No. 14-1538

IN THE

Supreme Court of the United States

LIFE TECHNOLOGIES CORPORATION, *et al.*,

Petitioners,

v.

PROMEGA CORPORATION,

Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* AGILENT TECHNOLOGIES, INC. IN SUPPORT OF PETITIONERS

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INTEREST OF AMICUS CURIAE

Agilent Technologies, Inc. ("Agilent")[1] is a $4 billion publicly-traded U.S. company, incorporated in Delaware and headquartered in California, with global manufacturing, sales, revenue and workforce.[2] Originally part of Hewlett-Packard, it was spun off as a separate company in 1999.[3] It is a leader in developing products and services for life sciences, diagnostics and chemical testing industries.[4] Agilent's products and services help diagnose and research disease, assess petrochemical products, evaluate environmental contamination, detect impurities in materials used in electronics manufacturing, and ensure food safety.[5]

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[1] All parties have been given appropriate notice and consented to the filing of this brief in letters that are on file with the Clerk. Petitioners have filed a blanket consent and the consent of Respondent is being lodged herewith. Pursuant to S. Ct. R. 37.6, counsel for *Amicus* state that no counsel for a party authored this brief in whole or in part and no person or entity, other than *Amicus* or its counsel, made a monetary contribution to the preparation or submission of this brief.

[2] *See* Agilent, Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (Dec. 21, 2015), Sec. & Exch. Comm'n File No. 001-15405 (hereafter, "Agilent 2015 10-K") at p. 3-4; *See also* Agilent, Agilent Fact Sheet (Mar. 18, 2015), http://www.agilent.com/about/companyinfo/agilent-fact-sheet.pdf. (hereafter, "Agilent Fact Sheet") (clarifying financials after spinoff of measurement business, now Keysight Technologies, Inc.).

[3] *See* Agilent, Company Information, http://www.agilent.com/about/companyinfo/index.html.

[4] *See* Agilent 2015 10-K at pp. 3-8.

[5] *See id.* at pp. 3-8.

Agilent has manufacturing activities in the United States and around the world that represent substantial investments. Agilent's life sciences and diagnostic business has manufacturing facilities in California, Colorado and North Carolina in the U.S. Outside of the U.S., Agilent has life sciences manufacturing facilities in Germany, Malaysia, Singapore and the U.K. Its FDA-registered sites include Texas, Colorado, Denmark and California.[6] Agilent's chemical analysis business is similarly diverse and global. Agilent's chemical analysis business has manufacturing facilities in California and Delaware in the U.S. Outside of the U.S., it has manufacturing facilities in the Netherlands and the United Kingdom.[7] Agilent's revenue is generated 35% in the Americas, 32% in Europe, and 33% in the Asia-Pacific region. Its 12,000-person workforce is located 36% in the Americas, 27% in Europe, and 37% in the Asia Pacific region.[8]

As is typical of global advanced technology companies, Agilent manufactures some standard products and also makes highly configurable products.[9] Many of its products incorporate individual components that are used in multiple other Agilent products. It utilizes just-in-time manufacturing and does not maintain a high level of inventory.[10] Accord-

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[6] *See id.* at pp. 7, 9.

[7] *See id.* at p. 11.

[8] *See* Agilent Fact Sheet.

[9] *See* Agilent 2015 10-K at pp. 7, 9.

[10] *See id* at pp. 7, 9.

ingly, Agilent must employ advanced global supply chain management systems that are flexible and responsive.

Agilent respects the intellectual property rights of others as a core corporate operating principle, so Agilent seeks reasonable certainty regarding patent infringement liability for making and sourcing U.S.-made components in a global supply and manufacturing system. The short timeframes for response in organization-wide supply chain management systems do not accommodate extended legal analysis of patent liability exposure as part of a decision on where to make or source a component, especially where that potential liability is based on a common, staple component used in multiple products. In addition, it can be expensive, time-consuming, and disruptive to establish new manufacturing facilities or move manufacturing to a different facility or country.[11] Thus, once approved manufacturing processes and practices are established at a particular facility or set of facilities, manufacturing will stay there absent emergency or other extenuating circumstances. This is particularly true in highly regulated industries such as Agilent's diagnostics business.

Accordingly, Agilent's worldwide manufacturing operations stand to be adversely impacted by the decision of the U.S. Court of Appeals for the Feder-

[11] *See* James Manyika *et al.*, *Manufacturing the Future: The Next Era of Global Growth and Innovation*, McKinsey & Co., Nov. 2012, at p. 54, http://www.nist.gov/mep/data/upload/Manufacturing-the-Future.pdf.

al Circuit in *Promega Corp. v. Life Technologies Corp.,* 773 F.3d 1338 (Fed. Cir. 2014). That decision created a test that imposes outsized liability for global sales of multi-component products based on manufacturing and shipment of commonplace, but technologically essential, components in and from the United States. That decision alters the patent law in a manner that reduces flexibility, increases risk and cost of U.S. manufacturing, and threatens to penalize U.S. manufacturing of components. The Federal Circuit's decision also makes U.S.-based manufacturers a target for speculative patent infringement allegations by exposing them to significant infringement liability for activities and sales occurring outside the U.S. based on a nominal or *de minimis* connection to the U.S.

SUMMARY OF ARGUMENT

This case does not merely concern an arcane point of patent law. Rather, it involves a serious threat to United States manufacturing operations reflecting a lack of understanding of modern manufacturing and supply chain management, global sourcing of components, and manufacturing constraints in regulated industries.

The Federal Circuit's decision imposed $52 million in U.S. patent damages based on worldwide sales of a completed product, triggered by the sourcing of a single staple component from the United States. This is a dramatic expansion of the text and purpose of 35 U.S.C. § 271, which was enacted to

target products that were effectively manufactured in the United States, but assembled overseas to artificially avoid the infringement statute. Section 271(f) addresses that problem by imposing liability in two narrow, and complementary, scenarios.

