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IN THE SUPREME COURT OF THE UNITED STATES

MERCK & CIE, BAYER PHARMA AG and
BAYER HEALTHCARE PHARMACEUTICALS INC.,
Applicants,

v.

WATSON LABORATORIES, INC.,
Respondent.

APPLICATION OF MERCK & CIE, BAYER PHARMA AG, AND BAYER HEALTHCARE PHARMACEUTICALS INC. FOR IMMEDIATE STAY OF ACTION PENDING APPELLATE REVIEW

DIRECTED TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, applicants state as follows:

Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. are wholly owned subsidiaries of Bayer AG, a publicly held company.

Merck KGaA is a publicly held company that owns more than 10% of Merck & Cie.

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TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Pursuant to Supreme Court Rule 23.1 and 28 U.S.C. § 2101(f), Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Applicants") respectfully seek a stay pending Applicants' forthcoming petition for a writ of certiorari, which is due on October 12, 2016. The Federal Circuit denied Applicants' petitions for rehearing and rehearing en banc on Friday, July 15, 2016, and Applicants filed a request for a stay the next business day, July 18, 2016. The Federal Circuit denied the stay request on July 19, 2016. Absent a stay, the mandate will issue this Friday, July 22, 2016, causing Applicants significant irreparable harm.

INTRODUCTION

Once again, the Federal Circuit has disregarded Supreme Court precedent and statutory text. This time, the mistaken decision arises in the context of the "on sale" bar, *see* 35 U.S.C. § 102(b) (2006), which precludes patenting inventions that have been "on sale" for over a year. For almost two centuries, this Court and Congress have repeatedly recognized that the "on sale" bar applies only to sales, or offers for sale, that were made *to the public*. Confidential transactions and negotiations—which patent holders necessarily conduct with wholesalers, manufacturers, and other participants in the supply chain before bringing a product to market—do not trigger the bar.

The Federal Circuit, however, has taken an entirely different approach. In the decision below, the court held that a confidential transaction constituted an

offer for sale, and on that basis, invalidated the patent claim at issue. Leaving no doubt as to where the court stood, it contemporaneously held in an en banc decision in another case that confidentiality is only a "factor" to be considered. The Federal Circuit reached this erroneous conclusion despite this Court's clear precedent rejecting the "totality of the circumstances" test for the on-sale bar, *see Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55 (1998), and despite a brief from the Department of Justice, which persuasively explained that the bar applies only to *public* sales or offers.

The consequences of the Federal Circuit's errant decision are likely to be severe. As with Applicants, inventors often do not have the manufacturing or marketing capabilities to launch their products to the public on their own. Obtaining the assistance of other firms is crucial and customary. But, under the Federal Circuit's decision, every inventor who has taken such steps now has a black cloud hanging over its patents, requiring litigation and a *post hoc* judicial assessment of "factors" that remain largely unidentified.

Further, Applicants here face significant irreparable harm. As explained in the attached declaration, the introduction of generic competitors will immediately diminish Applicants' sales to as little as one-tenth of the current amount, and will permanently genericize the market, whether or not Applicants ultimately prevail in this suit. And while the amount of harm is significant and irreversible, the losses are not easily calculable, rendering money damages an inadequate substitute for a stay.

Only this Court can fix the Federal Circuit's misguided decision, which contradicts this Court's precedents, the text of the statute, and the views of the Department of Justice. Accordingly, Applicants respectfully request a stay pending the forthcoming petition for a writ of certiorari.

OPINION BELOW

The Federal Circuit's order denying the Applicants' Petition for Rehearing and Rehearing En Banc is unpublished and may be found at Ex. A. The Federal Circuit's Opinion in this case is reprinted at Ex. B. Applicants filed a motion to the Federal Circuit to stay its mandate on July 18, 2016. The Federal Circuit's order on July 19, 2016 denying that stay motion is reprinted at Ex. C.

JURISDICTION

This Court has jurisdiction over this Application pursuant to 28 U.S.C. §1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS

Pertinent constitutional, statutory, and regulatory provisions are reprinted at Ex. D.

BACKGROUND

A. Factual Background

In 1997, Applicants invented a crystalline calcium salt form of 5-methyl-(6S)-tetrahydrofolate ("MTHF") that has unique properties and therapeutic benefits. MTHF is sold under the tradename Metafolin® and is used in the manufacture of the oral contraceptives Safyral® and Beyaz®. Applicants filed for a patent of this invention on April 17, 2000, and on August 27, 2002 Applicants were issued U.S.

