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## **The (Pharmaceutical) Door is Open**

In late May 2017, the Supreme Court published its decision in *Impression Products, Inc. v. Lexmark International, Inc.*<sup>1</sup> I think that this case opens the door to a wide variety of activity that at least some major industries will not like.

### **The Facts of the Case**

Lexmark International is known to many as a manufacturer of laser printers and related supplies. Among these supplies are toner cartridges. Toner cartridges contain the “ink” (in powder form) used to print images or text on paper. Toner, like paper, is a consumable in operating a printer. Typically, laser printers come with one toner cartridge. When that toner cartridge no longer has enough toner to be usable, the customer can remove that toner cartridge and replace it with a new one that is full.

But while almost any paper can be used in any laser printer, toner cartridges are typically designed to fit one or only a small number of different laser printers. Toner cartridges also tend to be fairly expensive: prices approaching \$100.00 for an individual toner cartridge are not unusual, depending in part on the amount of toner stored in the cartridge (which in turn affects how many pages can be printed before the toner cartridge needs to be replaced).

The rise of remanufacturers has presented consumers with alternative sources for toner cartridges for their laser printers. Remanufacturers acquire used toner cartridges and fill them with fresh toner, then sell the remanufactured toner cartridges to people who own laser printers. As sales by remanufacturers cut into a printer manufacturer’s profit margin, printer manufacturers, including Lexmark, prefer that their customers purchase toner cartridges from them rather than some other party.

To that end, Lexmark, like other laser printer manufacturers, has received patent protection for inventions that, among other things, relate to toner cartridges. These patents cover varying technologies, including technology that limits how toner cartridges can be used. For example, the toner cartridges can include a microchip that synchronizes itself with a specific laser printer: if the toner cartridge is later installed in another laser printer, the toner cartridge can refuse to work with the other laser printer.

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<sup>1</sup> *Impression Prods. Inc. v. Lexmark Int’l, Inc.*, 581 U.S. \_\_\_\_ (2017).

When Lexmark would sell a toner cartridge to a customer, Lexmark would offer the customer a choice. The customer could pay full price and own the toner cartridge outright: the customer could do anything he wanted with the toner cartridge, including sell the toner cartridge to a remanufacturer. Or the customer could purchase the toner cartridge through Lexmark's "Return Program". Under Lexmark's "Return Program", the customer promised to transfer ownership of the toner cartridge only to Lexmark, and not to anyone else. In exchange for this promise, the customer was permitted to purchase the toner cartridge at a discounted price. And to help enforce this promise, the toner cartridge sold by Lexmark included a microchip that prevented reuse of the toner cartridge when the toner in the toner cartridge ran out.

Some remanufacturers developed solutions to the technological barriers that prevented toner cartridge reuse, such as the microchip described above. With that problem addressed, the remanufacturers, such as Impression Products, felt free to purchase "Return Program" cartridges, remanufacture them, and sell them to customers. After all, any promise Lexmark had received from its customer would not be binding on the remanufacturer.

Not willing to give up without a fight, Lexmark sued a number of remanufacturers for selling remanufactured toner cartridges. Lexmark had two theories to its case. The first theory was that by remanufacturing "Return Program" toner cartridges that Lexmark had sold in exchange for the customer's promise to sell the toner cartridges to Lexmark alone, the remanufacturers were infringing Lexmark's patent rights<sup>2</sup>. The second theory was that by importing into the U.S. remanufactured toner cartridges sold in other countries (whether or not sold under the "Return Program"), the remanufacturers were again infringing Lexmark's patent rights. Eventually, the lawsuit between Lexmark and the remanufacturers was reduced to a single defendant—Impression Products—and a single defense: that Lexmark had exhausted its patent rights<sup>3</sup> by selling the toner cartridges<sup>4</sup>.

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<sup>2</sup> "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent" (*see* [35 U.S.C. § 271](#)).

<sup>3</sup> Patent exhaustion, in simple terms, holds that once a patent holder sells a product that is covered by a patent, that sale prevents the patent holder from asserting any patent rights against any use of the product.

<sup>4</sup> Although the Supreme Court decision implies Impression Products (or other remanufacturers) had asserted other defenses, the Supreme Court decision does not indicate what those defenses were or why they were dropped from the case.

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## The Lower Court Decisions

Before the District Court, Impression Products filed motions to dismiss Lexmark's case under both theories. The District Court granted Impression Products's motion with respect to the "Return Program" toner cartridges sold in the U.S., but denied the motion with respect to Lexmark's toner cartridges sold internationally. Both Lexmark and Impression Products appealed this decision.

The Federal Circuit heard the appeal *en banc*<sup>5</sup>, and ruled in favor of Lexmark on both motions. With respect to the "Return Program" toner cartridges, the Federal Circuit decided that Lexmark was within its rights to limit what the customer could do with the "Return Program" toner cartridges, and that those limits prevented Lexmark's patents from being exhausted. With respect to the foreign toner cartridges, the Federal Circuit decided that selling a product abroad did not terminate a patent owner's right to bring an infringement suit for importing the product into the U.S.

## At the Supreme Court

The Supreme Court, in a 7-1 decision<sup>6</sup>, reversed the Federal Circuit on both counts.

