sobol