The Federal Circuit's test incorrectly expands section 271(f)(1) to impose liability where a single staple or commodity component is sourced from the United States. But U.S. sourcing of staple or commodity components is often desirable in modern supply chain management systems, which developed for legitimate business reasons—not from any attempt to artificially evade U.S. patent liability—and have become well-established and essential in the 30 years since Section 271 was enacted. Agilent's manufacturing of diagnostic kits provides an illustrative example of features of modern supply chain management and the pervasiveness and importance of the global sourcing of components, as well as the problems and risks of the Federal Circuit's incorrect test.

The Federal Circuit's "qualitative importance" test for staple components to trigger U.S. liability transforms millions of commonplace components into jurisdictional hooks for U.S. patent liability on entire products having minimal connection to the United States. This result is inconsistent with the text and purpose of the statute, unpredictable, and difficult to risk-manage except by moving component manufacturing abroad. Paradoxically, the outsized damages amount in this case, of $52 million for a single component, is significant enough to

have material effects on manufacturing and sourcing decisions, and has the potential to drive component manufacturing overseas even when U.S. manufacturing would otherwise be optimal.

ARGUMENT

I. SECTION 271(f) PRECLUDES SPECIFIC SETS OF CONDUCT AND CIRCUMSTANCES THAT CONGRESS DETERMINED UNFAIRLY CIRCUMVENT U.S. PATENT LAW

Section 271(f) was enacted to prevent the avoidance of liability under U.S. patent law by the mere expedient of exporting a patented invention in unassembled pieces where the patented invention is otherwise substantially manufactured entirely within the United States. Section 271(f) addresses two scenarios, the first where multiple components (including commodity components) are made in and exported from the United States and the second where individual specialized components are made in and exported from the United States. The statute imposes specific sets of conduct and circumstances necessary to trigger liability.

A. Section 271(f) Remedies a "Fraud on the Infringement Statute"

Congress enacted 271(f) in response to *Deepsouth Packing Co., Inc. v. Laitram Corp.*, 406 U.S. 518, 524 (1972)("*Deepsouth*"). *Deepsouth* was decided in the context of several earlier cases with which it shares a common foundation: substantial conduct

within the United States in furtherance of infringement of a U.S. patent that artificially avoids liability by deferral of routine final assembly.

An early Second Circuit case, *Radio Corporation of America v. Andrea*, 79 F.2d 626 (2nd Cir. 1935) involved the export from the United States of all of the parts of a patented combination invention (a combination of electrical circuits embodied in a radio receiver and vacuum tubes) in unassembled form with the intent that the parts be assembled by the purchasers into the patented combination outside the United States (by placing the vacuum tubes into the receiver's sockets). 79 F.2d at 627. The defendant both manufactured the receiver and purchased the vacuum tubes within the United States, and exported them together in the same carton but with the vacuum tubes not placed in the sockets. *Id*. The Second Circuit initially found no infringement because the individual receiver and vacuum tube components were not combined into the invention until after those individual components were outside the United States. *Id*. at 628 (the patentee's "monopoly does not cover the manufacture or sale of separate elements capable of being, but never actually, associated to form the invention. Only when such association is made is there a direct infringement of his monopoly, and not even then if it is done outside the territory for which the monopoly was granted.").

The Second Circuit reversed course, however, after new facts came to light on remand. The defendant conceded that the vacuum tubes were placed

into the sockets of the receiver within the United States for testing before then being disassembled for export. *Radio Corporation of America v. Andrea*, 90 F.2d 612, 613 (2nd Cir. 1937). The court found that "[w]here the elements of an invention are thus sold in substantially unified and combined form, infringement may not be avoided by a separation or division of parts which leaves to the purchaser a simple task of integration" because "[o]therwise a patentee would be denied adequate protection." *Id*. This second *Andrea* decision was construed in subsequent decisions as imposing liability only where the components were initially assembled into the patented invention within the United States before being disassembled for export and re-assembly abroad.

In *Cold Metal Process Co. v. United Engineering & Foundry Co*., 235 F.2d 224 (3rd Cir. 1956), the Third Circuit applied the rule of the first *Andrea* decision. The defendant manufactured all of the parts for 14 steel rolling mills within the United States and exported those unassembled parts to be assembled by the purchasers into completed mills outside the United States. 235 F.2d at 229. Where those parts were exported in unassembled form for assembly outside the United States, manufacturing all of the parts of a patent invention within the United States was not infringing. *Id*. at 230. The Third Circuit distinguished the second *Andrea* decision on the grounds that the mills had not been initially assembled and tested within the United States and then disassembled for export. *Id*. at 230

("In the present case, however, no such assembling or testing in this country took place. Accordingly the rule laid down in the first *Andrea* opinion applies here rather than that stated in the second.").

The Seventh Circuit also followed the first *Andrea* decision in *Hewitt Robins, Inc. v. Link-Belt Company*, 371 F.2d 225 (7th Cir. 1966), where the defendant manufactured the individual parts for a patented reclaiming device, assembled certain portions of it within the United States to "check clearances" and "to ensure fit," and exported the parts in multiple shipments to Turkey where they were assembled into the completed reclaimers with the defendant's assistance. *Id*. at 227-28. The Seventh Circuit affirmed the district court's determination that there was no infringement because "the manufacture and sale in this country of parts of an apparatus to be assembled outside the territorial limits of the United States does not infringe a combination patent limited to the embodiment of those parts as elements in combination." *Id*. at 229.

The *Deepsouth* cases arose in the Fifth Circuit from an adjudged infringer's request for relief from an injunction, seeking court approval to manufacture in the United States all of the components of a multicomponent shrimp vein-removing device and export those components to Brazil with the intent that they be assembled there. *Laitram Corp. v. Deepsouth Packing Co.*, 310 F.Supp. 926, 926 (E.D. La 1970)("defendant will supply all of the parts necessary for the complete operation of the slitter and deveiner"); *Laitram Corp. v. Deepsouth Pack-*

ing Co., 443 F.2d 936, 938 (5th Cir. 1971)(quoting the president of Deepsouth advising a foreign customer that "we can manufacture the entire machine without any complication in the United States, with the exception that there are two parts that must not be assembled in the United States, but assembled after the machine arrives in Brazil"); *Deepsouth*, 406 U.S. at 524 ("Deepsouth in all respects save final assembly of the parts 'makes' the invention. It does so with the intent of having the foreign user effect the combination without Laitram's permission.").

