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Supreme Court Holds That the Shipment Abroad of a Single Component of a Multi-Component System Does Not Constitute Patent Infringement Under 35 U.S.C. 271(f)(1)

On February 22, 2017, the U.S. Supreme Court decided the case of *Life Technologies Corp., v. Promega Corp.*, which may have important implications for the use of international supply chains, and the ability of owners of U.S. patents to enforce their rights against uses of patented inventions that take place outside of the United States. *Life Technologies* presented the issue of whether a U.S. patent can be infringed under 35 U.S.C. 271(f)(1) if the infringing product was manufactured or assembled entirely abroad, and only a single component of that product was exported from the United States. Section 271(f)(1) prohibits the supply from the United States of "all or a substantial portion" of the components of a patented invention for combination abroad. In other words, if "all or a substantial portion" of the components of a patented invention are shipped from the United States to a foreign country for additional manufacturing or assembly, then that product still infringes the U.S. patent, even though that manufacturing or assembly occurred entirely outside of the United States. Section 271(f)(1) therefore extends the reach of U.S. patent laws to cover activities that occur outside of the U.S. The Supreme Court was therefore called upon to determine the scope of this extraterritorial reach of the U.S. patent laws.

Life Technologies involved the Tautz patent, U.S. Patent No. RE37,984, which claims a toolkit for genetic testing. The toolkit covered by the Tautz patent enabled the synthesis of multiple copies of

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a particular DNA sequence in order to "amplify" it. The Tautz patent's toolkit contained five (5) components. Promega was the exclusive licensee of the Tautz patent, and Life Technologies manufactured genetic testing kits. Promega sublicensed the Tautz patent to Life Technologies for the manufacture and sale of toolkits to law enforcement agencies worldwide. Life technologies manufactures all but one component of the kits in the United Kingdom. It manufactured the Taq polymerase component in the United States, and shipped that component to its U.K. facility, where it was combined with the other four components of the kit.

A few years into the license agreement, Promega learned that Life Technologies was violating its sublicense agreement by selling genetic testing kits to clinical and research markets outside of the licensed fields of use. As a result, Promega sued Life Technologies for infringing the Tautz patent. Promega alleged that Life Technologies' supply of Taq polymerase from the United States to its U.K. manufacturing facility made it liable for patent infringement under Section 271(f)(1) because that component was the main component of the toolkit. At trial, the parties disputed the scope and meaning of Section 271(a)(1)'s coverage of allegedly infringing activities that occurred outside the United States. The jury returned a verdict for Promega, finding that Life Technologies willfully infringed the Tautz patent. Life Technologies moved to set aside the jury's verdict, arguing that Section 271(f)(1) did not apply, because the phrase "all or a substantial portion" from the statute does not cover the supply of only a single component of a multi-component invention.

The Federal District Court agreed, and granted Life Technologies' motion. The Court interpreted Section 271(f)(1)'s reference to "a substantial portion of the components" to exclude the supply of only a single component. Promega appealed the District Court's decision to the U.S. Court of Appeals for the Federal Circuit, which disagreed with the District Court's interpretation of Section 271(f)(1), finding instead that "there are circumstances in which a party may be liable under Section 271(f)(1) for supplying or causing to be supplied a single component for combination outside of the United States." The Court referred to the dictionary

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definition of "substantial" as meaning "important" or "essential," which is a ***qualitative*** measure that suggests a single important component can be a "substantial portion of the components" of a patented invention. Since expert testimony described Taq polymerase as a "main" and "major" component of the kits, the Federal Circuit ruled that the Taq polymerase component was a substantial component for purposes of infringement under Section 271(f)(1)

The Supreme Court disagreed, and ruled, as the District Court had done, that supplying a single component of a multi-component invention is not an infringing act under Section 271(f)(1). For the Court, the decision came down to whether the requirement of "a substantial portion" of the components referred to a ***quantitative*** or ***qualitative*** measurement. The Court noted that the Patent Act did not define the term "substantial," so that the ordinary meaning of that term must be determined. While the Court acknowledged that the dictionary definition of "substantial" may refer to either a qualitative importance or to a quantitatively large size, the context of its usage in the statute points to a quantitative meaning. Neighboring words such as "all" and "portion" were found to convey a quantitative meaning, with "all" meaning the "entire quantity," without reference to any relative importance. "Portion" was found to refer to some quantity less than all. The fact that those words modified the phrase "of the components" of a patented invention further suggested a quantitative meaning, *i.e.,* the number of components. On that basis, the Supreme Court held that, as a matter of law, a single component can never constitute a "substantial portion" of a multi-component invention, so as to trigger infringement under Section 271(f)(1).

