

LEXMARK: INTERNATIONAL PATENT EXHAUSTION*

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I. OVERVIEW

The doctrine of “patent exhaustion” provides that a patent owner on his “first sale” of his patented product loses all right to control the use or resale of that now-sold patented product. See *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U. S. 617 (2008); *Bowman v. Monsanto Co.*, 133 S.Ct. 1761 (2013). The Supreme Court in *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S.Ct. 1351 (2013) – decided less than two months prior to *Bowman v. Monsanto* – has ruled that in the case of a *copyright* the owner of that intellectual property right “exhausts” the right when his copyright-protected right is sold abroad, so that importation and use of an article purchased abroad “exhausts” the copyright. The Supreme Court has yet to issue a post-*Kirtsaeng* opinion asking whether a patent owner’s American *patent* rights are “exhausted” by the patentee’s first sale in a foreign country. An affirmative result would require a “nongeographic” interpretation of the relevant patent infringement statute. In simple terms, this would mean that there *is* “international patent exhaustion”.

A definitive ruling is on the horizon.

At some point the Federal Circuit or the Supreme Court will issue a ruling to determine whether there is a “geographic” or “nongeographic” scope to the “first sale” doctrine of patent exhaustion. A nongeographic approach would for the first time introduce international patent exhaustion into United States law and practice. The vehicle is an as yet undecided case heard in 2015 by the *en banc* Federal Circuit, *Lexmark International, Inc. v. Impression Products, Inc.*, No. 2014-1617, *unpublished* (Fed. Cir. April 14, 2015)(*en banc*)(Order granting *en banc* review). The *en banc* Court will consider whether the “nongeographic” approach for

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copyrights in *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S.Ct. 1351 (2013), should be adopted for patents:

A “nongeographic” approach would mean that the *en banc* Court would overrule the “geographic” interpretation in its leading case, *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001) (Newman, J.). Particularly if the Federal Circuit sustains the *Jazz Photo* holding, a strong possibility would then exist for grant of *certiorari* in *Lexmark* and – if review is granted – a Supreme Court ruling at some point possibly as early as 2017.

The starting point for this paper is the historic precedent from England dating back to the writings of Lord Coke nearly four hundred years ago in 1628. See § II, *Historic Roots of International Patent Exhaustion*. There is also a rich history of American precedent that should be considered. See § III, *Supreme Court Patent “Exhaustion” Case Law*. The Supreme Court has recently spoken on the topic of patent exhaustion in *Quanta Computer* and *Bowman v. Monsanto*. See § III-A, *Quanta and Bowman View of Patent “Exhaustion”*.

The Court has reiterated in *Quanta* that exhaustion occurs where *the patentee* makes the “first sale”. See § III-B, *The Patentee’s “Authorized Sale” under Quanta*.

In distinction to an authorized sale *by the patentee*, a governmentally sanctioned (and in that sense “authorized”) sale that is not by the patentee (or his licensee or other party authorized by the patentee) is not basis for exhaustion. See § III-C, *Third Party “Authorized Sale” under Boesch v. Graff*.

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Historically, the United States has taken a “geographic” view of intellectual property right exhaustion for patents and copyrights. However, in *Kirtsaeng* the Supreme Court has reached a “nongeographic” conclusion: The offshore first sale of copyright-protected material by the copyright holder *does* result in international exhaustion. See § III-D, *Kirtsaeng “Nongeographic” Exhaustion Rule*. Contemporaneously with *Kirtsaeng* the Court in the same term issued *dicta* concerning exhaustion in the *Bowman* case. See § III-E, *Bowman v. Monsanto*.

With a “nongeographic” interpretation for copyright exhaustion, should the same result apply for patent exhaustion? This is the question squarely before the *en banc* Federal Circuit where the court could go either way. No matter what decision the Federal Circuit reaches it is likely that the losing party will seek Supreme Court review. See § IV, *Should Kirtsaeng Be Followed For Patents?*

The vehicle for the Federal Circuit to rethink *Jazz Photo* is the *Lexmark* case which squarely raises the issue as to whether there is or is not international patent exhaustion. See V, *Lexmark En Banc at the Federal Circuit*. Absent settlement by the parties, it is likely that the losing party in *Lexmark* will seek *certiorari* review at the Supreme Court. See § VI, *Lexmark at the Supreme Court*. Grant of Supreme Court *certiorari* review would be enhanced, particularly if the petitioner presents a tightly crafted *Question Presented*, the Federal Circuit reaffirms *Jazz Photo* and there are multiple opinions by the Federal Circuit. Depending upon whether *certiorari* is granted or not, the final outcome in *Lexmark* may not be reached until 2017 or later.

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The pharmaceutical industry will be hit the hardest if there is a broad international patent exhaustion regime introduced into the United States. An attempt should be considered at the Supreme Court to *cabin* any international exhaustion to cases where the patentee *voluntarily* places goods on the market. See § VII, *Cabining Lexmark to Voluntary Exhaustion*.

One of the loose ends regarding exhaustion of any kind is in the area of self-replicating technology, which is only partially solved in *Monsanto v. Bowman* where the Court denied patent exhaustion in the case of second generation patented seeds, but warned that the holding of the case is strictly limited. See § VIII, *Self-Replicating Technologies*.

In the event the rule of *Jazz Photo* is overturned and the United States adopts international patent exhaustion, there are a variety of issues that need to be considered where foreign models come into play. See § IX, *Exhaustion Lessons from Other Countries*. At the outset, one must see the global picture as one where there is strong pressure from some countries for a more expansive definition of exhaustion. See § IX-A, *The “North”/ “South” Global Reality*. A starting point for an understanding of international attitudes on patent exhaustion is the first major case from a major European country reaching a conclusion of international exhaustion, the decision of the European Court of Justice more than forty years ago in the *Negram* case. See § IX-B, *The European Negram (Centrafarm) Case*. The European *Primecrown* case deals with the question whether the patent right is “exhausted” where a first sale is made by the patentee in a country *without* patent protection. See § IX-C, *Does “Exhaustion” Exist without a Parallel Patent?* The European *Pharmon* case deals with the question whether the patent right is “exhausted” where a first sale is made by a *compulsory* licensee. See § IX-D, *Does a Compulsory License “Exhaust” the Patent Right?* The Japanese *Aluminum Wheels* case deals

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with the question whether there is international patent exhaustion only if there is a failure to provide *notice* of the first patent. See § IX-E, *Does International Exhaustion Exist without Notice of the Patent?* Whatever the Supreme Court eventually does in *Lexmark*, the Executive Branch has failed in international negotiations to either provide proscriptions on international patent exhaustion or price discrimination in pharmaceuticals. See § IX-F, *The Trans-Pacific Partnership*.

II.. HISTORIC ROOTS OF INTERNATIONAL PATENT EXHAUSTION

“Patent exhaustion” is the doctrine whereby a patent owner on his “first sale” loses all right to control the use or resale of patented goods. After the patent owner has received whatever reward through the purchase price or otherwise in the first sale, the customer is then free to resell or otherwise dispose of the patented product free from the patent right. “[A]ncient common law had ordinarily forbidden a general restraint upon alienation.” *Greene v. General Foods Corp.*, 517 F. 2d 635, 649 (5th Cir. 1975)(citing 2 Coke on Littleton § 360).

The *Kirtsaeng* establishment of a doctrine of international intellectual property rights exhaustion was in the context of copyright law.

The issue in *Kirtsaeng* as phrased by the majority was “whether the ‘first sale’ doctrine applies to protect a buyer or other lawful owner of a copy (of a copyrighted work) lawfully manufactured abroad. Can that buyer bring that copy into the United States (and sell it or give it away) without obtaining permission to do so from the copyright owner? Can, for example, someone who purchases, say at a used bookstore, a book printed abroad subsequently resell it without the copyright owner's permission?” *Kirtsaeng*, 133 S.Ct. at 1355.