The district court followed the rule of the first *Andrea* case and the *Cold Metal Process* and *Hewitt Robins* cases and determined that the proposed course of action would not infringe and was therefore permissible under the injunction. *Laitram Corp.*, 310 F.Supp. at 927-29 (E.D. La 1970). The Fifth Circuit disagreed, however, holding that "when all the parts of a patented machine are produced in the United States and, in merely minor respects, the machine is to be finally assembled for its intended use in a foreign country . . . the machine is 'made' within the United States." 443 F.2d 936, 939 (5th Cir. 1971). The Fifth Circuit expressed concern that a person could "set up shop next door to a patent-protected inventor whose product enjoys a substantial foreign market and deprive him of this valuable business" and thus "be allowed to reap the fruits of the American economy—technology, labor, materials, etc." without being "sub-

ject to the responsibilities of the American patent laws." *Id*.

This Court reversed, endorsing the rule of the first *Andrea* case and the *Cold Metal Process* and *Hewitt Robins* cases. This Court framed the issue in terms of what was made and sold within the United States. 406 U.S. at 527 ("[t]he sales question thus resolves itself into the question of manufacture: did Deepsouth 'make' (and then sell) something cognizable under the patent law as the patented invention, or did it 'make' (and then sell) something that fell short of infringement?"), and determined that the patented invention had not been "made" within the United States, *id*. at 528 ("We cannot endorse the view that the 'substantial manufacture of the constituent parts of [a] machine' constitutes direct infringement when we have so often held that a combination patent protects only against the operable assembly of the whole and not the manufacture of its parts.").

This Court recognized how close Deepsouth had come to infringing, 406 U.S. at 524 ("Deepsouth in all respects save final assembly of the parts 'makes' the invention. It does so with the intent of having the foreign user effect the combination without Laitram's permission. Deepsouth sells these components as though they were the machines themselves; the act of assembly is regarded, indeed advertised, as of no importance"), but explained that the substantial manufacture of the constituent parts of a patent invention could not be a

direct infringement "absent a congressional recasting of the statute." *Id.* at 528.

In each of these cases, the defendants reaped the reward of substantial conduct within the United States while narrowly and artificially evading the literal reach of the patent infringement statute. Each of the defendants manufactured or sourced all of the components of a patented invention within the United States and exported them from the United States, thereby exploiting "the fruits of the American economy—technology, labor, materials, etc." (as the Fifth Circuit explained in its *Deepsouth* decision) as well as the benefits and protections of United States law and other conveniences and efficiencies of operating locally. Each of the defendants also intended the parts to be assembled outside the United States, and thereby to compete with the owner of the U.S. patent for foreign sales. Despite the significant U.S.-based activities and interests, each of the defendants nevertheless successfully remained a hair's breadth away from infringing U.S. patents.

In 1984, Congress "recast" the statute, enacting section 271(f) to provide a remedy for the foregoing scenario. PUB. L. 98-622, NOV. 8, 1984, SECTION 101(A), 98 STAT. 3383. Section 271(f) is analogous to the doctrine of equivalents where the "fraud on a patent" remedied by that doctrine may be likened to a "fraud on the infringement statute" remedied by 271(f). For example, in the same way that "permit[ting] imitation of a patented invention which does not copy every literal detail . . . convert[s] the

protection of the patent grant into a hollow and useless thing," *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950), permitting an invention to be substantially completed before leaving the United States, with only routine extraterritorial effort required to complete it and put it into service, rendered Section 271 unable to offer a remedy. The deferral of the final assembly which artificially avoided the reach of Section 271 can be viewed as an "unimportant and insubstantial change[]" that "place[s] the inventor at the mercy of verbalism and would be subordinating substance to form." *Id.* at 607. By enacting Section 271(f), Congress patched a hole in the patent law that was "leav[ing] room for—indeed encourage[ing]—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law." *Id.*

B. Congressional Limits on the Scope of Section 271(f): The Anatomy and Harmony of Section 271(f)

In simple conceptual terms, the essential act of infringement set forth in 271(f) is supplying one or more components of an invention from the United States to be combined outside the United States into that invention. But section 271(f) imposes specific conditions on that essential act of infringement to ensure that the prohibited conduct is narrowly targeted and does not amount to an

improper or undue extraterritorial application of U.S. patent law. Each of the subsections, (f)(1) and (f)(2), target specific conduct and circumstances, and each has two basic parts: First, a characteristic or characteristics of that which is supplied from the United States, and, second, an act or state of mind of the supplying person.

Section 271(f)(1) provides only one essential characteristic of that which is supplied from the United States: That it be "all or a substantial portion" of the components of a patented invention. The act or state of mind of the supplying person is supplying in a manner to "actively induce" someone to combine those supplied components outside the United States in a manner that would infringe the patent if such combining were done within the United States. Pursuant to well-recognized statutory construction principles, "actively induce" in 271(f)(1) should mean the same thing as "actively induces" in 271(b) such that there is a state of mind element and an objective act element. *See, e.g.*, *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060 (2011)("Although the text of § 271(b) makes no mention of intent, we infer that at least some intent is required. The term 'induce' means '[t]o lead on; to influence; to prevail on; to move by persuasion or influence.' WEBSTER'S NEW INTERNATIONAL DICTIONARY 1269 (2d ed. 1945). The addition of the adverb 'actively' suggests that the inducement must involve the taking of affirmative steps to bring about the desired result, *see id.*, at 27.").

The requirements of (f)(1) are logically linked to ensure that the covered circumstances would, but for the statute, be an artificial evasion of what Congress deemed the otherwise appropriate domestic reach of U.S. patent law. For example, under (f)(1) the manufacturing and export of staple or commodity goods invokes liability under U.S. patent law only where those commodity goods represent all or a substantial portion of the patented invention and there is active inducement to combine them into the invention abroad. Those specific requirements provide the indicia that the conduct at issue is properly subject to U.S. patent law and not an improper extraterritorial application of U.S. patent law.