The Supreme Court decided to narrowly interpret Section 271(f)(1), and thereby narrow the scope of the extraterritorial effect that that provision of the Patent Act would have on activities that take place, for the most part, entirely outside the United States. This is consistent with the Court's decisions in other cases, which have assigned a very narrow, restrictive scope to the extraterritorial effect of other federal statutes, thus evidencing a continued overall reluctance on the part of the Court to extend the reach of U.S. law outside of U.S. territorial boundaries.

The Supreme Court's decision in *Life Technologies* also raises as many questions as it answers, because it did not decide how close to "all" of the components "a substantial portion" must be. Therefore, left open is the question of whether supplying from the United States one component of a two-component article would be sufficient to trigger patent infringement liability under Section 271(f)(1). The Court's opinion suggests that it would not. Similarly, the Court did not provide any further parameters for making this decision, such as will there have to be a majority of the components of a multi-component system that are shipped from the United States, or will only two or more (or any other intermediate number) be sufficient? Also, the Court did not address how it would be possible to make that determination, as a practical matter, if it is not allowed to consider the ***qualitative*** role that the components play in the assembled multi-component product or system?

Focusing only on a ***quantitative*** measure, such as the number of components shipped from the United States, may also lead to seemingly arbitrary and potentially absurd results, such as where the one obviously dominant component is shipped from the United States to be assembled with a few other minor

components abroad. Therefore, until the Federal Circuit or the Supreme Court further clarify these issues, and the methodology that is used to decide infringement, there remains a substantial risk that multinational businesses that ship more than one component from the U.S. for further manufacture and assembly abroad will be found to infringe U.S. design or utility patents under Section 271(f)(1).

Federal Circuit Interprets Patent Claims In View of Prior Art, Statements Made in Specification and Prosecution File History

In a recent precedential decision, *The Medicines Co. v. Mylan, Inc.,* the U.S Court of Appeals for the Federal Circuit narrowed the interpretation of two patents' claims, based on statements describing "the invention" that were made in the specification of the patent, and its prosecution file history. The Medicines Company owned two U.S. Patents (U.S. Patent Nos. 7,582,727 and 7,598,343) that are directed to pharmaceutical formulations, known as "batches," of the drug bivalirudin (used to prevent blood clotting during cardiac catheterization procedures) that is produced through a process that consistently minimizes impurities. The claimed inventions of the '727 and '343 Patents are directed to minimizing to "below about 0.6%" the level of a specific impurity in batches of bivalirudin that have been compounded with a base. Bivalirudin requires such compounding before it may be safely administered intravenously, since it is sold as a dry powder that may become too acidic

Medicines received FDA approval to market a base-compounded bivalirudin drug product that was sold under the brand name ANGIOMAX® several years before applying for the '727 and '343 Patents. However, as a condition of approval, the FDA required that Medicines limit to 1.5% the level of a particular impurity generated during the compounding process, because it limits bivalirudin's shelf life. Although Medicines and its contract manufacturer were able to produce batches of bivalirudin with less than 1.5% of the impurity, the level of that impurity was variable in each batch, often close to the 1.5% limit. However, during this pre-patent period, the vast majority of batches that were produced had levels of the impurity below 0.6%, thus making that property of the compound a part of the prior art. Medicines subsequently isolated the cause of the high impurity levels. Based on these findings, Medicines then developed an improved "efficient mixing" process for compounding the pH-adjusting base solution with the bivalirudin solution in order to minimize the formation of observed "hot spots" that resulted in the high level of impurity. This "efficient mixing" process is what is described and claimed in the '727 and '343 Patents.

As the '727 and '343 patents approached their expiration dates, Mylan filed an Abbreviated New Drug Application ("ANDA"), which prompted Medicines to file a lawsuit against Mylan alleging the '727 and '343 Patents were infringed by the generic drug formulation described in the ANDA. The Federal District Court ruled on summary judgment that the asserted claims of the '343 Patent were not infringed, because Mylan did not satisfy the "efficient mixing" limitation of those claims. After a bench trial, the Court found that Mylan infringed the asserted claims of the '727 Patent, because those claims did not include an "efficient mixing" limitation. In finding infringement, the District Court assumed that any batch of bivalirudin made according to the ANDA that included an impurity level below 0.6% would infringe the claims, even though that level of impurity was achieved in the prior art, including batches that

had been made by Medicines itself before the patent applications were filed. Mylan then appealed the District Court's ruling to the U.S. Court of Appeals for the Federal Circuit.