With respect to the "Return Program" toner cartridges, the Supreme Court held that Lexmark could add restrictions under contract law, but selling the product exhausted Lexmark's patent rights. Tracing common law principles back to the 17<sup>th</sup> century, the Supreme Court said that it was well established that a party could negotiate the price at which a product was sold, but could not, by virtue of the patent, control the use or disposition of the product after its sale.

The Supreme Court explained that the Federal Circuit's decision erred by presuming that a patent owner could preserve patent rights as part of the product sale. The patent exhaustion doctrine is not, according to the Supreme Court, a presumption: it is a limit on the patent owner's rights. As such, the patent owner cannot preserve his rights under contract to avoid patent exhaustion.

The Supreme Court also drew a distinction between a patent owner selling the product and granting a license to another party to sell the product, at least with respect to the patent owner preserving patent rights. The patent owner can preserve patent rights as part of a licensing

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<sup>5</sup> That is, before the entire court, rather than just a three-judge panel.

<sup>6</sup> Justice Gorsuch did not take part in deciding the case.

arrangement, since the license does not transfer ownership of the product; the same is not possible when the product is sold<sup>7</sup>. Nor does it matter whether the product is sold by the patent owner or by the licensee: if the licensee is acting under authority of the patent owner, a sale by a licensee exhausts the patent owner's rights just as if the patent owner had sold the product himself<sup>8</sup>.

With respect to foreign sales, the Supreme Court held that a sale by the patent owner (or a licensee) outside the U.S. exhausts the patent owner's U.S. patent rights just as if the sale had occurred in the U.S. The Supreme Court looked to the "first sale doctrine" of copyright law<sup>9</sup>, which grants the purchaser of a copy of a copyrighted work the authority to sell or otherwise dispose of his copy without infringing the copyright. In particular, the Supreme Court looked to the case of *Kirtsaeng v. John Wiley & Sons, Inc.*<sup>10</sup> to support the assertion that the first sale doctrine applies to the sale of a copyrighted work outside the U.S. The Supreme Court argued that patent exhaustion and the first sale doctrine "share a 'strong similarity ... and identity of purpose'"<sup>11</sup> as a basis for treating sales outside the U.S. equivalently with respect to both patent and copyright law.

The Supreme Court was not persuaded by Lexmark's argument that a U.S. patent does not grant the patent owner any rights outside the U.S. According to the Supreme Court, copyrights do not have territorial limits any more than patents, and therefore there was no reason to distinguish patent exhaustion from the first sale doctrine based on territorial limits.

The Supreme Court briefly touched on the issue of the price at which a product could be sold. A patent owner might be able to negotiate different sale prices for a product inside the U.S. as outside the U.S. But patent laws do not guarantee a patent owner any particular price for selling a product. Assuming the patent owner sells the product, regardless of location, the patent owner has received adequate compensation for the product.

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<sup>7</sup> "[A] license is not about passing title to a product, it is about changing the contours of the patentee's monopoly" (see *Impression Prods. Inc.*, 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 11 (2017)).

<sup>8</sup> The Supreme Court distinguished *General Talking Pictures Corp. v. Western Elec. Co.*, 305 U.S. 124 (1938), on the grounds that in *General Talking Pictures*, the licensee made a sale outside the scope of the license. If the licensee acts outside the scope of the license, the licensee is potentially liable for patent infringement just as if the patent owner had not granted a license.

<sup>9</sup> "[T]he owner of a particular copy or phonorecord lawfully made under this title, or any person authorized by such owner, is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord" (see [17 U.S.C. § 109](#)).

<sup>10</sup> 568 U.S. 519 (2013).

<sup>11</sup> See *Impression Prods. Inc.*, 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 14 (2017) (citing *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 13 (1913)).

The Supreme Court also distinguished *Boesch v. Gräff*<sup>12</sup>, the only other Supreme Court case to address international patent exhaustion. In *Boesch*, a retailer purchased lamp burners in Germany with plans to sell the lamp burners in the U.S. The retailer purchased the lamp burners from a manufacturer that had authority under German law to manufacture the lamp burners. But the U.S. patent covering the lamp burners was owned by a party unrelated to transaction in Germany. The U.S. patent owners sued the retailer for patent infringement. The Supreme Court held that because the retailer did not purchase the lamp burners from the party that owned the U.S. patent rights, the U.S. patent rights were not exhausted by the retailer's purchase in Germany. Since Lexmark was seller of the toner cartridges both in the U.S. and internationally, the sales outside the U.S. were authorized by the U.S. patent holder, and the ruling in *Boesch* did not apply.

### **Justice Ginsburg's Dissent**

Justice Ginsburg agreed with the majority opinion that Lexmark had exhausted its patent rights by selling the "Return Program" toner cartridges in the U.S. But she disagreed with the majority that sales outside the U.S. exhausted U.S. patent rights. Justice Ginsburg argued that patents are limited to national borders: if a party wants to own patents in countries other than the U.S., the party must file patent applications in each such country<sup>13</sup>. In addition, patent laws vary by country, affording a patent owner varying rights depending on the country. As a result, if an unauthorized party sold a product outside the U.S., even if the sale would have infringed a U.S. patent had the sale occurred in the U.S., the patent owner would have no cause of action under U.S. patent law.