In contrast, section 271(f)(2) provides three essential characteristics of that which is supplied from the United States: (i) at least one (*i.e.*, "a") component of a patented invention (ii) that is especially made or especially adapted for use in the patented invention and (iii) not a staple article or commodity of commerce suitable for substantial non-infringing use. The act or state of mind of the supplying person is knowledge of those characteristics of the component and intent that the component will be combined in a manner that would infringe if done within the United States. As with "actively induces" in section 271(f)(1), the knowledge requirement in 271(f)(2) should mean the same thing as "knowing the same to be especially made or especially adapted for use in an infringement of such patent" state of mind requirement of

section 271(c). *See, e.g., Global-Tech*, 131 S. Ct. at 2067 ("A violator of § 271(c) must know 'that the combination for which his component was especially designed was both patented and infringing.'"); *Commil v. Cisco*, 135 S.Ct. 1920, 1926 (2015)("Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement.").

Like subsection (f)(1), the requirements of (f)(2) are logically linked to ensure that the covered circumstances would, but for the statute, be an artificial evasion of what Congress deemed the otherwise appropriate reach of U.S. patent law. For example, (f)(2) applies where only a single component especially made or especially adapted for use in the patented invention is supplied, and in that situation only the associated knowledge and intent, as opposed to active inducement, are needed to provide sufficient indicia that the supply of that specialized component is properly subject to U.S. patent law and not an improper extraterritorial application of U.S. patent law.

Subsections (f)(1) and (f)(2) and their respective (and very different) requirements present not only contrast but harmony in providing remedies while avoiding unintended or improper extraterritorial application of U.S. law. For example, the specialization of the component—an objective fact—in (f)(2) speaks for itself in a manner that commodity goods cannot, and active inducement—an objective act—in (f)(1) adds evidentiary weight that subjective knowledge and intent cannot.

For interpretive purposes, subsection (f)(1) directly echoes the facts of the above-discussed cases against which section 271(f) was enacted, where all of the components of the patented inventions were made in the United States and exported with an intent they be routinely combined. That should be the starting point for determining the scope of liability under subsection (f)(1). The additional scope introduced by the words "or a substantial portion" should therefore be evaluated from the perspective of how close the portion of the components supplied comes to being "all" of the components of the patented combination.

At very least, then, the manufacture within and export from the United States of a single component of a multicomponent product should not trigger potential liability under subsection (f)(1). In such a scenario, the patentee should have remedy, if any at all, solely under subsection (f)(2). Where a single component manufactured within and exported from the United States is a commodity component, there should be no remedy at all under section 271(f).

II. MODERN SUPPLY CHAIN MANAGEMENT SYSTEMS AND THE GLOBAL SOURCING OF COMPONENTS FROM VARIOUS COUNTRIES EVOLVED FOR VALID ECONOMIC REASONS, NOT TO CIRCUMVENT U.S. PATENT LAW

Manufacturing has changed profoundly in the 30 years since Section 271(f) was enacted, due to the

development and widespread adoption of supply chain management. These changes occurred for valid economic reasons and not to circumvent U.S. patent law.

A. Supply Chain Management Systems & Global Sourcing Have Dramatically Altered Manufacturing

1. Origins of Supply Chain Management Systems

Although the concept may seem intuitive today, the term "supply chain management" was only coined by the management consultant Keith Oliver in 1982, two years before § 271(f) was enacted.[12] At that time, it was radical to suggest that a company's production, sales, finance, marketing and distribution functions should work in a coordinated fashion, to eliminate problems arising from each function viewing its goals and plans in isolation, and to instead view these functions as part of an integrated supply chain in order to make finished goods available more efficiently.[13]

Today, supply chain management is a well-established field, with academic programs at the Massachusetts Institute of Technology,[14] Michigan State

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[12] *See* Tim Laseter & Keith Oliver, *When Will Supply Chain Management Grow Up?*, strategy+business, Fall 2003, http://www.strategy-business.com/article/03304?gko=54182.

[13] *See id.*

[14] Mass. Inst. of Technology, MIT Supply Chain Management, http://scm.mit.edu/program.

University,[15] and Penn State,[16] among many others. Companies have chief procurement officers to lead these efforts.[17] Specialized software is employed to design and monitor the supply chain.[18] Supply chain management systems are ever more sophisticated in their efforts to analyze the entire supply chain strategically to balance cost, risk, and flexibility.[19] There is a greater understanding and sophistication of these tradeoffs, as early efforts at high-speed, low-cost supply chains proved unable to respond to unexpected changes in supply.[20] There is constant attention to designing supply chains that have sufficient flexibility and redundancy to be resilient in the face of political unrest and natural disasters.[21]

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[15] Michigan State Univ. Eli Broad School of Business, Department of Supply Chain Management, https://supply-chain.broad.msu.edu/.

[16] Penn. State Univ. Smeal College of Business, Master of Professional Studies in Supply Chain Management, http://www.smeal.psu.edu/mps.

[17] *See* Laseter & Oliver, *supra* n.12.

[18] *See* Claudia H. Deutsch, *Supply Chain Software: An Industry on a Thrill Ride,* N.Y. Times, May 31, 1998.

[19] *See* Laseter & Oliver, *supra* n.12.

[20] *See* Hau L. Lee, *The Triple-A Supply Chain,* Harvard Bus. Rev., Oct. 2004.

[21] *See* David Simchi-Levi *et al.*, *From Superstorms to Factory Fires: Managing Unpredictable Supply-Chain Disruptions*, Harvard Bus. Rev., Jan. 1, 2014.

2. Evolution From Initial Focus on Cost-Cutting to Reflect the Need for Resilience to Disruptions and Disasters

Modern supply chain management requires efficient, flexible, responsive and resilient manufacturing operations that minimize inventory and cost, while allowing for rapid response to changes in customer demand or to crises that disrupt operations. To be competitive, companies must design rapidly adaptable products and be able to rapidly adapt individual manufacturing sites. This is accomplished through modern supply chain management systems, in which each manufacturing site must be an integrated component of the company's operations.