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The Court held that international exhaustion *does* apply: “In our view, the answers to these questions are, yes. We hold that the ‘first sale’ doctrine applies to copies of a copyrighted work lawfully made abroad. “*Kirtsaeng*, 133 S.Ct. at 1355-56.

While the *Kirtsaeng* case dealt with specific statutory language relevant to copyright law, nevertheless the majority opinion delved deeply into policy considerations including the history of the law in England:

The “first sale” doctrine is a common-law doctrine with an impeccable historic pedigree. In the early 17th century Lord Coke* explained the common law's refusal to permit restraints on the alienation of chattels. Referring to Littleton, who wrote in the 15th century, Gray, *Two Contributions to Coke Studies*, 72 U. Chi. L.Rev. 1127, 1135 (2005), Lord Coke wrote:

“[If] a man be possessed of ... a horse, or of any other chattell ... and give or sell his whole interest ... therein upon condition that the Donee or Vendee shall not alien[ate] the same, the [condition] is voi[d], because his whole interest ... is out of him, so as he hath no possibilit[y] of a Reverter, and it is against Trade and Traffi[c], and bargaining and contracting betwee[n] man and man: and it is within the reason of our Author that it should ouster him of all power given to him.” 1 E. Coke, *Institutes of the Laws of England* § 360, p. 223 (1628).

* “Lord Coke [was] widely recognized by the American colonists ‘as the greatest authority of his time on the laws of England[.]’” *Payton v. New York*, 445 U.S. 573, 594-95 (1980)(footnote omitted). “The popularity of Coke in the colonies is of no small significance. Coke himself had been at the eye of the storm in the clashes between King and Parliament in the early seventeenth century which did so much to shape the English Constitution. He rose to high office at the instance of the Crown—he was Speaker of the House of Commons and Attorney General under Queen Elizabeth, and James I made Coke first his Chief Justice of Common Pleas and then his Chief Justice of King's Bench. During this time Coke gained an unchallenged position as the greatest authority of his time on the laws of England, frequently burying an opponent with learned citations from early Year Books. Having been a champion of the Crown's interests, Coke (in a change of role that recalls the metamorphosis of Thomas a Becket) became instead the defender of the common law.” *Payton*, 445 U.S. at 594 n.36 (quoting A. Howard, *The Road From Runnymede* 118-19 (1968) (footnotes omitted).

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A law that permits a copyright holder to control the resale or other disposition of a chattel once sold is similarly “against Trade and Traffi[c], and bargaining and contracting.” *Ibid.*

With these last few words, Coke emphasizes the importance of leaving buyers of goods free to compete with each other when reselling or otherwise disposing of those goods. American law too has generally thought that competition, including freedom to resell, can work to the advantage of the consumer. See, e.g., *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 886 (2007)(restraints with “manifestly anticompetitive effects” are per se illegal; others are subject to the rule of reason (internal quotation marks omitted)); 1 P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 100, p. 4 (3d ed. 2006) (“[T]he principal objective of antitrust policy is to maximize consumer welfare by encouraging firms to behave competitively”).

The “first sale” doctrine also frees courts from the administrative burden of trying to enforce restrictions upon difficult-to-trace, readily movable goods. And it avoids the selective enforcement inherent in any such effort. Thus, it is not surprising that for at least a century the “first sale” doctrine has played an important role in American copyright law. See *Bobbs–Merrill Co. v. Straus*, 210 U.S. 339 (1908); Copyright Act of 1909, § 41, 35 Stat. 1084. See also Copyright Law Revision, Further Discussions and Comments on Preliminary Draft for Revised U.S. Copyright Law, 88th Cong., 2d Sess., pt. 4, p. 212 (Comm. Print 1964) (Irwin Karp of Authors' League of America expressing concern for “the very basic concept of copyright law that, once you've sold a copy legally, you can't restrict its resale”).

Kirtsaeng, 133 S.Ct. at 1363.

As explained by the Supreme Court in *Quanta Computer*:

“The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item. This Court first applied the doctrine in 19th-century cases addressing patent extensions on the Woodworth planing machine. Purchasers of licenses to sell and use the machine for the duration of the original patent term sought to continue using the licenses through the extended term. The Court held that the extension of the patent term did not affect the rights already secured by purchasers who bought the item for use ‘in

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the ordinary pursuits of life.’ *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1853); see also *ibid.* (‘[W]hen the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly’); *Bloomer v. Millinger*, 68 U.S. (1 Wall.) 340, 351 (1864). In *Adams v. Burke*, 84 U.S. (17 Wall.) 453 (1873), the Court affirmed the dismissal of a patent holder's suit alleging that a licensee had violated postsale restrictions on where patented coffin-lids could be used. ‘[W]here a person ha[s] purchased a patented machine of the patentee or his assignee,’ the Court held, ‘this purchase carrie[s] with it the right to the use of that machine so long as it [is] capable of use.’ *Id.*, 84 U.S. (17 Wall.) at 455.”

Quanta Computer, 533 U.S. at 625.

International patent exhaustion refers to the situation where the patentee holds parallel patents in two countries, a first sale occurs in the first country, and the purchaser then resells the patented product in the second country without further permission from the patentee.

The Federal Circuit has acknowledged the common law origins of patent exhaustion in *Lifescan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361 (Fed. Cir. 2013); and *Helferich Patent Licensing, LLC v. N.Y. Times Co.*, 778 F.3d 1293 (Fed. Cir., 2015).

In *Lifescan* the court explained:

“[T]he Court [in *Kirtsaeng*] held that the first sale doctrine in copyright law (comparable to the patent exhaustion doctrine) applies equally whether the copyrighted work is manufactured in the United States or abroad. 133 S.Ct. 1351, 1355–56 (2013). Although copyright's first sale doctrine, unlike patent exhaustion, has been codified by statute, see 17 U.S.C. § 109(a), the Supreme Court looked to the doctrine's common law roots to interpret that provision. *Kirtsaeng*, 133 S.Ct. at 1363 (‘The ‘first sale’ doctrine is a common-law doctrine with an impeccable historic pedigree.’). The Court explained that the first sale doctrine was traceable to ‘the common law's refusal to permit restraints on the alienation of chattels.’ *Id.*”

Lifescan Scotland, 734 F.3d at 1376. In *Helferich Patent Licensing v. N.Y. Times* the court stated that:

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“The role that the exhaustion doctrine has played to date—avoiding re-imposition of section 271 constraints on an authorized acquirer—reflects the doctrine's origin in common-law rules limiting servitudes, and specifically alienability restrictions, on personal property. In *Kirtsaeng v. John Wiley & Sons, Inc.*, the Supreme Court explained the ‘impeccable historic pedigree’ of the Copyright Act's express ‘first sale’ doctrine, codified at 17 U.S.C. § 109(a), which authorizes a lawful owner of a copy to sell or dispose of it without permission from the copyright owner. 133 S.Ct. 1351, 1363 (2013) (describing the doctrine as rooted in the common law's refusal to allow the seller of property to ‘control the resale or other disposition of a chattel once sold’). The common-law background, coupled with the fact that exhaustion is triggered by ‘authorized transfers of title in [the] property’ at issue, *LifeScan*, 734 F.3d at 1377, fits the doctrine's limited role to date: ensuring the continued absence of certain legal restrictions on the rights of the *transferee* (and successors) in the acquired item.”).

Helperich Patent Licensing v. N.Y. Times, 778 F.3d at 1305-06.

III. SUPREME COURT PATENT “EXHAUSTION” CASE LAW

Patent “exhaustion” has a rich history of case law dating to the nineteenth century, although the term “exhaustion” was first popularized in the 1902 *Guajako-Karbonat* decision of *Reichsgericht*: “[By a first sale by the patentee, t]he effect of the protection conferred by the patent is *exhausted*. The proprietor who has manufactured the product and has put it on the market under this protection which excludes competition from other parties, has enjoyed advantages which the patent confers upon him and has thus *exhausted* his right.” Christopher Stothers, *Patent Exhaustion: the UK Perspective*, 16th Annual Conference on Intellectual Property Law and Policy (Fordham University School of Law 2008))(quoting *Guajako-Karbonat* 51 RGZ 139 ((Reichsgericht 1902)))(“exhaustion” is the translation for “Erschopfung”)(emphasis added).