Patent No. 6,44,168 ("the '168 Patent"), claim 4 of which protected the invention of Metafolin®.

Shortly after inventing Metafolin®, Applicants, like many other foreign inventors who wish to bring their products to market in the United States, investigated potential arrangements with American companies that could help promote Metafolin®. By the end of 1997, Applicants began preliminary discussions with Weider Nutrition International, Inc. ("Weider"), to potentially co-develop commercial uses for Metafolin®. After a brief initial meeting between Applicants and Weider, Applicants suggested that both companies should sign a confidential disclosure agreement ("CDA") before engaging in more detailed discussions. Both companies signed the agreement in February 1998.

Applicants and Weider engaged in continued negotiations, working toward an exclusive supply arrangement wherein Weider would act as Applicants' strategic partner in marketing Metafolin® to the United States. But, by August 1998 Weider decided not to proceed with this joint venture and the parties shifted to discussing alternative arrangements. Weider remained interested in Metafolin® and initiated negotiations to purchase two kilograms of the product. Shortly thereafter, Applicants' sent Weider a fax about its interest in a launch supply of Metafolin®, containing details about the product, including the potential price, as well as delivery and payment terms. Weider responded indicating that it would send a purchase order after receiving additional information.[1]

[1] It remains unclear whether Weider ever sent a purchase order for the two kilograms.

While a number of issues were being sorted out regarding the potential sale, Applicants and Weider continued to discuss projects they could start together. But, by January 1999 it was clear to both companies that the potential venture would not be fruitful and they parted ways. Ultimately, Weider never purchased any Metafolin®.

More than a year later, in April 2000, Applicants filed their patent application, which was granted. Applicants made their first sale of Metafolin® in January 2002.

B. Procedural Background

In December 2011, Watson Laboratories, Inc. ("Watson") filed with the FDA two Abbreviated New Drug Applications ("ANDAs"), seeking to manufacture and sell generic versions of Safyral® and Beyaz®. To protect their patent, Applicants filed an infringement suit against Watson in the United States District Court for the District of Delaware. Watson defended by claiming that Applicants' patent was invalid under § 102(b) of the Patent Act, which bars the patenting of inventions that were "on sale" or offered for sale in the United States for more than one year prior to the date of the patent application. 35 U.S.C. § 102(b) (2006). The premise of Watson's argument was that Applicants had made an offer to Weider in 1998, more than a year before the patent application in April 2000. In response, Applicants explained that their confidential discussions with Weider did not give rise to a commercial offer for sale that would trigger the on-sale bar.[2]

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[2] The district court found that the confidentiality agreement between Applicants and Weider indisputably applied to the fall 1998 communications, which form the basis of the

The district court sided with Applicants, and held that their patent was not invalid. The district court found that the CDA governed the interactions between Applicants and Weider and that the CDA's terms precluded any offer for sale stemming from the indefinite discussions between the parties. *See Merck & Cie v. Watson Labs., Inc.*, 125 F. Supp. 3d 503, 510 (D. Del. 2015).

Watson appealed the district court's decision, and the Federal Circuit reversed. The panel deemed the patent invalid under the on-sale bar because Applicants' discussions with Weider constituted a "premature commercial exploitation of its invention." *Merck & Cie v. Watson Labs., Inc.*, Nos. 2015-2063, -2064, slip op. at 14 (Fed. Cir. May 13, 2016). The panel assumed that the contractual confidentiality agreement governed the transaction, *see id.* at 13, but found that the discussions with Weider were nevertheless within the scope of § 102(b)'s on-sale bar.