Supply chain management must be capable of dealing not only with ordinary recurring risks, such as labor disputes, transportation breakdowns, and changes in customer preference, but also with rare but significant disruptions.[22]

The difference between the response of Cisco Systems, Inc. ("Cisco") to Hurricane Katrina in 2005 and to the Japanese earthquake and tsunami in 2011 demonstrates the continuing evolution of supply chain management, and is illustrative of the level of responsiveness that is expected in today's

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[22] *See* Sunil Chopra & Manhohan S. Sodhi, *Reducing the Risk of Supply Chain Disruptions*, MIT Mgmt. Rev., Spring 2014, at 73, 74, http://sloanreview.mit.edu/article/reducing-the-risk-of-supply-chain-disruptions/.

business environment. After Hurricane Katrina, Cisco found that its supply chain management was inadequate to satisfy the immediate demand for $1 billion in new equipment to replace damaged telecommunications infrastructure. Cisco's risk mitigation and response system could not locate all its products in the supply chain or determine the financial effects of emergency sales. In response to this failure, Cisco redesigned its supply chain management and six years later, after the March 11, 2011 Japanese earthquake and tsunami, Cisco was able within 12 hours to assess the effects on 300 suppliers in the region and 7,000 affected parts, plan a response, and identify teams to field customer inquiries. [23]

This current emphasis on adaptability and resilience represents a shift from previous decades, when manufacturers focused more narrowly on minimizing inventory and trimming costs of production. Some of the techniques used to lower production cost—such as outsourcing to low-cost production sites in faraway countries, relying on fewer suppliers, and excessively relying on common interchangeable parts—were rejected in favor of truly modern supply chain systems that balanced many factors.[24]

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[23] *See* Maria Jesús Sáenz & Elena Revilla, *Creating More Resilient Supply Chains*, MIT Mgmt. Rev., Summer 2014, http://sloanreview.mit.edu/article/creating-more-resilient-supply-chains/.

[24] *See* Chopra & Sodhi, *supra* n.21, at 74.

3. "Postponement" and the Use of Multi-purpose Components are Essential Strategies in "High Mix-Low Volume" Markets

Agilent is typical of modern supply chain management trends for advanced technology global companies. Like its peers, Agilent relies upon sophisticated supply chain management consulting and tools to manage the variation in demand for its products.[25] Its market is global, drawn equally from Europe, Asia and the Americas, and Agilent deploys its workforce and manufacturing operations among those regions as well. It faces routine fluctuations in demand as well as the risk of major unexpected disruptions.

Much of Agilent's market is "high mix-low volume"—that is, it moves a comparatively small number of units of each of its products, and clients demand a much greater degree of customization. [26] Agilent has responded to this "high mix-low volume" market by designing products that use common components that can be readily customized in different configurations in response to demand. This process is termed "postponement" because it

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[25] *See* Kinaxis, *Comprehensive Supply Chain Visibility Across a Multi-Enterprise Supply Chain*, http://www.kinaxis.com/ Global/resources/case-studies/comprehensive-supply-chain-visibility-agilent-case-study-kinaxis.pdf (hereafter, "Kinaxis Study"). (While this study was prepared prior to the spinoff of Keysight from Agilent in 2014, the case study remains accurate for the facts cited in this *amicus* brief.).

[26] *See* Kinaxis Study, *supra* n.25.

allows companies to maintain the ability to respond to market demand later in the production cycle.[27] Indeed, Hewlett-Packard, from which Agilent was spun off in 1999, was a pioneer in successfully using modular product design to "mass-customize" products quickly while keeping its costs low, as when purchasers of personal computers select the desired features and the product is assembled to order.[28] Like its peers, Agilent manages risk by establishing multiple sources of supply and redesigning products to use alternative components.[29] Agilent must be able to plan, instantly monitor and tightly manage a supply chain network that involves participants scattered around the globe. [30]

4. The Use of Globally-Sourced Components Has Significant Public Benefits And Is Not For the Purpose of Circumventing U.S. Patent Law

In contrast to the facts of *Deepsouth* and the other pre-271(f) cases, modern supply chain management practices did not arise from any desire to thwart or artificially avoid liability under U.S.

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[27] *See* Hau L. Lee, *supra* n.20.

[28] Edward Feitzinger & Hau L. Lee, *Mass Customization at Hewlett-Packard: The Power of Postponement,* Harvard Bus. Rev., Jan. 1997. *See also Mass Customization,* The Economist, Oct. 22, 2009, http://www.economist.com/node/14299807.

[29] *See* Agilent 2015 10-K at p. 12.

[30] *See* Kinaxis Study, *supra* n.25.

patent law. The use of global sourcing of components is consistent with trends in consumer goods, and evolved in the life sciences industry, as it did in other industries, for the purpose of remaining economically competitive by delivering high-quality products that meet market demand in a timely fashion.

There are also significant public policy benefits to supply chain management in the diagnostic, pathology and life science businesses. In these businesses, shortages have consequences of substantial public concern. Shortages in the health care industry make manufactures, consumers, and patients vulnerable to counterfeiters and gray market vendors selling healthcare products at a significant markup, which poses risks to patients.[31] Shortages can therefore result in ineffective therapy, increased drug resistance due to substandard medications, and injury from counterfeit substances.[32] Shortages can also delay treatment, cause physicians to choose therapies that are less effective or have avoidable risks, and disrupt clinical trials and other research.[33]

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[31] *See* Thomas Ebel *et al.*, *Building New Strengths in the Healthcare Supply Chain*, McKinsey & Co., Jan. 2013, at 3, http://www.mckinsey.com/insights/health_systems_and_services/strengthening_health_cares_supply_chain_a_five_step_plan.

[32] *See id.* at 4.

[33] *See* U.S. Food and Drug Administration, *Strategic Plan for Preventing and Mitigating Drug Shortages* (Oct. 2013) at 8, http://www.fda.gov/downloads/-Drugs/DrugSafety/DrugShortages/UCM372566.pdf.

B. Agilent's Diagnostic Kits Are Illustrative of Key Features of Modern Supply-Chain Management

Agilent's diagnostic kits illustrate how modern supply chains systems use common commodity components across multiple products. They also illustrate a complementary feature: the need for certainty and stability for manufacturing in regulated industries.