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A. *Quanta* and *Bowman* View of Patent “Exhaustion”

After the patent owner has received whatever reward through the purchase price or otherwise in the first sale, the customer is then free to resell or otherwise dispose of the patented product free from the patent right. Already by 2008 in *Quanta* the Supreme Court had signaled the importance of the exhaustion issue. See Harold C. Wegner, *Post-Quanta, Post-Sale Patentee Controls*, 7 J. Marshall Rev. Intell. Prop. L. 682, 698 (2008).

As explained by the Supreme Court in *Quanta Computer*:

“The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item. This Court first applied the doctrine in 19th-century cases ***. The Court held that [during the period of a patent term extension] the extension of the patent term did not affect the rights already secured by purchasers who bought the item for use ‘in the ordinary pursuits of life.’ *Bloomer v. McQuewan*, 55 U.S. (14 How.) 539, 549 (1853); see also *ibid.* (‘[W]hen the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly’); *Bloomer v. Millinger*, 68 U.S. (1 Wall.) 340, 351 (1864). In *Adams v. Burke*, 84 U.S. (17 Wall.) 453 (1873), the Court affirmed the dismissal of a patent holder’s suit alleging that a licensee had violated postsale restrictions on where patented coffin-lids could be used. ‘[W]here a person ha[s] purchased a patented machine of the patentee or his assignee,’ the Court held, ‘this purchase carrie[s] with it the right to the use of that machine so long as it [is] capable of use.’ *Id.*, 84 U.S. (17 Wall.) at 455.”

Quanta Computer, 533 U.S.at 625.

“Patent exhaustion” is the denial of a patentee’s right to control his patented product upon *the patentee’s* “first sale” of that product. Upon such first sale, the patentee has received his patent-keyed reward, whereupon his patent right has been “exhausted”: He no longer has any power under the patent law to control what the purchaser does with that product, whether it is to use that product himself or to sell the product to a third party. Patent exhaustion case law became well established in

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the nineteenth century: “For over 150 years [the Supreme] Court has applied the doctrine of patent exhaustion to limit the patent rights that survive the initial authorized sale of a patented item.’ *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U. S. 617, 621 (2008). ‘Under the doctrine of patent exhaustion, the *authorized sale* of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article.’” *Bowman v. Monsanto*, 133 S.Ct. at 1764 (emphasis supplied).

Thus, “[t]he doctrine of patent exhaustion limits a patentee’s right to control what others can do with an article embodying or containing an invention. Under the doctrine, ‘the initial authorized sale of a patented item terminates all patent rights to that item.’ *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 625 (2008). And by ‘exhaust[ing] the [patentee’s] monopoly’ in that item, the sale confers on the purchaser, or any subsequent owner, ‘the right to use [or] sell’ the thing as he sees fit. *United States v. Univis Lens Co.*, 316 U.S. 241, 249–50 (1942). We have explained the basis for the doctrine as follows: ‘[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward ... by the sale of the article’; once that ‘purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold.’ *Id.*, at 251.” *Bowman*, 133 S.Ct. at 1766 (emphasis added; footnote omitted)

As explained in *Aro Manufacturing Co v. Convertible Top Replacement Co*, 377 U.S. 476 (1964), the essence of patent “exhaustion” is that upon the first sale of a patented product by the patentee the patentee has received his reward, whereupon the patent right in that particular article of commerce is “exhausted. Thus, “[w]hen *the patentee* has sold the patented article or authorized its sale and has thus granted to the purchaser an ‘implied license to use,’ it is clear that he

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cannot thereafter restrict that use; 'so far as the use of it was concerned, *the patentee had received his consideration*, and it was no longer within the monopoly of the patent.' *Adams v. Burke*, 84 U.S. (17 Wall.) 453, 456 (1873). In particular, he cannot impose conditions concerning the unpatented supplies, ancillary materials, or components with which the use is to be effected." *Aro*, 377 U.S. at 497 (citations omitted).

B. The Patentee's "Authorized Sale" under *Quanta*

Sales by other than the patentee may create patent exhaustion where the sale can be traced to the patentee who has received his reward for the sale. In the wording of *Quanta*, exhaustion is triggered by an "authorized sale of a patented item [which] terminates all patent rights to that item." *Quanta Computer*, 533 U.S. at 625. The key point is that the item entered the stream of commerce where the patent owner had transferred his patent rights to that item to the purchaser, either directly (by a sale from the patentee himself) or indirectly (e.g., a sale by a licensee of the patentee).

C. Third Party "Authorized Sale" under *Boesch v. Graff*

As seen from *Boesch v. Graff*, 133 U.S. 697 (1890), a sale may be an "authorized sale" in terms of governmental sanction but this does not create patent exhaustion when the sale otherwise considered to be a patent infringement is made without consideration to the patentee.

Boesch v. Graff involved a sale of a product by the patentee's competitor authorized by a foreign government without remuneration to the patentee. The sale was thus "authorized" in the sense that it is permitted by such action, but it is not an "authorized sale" in the sense of patent exhaustion because the patentee has received no consideration for such a sale.

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What happened in *Boesch v. Graff* is that the patentee owned patents to its lamp-burner in both countries “A” (Germany) and “B” (the United States), but the patentee did not sell the lamp-burner in Country “A”. Rather, the seller in Country “A” was one Hecht, an *independent competitor* of the patentee; Hecht was able to lawfully sell the lamp-burner in Country “A” because he had defeated a patent infringement lawsuit in Germany on the basis that he had *independently* invented the lamp-burner prior to the critical date for establishment of a prior user right (a feature of German law not then found in American patent law). Thus, the dealers purchasing from Hecht sold *Hecht’s* lamp-burner in Country “B” (the United States) without permission from or reward to the patentee based upon the German national prior user right statute:

“Letters patent had been granted to the original [Graff] patentees for the invention by the government of Germany in 1879 and 1880. *** [T]he lamp-burners in question were purchased in Germany from one Hecht, who had the right to make and sell them there. By section 5 of the imperial patent law of Germany, of May 25, 1877, it was provided that 'the patent does not affect persons who, at the time of the patentee's application, have already commenced to make use of the invention in the country, or made the preparations requisite for such use.' 12 O. G. 183. Hecht had made preparations to manufacture the lamp-burners prior to the application for the German patent. The official report of a prosecution against Hecht in the first criminal division of the royal district court, No. 1, at Berlin, in its session of March 1, 1882, for an infringement of the patent law, was put in evidence; wherefrom it appeared that he was found not guilty, and judgment for costs given in his favor, upon the ground 'that the defendant has already prior to November 14, 1879,—that is to say, at the time of the application by the patentees for and within the state,—made use of the invention in question, especially, however, had made the necessary preparations for its use. Section 5, *eodem*. Thus [the Graff] patent is of no effect against him, and he had to be acquitted accordingly.'”

Boesch v. Graff, 133 U.S. at 701-02.

D. *Kirtsaeng* “Nongeographic” Exhaustion Rule

Supreme Court holdings of patent exhaustion have been in the context of a *domestic* first sale by the patentee or an “authorized sale” based upon the patent right. Does the patentee’s “first sale” in a foreign country under his foreign patent “exhaust” the patent right in the United States? Under modern terminology in *Kirtsaeng*, is there a “geographic” limitation to exhaustion so that a first sale *outside* the United States does not create exhaustion of the American patent right. Or, is the exhaustion law “nongeographic”: Does the first sale by the patentee *anywhere* in the world create exhaustion of the United States patent right? In more traditional terminology, the “nongeographic” view of exhaustion is termed “international patent exhaustion”: The patentee’s first sale in any market of a patented item exhausts the American patent right.

