STAAS & HALSEY LLP

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Impression Products, Inc. v. Lemark International, Inc.

On May 30, 2017, the U.S. Supreme Court ("Supreme Court") issued its opinion in *Impression Products, Inc. v. Lexmark International, Inc.*, reversing the U.S. Court of Appeals for the Federal Circuit's ("Federal Circuit") ruling that the sale of a patented product subject to clearly communicated restrictions on post-sale use does not exhaust all of the patentee's patent rights. The Supreme Court also reversed the Federal Circuit's ruling on the second issue pertaining to international exhaustion of patent rights, holding that an authorized sale outside the United States also exhausts all of the patentee's rights under the U.S. Patent Act.

Lexmark International Inc. ("Lexmark"), a printer manufacturer, sells printer and toner cartridges for its patented printers throughout the United States and internationally. Lexmark also implements technology within their cartridges to prevent third parties from refilling their cartridges and selling them at a lower price. However, third parties were able to circumvent Lexmark's efforts. Impression Products, Inc. ("Impression") purchased Lexmark's cartridges at a discounted rate from these third parties and resold them throughout the United States. Subsequently, Lexmark sued Impression, claiming that Impression's resale of the cartridges infringed Lexmark's patents.

The U.S. district court granted Impression's motion to dismiss and held that the patent rights had been exhausted by Lexmark's initial sale of the cartridges. On appeal, the Federal Circuit relied on its decision in *Mallinckrodt, Inc. v. Medipart, Inc.,* 976 F.2d 700 (1992) and reversed the district court's ruling, holding that, while a sale of a patented good would normally grant this authority, clearly communicated restrictions on post-sale use by the purchaser do not exhaust the patent right. Relying on another of its decisions in *Jazz Photo Corp. v. International Trade Commission,* 264 F.3d 1094 (2001), the Federal Circuit also held that Lexmark's sale of the cartridges internationally did not authorize Impression to import the cartridges into the United States because those sales were conditional upon the purchaser's agreement to not resell the cartridges.

In its reversal of the Federal Circuit, the Supreme Court unanimously found that the sale of a patented product, both domestically and internationally, exhausts patent rights. The Supreme Court justified its ruling based on common law principles of ownership, providing that "[w]hen a patentee chooses to sell an item, that product 'is no longer within the limits of the monopoly' and instead becomes the 'private, individual property' of the purchaser, with the rights and benefits that come along with ownership." Slip Op. at 5-6. Once a patented product is sold and transferred to the purchaser, the patentee may no longer rely on patent law and no longer exercises ownership of that product. Chief Justice Roberts further elaborated that "the exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on 'the scope of the patentee's rights.'" Slip Op. at 10, quoting *United States v. General Elec. Co.,* 272 U.S. 476, 489 (1926). In other words, the sale of a product transfers the foundational rights to use, sell, or import the product sold to the purchaser and exhausts the patentee's patent rights. This applies to products being sold both domestically and internationally as common law refuses "to permit restraints on the alienation of chattels." Slip Op. at 14, quoting *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 538 (2013).

TC Heartland LLC v. Kraft Group Brands LLC

On May 22, 2017, the U.S. Supreme Court ("Supreme Court") reversed the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") in *TC Heartland LLC v. Kraft Foods Group Brands LLC* regarding venue in patent infringement lawsuits. Generally, venue is the proper or most convenient location for trial of a lawsuit.

The patent venue statute, 28 U.S.C. § 1400(b), provides that "[a]ny civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." The Supreme Court earlier held that §1400(b) “is the sole and exclusive provision controlling venue in patent infringement actions, and that it is not to be supplemented by the provisions of 28 U.S.C. § 1391(c)”. *Fourco Glass Co. v. Transmirra Products Corp*., 353 U.S. 229, 222 (1957).

After the U.S. Congress subsequently amended the general venue statute several times, 28 U.S.C. § 1391(c) now provides a broad definition of "reside." §1391(c) states: “Except as otherwise provided by law . . . For all venue purposes . . . an entity . . . shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.” The Federal Circuit has held that “§1391(c) applie[s] to the patent venue statute, 28 U.S.C. §1400(b).” *VE Holding Corp. v. Johnson Gas Appliance Co*., 918 F.2d 1578, 1574 (Fed. Cir. 1990). The Federal Circuit additionally has held that “*Fourco* was not and is not the prevailing law” on proper venue in patent litigation under §1400(b). In *re TC Heartland LLC*, 821 F.3d 1338, 1342 (Fed. Cir. 2016).