1. Agilent's Estrogen/Progesterone Diagnostic Test Kits for Breast Cancer

In the diagnosis of breast cancer, testing for various biomarkers is now routine to help assess the aggressiveness of the cancer and identify factors that may fuel tumor growth or be responsive to treatment. Receptivity to estrogen and progesterone is one of these factors, and testing of tumor samples for estrogen-progesterone responsiveness ("ER/PR") is standard of care.[34] Patients whose tumors are strongly ER/PR receptive can make lifestyle changes (such as avoiding hormonal methods of birth control, pregnancy, and estrogen replacement therapy for menopause) and are treated with medications that alter the body's production and response to these hormones.[35]

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[34] American Society of Clinical Oncology, *Estrogen and Progesterone Receptor Testing for Breast Cancer,* http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/estrogen-and-progesterone-receptor-testing-breast-cancer.

[35] *See id.*

Agilent offers several ER/PR kits and products, which are described in the pathology catalogue of Agilent's Dako subsidiary.[36] One of these products is product number SK310, an ER/PR test kit, which is designed for use in automated pathology slide staining instruments,[37] which allow tissue samples to be processed more rapidly.[38] Agilent also sells the ER and PR antibodies separately.[39]

The SK310 ER/PR kit product specification lists the kit components.[40] These include:

- Epitope retrieval solution (a citrate buffer with an antimicrobial agent);
- Peroxidase-blocking reagent;
- ER antibody cocktail;
- PR antibody;
- Negative control reagent;

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[36] Dako, *2016 Catalog: Products and Services (Pathology)*, pp. 146-147, http://www.dako.com/us/08005_pathology-catalog-2016_us.pdf (hereafter, "Pathology Catalog"). Dako was acquired by Agilent in 2012. *See* Agilent 2015 10-K at 29, n.1.

[37] *See* Pathology Catalog at pp. 38, 146-147. Dako, ER/PR pharmDx Kit for the Dako Autostainer, http://www.dako.com/us/ar49/p235372/prod_products.htm.

[38] *See* Dako, *Dako Autostainer Plus User Guide*, http://www.dako.com/0003107_rev_d_man_user_guide_autostainer_plus_english.pdf; Dako, Autostainer Link 48, http://www.dako.com/us/ar48/p235462/prod_products.htm.

[39] *See* Pathology Catalog, at pp. 46, 50.

[40] *See* Dako, ER/PR pharmDx Kit (Link) (SK310), http://www.dako.com/us/download.pdf?objectid=128036002 (hereafter, SK310 Product Specifications).

- Visualization reagent;
- DAB+ substrate buffer;
- DAB+ chromogen;
- Reagent bottles;
- Wash buffer concentrate; and
- Control slides.[41]

Additional materials and equipment, such as slides, coverslips, water, a microscope, a pressure cooker, and tissue samples, are required, but not supplied with the kit.[42]

2. Agilent's ER/PR Kit Includes Interchangeable Staple Components

The wash buffer concentrate used with Agilent's SK310 ER/PR Kit is an example of a staple, commonplace component used in Agilent's diagnostic products. This component is used to prepare a wash buffer for use in immunohistochemical testing procedures, which use antibodies to identify specific protein components of tissue samples.[43] The wash buffer can be used in Dako testing equipment or when staining manually.[44] This particular

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[41] *See* SK310 Product Specifications at pp. 1-3.

[42] *See id.* at p. 3.

[43] Dako, Wash Buffer 10x (S3006) Product Specification Sheet, p. 1, http://www.dako.com/us/download.pdf?objectid=107011002.

[44] *See id.*

wash buffer concentrate is included in seven Agilent products, including both ER/PR test kits, and other test kits, and is sold separately.[45]

The wash buffer is technically essential to the test. It is used to remove unwanted molecules, but is relatively inert so that it does not react with and alter the specimen.[46] While it is important for a wash buffer to be formulated correctly to avoid generating false negative or positive results, wash buffer is a commonplace component in many tissue testing procedures and finished products.

3. Agilent's Diagnostic Business Includes U.S. Manufacturing Facilities

Agilent's diagnostics business is also typical of regulated industries in which manufacturing facilities require governmental approvals to operate, and component manufacturing needs to meet stringent quality control requirements.[47] Because it is costly and time consuming to establish such facili-

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[45] Dako, Safety Data Sheet: Wash Buffer 10x, http://www.dako.com/us/download.pdf?objectid=126645001 (Listing products in which the wash buffer is used, under "material uses.").

[46] *See* SK310 Product Specifications, at p. 8 (general limitations no. 7), p. 10 ("Troubleshooting").

[47] *See, e.g.,* U.S. Food and Drug Administration, Overview of IVD Regulation, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm#14 (in particular, sections entitled "How does FDA Look at Quality Control?: and "What are Good Manufacturing Practices (GMPs) and Quality System Regulations (QSRs)?)."

ties, manufacturers like Agilent site them with the goal of having them operate long-term. Agilent's life sciences and diagnostic business has manufacturing facilities in California, Colorado and North Carolina in the U.S.[48] It has long been recognized, particularly in the pharmaceutical and life sciences industries, that an agile supply chain requires stability in planning, scheduling, and performance management to meet demand in regulated industries and if the supply chain is to be responsive to demand changes.[49]

III. THE FEDERAL CIRCUIT'S "QUALITATIVE IMPORTANCE" TEST IS CONTRARY TO THE STATUTE, VAGUE AND IMPRACTICABLE, AND WILL PROFOUNDLY AFFECT COMPANIES THAT MANUFACTURE COMPONENTS IN THE UNITED STATES

A. The Federal Circuit's "Qualitative Importance" Test Blurs (f)(1) and (f)(2), Extends Far Beyond Reversing *Deepsouth*, and Frustrates the Statutory Scheme

As discussed Section I *supra*, sections 271(f)(1) and 271(f)(2) provide harmonious and complementary protections where an invention is substantially completed within the United States but patent infringement liability is avoided merely because the insubstantial assembly of the completed invention occurs outside the territorial limits of the

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[48] *Supra* n. 6.