There is no Supreme Court holding on all fours that permits the conclusion of international patent exhaustion. But, in *Kirstaeng* – considered contemporaneously with *Bowman v. Monsanto* – the Supreme Court established a doctrine of international *copyright* exhaustion.

A critical question is whether the reasoning in *Kirtsaeng* that can be applied to patent exhaustion. Phrased differently, is there a reasoned basis to make a meaningful distinction from *Kirtsaeng* to permit a continued denial of international patent exhaustion?

In neither the patent nor copyright statute is there a textual indication whether the “first sale” exhaustion rule be based upon a “geographic” or “nongeographic” interpretation of the law. In other words, if there is a “nongeographic” interpretation of the intellectual property law, there *is* international exhaustion of the intellectual property right: Phrased differently, the

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“nongeographic” interpretation is a repudiation of the traditional view that there is no exhaustion of the right to sue for infringement in the United States where the accused product was purchased in a foreign country from the same intellectual property right holder.

In *Kirtsaeng*, the Court adopted for copyright law a “nongeographic” interpretation: The statute makes no mention whether there is exhaustion of the intellectual property right based upon a first sale keyed to the location of the first sale. In reaching a “nongeographic” interpretation, the Court thus established a rule of international exhaustion of intellectual property rights in the factual context of the Copyright Act.

1. The Factual Context of *Kirtsaeng*

In *Kirtsaeng*, copyright owner John Wiley publishes two versions of its academic textbooks, a “domestic” version at a relatively high price and a “foreign” market version at a much lower price. The lower foreign price has less to do with altruistic virtues to make its textbooks available in poorer economies, but more to do with the reality that only with a lower priced version are significant sales possible in such markets.

Thai national and accused copyright infringer Supap Kirtsaeng witnessed the reality of the pricing disparities when he spent several years in the United States pursuing higher education opportunities at Cornell University (where he gained an undergraduate degree in mathematics) and Southern California (where he earned his Ph.D.). As a condition of his scholarship funded by the Thai government, he returned home to his native country where he supported himself in part by

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purchasing the “foreign” edition in Thailand and then having them resold in the United States in competition with the “domestic” version.

2. International Exhaustion, a “Nongeographic” Interpretation

The resale raised the question answer in *Kirtsaeng*: Is the resale in the United States an act of infringement under the Copyright Act? Or, is there a denial of a rule of international exhaustion under a “geographic interpretation” of the Copyright Act? Or, should there be a “nongeographic interpretation” of the Copyright Act so that a copyright holder’s sale anywhere in the world “exhausts” the American copyright protection for that specific product?

In neither the patent law nor the Copyright Act is infringement *literally* interpreted in terms “geography”. In other words, should there be a “geographical” interpretation of either law? In terms of the Copyright Act, the Supreme Court in *Kirtsaeng* stated that “[t]he language of [the Copyright Act] read literally favors [accused infringer] Kirtsaeng's nongeographical interpretation * * *. The language of [the Copyright Act] says nothing about geography. * * * [T]he nongeographical reading is simple, it promotes a traditional copyright objective (combatting piracy), and it makes word-by-word linguistic sense.” *Kirtsaeng*, 133 S.Ct. at 1358.

In reaching a conclusion in favor of international exhaustion – or a “nongeographical” interpretation of the Copyright Law – the Court also relied upon public policy considerations: “[C]onsiderations of simplicity and coherence tip the purely linguistic balance in [accused infringer] Kirtsaeng's, nongeographical, favor.” *Kirtsaeng*, 133 S.Ct. at 1360.

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Beyond specific public policy concerns unique to copyright the Court also traced the Copyright Act to the English common law heritage applicable to both patents and copyrights:

“A relevant canon of statutory interpretation favors a nongeographical reading [which leads to a conclusion of exhaustion based upon a foreign sale]. ‘[W]hen a statute covers an issue previously governed by the common law,’ we must presume that ‘Congress intended to retain the substance of the common law.’ *Samantar v. Yousuf*, 560 U.S. 305 n. 13 (2010). See also *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952) (‘Statutes which invade the common law ... are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident’).

“The ‘first sale’ doctrine is a common-law doctrine with an impeccable historic pedigree. In the early 17th century Lord Coke explained the common law's refusal to permit restraints on the alienation of chattels. Referring to Littleton, who wrote in the 15th century, Gray, *Two Contributions to Coke Studies*, 72 U. Chi. L.Rev. 1127, 1135 (2005), Lord Coke wrote:

“‘[If] a man be possessed of ... a horse, or of any other chattell ... and give or sell his whole interest ... therein upon condition that the Donee or Vendee shall not alien[ate] the same, the [condition] is voi[d], because his whole interest ... is out of him, so as he hath no possibilit[y] of a Reverter, and it is against Trade and Traffi[c], and bargaining and contracting betwee[n] man and man: and it is within the reason of our Author that it should ouster him of all power given to him.’ 1 E. Coke, *Institutes of the Laws of England* § 360, p. 223 (1628).

“‘A law that permits a copyright holder to control the resale or other disposition of a chattel once sold is similarly ‘against Trade and Traffi[c], and bargaining and contracting.’ *Ibid.*”

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“With these last few words, Coke emphasizes the importance of leaving buyers of goods free to compete with each other when reselling or otherwise disposing of those goods. American law too has generally thought that competition, including freedom to resell, can work to the advantage of the consumer. See, e.g., *Leegin Creative Leather Products, Inc. v. PSKS, Inc.*, 551 U.S. 877, 886 (2007) (restraints with ‘manifestly anticompetitive effects’ are *per se* illegal; others are subject to the rule of reason (internal quotation marks omitted)); 1 P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 100, p. 4 (3d ed. 2006) (‘[T]he principal objective of antitrust policy is to maximize consumer welfare by encouraging firms to behave competitively’).

“The ‘first sale’ doctrine also frees courts from the administrative burden of trying to enforce restrictions upon difficult-to-trace, readily movable goods. And it avoids the selective enforcement inherent in any such effort. Thus, it is not surprising that for at least a century the ‘first sale’ doctrine has played an important role in American copyright law. See *Bobbs–Merrill Co. v. Straus*, 210 U.S. 339 (1908); Copyright Act of 1909, § 41, 35 Stat. 1084. See also Copyright Law Revision, Further Discussions and Comments on Preliminary Draft for Revised U.S. Copyright Law, 88th Cong., 2d Sess., pt. 4, p. 212 (Comm. Print 1964) (Irwin Karp of Authors' League of America expressing concern for ‘the very basic concept of copyright law that, once you've sold a copy legally, you can't restrict its resale’).

“The common-law doctrine makes no geographical distinctions; nor can we find any in *Bobbs–Merrill* (where this Court first applied the ‘first sale’ doctrine) or in § 109(a)'s predecessor provision, which Congress enacted a year later. See *supra*, at 1360. Rather, as the Solicitor General acknowledges, ‘a straightforward application of *Bobbs–Merrill* ‘ would not preclude the ‘first sale’ defense from applying to authorized copies made overseas. Brief for United States 27. And we can find no language, context, purpose, or history that would rebut a ‘straightforward application’ of that doctrine here.”

Kirtsaeng, 133 S.Ct. at 1363-64.

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E. Bowman v. Monsanto

During the same term of the Court as *Kirtsaeng* the Court gave a further explanation of patent exhaustion in *Monsanto Co. v. Bowman*, 133 S.Ct. 1761, 1766 (2013), *aff'g* 657 F.3d 1341 (Fed. Cir. 2011)(Linn, J.):

“The doctrine of patent exhaustion limits a patentee's right to control what others can do with an article embodying or containing an invention. Under the doctrine, “the initial authorized sale of a patented item terminates all patent rights to that item.” *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 625 (2008). And by “exhaust[ing] the [patentee's] monopoly” in that item, the sale confers on the purchaser, or any subsequent owner, “the right to use [or] sell” the thing as he sees fit. *United States v. Univis Lens Co.*, 316 U.S. 241, 249–250 (1942). We have explained the basis for the doctrine as follows: “[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward ... by the sale of the article”; once that “purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold.” *Id.*, at 251.