The Supreme Court has now ruled that 28 U.S.C. § 1400(b) is the sole and exclusive authority in governing venue in patent cases and is not to be supplemented by 28 U.S.C. § 1391(c). Accordingly, the Supreme Court held that for domestic corporations, the term “resides” refers to the corporation’s state of incorporation. Currently, numerous patent infringement cases are filed in plaintiff-friendly U.S. District Court for the Texas Eastern District. However, the number of those cases is expected to decrease as few patent defendants are actually located there. An influx of patent cases is expected to shift to Delaware and California, where many corporations are incorporated (“reside”).

While the Supreme Court addressed the issue of patent venues for domestic corporations, the Supreme Court did not address proper venue for foreign corporations. Additionally, the Supreme Court did not address the issue of patent venue if a corporation is not yet incorporated.

SUPREME COURT

Amgen Inc. et al. v. Sandoz Inc.

On June 12, 2017, the U.S. Supreme Court ("Supreme Court") issued its opinion in *Sandoz Inc. v. Amgen Inc.,* Nos. 15-1039, 15-1195, vacating in part and reversing in part the U.S. Court of Appeals for the Federal Circuit's ("Federal Circuit") rulings on the interpretations for two key provisions of the Biologics Price Competition and Innovation Act ("BPCIA").

Amgen Inc. ("Amgen") owned the patent rights to a drug, filgastrim, under the brand name Neupogen. On May 2014, Sandoz Inc. ("Sandoz")" filed an aBLA seeking FDA approval of Zarxio, a biosimilar to Neupogen. On July 7, 2014, the FDA notified Sandoz that its application for Zarxio was under review. The next day, Sandoz notified Amgen about the development of Zarxio and made clear to Amgen that they intended on commercially marketing Zarxio upon FDA approval. Furthermore, Sandoz informed Amgen that it was not going to share details of its aBLA with Amgen as required under the BPCIA and thus, Amgen was entitled to sue Sandoz. Upon the FDA's approval of Sandoz's aBLA, Sandoz began commercially marketing Zarxio, claiming that it provided notice to Amgen on July 8, 2014. Usually, companies are required to wait 180 days from FDA approval before they are allowed to start commercially market biosimilar products.

In October 2014, Amgen sued Sandoz in District Court, alleging that Sandoz failed to provide the required information about its aBLA for Zarxio under Paragraph (l)(2)(A) of the BPCIA. Amgen further alleged that Sandoz did not provide proper notice of its intent to commercially market Zarxio because they did not wait the full 180 days from the date of the FDA approval before commercially marketing Zarxio under Paragraph (l)(8)(A) of the BPCIA. BPCIA paragraph (l)(2)(A) provides that:

"Not later than twenty days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application."

BPCIA paragraph (l)(8)(A) provides that:

"…the subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

At trial, the District Court found in favor of Sandoz and held that Sandoz's failure to disclose information of its aBLA to Amgen did not entitle Amgen to receive damages from Sandoz nor to prevent the sale of Zarxio. On the second issue, the District Court again found in favor of Sandoz, holding that an applicant could give notice of commercial marketing prior to FDA approval. On appeal, the Federal Circuit affirmed the District Court's ruling that Sandoz's failure to disclose information of its aBLA did not entitle Amgen to receive damages nor to prevent the sale of Zarxio.

Amgen Inc. et al. v. Sandoz Inc. (cont'd.)

The Federal Circuit's justification relied on the fact that the U.S. Patent Act, specifically 35 U.S.C. § 271(e), only permits remedies based on patent infringement claims, not on non-compliance claims. On the second issue however, the Federal Circuit found in favor of Amgen and vacated the District Court's holding that an applicant could give notice of commercial marketing prior to FDA approval, holding that the notice must be provided after the FDA has approved the aBLA. The Federal Circuit concluded that "the 'shall' provision in paragraph (l)(2)(A) appears to mean that a subsection (k) applicant is required to disclose its aBLA and manufacturing information to the [reference product sponsor] by the deadline specified in the statute." Slip Op. at 12.

The Supreme Court came to the same conclusion on the first issue – that Sandoz's failure to disclose information of its aBLA did not entitle Amgen to receive damages nor to prevent the sale of Zarxio. But, the two courts differed on the reasoning. The Supreme Court relied exclusively on 42 U.S.C. § 262(l)(9)(C), which is the provision in the BPCIA that authorizes research pharmaceutical companies, such as Amgen, to sue for declaratory injunctions if generic companies, such as Sandoz, do not turn over their aBLA. Further, as these claims arose under California's unfair competition law, the question of whether Sandoz's failure to participate in the information exchange is "unlawful" under California law involves the application of state law and cannot be adequately addressed by the provisions of the BPICA alone. Thus, the Supreme Court remanded the case, providing that this issue is a state issue and not a federal issue. The Supreme Court requested that the Federal Circuit determine whether California law would view a biosimilar applicant's failure to abide by the information exchange as "unlawful."