[49] *See,* Ebel, *supra* n. 31, at 6.

United States. The statutory requirements regarding that which is supplied from the United States and the action or state of mind of the supplier are specific, different, and complementary, and the statute expressly sets forth minimum connections to intra-United States activity and interests necessary for liability to be imposed.

The Federal Circuit's test for liability under 271(f)(1) is incorrect because instead of asking whether "all or a substantial portion of the components of the invention" are at issue, the Federal Circuit's test asks how "important" a component is to the invention. *See Promega Corp. v. Life Technologies Corp.*, 773 F.3d 1338, 1353 (Fed. Cir. 2014)("we disagree with the district court that a single component supplied from the United States, no matter how important or central to the invention, can never constitute 'a substantial portion of the components of a patented invention.' "). Subsection (f)(1) focuses on the substantiality of U.S.-based activity in terms of how much of a multi-component invention is made in the United States, not how important a particular component is. The Federal Circuit's test imposes liability in circumstances with far more limited U.S. connections and interests than were at issue in the judicial decisions that section 271(f) was designed to overrule, disrupts the harmony of the two subsections, and introduces vagueness by importing (f)(2)-like considerations into (f)(1).

Subsection (f)(1) is based on *Deepsouth* and each of the other related decisions that involved supply

of all of the components of the invention. Congress extended liability where "a substantial portion" of all of the components are supplied from the United States to allow limited flexibility and in keeping with the statute's intent to prevent essentially fraudulent efforts to circumvent liability under section 271. But this flexibility cannot fairly be read to extend to imposing liability for the supply of a single technologically "important" component. The technological "importance" of a particular component is relevant, if at all, only to whether the component is "especially made or especially adapted for use in the invention" under subsection (f)(2). The Federal Circuit's test essentially converts (f)(1) into a vague and more lenient backup for (f)(2) where the latter's requirements are not satisfied.

B. The Federal Circuit's Test Adversely Affects Legitimate Interests in Efficient Supply Chain Management

The problem with the Federal Circuit test is exacerbated by unavoidable aspects of widely applied global sourcing and supply chain management systems, where products may include staple elements sourced from numerous countries. For example, if a single commodity or staple component such as Taq polymerase can be viewed as sufficiently "important" to an invention to trigger liability under 271(f)(1), then presumably so could many other staple, commodity goods. Modern supply chain management systems and global sourcing of components are legitimate features of the modern

business landscape with valid economic rationales, and they did not develop, and are not intended, as mechanisms to evade the otherwise legitimate reach of U.S. patent law. Accordingly, the implementation of modern supply chain management and global sourcing should not be routinely or presumptively suspect, or viewed as an intent to evade U.S. patent liability.

Further, companies like Agilent source components and site component manufacturing based on factors such as cost, safety, labor, proximity to markets, political stability, and predictable rules of law. The Federal Circuit's test would unduly burden companies relying on global sourcing of components because they will now need to factor in the potential for patent liability on worldwide sales on finished products whenever they site a component manufacturing facility in the United States or consider using a common component sourced from the U.S. Thus, cabining the concept of technological importance of a component within subsection (f)(2), where it belongs, would yield greater predictability and reduced burden.

C. The Federal Circuit's Test Creates An Exception That Swallows the Rule, Especially for Diagnostic and Life Sciences Businesses Such as Agilent

In this case, Life Technologies' Taq polymerase performed a standard molecular biology process (amplifying and increasing the quantity of DNA) in the context of a larger and more complex set of

reactions and steps to analyze a biological sample. If the Taq polymerase used by Life Technologies is deemed to be a "main" or "major" component because it is essential to the functioning of the test as a technological matter, or because witnesses testify to its technological importance to the overall functioning of test kit, any commodity or staple component that performs a necessary technological process could also be considered a "main" or "major" component of a patented invention.

The Federal Circuit's test is especially problematic in diagnostic businesses, because the nature of a diagnostic kit is such that all its components must function properly together to obtain a correct result, and each component is therefore arguably "important."

1. Most Components in Diagnostic Kits Could Be Deemed "Essential" Under The Federal Circuit's Test

The Federal Circuit cited two factors for the "qualitative importance" test for determining whether a component is a "substantial" portion of the components: First, (i) inoperability in absence of the component; and second, (ii) admission by defendant that the component was "one of the 'main' and 'major' components of the kits." *Promega,* 773 F.3d at 1356.

Assuming hypothetically that Agilent's ER/PR kit corresponds to a U.S. patented invention, virtually any component could be viewed as "qualitatively important." For example, the kit is used to

perform a chemical process and the wash buffer performs an essential function in that chemical process by washing away unwanted molecules from the specimen so that the remaining, stained portions of the sample can be evaluated. In the SK310 ER/PR kit, the wash buffer is one of eleven items, and one of three items for which there is a Safety Data Sheet. In a similar product, the K4071 ER/PR kit, it is one of eleven items, and one of just five items for which there is a Safety Data Sheet. Agilent's ER/PR kits would be inoperable without the wash buffer, and a witness might view the wash buffer in its technological context and testify that it is important or essential to the kit.

It is not plausible, however, that supplying wash buffer from the United States as a commodity component of a multicomponent diagnostic test kit is what section 271(f)(1) is designed to prohibit, especially on pain of patent infringement liability for the entire test kit. Perhaps if *all* of the components *besides* the wash buffer were supplied from the United States, and the necessary intent to actively induce infringement existed, a situation comparable to that in the cases and to that contemplated by 271(f)(1) would be present. But certainly supplying one non-specialized component should not trigger liability under Section 271(f)(1).

2. "Qualitative Importance" of a Component Is Relevant, If At All, Only Under Section 271(f)(2)

The Federal Circuit's test undermines the role of subsection (f)(1) and essentially creates a less stringent version of 271(f)(2). To the extent that the qualitative importance of a single component to an invention is relevant at all, it is addressed in Section 271(f)(2) in the form of that subsection's requirement that the supplied component be "especially made or adapted" for the invention and not a "staple article or commodity of commerce suitable for substantial noninfringing use."