Applicants filed a timely petition for panel rehearing and rehearing en banc, emphasizing that the panel decision was contrary to Supreme Court precedents, which require any invalidating sale under § 102(b) to be available *to the public*. As

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"offer for sale" of two kilograms of Metafolin®. *See Merck & Cie v. Watson Labs., Inc.*, 125 F. Supp. 3d 503, 509-10 (D. Del. 2015). While the Federal Circuit expressed some hesitation accepting that conclusion, it ultimately assumed *arguendo* that the confidentiality agreement applied and rendered its decision without displacing the district court's fact-finding. *See Merck & Cie v. Watson Labs., Inc.*, Nos. 2015-2063, -2064, slip op. at 13 (Fed. Cir. May 13, 2016). Moreover, the panel could not have possibly upset the district court's findings on the applicability of the confidentiality agreement. On appeal, Watson never argued that the potential two-kilogram transaction fell outside the scope of the confidentiality agreement, and at oral argument conceded as such. Combined with the fact that Watson unsuccessfully argued that same issue in the district court, Watson "clearly understood the issue, but simply never made the argument," thereby waiving the issue by failing to raise it in its opening brief. *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 833 (Fed. Cir. 2010).

Applicants explained, given the confidential nature of the discussions with Weider, the on-sale bar is inapplicable. The Federal Circuit denied both petitions on July 15, 2016.

C. En Banc Decision in *The Medicines Company*

Contemporaneous with this litigation, the Federal Circuit en banc addressed the on-sale bar in *The Medicines Company v. Hospira, Inc.*, Nos. 2014-1469, -1504 (Fed. Cir. July 11, 2016), which likewise raised the question of whether § 102(b) applies to confidential transactions between a patent owner and a third party. In that case, the third party was a manufacturer whom the inventor sought out to manufacture its product.

After the oral argument, but prior to the Federal Circuit opinion in the case here, the United States submitted an amicus brief in *The Medicines Company* at the invitation of the Court of Appeals. The United States argued—just like Applicants do here—that the Supreme Court has consistently interpreted § 102(b) to require a *public* sale or offer for sale. The on-sale bar does not apply if "the invention was never made available for sale to the public." *See* En Banc Brief for the United States as Amicus Curiae in Support of Appellant at 2, *The Medicines Co. v. Hospira, Inc.*, Nos. 2014-1469, -1504 (Fed. Cir. Mar. 2, 2016) ("U.S. Amicus Br."). So long as the transactions between two parties are "confidential and exclusive, such that no member of the public could have purchased the drug product," the drug remained patentable. *Id.* Because the United States also believed that the Federal Circuit "in several instances [had] concluded that the on-sale bar was triggered by ... sales made under contractual commitments of exclusivity and confidentiality," it urged

the Court of Appeals in *The Medicines Company* to "overrule its decisions interpreting the on-sale bar to reach non-public sales." *Id.* at 17, 18.

On July 11, 2016, approximately one month after Applicants filed their rehearing petitions in the present case, the Federal Circuit rendered its en banc opinion in *The Medicines Company*. The Court of Appeals held that the inventor's patent was not invalid under the on-sale bar because the transactions between the inventor and the third-party manufacturer did not constitute a "commercial sale" of the invention. *The Medicines Co.*, slip op. at 19. The Federal Circuit focused primarily on the fact that the transaction involved the sale of a manufacturing process to the inventor, and that title to the invention itself did not change hands. *See id.* at 20-24. However, the court also reaffirmed its prior decisions holding that confidential transactions *could* invalidate patents. According to the Federal Circuit, confidentiality is only "a factor" in determining whether a transaction constitutes a sale or offer for sale in the § 102(b) analysis, *see id.* at 24-25, rejecting the position of the Department of Justice.

ARGUMENT

This Court is authorized to issue a stay "for a reasonable time to enable the party aggrieved to obtain a writ of certiorari." 28 U.S.C. § 2101(f). The Court may issue a stay if there is "(1) 'a reasonable probability' that this Court will grant certiorari, (2) 'a fair prospect' that the Court will then reverse the decision below, and (3) 'a likelihood that irreparable harm [will] result from the denial of a stay.'" *Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers) (quoting *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers)).

Additionally, "in a close case it may be appropriate to 'balance the equities'—to explore the relative harms to applicant and respondent, as well as the interests of the public at large." *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers). Finally, when gauging irreparable harm, the Court must assume that the applicant's position on the merits is correct. *Planned Parenthood of Se. Pa. v. Casey*, 510 U.S. 1309, 1312 (1994) (Souter, J., in chambers).