SUPREME COURT

Oil States Energy Services, LLC v. Greene's Energy Group, LLC

On June 12, 2017, the U.S. Supreme Court ("Supreme Court") granted certiorari in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC,* to consider "whether inter partes review … violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury." Petition for a Writ of Certiorari at i, *Oil States Energy Services LLC v. Greene's Energy Group, LLC,* 639 F.App'x 639 (2016) (No. 16-712). This case questions the constitutionality of the U. S. Patent and Trademark Office ("USPTO") post-grant proceedings enacted by the America Invents Act ("AIA") as many believe that the proceedings deprive patentees of the right to a jury trial on the validity of their patents.

Oil State Energy Services, LLC ("Oil States"), a unit of Oil States International Inc., owned U.S. Patent No. 6,179,053 ("the '053 Patent"), which discloses a lockdown mechanism for well tools. In 2012, Oil States asserted the '053 patent against Greene's Energy Group LLC ("Greene"), an oilfield services company, alleging patent infringement. Subsequently, Greene petitioned to the "USPTO" Patent Trial and Appeal Board ("PTAB") to institute an inter partes review ("IPR") of the '053 patent. After instituting the IPR, the PTAB applied the broadest reasonable interpretation when construing the '053 patent and found the '053 patent to be anticipated by another application. Oil States wanted to amend its claims; however, the PTAB found the proposed amendments to be lacking sufficient support from the specification.

Oil States appealed the PTAB's decision to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"), arguing that the PTAB had improperly construed the '053 patent claims by applying the broadest reasonable interpretation. Furthermore, Oil States argued that IPRs are unconstitutional under Article III and the Seventh Amendment, which provides the right to a jury trial. Rejecting Oil States' arguments, the Federal Circuit affirmed the PTAB's decision without an opinion.

Oil States then filed a petition for certiorari to the Supreme Court on three issues: (1) whether IPRs violate the Constitution by "extinguishing private property rights through a non-Article III forum without a jury;" (2) whether the amendment process as implemented by the USPTO conflicts with Supreme Court precedent and congressional design; and (3) whether traditional claim construction doctrines must be applied by the PTAB when construing a claim under the broadest reasonable interpretation.

Greene and the U.S. government both filed a brief in opposition, providing that patents are "public rights" and their validity is susceptible to review by an administrative agency. They further added that the USPTO is well within its authority to review issued patents in post-grant proceedings enacted by the AIA.

The Supreme Court only granted certiorari to the first issue, the constitutional question of IPRs. If the Supreme Court had reversed the Federal Circuit's decision, it could have significantly impacted a defendant's ability to safeguard frivolous suits through invalidating the plaintiff's patent. A decision by the Supreme Court holding IPRs to be unconstitutional may also have a significant effect on the value of existing patents and increase the amount of litigation, offsetting U.S. Congress's intentions for the AIA.

Cisco Systems v. Cirrex Systems, LLC

On May 10, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") ruled that all appealed claims of a fiber optic patent held by Cirrex System, LLC ("Cirrex") are invalid under 35 U.S.C. § 112 in *Cisco Systems v. Cirrex Systems, LLC*.

Cirrex owns U.S. Patent No. 6,415,082 ("'082"), which is directed to fiber optic communication signals. Specifically, fiber optic communication signals that use light energy from multiple different wavelengths within a single fiber optic cable. The "'082 patent discloses optic cables in an optical network system that diverts light signals away from a planar light guide circuit ("PLC"). The '082 specification teaches equalization of light signals outside the PLC and only collective (not discrete) attenuation within the PLC. Cisco Systems requested an inter partes reexamination for all of the '082 patent claims, asserting a lack of written description. Cirrex added claims 35-124 and amended and canceled other claims. All of the amended claims recite either equalization or discrete attenuation of light signals inside the PLC.

During reexamination, the U.S. Patent and Trademark Office ("USPTO") Examiner rejected most of the newly added claims as invalid for lacking a written description, but found five claims as patentable. The USPTO's Patent Trial and Appeals Board (PTAB) affirmed.

The Federal Circuit reversed the PTAB's decision and invalidated all amended claims of the fiber optic patent under 35 U.S.C. § 112. The Federal Circuit asserted that none of the added claims were part of the `082 patent's original disclosure and Cirrex cannot rely on written support for the added claims.

The Federal Circuit stated that the '082 claims fail to satisfy the "*quid pro quo*" requirement for the written description and that the '082 specification does not solve, contemplate, or suggest as a goal or desired result for the disputed claims. Additionally, the Federal Circuit stated that there was not anything in the specification that suggested the inventor debated the approach stated in the claims. In fact, the specification teaches away from the amended claims. The Federal Circuit stated: "[the written description must] clearly allow persons of ordinary skill in the art to recognize that [he] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)).