Consistent with that rationale, the doctrine restricts a patentee's rights only as to the “particular article” sold, *ibid.*; it leaves untouched the patentee's ability to prevent a buyer from making new copies of the patented item. “[T]he purchaser of the [patented] machine ... does not acquire any right to construct another machine either for his own use or to be vended to another.” *Mitchell v. Hawley*, 83 U.S. (16 Wall.) 544, 548 (1873); see *Wilbur–Ellis Co. v. Kuther*, 377 U.S. 422, 424 (1964) (holding that a purchaser's “reconstruction” of a patented machine “would impinge on the patentee's right ‘to exclude others from making’ ... the article” (quoting 35 U.S.C. § 154 (1964 ed.))). Rather, “a second creation” of the patented item “call[s] the monopoly, conferred by the patent grant, into play for a second time.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961). That is because the patent holder has “received his reward” only for the actual article sold, and not for subsequent recreations of it. *Univis*, 316 U.S., at 251. If the purchaser of that article could make and sell endless copies, the patent would effectively protect the invention for just a single sale. [Accused infringer-farmer] Bowman himself disputes none of this analysis as a general matter: He forthrightly acknowledges the “well settled” principle “that the exhaustion doctrine

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does not extend to the right to ‘make’ a new product.” Brief for Petitioner 37 (citing *Aro*, 365 U.S., at 346).

The statement quoted above is *dicta* as in the end there was a holding of *no* exhaustion of patent rights based upon a unique theory that is discussed in detail at § X, *Self-Replicating Technologies* .

IV. SHOULD *KIR TSAENG* BE FOLLOWED FOR PATENTS?

A. *Jazz Photo*, a Case of First Federal Circuit Impression

The Federal Circuit for nearly fifteen years has applied a “geographic” limitation to patent exhaustion to deny the existence of international patent exhaustion under its case of first impression, *Jazz Photo v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), in distinction to the “nongeographic” result for copyrights that the Supreme Court reached in *Kirtsaeng*.

Jazz Photo has been followed in *FujiFilm Corp. v. Benum*, 605 F.3d 1366 (Fed. Cir. 2010)(per curiam)(Michel, C.J., Mayer, Linn, JJ.); *see Fuji Photo Film Co., Ltd. v. International Trade Com'n*, 474 F.3d 1281, 1285 (Fed. Cir. 2007)(Dyk, J.)(discussing *Jazz Photo Corp. v. United States*, 439 F.3d 1344 (Fed.Cir.2006); *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368 (Fed.Cir.2005); *Fuji Photo Film Co. v. Int'l Trade Comm'n*, 386 F.3d 1095 (Fed.Cir.2004).

Jazz Photo has had a remarkable history as precedent, given the shallow treatment of the issue. It survived review in the wake of *Quanta Computer, Inc. v. LG Electronics, Inc.*, 533 U.S. 617 (2008). *See* Harold C. Wegner, *Post-Quanta, Post-Sale Patentee Controls*, 7 J. Marshall Rev. Intell. Prop. L. 682, 698 (2008).

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Given the importance of an issue of first impression at the Supreme Court first arising in the twenty-first century, it would be thought that there would have been an extensive discussion of public policy and previous case law in the deliberations by the Federal Circuit.

Instead, there is no such discussion but rather the simple statement that “[t]o invoke the protection of the first sale doctrine [of exhaustion], the authorized first sale must have occurred under the United States patent.” *Jazz Photo*, 264 F.3d at 1105. The court gives no reason but merely cites to *Boesch v. Graff* with a parenthetical statement of what it viewed as the holding of that case: “[A] lawful foreign purchase does not obviate the need for license from the United States patentee before importation into and sale in the United States.” *Id.*, citing *Boesch v. Graff*, 133 U.S. at 701-03.

But, *Boesch v. Graff* has nothing to do with international patent exhaustion, because the patentee never sold the patented product at issue so he never “exhausted” any right under any patent.

What happened in *Boesch v. Graff* is that the patentee owned patents in both countries “A” and “B”, but the patentee did not sell the Framus in Country “A”. Rather, the seller in Country “A” was an *independent competitor* of the patentee who was able to lawfully sell the Framus in Country “A” because he had defeated a patent infringement lawsuit in Germany on the basis that he had *independently* invented the Framus prior to the critical date for establishment of a prior user right. Thus, the *independent competitor* sold *his* Framus without permission or reward from the patentee based upon the German national prior user right statute.

B. Is *Jazz Photo* Good Law in view of *Kirtsaeng*?

In the area of particularly older international intellectual property rights case law there are many statements that were made that were not fully debated nor *necessary* to the decision. As such, they represent *dicta* that is nonbinding on later tribunals. (This is in contrast to a *holding* necessary for a decision, which is given greater weight.)

Boesch v. Graff is not entitled to *stare decisis* respect as to an issue of patent exhaustion. In the first instance, the holding has absolutely nothing to do with exhaustion in any way, shape or form.

As stated in *Kirtsaeng*:

“[W]e are not necessarily bound by dicta should more complete argument demonstrate that the dicta is not correct. *Central Va. Community College v. Katz*, 546 U.S. 356, 363 (2006) (‘[W]e are not bound to follow our dicta in a prior case in which the point now at issue was not fully debated’); *Humphrey’s Executor v. United States*, 295 U.S. 602, 627–28 (1935) (rejecting, under *stare decisis*, dicta, ‘which may be followed if sufficiently persuasive but which are not controlling’).”
Kirtsaeng, 133 S. Ct. at 1368.

To be sure, some Supreme Court cases have *dicta* that have been given great respect, as seen by numerous later decisions of that court that cite such cases. But, there is little if any case law from the Supreme Court or the appellate courts where *Boesch v. Graff* has been cited for its ruling relative to exhaustion since the beginning of the twentieth century.*

* Cf. *Deepsouth Packing Co v. Laitram Corp.*, 406 U.S. 518, 531 (1972) (“[W]e note that what is at stake here is the right of American companies to compete with an American patent holder in foreign markets. Our patent system makes no claim to extraterritorial effect; ‘these acts of Congress do not, and were not intended to, operate beyond the limits of the United States,’

3. As a Policy Matter, is *Jazz Photo* Sustainable?

There are many policy arguments in the academic journals that speak against the holding in *Jazz Photo*. Yet, there are also public policy reasons to support a geographical interpretation to continue the denial of international patent exhaustion, particularly in the pharmaceutical field. In pharmaceuticals the price for a patent-protected prescription drug in the United States (or Europe or Japan or other developed country) may be many times that in third world country. If there is a nongeographic interpretation of the first sale doctrine, this would mean that drugs purchased in developing countries could be brought back to the United States and sold in competition with the branded manufacturer. Unlimited sales in the developing country would open the door to such competition.

There are two reasons why pharmaceuticals would be hardest hit through a nongeographical interpretation of exhaustion. First, the cost of transportation from the developing country to the United States of a drum of say 10,000 tablets is virtually nonexistent (as compared, for example, with the transportation costs of patented “steel girders”). Second, there is a huge price differential between drugs sold in the United States versus a developing country. Should the sales price be uniform *everywhere* to eliminate price differentials to avoid parallel imports under a nongeographic interpretation? If the local developing country has price

Brown v. Duchesne, 60 U.S. (19 How.) 183, 195 (1856), and we correspondingly reject the claims of others to such control over our markets. Cf. *Boesch v. Graff*, 133 U.S. 697, 703 (1890).”); *Bourjois Co v. Katzel*, 260 U.S. 689, 692 (1923)(dictum in trademark case)(“Ownership of the goods does not carry the right to sell them with a specific [trademark]. It does not necessarily carry the right to sell them at all in a given place. If the goods were patented in the United States a dealer who lawfully bought similar goods abroad from one who had a right to make and sell them there could not sell them in the United States. *Boesch v. Graff*, 133 U. S. 697 (1890).”)