Justice Ginsburg also argued that the parallels between patent exhaustion and the first sale doctrine did not extend as far as the majority had held. U.S. patent law includes no analog to the first sale doctrine: patent exhaustion is a common law defense. And copyright law is harmonized across many countries under the Berne Convention<sup>14</sup>. Obtain a copyright in the

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<sup>12</sup> 133 U.S. 697 (1890).

<sup>13</sup> Copyrights, in contrast, exist in any country that will enforce the copyright from the moment an authored work is fixed in a tangible medium. There is no requirement that the work be published, nor any paperwork that needs to be filed to enforce the copyright. Registration with the U.S. Copyright Office offers additional benefits to copyright holders, but is not required to establish the copyright (although registration is required in the U.S. to sue for copyright infringement).

<sup>14</sup> See Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Stockholm on July 14, 1967, Arts. 1, 5(1), 828 U.N.T.S. 225, 231-233.

U.S., and that copyright is enforceable with similar effect by other countries. No such harmonization exists for patent law.

### **A Path to Cheaper Drugs?**

Before I explain why I think Justice Ginsburg is right (and the majority is wrong), let me add a preface. I have many years of experience in prosecuting patents before the U.S. Patent & Trademark Office, and I think I understand patent law as well as most patent attorneys. But while my analysis below focuses on the implications for the pharmaceutical industry, I am not a chemist or a chemical engineer. I am not specifically experienced in pharmaceutical patents, or the laws regarding pharmaceuticals in general. My analysis is based on my lay understanding of the pharmaceutical industry.

Let me begin by saying that I, like Justice Ginsburg, have no problem with the majority's opinion regarding Lexmark's "Return Program" toner cartridge sales in the U.S. A sale in the U.S. is a sale in the U.S.: the sale in the U.S. exhausts any patent rights the patent owner had. But sales in other countries are a different matter.

We have all heard news reports about the high cost of medicines in the U.S., often with a comparison of the cost for the same medication in other countries. The pharmaceutical industry argues that the high cost of medicines in the U.S. is necessary to recoup the cost of researching, developing, testing, and marketing new medicines<sup>15</sup>. On the other hand, we also hear reports

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<sup>15</sup> I do not intend to state or imply any personal position regarding the truth of these assertions. I have no evidence to reject assertions that the cost to bring a new medicine to market can exceed \$1,000,000,000.00 (that is, one *billion* dollars). While I personally question whether these costs are entirely justified, I do not doubt that developing and researching new drugs is an expensive process, before even reaching the question of U.S. Food and Drug Administration (FDA) testing and approval.

On the other hand, the past decade has shown a significant change in how drugs are *marketed*: specifically, direct marketing to end users (patients). Direct marketing to patients seems inappropriate to me. Doctors have greater knowledge and expertise regarding what medicine is "best" for a patient and what the side effects of various medications are. When patients come into their doctor's office and ask for a specific medicine, the doctor's knowledge and expertise is partially removed from the equation. (Some, perhaps most, doctors could be expected to assert to a patient what medicine they think is best and/or explain why the medicine the patient requests is not the best choice. But some doctors would likely prescribe exactly what the patient requests without discussion, and even assertive doctors might not argue extensively with a patient who thinks they know best. It is likely patients in the latter cases that the pharmaceutical companies are targeting with their marketing.) And direct marketing to patients is not permitted by most countries around the world (*see Direct-to-consumer advertising under fire*, Bulletin of the World Health Organization, Volume 87, Number 8, 576-77, <http://www.who.int/bulletin/volumes/87/8/09-040809/en/> (August 2009)).

about companies raising the price of medicines simply to increase the profitability of a pharmaceutical company<sup>16</sup>.

The primary issue appears to be bargaining power. Some other countries also institute price controls, limiting the price that can be charged for various drugs<sup>17</sup>. With prices limited by law in other countries, pharmaceutical companies cannot charge as much for their drugs as they can in the U.S., where such price controls do not exist.

In addition, in other countries there are far fewer parties at the table: for example, the United Kingdom's National Health Service purchases all drugs for the entire country<sup>18</sup>. When the pharmaceutical company has only one party to which it can sell drugs, that purchasing party has a monopoly (a buyer's monopoly as opposed to a seller's monopoly), and therefore can dictate the price to be paid for drugs. While corporate monopolies are generally against the law<sup>19</sup>, governmental monopolies are routine: almost any aspect of life that the government takes as its own responsibility is subject to a governmental monopoly.

In the U.S., on the other hand, pharmaceutical companies deal with many different parties (such as insurance companies and hospitals) to negotiate prices for their drugs. And Medicare, which buys drugs from pharmaceutical companies on behalf of the federal government and is one of the largest purchasers of drugs in the U.S., is prohibited *by law* from negotiating with pharmaceutical companies<sup>20</sup>. In other words, the pharmaceutical companies can set the prices at which they want to sell their drugs to Medicare, and Medicare either agrees to purchase the drugs at that price point or not<sup>21</sup>.

The majority's opinion in *Impression Products* makes it clear that a sale by the patent owner or its licensee, anywhere in the world, exhausts the patent owner's patent rights in the U.S. In other words, an enterprising individual could travel to, say, Canada, purchase drugs

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<sup>16</sup> See, e.g., *EpiPens cost just several dollars to make. Customers pay more than \$600 for them*, <http://www.cnbc.com/2016/08/25/epipens-cost-just-several-dollars-to-make-customers-pay-more-than-600-dollars-for-them.html> (August 25, 2016).