Rivera v. International Trade Commission and Solofill, LLC

On May 23, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issued its opinion in *Rivera v. International Trade Commission and Solofill, LLC*, affirming the U. S. District Court's ruling that Rivera's patent is invalid for lack of written description.

Adrian Rivera and Adrian Rivera Maynez Enterprises ("Rivera") own U.S. Patent No. 8,720,320 ("the '320 patent") covering a re-usable K-cup that works with coffee pods in a standard single-cup brewing machine. On September 9, 2014, Rivera filed a complaint with the International Trade Commission ("ITC"), alleging that Solofill, LLC ("Solofill") was importing beverage capsules that infringed claims 5-8 and 18-20 of the '320 patent, in violation of Section 337 of the Tariff Act of 1930. Subsequently, Rivera withdrew its allegations with respect to claims 8 and 19, leaving pending claims 5-7, 18, and 20. Claim 5 was the independent claim with claims 6-7, 18, and 20 being claim 5's dependent claims. Claim 5 of the '320 patent recited the following:

> A beverage brewer, comprising:
>
> a brewing chamber;
>
> a container, disposed within the brewing chamber and adapted to hold brewing material while brewed by a beverage brewer, the container comprising:
>
> a receptacle configured to receive the brewing material; and
>
> a cover;
>
> wherein the receptacle includes
>
> a base, having an interior surface and an exterior surface, wherein at least a portion of the base is disposed a predetermined distance above a bottom surface of the brewing chamber, and at least one sidewall extending upwardly from the interior surface of the base, wherein the receptacle has at least one passageway that provides fluid flow from an interior of the receptacle to an exterior of the receptacle;
>
> wherein the cover is adapted to sealingly engage with a top edge of the at least one sidewall, the cover including an opening, and
>
> wherein the cover is adapted to accept input fluid through the opening and to provide a corresponding outflow of fluid through the passageway;
>
> an inlet port, adapted to provide the input fluid to the container; and
>
> a needle-like structure, disposed below the base;
>
> wherein the predetermined distance is selected such that a tip of the needle-like structure does not penetrate the exterior surface of the base.

At the ITC, the Commission concluded that there was no violation of Section 337, holding that the asserted claims were invalid for lack of written description, and that claims 5 and 6 were additionally invalid as anticipated by U.S. Patent No. 6,079,315 to *Beaulieu.*

Rivera v. International Trade Commission and Solofill, LLC (cont'd.)

Written description is a question of fact under 35 U.S.C. § 112, meaning that the appellate court gives deference to the lower court's or agency's determination on appeal. Additionally, the written description requirement is satisfied when the specification "'reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date' of the patent." Slip Op. at 8, quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*).

On appeal, the Federal Circuit affirmed the ITC's decision, noting that there was substantial evidence supporting the Commission's holding. In its analysis, the Federal Circuit focused on whether the "pod adaptor assembly," "pod," and "receptacle" disclosures in the patent as filed, support Rivera's "container … adapted hold brewing material," as recited in independent claim 5. While Rivera argued that "the broad definition of 'pod' contained in the specification … provided written description support for the claimed integrated filter cartridge," that broader definition of a "pod" did not provide written description support for the claimed "container … adapted to hold brewing material." Slip Op. at 9.

Rejecting Rivera's argument and agreeing with the ITC and Solofill, the Federal Circuit provided that the specification stated that the claimed container and the "pod" were separate items.

Furthermore, the specification disclosed that "the distinction of the 'pod' from the cartridge or container is fundamental to the problem and solution" of the claimed invention. Slip Op. at 9. The Federal Circuit also noted that none of the embodiments in the patent would work without a separate filter. Because the specification did not disclose such embodiments, the asserted claims failed the written description requirement and therefore were invalid.

U.S. International Trade Commission, Washington, D.C.

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.

On May 1, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issued its opinion in *Helsinn Healthcare v. Teva Pharmaceuticals*, reversing the opinion of the U. S. District Court, holding that, with regards to the "on sale" bar under 35 U.S.C. § 102(a)(1) "after the AIA, if the existence of the sale is public, the details of the invention need not be publically disclosed in the terms of the sale."

Helsinn owns (collectively "the patents") U.S. Patent Nos 7,947,724 (" '724"), 7,947,725 (" '725"), 7,960,424 (" '424") and 8,598,219 (" '219"). '219 was filed on December 3, 2013 after the March 16, 2013 effective date for AIA. All four patents claim priority to provisional U.S. patent application 60/444,351 filed on January 30, 2003. The patents are directed to treating chemotherapy induced nausea and vomiting ("CINV") using palonosetron.