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regulations for drugs to keep the cost low, should the branded manufacturer refrain from selling in that country?

V. *LEXMARK EN BANC* AT THE FEDERAL CIRCUIT

The Federal Circuit in its series of panel opinions following *Jazz Photo* has chosen to essentially follow that opinion because it is binding precedent – unless overruled *en banc*. This rationale no longer applies in *Lexmark* because the case now *is* before the Court *en banc*.

There is simply no reasoning whatsoever given for a policy to support the position taken in *Jazz Photo*. The entire basis for the “geographical” holding is found in just twenty-one (21) words coupled with citation to *Boesch v. Graff* that is analyzed in a twenty-five (25) word snippet:

“To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent. See *Boesch v. Graff*, 133 U.S. 697, 701-03 (1890) (a lawful foreign purchase does not obviate the need for license from the United States patentee before importation into and sale in the United States).”

Remarkable.

There are essentially three options open to the Federal Circuit.

A. *Ninestar* Confirmation of *Jazz Photo*

Kirtsaeng can be factually distinguished. This is the approach that was taken in *Ninestar* to maintain *Jazz Photo* in the wake of *Quanta Computer*.

The *Ninestar* surprise was not in the holding in that case but, rather, in the fact that the Federal Circuit simply chose to ignore the issues involved with international patent exhaustion, and instead chose to parse *Quanta Computer* to draw a distinction to avoid dealing with the merits:

“*Ninestar* focuses on the ruling in *Jazz Photo Corp. v. U.S. Int'l Trade Comm'n*, 264 F.3d 1094 (Fed.Cir.2001), where this court held that United States patents are not exhausted as to products that are manufactured and sold in a foreign country, and that importation of such products may violate United States patents. As stated in *Jazz Photo*, ‘United States patent rights are not exhausted by products of foreign provenance. To invoke the protection of the first sale doctrine, the authorized first sale must have occurred under the United States patent.’ 264 F.3d at 1105. *Ninestar* states that this case and the precedent on which it relied were incorrectly decided, and were overruled by the Supreme Court in *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 632 n. 6 (2008). However, neither the facts nor the law in *Quanta Computer* concerned the issue of importation into the United States of a product not made or sold under a United States patent. In *Fujifilm Corp. v. Benun*, 605 F.3d 1366, 1371 (Fed.Cir.2010), the court remarked that ‘*Quanta Computer, Inc. v. LG Electronics, Inc.* did not eliminate the first sale rule's territoriality requirement.’ The patents, products, and methods in *Quanta Computer* all concerned products manufactured and first sold in the United States, and the Court held that method patents as well as product patents are subject to exhaustion upon sale of product or components in the United States.”

Ninestar, 667 F.3d at 1378.

The simplest factual distinction for *Jazz Photo* versus *Kirtsaeng* is that only *Jazz Photo* deals with the patent law.

B. A Supported “Geographical” Interpretation

There are many public policy reasons to support a geographical interpretation to continue the denial of international patent exhaustion, particularly in the pharmaceutical field. It remains to be seen whether there will be *amici* to raise these issues.

C. Adoption of *Kirtsaeng* for Patent Exhaustion

The final option would be for the Federal Circuit to adopt a nongeographical interpretation of the first sale doctrine and thus introduce international patent exhaustion.

VI. *LEXMARK* AT THE SUPREME COURT

A. What the Supreme Court May Do

Most likely, absent a settlement, the losing party in *Lexmark* will file a petition for *certiorari* at the Supreme Court to seek review of the Federal Circuit *en banc* decision.

It is far too early to predict whether the Supreme Court will grant such a petition. Grant of *certiorari* depends upon the affirmative vote of four of the nine members of the Court. The four (or more) voting for *certiorari* are not necessarily siding with the petition on the *merits* of the case, but only as to whether merits consideration is deserved.

Statistically, for every one hundred petitions filed for Supreme Court review, only one is granted. This means that in the case of many important matters where

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there is a solid reason for grant of review the Court will nevertheless *deny* review. For example, counsel may not have phrased a *Question Presented* that raises an issue that is *certiorari*-worthy. Or, the Court may feel that the issue is better left for another day with a more cleanly presented argument. Or, counsel at the *certiorari* stage may manifest a lack of familiarity with Supreme Court precedent and procedures, also leading toward denial of review.

Factors that would *favor* grant of review would include a divided Federal Circuit: If the *en banc* Court splits into two camps with sharply crafted dissents (particularly with an equally sharply worded rebuttal in the majority opinion), this factor further leads toward a grant of *certiorari*.

It is unlikely that the Federal Circuit will simply rubber stamp *Jazz Photo* without reasons other than a *Ninestar* approach to explain that *Jazz Photo* relates to patent law while *Kirtsaeng* relates to copyright law. Particularly if there is a split opinion by the Federal Circuit, the *Ninestar* approach would push the needle toward grant of *certiorari*.

If there is reasoned policy-based support for a unique basis to maintain a nongeographical exhaustion practice for patents to distinguish the policy and other reasons for the opposite result in *Kirtsaeng*, there would still be a chance that *certiorari* would be granted.

Finally, if the Federal Circuit *overrules* the holding in *Jazz Photo* and adopts international patent exhaustion, then it would be far less likely that the Supreme Court would grant review: The conflict between *Jazz Photo* and *Kirtsaeng* would have been dissipated by such a ruling

B. Impact on the Pharma Industry

One may assume, *arguendo*, that international exhaustion makes sense for copyrights and for patents in the largely *unregulated* industries. The copyright holder and the patentee in the largely *unregulated* areas has the choice where to market a product and what price to set for that product. As part of a free market where the patentee can set his own price for his patented goods, one can follow the rationale of *Kirtsaeng* and apply an international exhaustion rule.

The situation particularly in the pharmaceutical field has nuanced issues due to the nature of the product and, perhaps more importantly, due to the heavy regulation and government controls over the marketing of pharmaceuticals.

In terms of the nature of the product, consider the issue of parallel imports of “cement bricks” versus pharmaceutical tablets. Even if there is a significant price differential between the country of first sale “A” and the market of parallel import resale in the second country “B”, if the patented item is a “cement brick” the transportation cost should wipe out any price differential for a parallel import: Parallel importation makes no sense for patented “cement bricks”. But, if the patented item is a drum of 75,000 tablets of a patented pharmaceutical, the entire shipment could be flown over the ocean in a “suitcase”: There is *de minimis* transportation cost so the incentive to buy pharmaceuticals in lower priced country “A” and resell in country “B” makes sense even with a small price differential.

But, in the pharmaceutical field, there *is* an often huge price differential amongst countries. At the upper end of the price scale stands the United States, while there are numerous countries with lower end prices where it would make

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good sense to purchase pharmaceuticals in developing country “A” and then resell the pharmaceuticals in the United States – country “B”.

Unlike the unregulated sale of “cement bricks”, patented pharmaceuticals are *highly* regulated even amongst developed countries. For example, the *Koseisho* in Japan has varying price scales for reimbursement to patients that discriminates against drugs that to some extent are not breakthroughs permitting new or better therapies. Other countries simply have far more stringent laws to cut back the prices for pharmaceuticals. Other countries have compulsory licenses in their statutory provisions where the patentee is a “licensor” of the patented pharmaceutical, but, indeed, an unwilling licensor who has only consented to permit generic licensees to compete because of statutory provisions.

If *Lexmark* at the Supreme Court results in the broad adoption of international patent exhaustion without taking into account the special circumstances of the *regulated* industries, negative consequences will result:

First of all, if the patentee continues to sell its pharmaceuticals in countries with compulsory licensing or health ministries that make only small reimbursements, sales will continue to be at a much lower price than in the United States. If unlimited quantities of the patented drug are sold in such countries, then the parallel importation into the United States will squeeze the profitability of the drug product. This will in turn *decrease* the incentive to invest sometimes many millions if not billions of dollars in research and regulatory approval costs, to the detriment of the health and welfare of society that would be deprived of treatment for the still prevalent diseases not yet eradicated.