The Federal Circuit disagreed with the District Court that the '727 Patent did not require "efficient mixing," and it therefore found that Mylan's ANDA did not infringe either patent, since the ANDA specified the use of an "inefficient mixing" process. The Federal Circuit's decision was based on that Court's reassessment of the proper interpretation of the claims of the patents-in-suit. The parties disputed the meaning of the terms "pharmaceutical batches" and "efficient mixing," which were recited in the patents' claims. The parties ultimately agreed with the District Court's construction of the term "pharmaceutical batches" as either "(1) "a single batch, wherein the single batch is representative of all commercial batches . . . *made by a compounding process*, and wherein the levels of, for example, Asp9-bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent levels for all potential batches made by said process"; or (2) "all batches prepared by a same compounding process." The District Court's definition added to the express definition of this term that was found in the specification by clarifying that the "pharmaceutical batches" are "made by a compounding process."

The parties continued to dispute the proper interpretation of the term "efficient mixing." The District Court construed the term "efficient mixing" by referring to two examples that were included in the patents' specification which compared Medicines' "old compounding process" using "inefficient mixing conditions" (Example 4), with the improved "efficient mixing" process developed for the patents (Example 5). The District Court found that Medicines had disclaimed the "inefficient mixing conditions" of Example 4, and construed the term "efficient mixing" to require "not using inefficient mixing conditions such as described in Example 4." On appeal, the parties also disputed whether the claims of the '727 Patent required "efficient mixing" in order to be infringed.

In construing the term "efficient mixing" the Federal Circuit focused on the so-called "batches limitation," common to the claims of the two patents, which restricts those claims to "batches hav[ing] a maximum impurity level of Asp^9 –bivalirudin that does not exceed about 0.6%." The Court acknowledged, however, that the batches limitation could not be literally construed as it was written, because to do so would render the claims of the patents invalid in light of Medicines numerous pre-patent batches of ANGIOMAX® having impurity levels below 0.6%. In order to construe the batches limitation in order to preserve the validity of the patents, the Court found that it required the use of a process that achieves batch consistency. This definition was arrived at based on the definition of "pharmaceutical batches" that was included in the specification, as modified by the District Court, that required the "batches" to be made by a particular compounding process. The specification specifically discussed the fact that "development of a compounding process for formulating bivaliruden that consistently generates formulations having low levels of impurities is desirable." Therefore, the "batches limitation" required a process that achieves consistency between batches produced from the "same compounding process" – *i.e.,* batch consistency. This is the characteristic of the patented process that distinguishes it from the prior art "old compounding process" of Example 4.

The Federal Circuit also found that this definition was required by statements made by Medicines during the prosecution of the patent application. Medicines represented to the Examiner that "in the

present invention, various embodiments relate to a less subjective and more consistent process for the mixing of the pH-adjusting solution with the bivalirudin solution," and it distinguished the prior art batches of ANGIOMAX® by arguing that batches of bivalirudin "prepared by the new process of the present invention" have not been on sale or offered for sale more than one year before the filing date of the two patents.

The Court noted that Medicines admitted to the District Court that "when viewed in the context of the specification, "pharmaceutical batches" refers to the compounding process described in the patents-in-suit. Based on this evidence, the Federal Circuit concluded that the consistent compounding process must use "efficient mixing," which the Court interpreted in light of Example 5 in the specification, which Medicines used to distinguish anticipating prior art that had been cited by the Examiner. The Court also noted that although Example 5 was described as "non-limiting," it was the only description of "efficient mixing" found in the specification that discloses what "efficient mixing" is, so that the Court found it appropriate to limit the definition of that term to that description.

There are many things to be learned from the *Medicines* case regarding the Federal Circuit's current thinking about the methodologies that may be used to properly construe the disputed terms of a patent's claims. In *Medicines,* the Court confirmed that many of those methodologies continue to be valid, and therefore should be considered when framing claim construction arguments. If there is prior art that may affect the validity of the claims, as there was in *Medicines,* a court may select a narrower interpretation of claim terms in order to avoid that prior art, and maintain the validity of the patent's claims. Even though the descriptions of the preferred embodiments in the specification are not supposed to be limiting, a Court may limit a claim term to the express definition that it is given in the specification, as happened in *Medicines* with the "pharmaceutical batches" term, or it may limit a claim term to the essential qualities of the invention that are described in the specification, particularly if those qualities are what distinguish the claimed invention with the prior art. Express definitions of claim terms that are found in the specification may also influence the interpretation of other disputed claim terms, in ways that were neither anticipated nor intended. With respect to the "efficient mixing" term, the Court limited its meaning to the sole description or embodiment of that term that was found in the specification. Finally, the Court in *Medicines* relied on statement made by the patent owner during prosecution of the patent applications, particularly when they were made to distinguish the cited prior art, in order to further limit the meaning of the disputed claim terms.