Under this standard, the Court should issue a stay. First, Applicants are likely to prevail on the merits because the Federal Circuit's decision conflicts with this Court's precedents. This Court has long interpreted § 102(b)'s "on sale" requirement to include only sales or offers for sales that make the invention available *to the public*. By applying the on-sale bar to confidential discussions between two parties, the panel decision directly contradicts this Court's repeated insistence over the past 180 years that an invalidating sale or offer must have placed the invention in the public's hands, such that the original inventor cannot take it back. Discussions between two parties subject to a confidentiality agreement are not sufficiently "public" and therefore cannot trigger the bar. Accordingly, Applicants' petition has a reasonable probability of being granted and a fair prospect of prevailing on the merits.

Second, Applicants face substantial and irreparable harm without a stay of the Federal Circuit's mandate. As explained in the attached expert declaration, the very introduction of generic versions of Safyral® and Beyaz® by Watson would trigger events in the market for oral contraceptives that will have irreversible

effects, causing Applicants to lose upwards of 80-90% of their sales of Safyral® and Beyaz®. These losses (and others) would persist even if Watson were eventually enjoined from selling its generics.

Finally, comparing the relative hardships of the Applicants and Watson, Applicants face much more severe harms absent a stay than Watson would face by delaying the launch of its generics. Moreover, as this Court, Congress, and even the Federal Circuit have all recognized, the public benefits greatly when the law of patents encourages inventors to undertake the massive research and development costs necessary for scientific innovation.

I. APPLICANTS' PETITION FOR CERTIORARI HAS A REASONABLE PROBABILITY OF BEING GRANTED, AND APPLICANTS HAVE MORE THAN A FAIR PROSPECT OF PREVAILING ON THE MERITS.

The Federal Circuit erroneously decided an important federal question in direct conflict with this Court's precedent, the statutory text, and the position of the United States. It is thus more than reasonably probable that Applicants' petition will be granted and that Applicants will prevail on the merits. As the United States argued in *The Medicines Company*, confidential discussions do not trigger the on-sale bar of § 102(b). The Federal Circuit's decision to the contrary warrants this Court's immediate review. *See* Sup. Ct. R. 10(c) (prioritizing granting such petitions when a federal appeals court "has decided an important federal question in a way that conflicts with relevant decisions" of the Supreme Court).

For almost 200 years, this Court has recognized the distinction between confidential sales and public sales, and repeatedly held that an inventor loses

patent protection "*if* he suffers the thing invented to go into *public* use, or *to be publicly sold for use,* before he makes application for a patent." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 23-24 (1829) (emphasis added). In such instances, "[h]is voluntary act or acquiescence in *the public sale* and use is an abandonment of his right." *Id.* (emphasis added).

Congress codified this legal principle when it prohibited the patenting of any invention that was "in public use or on sale" at the time the application was filed. Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119; *see also Cannon v. Univ. of Chi.*, 441 U.S. 677, 698-99 (1979) (explaining that "evaluation of congressional action ... must take into account its contemporary legal context"). Although Congress has amended and revised the patent laws, it has consistently reenacted the on-sale bar and retained the "on sale" language present in the 1836 Act. *See, e.g.*, Act of July 8, 1870, ch. 230, § 102(b), 16 Stat. 198, 201; Act of July 19, 1952, ch. 950, § 24, 66 Stat. 792, 797.[3]

Following Congress's enactment, this Court has repeatedly interpreted this statutory language to trigger the on-sale bar only upon *public* sales or offers for sales, consistent with the Court's original articulation of the principle in *Pennock*. For example, in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878), this Court stated that so long as the inventor "does not voluntarily allow

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[3] Congress amended 35 U.S.C. § 102 in 2011 as part of the America Invents Act ("AIA"). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285-87 (2011). Because the '168 Patent application was filed in 2000, this case must be resolved under the pre-AIA version of the statute. Nevertheless, as discussed *infra*, the AIA retains the "on sale" language and its revisions only confirm that "on sale" means a sale or offer for sale that makes an invention available to the public.

others to make it and use it, and so long as it is not *on sale for general use*, he keeps the invention under his own control, and does not lose his title to a patent." *Id.* at 135 (emphasis added). However, if the inventor allowed his invention "to be used by other persons generally [or] put on sale for such use," the invention "will be in public use *and on public sale*, within the meaning of the law." *Id.* (emphasis added).