<sup>17</sup> See, e.g., *Prescription drug prices in the United States*, [https://en.wikipedia.org/wiki/Prescription\\_drug\\_prices\\_in\\_the\\_United\\_States](https://en.wikipedia.org/wiki/Prescription_drug_prices_in_the_United_States) (2017).

<sup>18</sup> See, e.g., *Why pharmaceuticals are cheaper abroad*, <http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/index.html> (September 28, 2015).

<sup>19</sup> Obviously aside from patents, which are a form of monopoly that is limited in time and the agreed-upon reward for innovation.

<sup>20</sup> See *supra* footnote 17.

<sup>21</sup> Medicare may be able to insist on purchasing drugs at the cheapest price to which the pharmaceutical company sells the drugs to any other party. But that result is not the same as negotiating the exact price to be paid for particular drugs.

there, travel back into the U.S., and resell those drugs in the U.S. without concern that his actions might infringe a U.S. patent<sup>22</sup>. With the wide difference between prices in the U.S. and prices internationally, there is ample room to find a middle price that is cheaper for the U.S. consumer than the price for the drug set by the manufacturer but still turns a profit for the entrepreneur. For example, Gleevec®<sup>23</sup> at one time sold for \$6214 per customer for a one-month supply in the U.S., but at the same time sold for only \$1141 in Canada<sup>24</sup>: more than 80% less in Canada than in the U.S. Assuming a price of \$3678 per customer for a one-month supply would provide ample profit to the entrepreneur, a U.S. customer would be able to purchase the drug at ½ the price set by Novartis Pharmaceuticals Corp.<sup>25</sup>

The logical defense for pharmaceutical companies would be to prevent sales in foreign countries. But there are a number of problems with such a strategy. First, while the pharmaceutical companies could refuse to sell their products anywhere but the U.S., that strategy would mean voluntarily closing off markets that cumulatively, in terms of customers, are many times the size of the U.S. market. Second, drugs are frequently important to people's lives (or at least the quality of their lives), and most governments are understandably interested in making their citizens' lives better. If the pharmaceutical company refuses to sell its drugs in a particular country, it is reasonable to conclude that the government in that country could simply ask (or start up) a local pharmaceutical company to manufacture the drug in question, resulting in lost sales for the pharmaceutical company<sup>26</sup>.

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<sup>22</sup> I am intentionally ignoring other issues that may well be pertinent, such as whether the U.S. Drug Enforcement Agency (DEA) or the U.S. FDA could bar importation of the drugs out of concern that the drugs do not satisfy U.S. purity, quality, or efficacy regulations, or issues regarding customs duty for importing goods into the U.S. for sale. I presume that any such issues can be resolved: for example, if the drugs were originally produced for sale in the U.S. market, they presumably satisfy U.S. purity and quality regulations despite being purchased in another country, and customs duty is simply an amount of money that needs to be paid to the U.S. Customs and Border Protection.

<sup>23</sup> Gleevec is a trademark or a registered trademark of Novartis Pharmaceuticals Corporation in the U.S. and abroad.

<sup>24</sup> See *supra* footnote 18.

<sup>25</sup> I am not singling out Gleevec and Novartis Pharmaceuticals Corp. in this article for any reason other than that the CNN article, cited *supra* footnote 18, provides comparative price information for this drug. Nor am I advocating that any entrepreneurs start using such a business model: I am simply taking the Supreme Court's decision to its logical conclusion.

<sup>26</sup> If a drug is manufactured outside the U.S. and then imported into the U.S. by a company without authorization from the U.S. patent holder, then the holding in *Boesch*, see *supra* footnote 12, would apply, and the pharmaceutical company that owns the U.S. patent could sue to prevent importation of the drug into the U.S. as an act that infringes the patent. But that position would not help the pharmaceutical company recoup any profits lost by their choice not to sell the drug in the foreign country.

The pharmaceutical company might consider foreign patents<sup>27</sup> the “solution” to this problem. But for a number of reasons, foreign patents would not necessarily protect the pharmaceutical company’s profits, and would not solve the problem created by *Impression Products*.

First, a foreign patent might give the pharmaceutical company a measure of control over who sells the drugs in that country. But then the pharmaceutical company would need to obtain a patent in every individual country in which it wants to sell its drugs. Patents are, in general, expensive<sup>28</sup>, and each country tends to examine patent applications without regard to examination done in other countries<sup>29</sup>. Thus, money spent protecting a patent in one country typically does not translate into reduced cost in obtaining patents in other countries.

Second, as noted above, governments tend to be interested in protecting the health of their citizens. Thus, if a pharmaceutical company were to patent a drug in another country and then refuse to sell the drug in that country, the government of that country could act to establish a market for the drug despite the patent: for example, change the local laws.

In fact, some countries already have laws on the books that achieve this result. India, for example, has a law that provides for compulsory patent licenses<sup>30</sup>. The compulsory license law in India prevents a patent holder from using his patent to limit the availability of his product to products imported from outside India. Essentially, the patent owner has three years in which to begin offering the product for sale in India, either offering the product personally or licensing a party in India to offer the product. If, after three years, the product is not offered for sale or the price at which the product is offered is not reasonable, an interested party can apply for the grant of a compulsory license.