On April 6, 2001, more than 1 year before filing the provisional U. S. patent application, Helsinn Healthcare S.A. ("Helsinn") and MGI Pharma, Inc. ("MGI") entered into (1) a License Agreement and (2) a Supply and Purchase Agreement announced in a press release in compliance with SEC regulations. Although the price and particular formulations (.25 mg and .75 mg per dose) were in the agreements, these portions of the agreements were not publicly disclosed. Helsinn brought suit against Teva Pharmaceuticals USA, Inc. ("Teva") alleging infringement of the patents when Teva filed an Abbreviated New Drug Application ("ANDA"). Teva argued that the on-sale bar invalidated the patents.

Helsinn argued that under the second prong of the two prong test of *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the invention was not ready for patenting because it was not sufficiently reduced to practice, in particular, because the drug formulation had not completed U.S. Food and Drug Administration ("FDA") clinical trials.

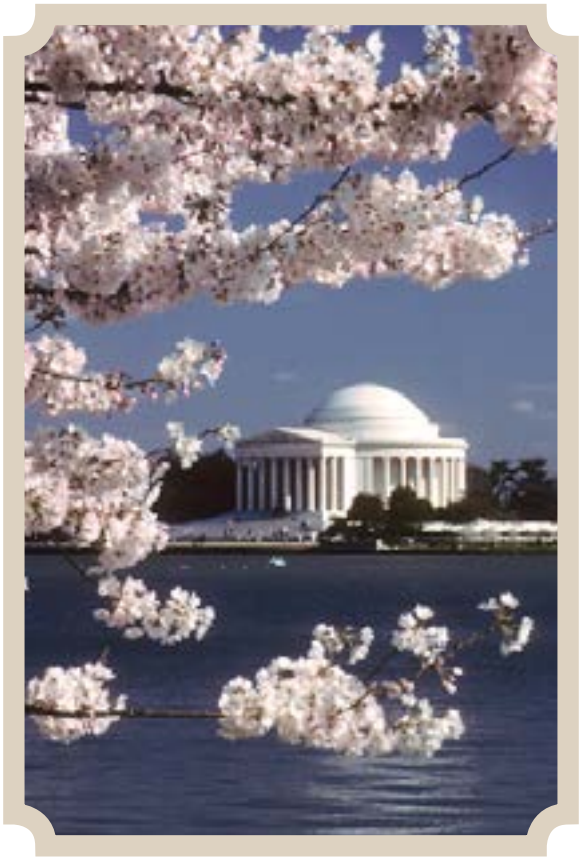
Under 35 U.S.C. 102(b) (pre-AIA), the U.S. Supreme Court and the Federal Circuit have previously held that "secret" prior art may serve as invalidating prior art without disclosing "details of the invention" to the public. The AIA on-sale bar 35 U.S.C. 102(a)(1) now recites: "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention."

The U. S. District Court reasoned that "otherwise available to the public" meant that only public sales can trigger the "on sale" bar under 35 U.S.C. 102(a)(1). The District Court held that the AIA had changed the meaning of the on-sale bar and 35 U.S.C. 102 now requires a public sale or offer for sale as the claimed invention. The District Court held that under 35 U.S.C. 102(a)(1), "public" means that a sale must publicly disclose the details of the invention and that the invention was not ready for patenting.

Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc. (cont'd.)

The Federal Circuit reversed the District Court's decision and held that the AIA did not change the statutory meaning of "on sale" under the circumstances. The Federal Circuit also found that the asserted claims of Helsinn's patents were subject to an invalidating contract for sale prior to the priority date, and that the asserted claims were ready for patenting prior to the priority date. The Federal Circuit held that the "[A]pplication of the on-sale bar requires that (1) the product must be the subject of a commercial offer for sale and (2) the invention must be ready for patenting."

The Federal Circuit did not address which circumstances constitute a "secret sale" as opposed to a publically known sale that does not disclose the details of the invention. The Federal Circuit held that Helsinn's patents were invalid because the sale itself was disclosed to the public, even if the details of the invention were not.



Washington, D.C. Tidal Basin

Nichia Corporation v. Everlight Electronics Co., Ltd.

On April 28, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") held that proof of irreparable harm is a necessary threshold test for permanent injunctive relief, regardless of whether the patentee is left with an adequate remedy at law.

Nichia Corporation ("Nichia") owns U.S. Patent Nos. 7,432,589, 7,462,870, and 8,530,250, which are all directed to package designs and methods of manufacturing LED devices. Everlight Electronics Co., Ltd. ("Everlight") buys chips from suppliers and packages them into LEDs. Nichia sued Everlight for patent infringement.

The U.S. District Court for the Eastern District of Texas ("District Court") held that Everlight infringed all three of Nichia's patents and that the patents were valid, but denied Nichia's request for injunction.