Neither Life's Taq polymerase nor Agilent's wash buffer would trigger liability under subsection (f)(2) because neither Taq polymerase nor wash buffer is "especially made or adapted for use in [any] invention." Indeed, both are staple items that can be used in many molecular biology processes or tissue analysis kits and other products, including no doubt many that do not implicate any patents.

The Federal Circuit's test effectively transforms 271(f)(1) into a "backup" that will "save" claims that do not meet the more stringent standards of Section 271(f)(2) regarding the character of the component supplied from the United States. If the infringement inquiry relates to a single component, then the question under 271(f) is whether the component is "especially made or adapted" for the invention and not a "staple article or commodity of commerce suitable for substantial noninfringing

use" under subsection (f)(2). The inquiry should not also be whether it is "important" to the invention under subsection (f)(1).

3. U.S. Manufacturing of Individual Commodity Components Is Not the Type of Fraudulent Avoidance of U.S. Patent Law that Was Targeted by Congress When It Enacted Section 271(f)

Deepsouth and the related earlier cases involved manufacturers that omitted the final step of the assembly in an obvious attempt to avoid the literal reach of the patent law. Congress enacted Section 271(f) in response. The focus on intentional evasion of U.S. patent law in 271(f)(1) is captured in the sum of the requirements of that subsection, that "all or a substantial portion" of the components of a patented invention are supplied from the United States and that the U.S. activity be in such manner as to "actively induce" a combination that would infringe U.S. patent law if the combination had occurred here. Complementarily, the focus on intentional evasion of U.S. patent law in 271(f)(2) is captured in the sum of the requirements of that subsection, that the component supplied be "especially made or adapted" for the invention and not a "staple article or commodity of commerce suitable for substantial noninfringing use," that the supplier know that to be true, and that the supplier intend that the component be assembled outside the United States in manner that would infringe

U.S. patent law if the combination had occurred here.

The supply of a commodity or staple component such as Taq polymerase or wash buffer from the United States is very different from the deliberate efforts in *Deepsouth* and the other cases to avoid U.S. patent liability for products that are effectively wholly manufactured within the United States. The supply of a commodity or staple component such as Taq polymerase or wash buffer from the United States is also very different from supplying a specially-made component of a patented invention.

Congress carefully delineated two narrow scenarios that impose liability where a component or multiple components of a patented invention are sourced from the United States. Any interpretation of the statute that exceeds those specific scenarios, as the Federal Circuit's interpretation does, infringes on Congress' role and responsibility to determine the proper reach of United States laws and avoid undue or improper extraterritorial reach. Congress certainly knew how to draft a broader statute, but chose not to do so. *See Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001).

D. The Federal Circuit's "Qualitative Importance" Test Will Discourage U.S. Manufacturing

Modern supply chain management requires adaptable multi-component products, global

responsiveness, and rapid response to disruptions and fluctuations in demand. Companies need to be able to move quickly, on an ongoing basis, to shift sourcing of components, without requiring unnecessary and excessive detailed patent analysis. Companies operating in regulated industries also need to establish stable manufacturing facilities for the long term. The Federal Circuit's "qualitative importance" test interferes with these legitimate business concerns, and will discourage U.S.-based manufacturing and the sourcing of components from the United States.

It is one thing to tell U.S. manufacturers that they cannot avoid global patent liability when they induce their customers to assemble overseas a product that consists of all or a substantial portion of U.S.-made components. It is quite another thing to say that sourcing from the United States of any "important" or "essential" component is a jurisdictional hook that potentially triggers U.S. patent liability. The Federal Circuit's decision will likely be read, especially in industries in which patent liability is a prevalent concern, as an instruction not to use U.S.-made components unless absolutely necessary.

The Federal Circuit's decision also discourages companies from investing in their own manufacturing infrastructure in the U.S. Because modern supply chain management requires companies to have the capacity to rapidly shift production and products worldwide in response to change, companies can ill afford the time or resources to undertake a

comprehensive component-by-component patent risk analysis when making decisions to source components from one location versus another, especially where the analysis is complex, potentially ambiguous, and relates to individual components that are common, staple, and would not themselves present patent liability risk.

In theory, a company could isolate U.S. manufactured components for use only in products that will be finished and sold in the U.S. But that is impracticable because it is inconsistent with the realities of modern manufacturing—the fundamental point of modern supply chain management is to promote efficiency, reduce cost, and facilitate rapid deployment of materials, components and products, globally.

In addition, under the Federal Circuit's test, the sourcing of even a single commodity component from the United States exposes the supplier to U.S. patent litigation and the potential for damages on world-wide sales of the related products. Such outsized costs and damages exposure are not proportional to the U.S. interests and connection at issue, and are inconsistent with the text and intent of Section 271(f). The Federal Circuit's test may also lead to mischief by which plaintiffs will rely on the cost of litigation, the magnitude of potential liability, and the uncertainty of the results on the merits to extract nuisance value settlements such that "a patent will reach beyond its lawful scope to discourage lawful activity" and result in "patent-related demands [that] will frustrate, rather than

'promote,' the 'Progress of Science and useful Arts.'" *Halo Electronics, Inc. v. Pulse Electronics, Inc.,* 136 S.Ct. 1923, 1937-38 (2016)(Breyer, J. concurrence).

Faced with the increased patent risks of U.S. manufacturing and the need for efficient global manufacturing solutions, many companies may choose the lower risk option and manufacture outside the United States. Thus, the Federal Circuit's "qualitative importance" test places a thumb on the scale in favor of foreign manufacturing, which is not what the statutory text requires, and not what Congress intended when enacting the statue.

CONCLUSION

This Court should reverse the decision of the Federal Circuit, for the reasons explained above and by Petitioners. Any new test for liability under Section 271(f)(1) should assess whether a patented device was for all intents and purposes manufactured in the United States. Regardless of the precise contours for liability under (f)(1), which may be developed and refined over time, two blaze marks should be clear: (i) the manufacture within and export from the United States of a single component of a multicomponent patented invention should not trigger liability under subsection (f)(1); and (ii) where a single component manufactured within and exported from the United States is a commodity component, there should be no liability at all under section 271(f).

Respectfully submitted.

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