In the pharmaceutical industry, the possibility of a compulsory license is not an abstract threat, although neither is it necessarily a great concern at this time. It was not until 2012 that

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<sup>27</sup> By “foreign patent”, I mean a patent obtained from a Patent Office in another country and therefore a patent under the laws of that country.

<sup>28</sup> Although relative to the cost of researching, developing, marketing, and getting a new drug approved, the cost of patent protection is relatively minor.

<sup>29</sup> Some countries (typically smaller countries with smaller annual budgets) effectively follow patent examination done in other jurisdictions, to save their own costs. But such countries would likely represent countries of lesser interest to the pharmaceutical company.

<sup>30</sup> See Section 84, Patent Act of 1970 ([http://ipindia.gov.in/writereaddata/Portal/IPOAct/1\\_31\\_1\\_patent-act-1970-11march2015.pdf](http://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf)).

the Indian Patent Office granted its first compulsory license to a generic drug maker<sup>31</sup>. Since then<sup>32</sup>, however, there have been only two applications for compulsory licenses to manufacture a drug, and both of those applications were rejected<sup>33</sup>. Thus, while there is a documented instance of a compulsory license being granted in India to locally manufacture a drug, the number of such cases is still small, nor is every such application being granted.

These facts illustrate another problem I have with the majority opinion in *Impression Products*. The majority opinion states that “[a] licensee’s sale is treated, for purposes of patent exhaustion, as if the patent owner made the sale itself”<sup>34</sup>. With this language, the majority opinion accords a licensee’s sales equal dignity to a patent owner’s sales, at least with respect to patent exhaustion. But should sales by a compulsory licensee be granted equivalent status? A patent owner has no ability to limit the rights granted to a compulsory licensee<sup>35</sup>. The patent owner has not acted voluntarily in granting a license to a compulsory licensee. There is not even a contractual relationship between the patent owner and a compulsory licensee, which means that theoretically the patent owner cannot sue the compulsory licensee even under a theory of breach of contract.

One could argue that the patent owner acted voluntarily in filing the patent application in the foreign country, and therefore knew that a compulsory license was a possibility. But such reasoning puts the pharmaceutical company in a real dilemma. File the patent application for the drug in the foreign country and market it himself (or license a local pharmaceutical company to manufacture the drug locally), and the patent owner has given up the right to block importation of the locally manufactured drug into the U.S. (because of patent exhaustion as decided by the majority opinion in *Impression Products*). File the patent application for the drug in the foreign country but refuse to manufacture the drug in that country or license a local pharmaceutical company to manufacture the drug, and the patent owner is vulnerable to a compulsory license,

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<sup>31</sup> See *India Grants First Compulsory License to Generic Drug Producer*, <http://www.ictsd.org/bridges-news/bridges/news/india-grants-first-compulsory-license-to-generic-drug-producer> (March 14, 2012).

<sup>32</sup> As of April 21, 2016.

<sup>33</sup> See *The Dismal History of Compulsory Licences in India*, <http://kluwerpatentblog.com/2016/04/21/the-dismal-history-of-compulsory-licences-in-india/> (April 21, 2016).

<sup>34</sup> See *Impression Prods.* 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 12 (2017).

<sup>35</sup> In the case where a compulsory license to manufacture a drug was granted in India, one of the reasons behind the grant of the compulsory license was because the party with a license to import the drug into India priced the drug “exorbitantly...and out of reach of most of the people” (see *supra* footnote 31). So if a foreign patent holder attempts to price a drug locally at the same price point as the U.S. (to prevent someone from purchasing the local drug supply and importing the purchased drug into the U.S.), that decision might be grounds to grant a compulsory license to manufacture the drug locally, undercutting the protections the patent owner was seeking.

which would apparently also exhaust U.S. patent rights. Fail to file the patent application in the foreign country, and *anyone* in the foreign country can manufacture the drug (although U.S. patent rights would not be exhausted<sup>36</sup>).

If the pharmaceutical company files the patent application in the foreign country (and the patent is granted), the pharmaceutical company also faces another conundrum: pricing. If the patent owner (or the licensee) sells the drug at a lower price in the foreign country than in the U.S., the patent owner opens the door to an enterprising party purchasing the drug in the foreign country and importing the drug for sale in the U.S. at a lower price. But if the patent owner (or the licensee) sells the drug at the same price in the foreign country as in the U.S., sales of the drug in the foreign market may fall precipitously (since foreign patients may be unwilling or unable to afford the price) or may disappear entirely (if the local health service that negotiates the purchase of the drug refuses to pay the price charged by the pharmaceutical company or if a compulsory license is granted as a result of the high price sought). (There is a third alternative—sell the drug in the U.S. at the same price charged in the foreign country—but I have discounted that approach since it would reduce the pharmaceutical company’s profits, given the high prices for drugs in the U.S.)

### **What About Software?**

There is another potential issue buried in the majority opinion. The majority states that “[a] purchaser buys an item, not patent rights. And exhaustion is triggered by the patent owner’s decision to give that item up and receive whatever fee it decides is appropriate ‘for the article and the invention which it embodies’”<sup>37</sup>. The majority also states that “a license is not about passing title to a product, it is about changing the contours of the patent owner’s monopoly: The patent owner agrees not to exclude a licensee from making or selling the patented invention, expanding the club of authorized producers and sellers”<sup>38</sup>.