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On the other hand, the patentee could *forbear* from selling his product in developing countries, although this would be a futile gesture for countries with compulsory licensing.

C. An Uncertain Fate until 2017 or 2018

Lexmark is likely to remain alive at least until 2016 and possibly until 2017. An *en banc* Federal Circuit decision by, say, October 2015 is a likely possibility (although there is no time deadline for a decision). If there is an October 2015 decision then a *certiorari* petition by about January 2016 would be likely; this would mean a decision whether to grant *certiorari* before the June 2016 end of the October 2015 Term of the Supreme Court; an argument would then be likely in late 2016 with a merits decision before the end of June 2017.

VII. CABINING *LEXMARK* TO VOLUNTARY EXHAUSTION

Should the *Lexmark* case wind its way to the Supreme Court, and to the extent that the Federal Circuit confirms the validity of its denial of international patent exhaustion, as a fallback position the pharmaceutical industry should consider an *amicus* effort to cabin any creation of international patent exhaustion to the situation where the patentee as a *voluntary* act places a patented pharmaceutical (or other patented invention) on the market.

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An argument of this nature finds support from within the European Union where there is exhaustion of patent rights upon a first sale in any country of that territory. The case in question is *Pharmon BV v. Hoechst AG*, Case 19/84, [1985] E.C.R. 2281, where the accused infringing goods were duly licensed by the patentee, but through a *compulsory* license.

VIII. SELF-REPLICATING TECHNOLOGIES

In *Monsanto Co. v. Bowman*, 133 S.Ct. 1761 (2013), the court sustained a denial of patent exhaustion under a unique theory created *sua sponte* by the appellate court, 657 F.3d 1341 (Fed. Cir. 2011)(Linn, J.). The case had originally been brought at the trial level as a question of “exhaustion”, which was also the case in Canada in parallel proceedings in *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 SCR 902, as explained by Judge Hughes in a separate paper prepared for this conference. Hon. Roger T Hughes, *Doctrine of Exhaustion, The Canadian Experience*, The Naples Roundtable (February 15, 2016).

Unlike the Canadian *Schmeiser* case, the American Supreme Court in *Bowman* explained that patent exhaustion is denied in the case of harvested seed from plants grown from patented seed:

Under the patent exhaustion doctrine, Bowman could resell the patented soybeans he purchased from the grain elevator [grown from previously purchased, patented seed]; so too he could consume the beans himself or feed them to his animals. Monsanto, although the patent holder, would have no business interfering in those uses of Roundup Ready beans. But the exhaustion doctrine does not enable Bowman to make *additional* patented soybeans without Monsanto's permission (either express or implied). And that is precisely what Bowman did. He took the soybeans he purchased home; planted them in his fields at the time he thought best;

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applied glyphosate to kill weeds (as well as any soy plants lacking the Roundup Ready trait); and finally harvested more (many more) beans than he started with. That is how “to ‘make’ a new product,” to use Bowman's words, when the original product is a seed. Brief for Petitioner 37; see Webster's Third New International Dictionary 1363 (1961) (“make” means “cause to exist, occur, or appear,” or more specifically, “plant and raise (a crop)”). Because Bowman thus reproduced Monsanto's patented invention, the exhaustion doctrine does not protect him.

Were the matter otherwise, Monsanto's patent would provide scant benefit. After inventing the Roundup Ready trait, Monsanto would, to be sure, “receiv[e] [its] reward” for the first seeds it sells. *Univis*, 316 U.S., at 251. But in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed once, whether from Monsanto, a competitor, or (as here) a grain elevator. The grower could multiply his initial purchase, and then multiply that new creation, *ad infinitum*—each time profiting from the patented seed without compensating its inventor. Bowman's late-season plantings offer a prime illustration. After buying beans for a single harvest, Bowman saved enough seed each year to reduce or eliminate the need for additional purchases. Monsanto still held its patent, but received no gain from Bowman's annual production and sale of Roundup Ready soybeans. The exhaustion doctrine is limited to the “particular item” sold to avoid just such a mismatch between invention and reward.

* * *

Bowman principally argues that exhaustion should apply here because seeds are meant to be planted. The exhaustion doctrine, he reminds us, typically prevents a patentee from controlling the use of a patented product following an authorized sale. And in planting Roundup Ready seeds, Bowman continues, he is merely using them in the normal way farmers do. Bowman thus concludes that allowing Monsanto to interfere with that use would “creat[e] an impermissible exception to the exhaustion doctrine” for patented seeds and other “self-replicating technologies.” Brief for Petitioner 16.

But it is really Bowman who is asking for an unprecedented exception—to what he concedes is the “well settled” rule that “the exhaustion doctrine does not extend to the right to ‘make’ a new product.” See *supra*, [133 S.Ct. at 1766]. Reproducing a patented article no doubt “uses” it after a fashion. But as already explained, we have always drawn the boundaries of the exhaustion doctrine to exclude that activity, so that the patentee retains an undiminished right to prohibit

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others from making the thing his patent protects. See, *e.g.*, *Cotton-Tie Co. v. Simmons*, 106 U.S. 89, 93–94 (1882) (holding that a purchaser could not “use” the buckle from a patented cotton-bale tie to “make” a new tie). That is because, once again, if simple copying were a protected use, a patent would plummet in value after the first sale of the first item containing the invention. The undiluted patent monopoly, it might be said, would extend not for 20 years (as the Patent Act promises), but for only one transaction. And that would result in less incentive for innovation than Congress wanted. Hence our repeated insistence that exhaustion applies only to the particular item sold, and not to reproductions.

Monsanto v. Bowman, 133 S.Ct. at 1766-68 (footnote deleted).

In the parallel Canadian *Schmeiser* case the court followed the more traditional arguments concerning exhaustion. As explained by Judge Hughes, accused infringer-farmer “Schmeiser knew that the seed *** contained Monsanto’s patented gene. Schmeiser then knowingly planted that seed the next year and grew a commercial crop. Not only that, but Schmeiser had sprayed the commercial crop with Roundup to get rid of weeds, thus using the benefit of the gene. The Supreme Court held that Schmeiser had ‘used’ the patented gene and thus infringed the patent. From this decision it can be inferred that however the seed was obtained, the rights of Monsanto were not ‘exhausted’ and were infringed by the reproduction of plant material containing the patented gene....” Hon. Roger T Hughes, *Doctrine of Exhaustion, The Canadian Experience*, The Naples Roundtable (February 15, 2016).

IX. EXHAUSTION LESSONS FROM OTHER COUNTRIES

A. The “North”/ “South” Global Reality

Parallel imports of patented medicines have been a hot topic of “North-South” debates throughout this century. Developing countries in the South have created a legal infrastructure that makes it difficult to obtain and enforce pharmaceutical patents. They frequently provide a compulsory licensing system whereby drugs sold at a higher price in the “North” are sold at extremely low prices in the developing nations of the “South”. The pricing disparity has created a situation where it is an attractive business proposition for a generic pharmaceutical company to purchase a drug in the “South” and then resell that drug in “North” at higher prices, *if the patent right in the North is exhausted under a theory of international exhaustion*.

The anti-patentee drumbeat coming from the South was fueled several years ago through the WTO’s 2001 “Doha Declaration”^{*} which at ¶ 1 “recognize[s] the gravity of the public health problems afflicting many developing and least-developed countries...”. The Doha Agreement states: “The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the [most favored nations] and national treatment provisions of [TRIPS] Articles 3 and 4.” *Id.* at ¶ 5(d).

* The “Doha Declaration” refers to the *Declaration on the TRIPS agreement and public health of the World Trade Organization*, WT/MIN(01)/DEC/2 (Nov. 2, 2001), available at https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited January 6, 2016).