Therefore, patent practitioners must give careful consideration to whether they should include express definitions of claim terms in a specification, whether they should describe the essential qualities or characteristics of the invention in the specification, whether the specification should include only a single example or embodiment of the claimed invention or elements of the claimed invention, as well as what statements should be made to the Examiner during prosecution of the patent application in order to establish the patentability of the claims. Particular care should be given to discussing prior art and its relationship to the claimed invention, either in the specification or to the Examiner during prosecution. Failure to consider these factors when drafting and prosecuting a patent application may result in the patent claim terms being given an unnecessarily narrow interpretation by a court, and a potential inability

to enforce the patent claims against infringers.

President Trump's Executive Order on Violations of Trade and Customs Laws Promises to Enhance Protection of Intellectual Property Rights.

On March 31, 2017, President Donald J. Trump signed an Executive Order establishing enhanced collection of antidumping and countervailing duties and enforcement of violations of trade and customs laws. In doing so, President Trump recognized in the Executive Order the pivotal role that the enforcement of intellectual property rights plays in ensuring fair trading arrangement with foreign countries, and protecting American jobs and businesses. Therefore, the Executive Order directs the Customs and Border Protection agency ("CBP") of the Department of Homeland Security within the next 90 days to develop and implement a strategy and plan for combating violations of U.S. trade and customs laws for goods, and for enabling the interdiction and disposal, including through methods other than seizure, of inadmissible merchandize entering the United States through any mode of transportation, including merchandise which may infringe U.S. intellectual property rights (IPR).

At the U.S. Border, CBP is authorized to exclude, detain and/or seize imported merchandise on its own authority that infringes federally registered trademarks and copyrights that have been registered with CBP through a simple online procedure. CBP may also seize imported merchandise that infringes U.S. design or utility patents, pursuant to an exclusion order issued by the U.S. International Trade Commission after the conclusion of an Unfair Import Investigation that is conducted under Section 337 of the Tariff Act of 1930. CBP carries out these responsibilities in coordination with the National Intellectual Property Rights Coordination Center (IPR Center), which facilitates the exchange of enforcement, targeting and intelligence data with other IPR Center partners to locate and seize counterfeit and pirated goods. CBP also investigates criminal violations of U.S. intellectual property laws as they pertain to imported goods, and works closely with the business and international trade communities to enforce their intellectual property rights at the border.

President Trump's Executive Order seeks to enhance the effectiveness of these partnerships that CBP relies on to carry out its IPR enforcement role, and enable it to more consistently detect and seize counterfeit and infringing products at the border. In particular, the Executive Order directs the U.S. Department of the Treasury and the U.S. Department of Homeland Security to ensure that CBP is able to: 1) provide any information to the intellectual property rights holder in order to determine whether there has been an IPR infringement; and 2) provide any information to the intellectual property rights holder regarding merchandize that has been voluntarily abandoned before seizure, if the Commissioner of CBP reasonably believes that successful importation of the merchandize would have violated U.S. trade laws.

Under current laws and regulations, CBP is not obligated to provide this information to IPR owners when it discovers it during its investigative and enforcement activities. Based on the new enhanced enforcement policy outlined in the Executive Order, it is expected that CBP will begin to regularly share with IPR owners information regarding the nature and characteristics of the goods that is suspects of

including the trademarks and materials used to market them. This will enable the IPR owner to determine whether any of its patents, trademarks or copyrights have been infringed by the imported goods. CBP may also share with IPR owners any information that it has regarding the ports of entry, importers, purchasers, manufacturers or sources of origin of the suspected goods or materials. Armed with this information, IPR owners will be empowered to register their most relevant trademarks and copyrights with CPB and/or to seek an exclusion order from the U.S. International Trade Commission for violations of their U.S. design and utility patent rights. This sharing of information will also likely foster a more effective interaction between IPR owners and CPB, as IPR owners may use this information to conduct their own investigations and surveillance of potentially infringing imports, and be better able to alert CBP to potentially infringing or counterfeit shipments at particular ports of entry, so that the offending goods and material can be seized. This should result in greater protection for the rights of IPR owners whose goods, trademarks and copyrighted materials are susceptible to counterfeiting and cheap infringing imports.

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