The Federal Circuit held that it was not abuse of discretion to deny Nichia an injunction because Nichia failed to prove that it would suffer irreparable harm. Additionally, Nichia failed to show that it lost sales to Everlight, and Nichia was also supporting other low-cost competitors by freely licensing its technology. The Federal Circuit used a four prong test to establish its holding:

> According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." A party seeking an injunction must demonstrate: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

The Federal Circuit held that the two companies generally sell to different parties. The Federal Circuit also found that, despite the parties' claims that they competed in the same market, Nichia failed to prove that this competition was meaningful. The Federal Circuit found that there was a "very small area of possible competition," and found instead that there was an "absence of actual competition." Because Nichia failed to establish one of the four equitable factors, the District Court did not abuse its discretion in denying Nichia's request for an injunction.

The Medicines Company v. Mylan, Inc.

On April 6, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") reversed the District Court's finding of Mylan's infringement under 35 U.S.C. 271(e)(2) of claim construction in *The Medicines Company v. Mylan, Inc.*

The Medicines Company ("MedCo") owns U.S. Patent Nos. 7,582,727 ("'727") and 7,598,343 ("'343"). These patents are directed to pharmaceutical formulations ("batches") of bivalirudin, which are used to prevent blood clotting. Both the '727 and the '343 patents include a limitation for consistent batches based on various impurity level targets and a target pH that is "adjusted by a base". Both patents are directed to an "efficient mixing" process used to ensure consistency of the batches, but do not expressly claim.

Claim 1 of the '727 patent is reproduced below:

1. Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1: [Phe Pro Arg Pro Gly Gly Gly Gly Asn Gly Asp Phe Glu Glu Ile Pro Glu Glu Tyr Leu]) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

Claim 1 of the '343 patent is reproduced below:

1. Pharmaceutical batches of a drug product comprising bivalirudin ... prepared by a compounding process comprising:
   (i) dissolving bivalirudin in a solvent to form a first solution;
   (ii) efficiently mixing a pH-adjusting solution with the first solution to form a second solution, wherein the pH-adjusting solution comprises a pH-adjusting solution solvent; and
   (iii) removing the solvent and pH-adjusting solution solvent from the second solution; wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp9-bivalirudin that does not exceed about 0.6% as measured by HPLC.

The Medicines Company v. Mylan, Inc. (cont'd.)

Mylan's Abbreviated New Drug Application ("ANDA") specified methods for formulations that did not use the "efficient mixing" limitations. Mylan's ANDA uses a different process to ensure batch consistency and pH level. The District Court found that the '343 patent required an "efficient mixing" process and Mylan did not infringe the '343 patent's claims. The District Court found that the '727 patent did not require "efficient mixing" and Mylan did infringe the '727 patent's claims.

The Federal Circuit affirmed the District Court's decision regarding the '343 patent, but reversed the District Court's decision regarding the '727 patent. The Federal Circuit based its decision on the claim construction of "batches", since the word "batches" required the use of efficient mixing methods as disclosed in the specification in both the '727 and the '343 patent. The Federal Circuit found that the compounding process had to be the "efficient mixing" process as described in Example 5 of the '727 specification. Example 5 recites in part "apart from efficient mixing, no part of the patent's disclosure teaches another method capable of producing consistent batches." The Federal Circuit found that Mylan's ANDA did not require the same process as the claims of the '727 patent to generate batches and thus did not infringe: "We hold that [the] patents include a 'batches' limitation that requires batch consistency, which, according to the patents in suit, is achieved through efficient mixing… We further construe efficient mixing as defined by Example 5 of the patents' specification."

Thales Visionix Inc. v. United States Government

On March 8, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") reversed a decision of the U. S. Court of Federal Claims regarding claims drawn to an inertial tracking system under 35 U.S.C. § 101.

Thales Visionix Inc. ("Thales") owns U.S. patent no. 6,747,159, which is directed to an "inertial tracking system for tracking the motion of an object relative to a moving reference frame." The United States Government owns a helmet mounted display system in the F-35 Joint Strike Fighter. Thales sued the United States Government, alleging infringement of the '159 patent.

Independent claim 1 and 22 of the '159 patent:

1. A system for tracking the motion of an object relative to a moving reference frame, comprising: a first inertial sensor mounted on the tracked object; a second inertial sensor mounted on the moving reference frame; and an element adapted to receive signals from said first and second inertial sensors and configured to determine an orientation of the object relative to the moving reference frame based on the signals received from the first and second inertial sensors.

22. A method comprising determining an orientation of an object relative to a moving reference frame based on signals from two inertial sensors mounted respectively on the object and on the moving reference frame.

The Court of Federal Claims found that the claims were directed to "the abstract idea of using laws of nature governing motion to track two objects" and "provide no inventive concept beyond the abstract idea", and thus not patent eligible under 35 U.S.C. § 101.