Likewise, in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), this Court emphasized that "[f]rom the Patent Act of 1790 to the present day, the *public sale* of an unpatented article has acted as a complete bar" to patenting an "idea embodied in the article thus placed in *public* commerce." *Id.* at 148-49 (emphases added). And in *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55 (1998), this Court reiterated that a "commercial offer for sale" triggers the on-sale bar because "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention." *Id.* at 67. Combining these statements from *Bonito Boats* and *Pfaff*, this Court has concluded that an invalidating offer for sale must place the article in public commerce, and therefore be made in pursuit of commercial marketing.

Moreover, Congress's most recent amendments to the patent laws in the AIA confirm that the "on sale" language of § 102(b) requires that the sale, or offer for sale, be available to the public. In the AIA, Congress revised the statute to provide that no person could validly patent an invention that was "in public use, on sale, *or otherwise available to the public* before the effective filing date." § 3(b)(1), 125 Stat. at 286 (emphasis added) (codified at 35 U.S.C. § 102(a)). The only interpretation of

this language that could possibly give effect to Congress's use of the phrase "or otherwise" entails that the preceding terms—"in public use" and "on sale"—also must make the invention "available to the public." *Cf. Williams v. Taylor*, 529 U.S. 362, 404 (2000) ("It is ... a cardinal principle of statutory construction that we must 'give effect, if possible, to every clause and word in a statute.'" (quoting *United States v. Menasche*, 348 U.S. 528, 538-39 (1955))). The legislative history of the AIA only confirms that Congress did not intend to impose any new requirements on invalidating sales. Instead, "the phrase 'available to the public' [was] added to clarify the broad scope of the relevant prior art, as well as to emphasize the fact that it must be publicly accessible." H.R. Rep. No. 112-98, pt. 1, at 43 (2011).

Only by reference to the Federal Circuit's wayward decisions can one explain why Congress would need to add clarifying language to the term "on sale" in the AIA. Despite the repeated expressions of this Court to the contrary, the Federal Circuit has issued several decisions concluding that the on-sale bar is triggered by confidential, non-public sales. *See, e.g.*, *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001) (stating that the on-sale bar would apply "even if a patentee's commercial activities took place in secret" (citing *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998))); *Brasseler U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999) (rejecting the argument that "sales activity kept secret from the trade does not trigger the on-sale bar" (citing *In re Caveney*, 761 F.2d 671, 675-76 (Fed. Cir. 1985))).

But in *Pfaff* and its preceding cases, this Court made clear that the on-sale bar—like the public-use bar—relates only to public disclosures. Both provisions stem from the same "reluctance to allow an inventor to remove existing knowledge from *public* use." *Pffaf*, 525 U.S. at 64 (emphasis added). Instead of following these precedents, however, the Federal Circuit ignored the practical effect of the confidentiality agreement between Applicants and Weider and invalidated Applicants' patent claim merely on the assertion that their alleged offer to Weider was "a premature commercial exploitation" of Metafolin®. *Merck*, slip op. at 14.

The Federal Circuit continued to misconstrue *Pfaff* in *The Medicines Company*. *Pfaff* rejected the "totality of the circumstances" standard that the Federal Circuit had regularly used in applying the on-sale bar, and instead imposed a two-step framework. *See* 525 U.S. at 67. *The Medicines Company*, by contrast, reinvigorated the "totality of the circumstances" test. Reducing confidentiality to a mere "factor" among many, *see The Medicines Co.*, slip op. at 17-19, 24-25, the Federal Circuit has smuggled a new totality-of-the-circumstances standard into the on-sale bar.

II. APPLICANTS FACE IRREPARABLE HARM ABSENT A STAY.

Under the traditional principles of equity, Applicants face significant likelihood of irreparable injury in the absence of a stay. Upon issuance of the mandate, the district court's permanent injunction against Watson will be lifted, permitting Watson to launch generic versions of Safyral® and Beyaz®. Even the Federal Circuit has repeatedly recognized that the unimpeded production of a generic drug during the pendency of an infringement suit results in harms to the

patent holder that cannot be adequately compensated by money damages. *See, e.g.*, *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1306 (Fed. Cir. 2012) (district court finding of lost market share and price erosion sufficient to show irreparable harm); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1152-53 (Fed. Cir. 2011) (irreversible price erosion, loss of market share, loss of customers, and loss of access to potential customers all favor finding irreparable harm); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (price erosion, loss of market share, and revenue loss demonstrates irreparable harm); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (expert testimony on price erosion and loss of market position is sufficient to show irreparable harm); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (potential loss of market share and threats to a movant's market position is evidence of irreparable harm); *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996) (generic entrance into the market would reduce revenues and goodwill and constitute irreparable harm); *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457 (Fed. Cir. 1988) (explaining that the federal patent laws center on the idea that future infringement "may have market effects never fully compensable in money").