In a world of physical products, where it is at the very least difficult to manufacture a new copy of an article, such a distinction makes sense. After all, while it is technically possible for a home tinkerer to build a car from scratch that is functionally and aesthetically identical to,

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<sup>36</sup> The reasoning of *Boesch*, *see supra* footnote 12, would apply.

<sup>37</sup> *See Impression Prods.* 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 15 (2017) (citing *United States v. Unis Lens Co.*, 316 U.S. 241, 251 (1942)).

<sup>38</sup> *See Impression Prods.* 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 11 (2017).

say, a Toyota® Camry®<sup>39</sup>, most people lack the skills, equipment, and resources needed to build such a vehicle. The same is not true of software: copying software is a trivial matter that almost anyone can do with minimal experience. That is why software developers go to such great lengths to prevent unauthorized copies of their products from reaching the marketplace<sup>40</sup>.

One tool software developers use to protect their software is the End User License Agreement (EULA). The vast majority of software sold in the past 30 years has been subject to a EULA. The EULA has become even more prevalent with the growth of high-speed Internet connections and the cloud: people can simply download the software they want from the Internet<sup>41</sup>, rather than driving to a software retailer and purchasing a boxed copy.

But EULAs have also become so cumbersome that few people read them. In addition, I think EULAs are a contract of adhesion: the end user has no ability to negotiate the terms of the EULA with the software developer. Even worse, the terms of many EULAs can only be learned when the end user attempts to install the software, which is after the end user has paid cash for the software. And if the software was purchased from a “brick-and-mortar” retailer rather than over the Internet, the retailer likely would refuse to take the software back if the end user rejects the EULA, since the packaging would have been opened by then<sup>42</sup> (not to mention the headache of taking the time to drive back to the retailer).

But even with full knowledge that the software is subject to a EULA, would any consumer<sup>43</sup> really concede that he is only “licensing” the software rather than “purchasing” it? I doubt it. And the majority’s position points to software “sales” as akin to product sales, rather than licenses. After all, the end user has taken possession of a “product” (albeit an intangible

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<sup>39</sup> Toyota and Camry are trademarks or registered trademarks of Toyota Motor Corporation in the United States and other countries.

<sup>40</sup> For example, some software manufacturers include an activation process in their software. The end user must provide a valid key, which is not included in the software itself, to activate the software. Until a valid key is provided, the end user is prevented from using the software, at least to its full potential: the software might work for only a limited period of time, or the end user might be permitted to use only a subset of the features of the software.

<sup>41</sup> In the past year or so, I have downloaded, each in a matter of minutes, at least two software products over the Internet that were roughly 1 GB in size. Roughly 10 years ago, a software package of that size would require at least 3 Compact Discs (CDs) to sell in a box (assuming a customer had a drive that could read a CD); 20+ years ago, when software was generally delivered on floppy disks, purchasing such a large software package for personal use would have been unthinkable.

<sup>42</sup> End users are often instructed to return software to their point of purchase—e.g., the software retailer—if the EULA is not accepted, but there is no guarantee that the software retailer will accept a return of the opened product.

<sup>43</sup> Lawyers, particularly intellectual property lawyers, would likely understand and concede the difference between licensing and selling software. But even lawyers might question whether such a distinction for software is sustainable.

product, if downloaded rather than purchased in a box), which I think meets the majority opinion's definition of a "sale". The end user "making or selling the patented invention"<sup>44</sup>, as the majority opinion defines a "license".

Nor would most end users think that what they are acquiring is a "patent right" rather than software. If a license "is about changing the contours of the patent owner's monopoly", does the use of software by an end user really meet this definition? I don't think it does. And end users do not think that all they are receiving is a change in the "contours of the patent owner's monopoly": they think are actually purchasing the software<sup>45</sup>.

In theory, one could draw a distinction between software that is purchased from a software retailer and software that is downloaded over the Internet. But I don't think such a distinction makes sense. First, should the end user be subject to different treatment based on how he acquired the software? I don't think so. Whether the end user purchases the software from a software retailer or downloads the software from the software developer, either way the end user has a copy of the software installed on his computer. In addition, distinguishing between purchases from a software retailer and downloads over the Internet means that the end user has to track how he acquired each copy of software on his computer. Given how much software can be installed on a computer, tracking such information can be a daunting task.

Second, most computers come pre-installed with software (how much software is pre-installed can vary greatly depending on the make and model of computer purchased). I do not think anyone would argue that that the purchase of the computer itself is a "license" as the majority opinion defines that term<sup>46</sup>. But why should the end user own the computer itself but only have a license to the software that was pre-installed on that computer at the time of

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<sup>44</sup> See *Impression Prods.* 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 11 (2017).

<sup>45</sup> For software sold in a box, most end users would think they have the right to sell the software to another person just like a car or a toy (at least, after uninstalling the software from their computer). And most end users would also think they are entitled to install the software on a second computer, if the first computer becomes inoperative. But under a license from the software developer, either or both of these "rights" could be denied.