On appeal, the Federal Circuit reversed. The Federal Circuit found that the claims were "nearly indistinguishable" from those in the Supreme Court's *Diamond v. Diehr* decision. In *Diamond,* the Supreme Court found claims that met the requirements of § 101 despite the inclusion of a mathematical formula because the claims were directed to an improved technology process instead of abstract math. The Federal Circuit held that the '159 patent applied laws of physics and using a mathematical equation "does not doom the claims to abstraction." The Federal Circuit stated that the claims do not claim the equations themselves, but rather, "seek to protect only the application of physics to the unconventional configuration of sensors." Thus, the Federal Court held that the claims were not directed to an abstract idea eligible.

RecogniCorp, LLC v. Nintendo Co.

On April 28, 2017, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issued its opinion in *RecogniCorp, LLC v. Nintendo Co*., holding that a patent's claims that are directed to the abstract idea of encoding and decoding image data is ineligible subject matter.

RecogniCorp, LLC ("RecogniCorp") owned U.S. Patent No. 8,005,303 ("the '303 patent") covering a method and an apparatus for encoding images and sued Nintendo Co. ("Nintendo") for infringement of the '303 patent. The '303 patent was directed to a method for creating a composite facial image using constituent parts. Claim 1 of the '303 patent recited the following:

> A method for creating a composite image, comprising:
>
> displaying facial feature images on a first area of a first display via a first device associated with the first display, wherein the facial feature images are associated with facial feature element codes; selecting a facial feature image form the first area of the first display via a user interface associated with the first device, wherein the first device incorporates the selected facial feature image into a composite image on a second area of the first display, wherein the composite image is associated with a composite facial image code having at least a facial feature element code and wherein the composite facial image code is derived by performing at least on multiplication operation on a facial code using one or more code factors as input parameters to the multiplication operation; and reproducing the composite image on a second display based on the composite facial image code.

The U.S. District Court held that the claims of the '303 patent were ineligible subject matter and granted Nintendo's motion of judgment on the pleadings based on that finding. Applying the two part *Alice* test, the District Court found that the claims were "directed to the abstract idea of encoding and decoding composite facial images using a mathematical formula" and that "the entirety of the '303 patent consists of encoding algorithm itself or purely conventional or obvious pre-solution activity and post-solution activity insufficient to transform the unpatentable abstract idea into a patent-eligible application."

The Federal Circuit affirmed the District Court decision that the claims were ineligible subject matter. In its application of the two part *Alice* test, the Federal Circuit compared the '303 patent to the patent in Enfish, LLC v. Microsoft Corp., stating that the '303 patent's claim did not recite a software method that improved the functioning of a computer but instead recited a process "for which computers are invoked merely as a tool."

RecogniCorp, LLC v. Nintendo Co. (cont'd.)

Furthermore, the Federal Circuit added that the '303 patent's claim "does not even require a computer" and can be done by a human. RecogniCorp argued that another claim of the '303 patent did make use of a computer; however, "it does exactly what [the Federal Circuit] has warned it may not: tell a user to take an abstract idea and apply it with a computer."

As a result, the Federal Circuit concluded that the '303 patent disclosed no inventive concept in its claims, failed the *Alice* test, and was ineligible subject matter under 35 U.S.C. § 101.

View of the Washington Monument and the Reflective Pool from the Lincoln Memorial at Sunset

Updates to § 101 Patent Subject Matter Eligibility Guidance provided by the USPTO

The U.S. Patent and Trademark Office ("USPTO") has been providing updates to its patent subject matter eligibility guidance throughout 2017. The USPTO updates its chart of subject matter eligibility court decisions whenever the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issues an opinion pertaining to subject matter eligibility. The updates serve as guidelines for patent examiners to determine whether the claims of a patent application are patentable under 35 U.S.C. § 101. The updates also allow patent applicants to prepare their applications appropriately to ensure that the claims in their patent applications are subject matter eligible. The updates can be found on this USPTO website labeled as "NEW": https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility

Previously released on November 2, 2016, a memoranda provided by the USPTO discussed the subject matter eligibility Federal Circuit decisions from *McRO, Inc. dba Planet Blue v. Bandi Namco Games America Inc.* and *BASCOM Global Internet Services v. AT&T Mobility LLC.* Takeaways from the cases are that when considering subject matter elilgibility, 1) examiners should consider the claim **as a whole** under Step 2A of teh *Mayo/Alice* test and 2) examiners should consider the additional elements **in combination** under Step 2B of the *Mayo/Alice* test.

This quick reference sheet helps examiners formulate § 101 rejections and evaluate an applicant's response to such rejections using the two-part *Mayo/Alice* test. The reference sheet can be accessed through this USPTO Website link: https://www.uspto.gov/sites/default/files/documents/ieg-qrs.pdf The two-part *Mayo/Alice* test goes as follows:

Step 1: Is the claim to a process, machine, manufacture or composition of matter? If the answer is no, the claim is not eligible subject matter under 35 U.S.C. § 101. If the answer is yes, move onto step 2A of the test.