Moreover, the sales lost by Applicants in competition with Watson and other potential generic manufacturers, like in any other competitive environment, are "difficult to quantify," as would be the harm to Applicants' ability to spread their brand names and goodwill to potential customers. *See Apple Inc. v. Samsung Elec. Co.*, 809 F.3d 633, 645 (Fed. Cir. 2015) (on lost sales), *cert. denied*, No. 15-1386 (U.S.

June 27, 2016); *see also Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1344 (Fed. Cir. 2013) ("Irreparable injury encompasses different types of losses that are often difficult to quantify, including lost sales and erosion in reputation and brand distinction.").

Applicants face precisely these kinds of substantial, yet not entirely calculable, losses if Watson were permitted to compete. As Dr. Christopher Vellturo's declaration explains, even if Watson's generics were removed from the market, their introduction alone would demote the "formulary position" of Safyral® and Beyaz® on numerous reimbursement schedules. *See* Vellturo Decl. Ex E, at 5-6. Additionally, because Watson's generics would likely remain in distribution channels long after Applicants prevail in this litigation, Applicants' sales of Safyral® and Beyaz® will remain compromised for some indefinite amount of time, *see id.* at 6, 15, further compounding the challenge of calculating their sales-loss-based harm. Finally, and most pressingly, Applicants' only practical response to competition from Watson would be to drastically reduce their branded volume in favor of a third-party generic launch. *See id.* at 16-18. Applicants' contract to launch a third-party generic grants Applicants no ability to retract the right to market and sell the generic, regardless of the outcome of this suit. *See id.* at 16-17. Thus, in Dr. Vellturo's expert opinion, the launch of Watson's generics will trigger the "full and irrevocable genericization" of Safyral® and Beyaz®; Applicants' difficult-to-calculate lost profits could not be restored even if they were to prevail in this litigation. *Id.* at 17-18.

Congress's choice of remedy in the Patent Act also confirms that Applicants would be irreparably harmed absent a stay of the mandate. In deciding to grant a stay, this Court has suggested that congressional judgment regarding mandatory or prohibited remedies is relevant in determining the likelihood of irreparable harm. *See Barnes v. E-Sys., Inc. Grp. Hosp. Med. & Surgical Ins. Plan*, 501 U.S. 1301, 1304 (1991) (Scalia, J., in chambers) ("In my view the Tax Injunction Act itself reflects a congressional judgment . . . that unlawful interference with state tax collection *always entails* [a] likelihood [of irreparable harm]." (emphasis added)).[4] Here, Congress provided that if a court finds infringement, it "*shall* order a permanent injunction." *See* 35 U.S.C. § 271(e)(4)(D) (emphasis added).

Watson was enjoined by the district court under this portion of the Patent Act. Contrasting this mandatory remedy with the baseline rule that federal courts have discretion in issuing injunctions in infringement cases, § 271(e)(4)(D) reflects a congressional judgment that the type of infringement at issue here *always* entails a likelihood of irreparable harm. And given the incalculable, harmful effects to any pharmaceutical company facing even the mere introduction of an infringing generic, this judgment makes complete sense. As the Court recognized in *Barnes*, the remedy that Congress chose here is a strong indicator that the harm to Applicants from Watson's generic launch is irreparable.

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[4] This Court has recently clarified that when the lower courts are given discretion by the Patent Act to issue injunctions according to the principles of equity (which require a showing of irreparable harm), they may not make broad classifications for large swaths of cases. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393 (2006). However, *eBay* was limited to the provision of the Patent Act stating that lower courts "may" grant injunctive relief consistent with principles of equity. *See* 35 U.S.C. § 283.