From a technical point of view, I suppose the EULA could be read as the software developer promising not to sue the end user for using the patented software: in that sense, the EULA is a license within the definition of the majority opinion. But that position feels like a considerable stretch.

<sup>46</sup> Recall that the majority opinion states that "a license is not about passing title to a product, it is about changing the contours of the patent owner's monopoly" (see *Impression Prods.* 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 11 (2017)). The end user is clearly acquiring title to the computer, and therefore cannot be acquiring just a "license".

purchase? The computer and the pre-installed software are all part of the same transaction: they should be subject to the same terms<sup>47</sup>.

Third, the transaction in which the end user downloads software looks the same as any transaction at a brick-and-mortar store, for software or any other product. The end user goes up and down the “aisles”, selects the items of interest, places them in a shopping cart<sup>48</sup>, and when the end user has located all the items of interest, they proceed to “checkout”, where they tender payment. The only difference between an online transaction and a transaction at a brick-and-mortar store is in the manner in which the end user receives the items: at a brick-and-mortar store the end user takes physical custody of the items immediately, whereas with an online retailer the items (if physical) are delivered to the end user or downloaded (if software) onto the end user’s computer. And this same model is used by most (if not all) online retailers, both of software and more tangible goods. Software developers using such models make the transaction look the same as an online purchase of a television or a dishwasher: only the product in question differs. And more importantly, software developers do not interrupt the transaction at any point to inform the end user that the end user is only acquiring a license to the software: the software developers continue to rely on the EULA for that purpose, which is generally not accessible until after the software has been downloaded and installation begun.

I do not see a good reason to distinguish between a sale and a license based on how the end user takes custody of the items, or that the manner of custody should matter. Consider, for example, tickets to a show (a concert, a comedian, a circus, or any other live performance). In the days before computers, someone who wanted to see a concert had to travel to a location where they could purchase tickets for the show, or else order tickets over the telephone and wait for them to be delivered (through the mail or by a delivery service). With the rise of the Internet, a concertgoer can purchase tickets to a show of interest online. What is more, the concertgoer frequently can choose between having the tickets physically delivered or downloading the tickets

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<sup>47</sup> With the rise of larger and larger software programs, some software developers are beginning to offer to sell their software on a USB key. That is, the software developer will copy the software onto a USB key, then ship the USB key to the end user. While delivery of a (physical) USB key is slower than downloading software over the Internet, the end user might find a large download onerous, because of the time required to complete the download, the potentially adverse consequences if the download is interrupted, or download limits imposed by their Internet Service Provider. But just as with the sale of a computer with pre-installed software, I do not think it makes sense to suggest that the end user owns the USB key itself, but only has a license to the software resident thereon.

<sup>48</sup> I think it is telling that online retailers, including software developers offering their software for download, use this (or a similar) term, intentionally drawing parallels with shopping at brick-and-mortar retailers.

and printing them at home. Does the fact that the tickets are downloaded and printed at home mean that the concertgoer has only acquired a license to the ticket and not ownership of the ticket? I would think not: electronic delivery vs. physical delivery should make no difference. Nor should it make any difference whether the concertgoer actually prints the ticket. Nowadays tickets can be scanned directly from a mobile device, without the concertgoer having to print the ticket on paper. Should the act of physically printing the ticket change the concertgoer's rights from a license to a sale? Again, I do not think so. But there is no reason to suggest that a concertgoer owns their ticket, while an end user of software only has a license to run the software: the distinction is arbitrary.

Returning to the broader question, a further issue with software transactions generally is whether the end user has actually acquired merely a license. Consider the scenario where an end user purchases a copy of the latest version of the Windows® operating system software, developed by Microsoft® Corporation, at Best Buy®<sup>49</sup>. In such a scenario, Best Buy does not limit what the end user can do with the copy of the software: the transaction is exactly the same as it would be if the end user had purchased, say, a television or a dishwasher<sup>50</sup>. Since the end user deals only with Best Buy, if Best Buy does not inform the end user that he has only acquired a license, the end user likely would not consider himself to be limited in what he can do with the copy of the software. If Best Buy was only supposed to license the software rather than selling it outright, Best Buy might be breaching its contract with Microsoft Corporation in not licensing the software to the end user, but the end user would do nothing wrong by reselling or otherwise using the software in a manner ostensibly prohibited by the EULA.

Further, in such a scenario, the software developer should have no cause of action against the end user, even for patent infringement. It is true that in such a scenario the software retailer might have exceeded its authority if it sold the copy of the software outright rather than merely issuing a license to use the copy of the software<sup>51</sup>. But from the end user's perspective, a sale is

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<sup>49</sup> Windows and Microsoft are trademarks or registered trademarks of Microsoft Corporation in the United States and other countries. Best Buy is a trademark of Best Buy and its affiliated companies.

I do not pick on Windows, Microsoft Corporation, or Best Buy because they are specifically doing anything unusual or untoward. I have selected these names because of their general familiarity to the public.

<sup>50</sup> I have purchased many different software products, in boxes, from numerous software retailers over the years. I cannot recall a single instance in which the transaction was or appeared to be different, in any way, from a purchase of a more tangible, less easily duplicated product. Put more bluntly, I cannot recall a single instance where the software retailer informed me that I was only acquiring a *license* to the software.