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The Doha Declaration special treatment of pharmaceuticals was to have expired in 2016, but in June 2015 “the World Trade Organization committee on intellectual property rights [] agreed to extend a waiver allowing [lesser developed countries] to avoid applying and enforcing IP rights on pharmaceutical products until 2033.” Catherine Saez, *LDC Pharma IP Waiver Until 2033 Approved By WTO TRIPS Council*, Intellectual Property Watch (June 11, 2015). Additionally, “the TRIPS Council decision is timely in view of the adoption by the United Nations of the Sustainable Development Goals (SDGs)... The SDG targets on health directly refer to the right to use TRIPS flexibilities, in the spirit of the Doha Declaration, to provide access to medicines for all.” *Id.*

The United States Executive branch of government has valiantly sought to curb the Doha movement but without great success. *A fortiori*, to the extent that the United States judiciary takes a position to encourage parallel importation of patented products into the United States by imposition of international patent exhaustion, it is difficult to see how undercutting of the Executive branch position will stem the parallel importation tide.

B. The European *Negram* (*Centrafarm*) Case

To be sure, it is not only the “South” that is putting pressure on permitting international exhaustion of patent rights. The major patent case to start the ball rolling toward international exhaustion of patent rights occurred in the notorious *Negram* case in 1974. See F.E. Müller & H.C. Wegner, *Negram: The Common Market-Wide Exhaustion of Patent Rights through Territorial Licenses*, 57 JOUR. PAT. & TRADEMARK OFF. SOC'Y 46 (1975)(discussing *Centrafarm BV v. Sterling Drug Inc.*, [1974] ECR 1147 (European Court of Justice 1974)). *Negram*

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involved the disparities within the European Common Market where the Dutch government permitted higher prices for patented pharmaceuticals whereas the British government permitted far lower prices for the same drugs through a scheme of statutory compulsory licenses. In *Negram* the generic seller purchased the patented product from the patentee in England at the lower price and then resold the drug in Holland free from patent infringement, thanks to the establishment of international patent exhaustion within the European Union. (*Negram* did not stand for the proposition that exhaustion occurs if the lower priced drug is purchased *outside* the European Union.)

Negram was only the beginning of ongoing disputes over parallel imports, and raises questions that are to be addressed on a country by country and region by region basis by the importing countries.

C. Does “Exhaustion” Exist without a Parallel Patent?

Is a drug purchased from Manufacturer “M” in country “A” *without* patent protection free from patents in country “B”? In *Merck & Co., Inc. v. Primecrown Ltd.*, [1996] ECR I-6285 (European Court of Justice 1996), dealing with a case at a time when Spain and Portugal had recently joined the European Union but before either country had patents to protect pharmaceuticals, the Court ruled that parallel imports of name brand drugs could be permitted to the higher priced markets of northern Europe.

D. Does a Compulsory License “Exhaust” the Patent Right?

Is a drug purchased from a compulsory licensee in Country “A” free from the parallel patent in Country “B”? It remains an open question whether drugs sold by a competitor under a compulsory license in one country “exhausts” the patent right in another for goods imported from a country with a compulsory license, a matter for each consuming country to decide. In *Pharmon v. Hoechst*, [1985] ECR 2281 (European Court of Justice 1985), the European Court of Justice has denied exhaustion in a situation where a lower priced drug was purchased from a third party manufacturer under a compulsory license which was held *not* to exhaust the patent right in the higher priced Dutch market.

E. Does International Exhaustion Exist without Notice of the Patent?

Japan, one of the most important countries of the “North” with one of the strongest patent systems in the world, has in the *Aluminum Wheels* case, Case H07 (O) No. 1988 (Japan Supreme Court 1997), adopted international patent exhaustion for purchasers without notice of the Japanese patent. An English translation is available from SOFTIC, <http://www.softic.or.jp/en/cases/BBS.html> (last visited January 6, 2016.) See H.C. Wegner, *Parallel Import Practice Restored in Japan: Negating the Implied License to Resell a Patented Product*, privately circulated analysis of the 1997 Japanese Supreme Court opinion keyed to the writer’s appearance by affidavit as expert in pleadings before the court; *Japan AIPPI Gotemba Intellectual Property Law Conference*, Gotemba, Japan, September 29-30, 1995; H.C. Wegner, *Patent Parallel Imports in Japan, Consumer Promise or Patent Peril: The Aluminum Wheels Parallel Import Case* (www.foleylardner.com) (1995);

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Japan Violation of Patent Trade Principles - Impact, Consequences and Dealing with the Decision Permitting Patent Parallel Imports into Japan, Dinwoodey Center White Paper, April 28, 1995.

F. The Trans-Pacific Partnership (TPP)

The newly completed but not yet ratified Trans-Pacific Partnership treaty represents a failure of diplomacy to positively deal with the issues of concern particularly to the pharmaceutical industry. The treaty neither proscribes international patent exhaustion nor deals with the price discrimination issues amongst nations.

1. A Mandate Permitting International Patent Exhaustion

The TPP expressly provides that a nation is free to reject international patent exhaustion. The treaty expressly provides that “[n]othing in this Agreement prevents a Party from determining whether or under what conditions the exhaustion of intellectual property rights applies under its legal system.” Trans-Pacific Partnership Article 18.11, *Exhaustion of Intellectual Property Rights* (footnote omitted).

2. Mandate for Continued Price Discrimination in Health Care

The continued ability of developing (and other) countries to provide lower costs for pharmaceuticals is underscored in the Trans-Pacific Partnership: “A Party may, in formulating or amending its laws and regulations, adopt measures necessary to protect public health ***, and to promote the public interest in sectors of vital importance to their socio-economic and technological development,

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provided that such measures are consistent with the provisions of this Chapter.”
Trans-Pacific Partnership, Article 18.3(1), *Principles*.

A country may provide “appropriate measures” for “the abuse of intellectual property rights”. More specifically, “[a]ppropriate measures, provided that they are consistent with the provisions of this Chapter, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.” Trans-Pacific Partnership, Article 18.3(2), *Principles*.

Going further, an additional loophole provides additional ways to maintain and introduce price discrimination in a provision designed “to promote access to medicines for all.” Trans-Pacific Partnership, Article 18.6(1)(a), *Understandings Regarding Certain Public Health Measures*. Thus:

“The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party’s right to protect public health and, in particular, to promote access to medicines for all. Each Party has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.” *Id.*

The Trans-Pacific Partnership further codifies recent trade agreements that have weakened the rights of patent holders:

“The Parties affirm their commitment to the Declaration on TRIPS and Public Health. In particular, the Parties have reached the following understandings regarding this Chapter: In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of August

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30, 2003 on the *Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health* (WT/L/540) and the WTO General Council Chairman's Statement Accompanying the Decision (JOB(03)/177, WT/GC/M/82), as well as the Decision of the WTO General Council of December 6, 2005 on the *Amendment of the TRIPS Agreement*, (WT/L/641) and the WTO General Council Chairperson's Statement Accompanying the Decision (JOB(05)319 and Corr. 1, WT/GC/M/100) (collectively, the "TRIPS/health solution"), *this Chapter does not and should not prevent the effective utilisation of the TRIPS/health solution.*"

Trans-Pacific Partnership, Article 18.6(1)(b), *Understandings Regarding Certain Public Health Measures*.

X. CONCLUSION

The American law and practice relating to international patent exhaustion will remain in a state of uncertainty until at least 2016 and quite possibly until 2017 or later, thanks to the factors unfolding in the *Lexmark* case.

Interested parties in the several industries impacted by international patent exhaustion should now actively consider and debate the policy issues involved that differ by industry and by interest of the various sectors of the public and the economy. While such input is important at the Federal Circuit, the views of the private sector will have greater impact in determining whether the Supreme Court ultimately grants *certiorari* to review the merits of the issue, as well as having impact on the merits result in the event *certiorari* is granted.