Ultimately, the Federal Circuit's test will irreparably harm inventors, including those in the pharmaceutical industry. Inventors of patentable products often will not have the manufacturing or marketing capabilities to publicly launch their own products. Instead, they seek to develop partnerships or joint ventures with other firms. This need is sometimes felt most acutely by foreign companies seeking to market their products in the United States. In fact, this is precisely the scenario that led Applicants to their discussions with Weider. *See Merck*, slip op. at 2-3. And in order to protect their inventions, Applicants sought to maintain secrecy through a confidentiality agreement. *See id.* at 3. The Federal Circuit's decision to apply the on-sale bar to these essential discussions is perverse. It penalizes Applicants "where [their] manufacturing is confidentially outsourced, rather than conducted confidentially in-house," U.S. Amicus Br. at 24, even though neither practice would "remove existing knowledge from public use," *Pfaff*, 525 U.S. at 64. Neither Congress nor this Court could have intended such a result.

III. THE EQUITIES BALANCE IN FAVOR OF A STAY.

Should this Court choose to balance the equities—"to explore the relative harms to the applicant and respondent, as well as the interests of the public at large," *see Rostker*, 448 U.S. at 1308 (Brennan, J., in chambers)—it is evident that they tip in favor of granting a stay. Regarding the relative balance of hardships between Applicants and Watson, Dr. Vellturo has explained that the negative effects borne by Applicants from Watson's entrance into the market would be enormous. In 2015, Applicant Bayer HealthCare Pharmaceuticals Inc. ("Bayer") had net sales of Safyral® and Beyaz® totaling approximately $90 million. Vellturo Decl.

Ex. E, at 9. Industry data indicate that Watson's launch of Safyral® and Beyaz® generics would cause Bayer to lose 80% or possibly more than 90% of its sales of those contraceptives that it would otherwise have made. *Id.* at 14. Staying the Federal Circuit's mandate would preserve the current market structure, *see Abbott Labs.*, 544 F.3d at 1362, and protect Applicants from these significant sale losses. *See Robert Bosch*, 659 F.3d at 1156 (explaining that requiring a patentee to "compete against its own patented invention, with the resultant harms" places a "substantial hardship" on that patentee). And because the "erosion of markets, customers, and prices, is rarely reversible," Applicants are unlikely to be made whole after enduring this immense hardship. *See Abbott Labs.*, 544 F.3d at 1362.

Moreover, any losses Watson might claim from delaying its launch are not only likely to be several orders of magnitude lower than Applicants' potential losses, but will deserve little weight in this Court's balancing given Applicants' likelihood of success. And any claim by Watson to lost expenses in designing and marketing its generics is an irrelevant hardship when the marketed products infringe on Applicants' patented invention. *See Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008) ("[O]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." (quoting *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986))).

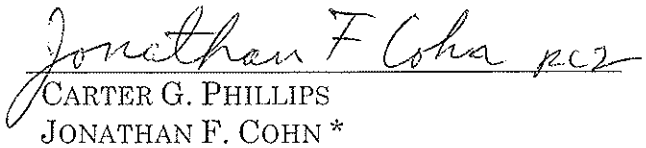
The public interest requires this Court to consider whether, "by shifting market benefits to the infringer while litigation is pending ..., the incentive for

discovery and development of new products is adversely affected." *Abbott Labs.*, 544 F.3d at 1362. The exclusionary nature of the patent right "reflects the congressional balance of interests, and warrants weight in considering the public interest." *Id.*; *see also Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) ("The patent laws promote [the] progress [of Science and useful Arts] by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development."); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir.) (explaining that the "encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude"), *modified on other grounds*, 771 F.2d 480 (Fed. Cir. 1985). As such, this Court should find that the "significant 'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents' tips the scales" even further in favor of granting a stay of the mandate. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1384 (Fed. Cir. 2006) (quoting *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 346 (S.D.N.Y. 2006)).

CONCLUSION

For the foregoing reasons, Applicants respectfully request a stay pending Applicants' forthcoming petition for a writ of certiorari.

Respectfully submitted,



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CERTIFICATE OF SERVICE

A.

Merck& Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc.,

Applicants,

v.

Watson Laboratories, Inc.,

Respondent.

I, Carter G. Phillips, do hereby certify that, on this nineteenth day of July, 2016, I caused a copy and an electronic copy of the Application Of Merck& Cie, Bayer Pharma AG, And Bayer HeathCare Pharmaceuticals Inc. For Immediate Stay Of Action Pending Appellate Review in the foregoing case to be served by first class mail, postage prepaid, and by email, on the following party:

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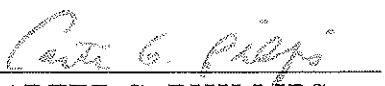

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