<sup>51</sup> In such a situation, *General Talking Pictures* would likely apply: *see supra* footnote 8.

a sale. The end user has no way to know that the software retailer exceeded its authority because the software retailer should only have issued a license to use the copy of the software. Even if the end user uses the copy of the software in a manner that was inconsistent with the license the end user should have received, it would be unreasonable to put the end user in a position where he does not know whether he owns the copy of the software outright or merely has a license to use the copy of the software. If “restraints on the alienation of chattels” are against public policy<sup>52</sup>, so should ambiguity about the end user’s rights, which is worse: the end user might be chilled from engaging in conduct that is entirely lawful and intended to be permitted.

Even the transaction between the software developer and the software retailer likely lacks the appearance of a licensing arrangement. Again, consider the scenario where the end user purchases a copy of the Windows operating system software, developed by Microsoft Corporation, from Best Buy. Best Buy and Microsoft are both large companies, and neither is likely to have the time or inclination to negotiate exactly what Best Buy is acquiring from Microsoft Corporation<sup>53</sup>. Thus, it is likely that Best Buy simply requests that Microsoft Corporation ship a certain number of copies of the latest version of the Windows operating system software, and pays a particular sum of money to receive those boxes. This transaction appears to be nothing more than a classic contract for sale. But if Best Buy is actually purchasing, rather than licensing, software from Microsoft Corporation, then Best Buy actually owns the copies of the software, and that sale automatically exhausts any patent rights. It seems unfair to impose a license arrangement on the end user when the software retailer is not similarly limited by its contract.

A further question is whether the EULA, a contract between the software developer and the end user, is enforceable. The end user has no relationship with the software developer: the end user purchased the copy of the software from the software retailer. As such, the EULA is a contract that is separate from any contract between the software developer and the software retailer, or between the software retailer and the end user. But the EULA lacks consideration<sup>54</sup>. The end user has purchased the copy of the software from the software retailer: now the software developer is imposing its own contract on the end user. But the software retailer does not give

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<sup>52</sup> See *Impression Prods.* 581 U.S. at \_\_\_, Docket 15-1189 slip opinion, page 6 (2017) (discussing limitations on copyrighted works in *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U. S. 519, 538 (2013)).

<sup>53</sup> This point being so given the number of software retailers each software developer would have to deal with, and the number of software developers each software retailer would have to deal with.

<sup>54</sup> Consideration is one of the requirements to find a valid contract.

anything to the end user in exchange for the end user agreeing to the terms of the EULA<sup>55</sup>.

Without consideration, a contract is not enforceable. So if the software developer does not provide the end user any consideration for agreeing to the terms of the EULA, the EULA should not be enforceable.

One should also consider the consequences of treating the sale of software as a true “sale”, rather than a “license”, from the copyright perspective. If an end user acquires software under a license, then neither patent exhaustion nor the first sale doctrine<sup>56</sup> should apply. Therefore, if the end user were to sell the software to another party, the end user might be liable to the software developer under both patent *and* copyright infringement theories. But if the end user acquires software as a result of a true sale, then under the reasoning of the majority opinion, both patent exhaustion and the first sale doctrine apply. Any attempt by the software developer, under either patent or copyright law, to prevent the end user from selling the software to another party would be ineffective.

But consider this: while the first sale doctrine permits the end user from selling the software to another party, the first sale doctrine does *not* terminate any copyrights the software developer has in the software. Software is almost always covered by copyrights, even if the software is not protected by a patent. So while the software developer may have no rights under patent law after the initial sale of the software to the end user (or the software retailer, depending on the form the transaction took), the software developer may still have rights under copyright law. For example, the end user can sell their copy of the software, but the end user cannot make additional copies of the software and sell those copies<sup>57</sup> to others without infringing the copyright(s) in the software. So the harmonization between patent law and copyright law that the majority opinion seems to favor is not as complete as the majority seems to think: the software developer may now have better protection under copyright law than under patent law.

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<sup>55</sup> If the end user owns title to the copy of the software after the transaction with the software retailer, the end user does not need permission from the software developer to use the copy of the software. And even if the end user only acquired a license to use the copy of the software from the software retailer, the end user still receives no consideration for agreeing to the EULA’s terms, which are more limiting than the “general license” (without any terms) received from the software retailer. Even an argument that the software developer is giving the end user “permission” to use the copy of the software is a suspect argument: in that case, what did the end user receive from the software retailer for the money paid?

<sup>56</sup> See *supra* footnote 9 and accompanying text.

<sup>57</sup> Or give them away for free.

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## **In Conclusion**

*Impression Products* “clarifies” some issues regarding patent exhaustion. But while I might personally think the consequences of the majority opinion are a good thing, the majority opinion sows confusion in major industries such as pharmaceuticals and software. And the majority opinion appears to draw too close a parallel between patents and copyrights, ignoring the realities of some significant differences between the two forms of intellectual property.

Ariel Rogson is the owner of the Law Office of Ariel S. Rogson, P.C. A former software developer (and continuing part-time programmer), he serves clients in software and high tech industries. He can be reached at 971-254-8967 or [Ariel.Rogson@RogsonIPLaw.com](mailto:Ariel.Rogson@RogsonIPLaw.com). The above article is general information, not legal advice. Regarding a specific situation, seek competent intellectual property legal counsel.