Step 2A: Is the claim directed to a low of nature, natural phenomenon, or abstract idea? If the answer is no, the claim qualifies as eligible subject matter under 35 U.S.C.

Updates to Patent Subject Matter Eligibility Guidance provided by the USPTO (cont'd.)

Step 2B: Does the claim recite additional elements that make the whole claim amount to significantly more than the judicial exception. If the answer is yes, the claim qualifies as eligible subject matter under 35 U.S.C. § 101. If the answer is no, the claim is not eligible subject matter under 35 U.S.C. §101.

Throughout 2017, the Federal Circuit released these precedential cases that provide further interpretations and exceptions for eligible subject matter 35 U.S.C. § 101:

- *Intellectual Ventures I LLC v. Erie Indemnity Co*., 850 F.3d 1315 (Fed. Cir. 2017). The Federal Circuit found that a mobile interface for accessing remotely stored documents is ineligible subject matter In addition, the Federal Circuit found that a method for retrieving data from a database using an index of XML tags and metafiles is ineligible subject matter.
- *Intellectual Ventures, LLC v. Capital One Financial Corp*., 850 F.3d 1332 (Fed. Cir. 2017). The Federal Circuit found that a method for managing multiple sets of XML data is ineligible subject matter.
- *Thales Visionix Inc. v. U.S*., 850 F.3d 1343 (Fed. Cir. 2017). The Federal Circuit found that an inertial tracking system is eligible subject matter.
- *Mentor Graphics v. EVE-USA*, 851 F.3d 1275 (Fed. Cir. 2017). The Federal Circuit found that hardware debugging in a hardware description language
- *RecogniCorp LLC v. Nintendo Co.*, 855 F.3d 1322 (Fed. Cir. 2017). The Federal Circuit found that a method for encoding and decoding image data is ineligible subject matter.
- *Credit Acceptance Corp. v. Westlake Services*, _ F.3d _ (Fed. Cir. 2017). The Federal Circuit found that a system and method for providing financing is ineligible subject matter.
- *Cleveland Clinic Foundation v. True Health Diagnostics, LLC* _ F.3d _ (Fed. Cir. 2017). The Federal Circuit found that a method for assessing the risk of a major adverse cardiac event in patients with chest pain using enzyme levels is ineligible subject matter.

For more information concerning any of the cases above, please contact our firm at info@staasandhalsey.com.

Matal v. Tam

On June 19, 2017, the United States Supreme Court ("Supreme Court") issued its opinion in *Matal v. Tam,* holding that the disparagement clause of the Lanham Act, a trademark law's restriction on federal registration of disparaging remarks, violates the First Amendment's free speech clause.

In 2011, Simon Tam filed a U. S. trademark application for his band's name, "The Slants." Tam acknowledged that the term "slants" is construed to be derogatory to people of Asian descent, but he hoped to utilize that term publicly to erase its negative connotation. Nonetheless, the U.S. Patent and Trademark Office ("USPTO") rejected his application, because the USPTO cannot issue trademarks that may disparage other people based on 15 U.S.C. § 1052(a). 15 U.S.C. §1052(a) provides that:

"No trademark by which the goods of the applicant may be distinguished from the goods of others shall be refused registration on the principal register on account of its nature unless it consists of or comprises immoral, deceptive, or scandalous matter; or matter which may disparage or falsely suggest a connection with persons, living or dead, institutions, beliefs, or national symbols, or bring them into contempt, or disrepute…"

Subsequently, Tam appealed the USPTO's initial decision to the USPTO Trademark Trial and Appeal Board ("TTAB"). There, the TTAB affirmed the examiner's refusal to register the trademark, finding that the mark was disparaging to a substantial component of people of Asian descent because "[t]he dictionary definitions, reference works and all other evidence unanimously categorize the word 'slant,' when meaning a person of Asian descent, as disparaging." In *re Tam*, No. 85472044, 2013 WL 5498164, at *7 (T.T.A.B. Sept. 26, 2013).

Tam appealed the TTAB's decision to the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit"), arguing that the TTAB erred in finding the trademark disparaging and that 15 U.S.C. §1052(a) is unconstitutional. The Federal Circuit did find that the mark is disparaging; however, it vacated and remanded the TTAB's decision, holding that 15 U.S.C. §1052(a) is unconstitutional under the intermediate scrutiny traditionally applied to regulation of the commercial aspects of speech. Additionally, the government has offered no legitimate reason to justify the statute.

On appeal, all eight justices of the U.S. Supreme Court affirmed the Federal Circuit's decision, rejecting the USPTO's argument that the trademarks are government speech, which is not subjected to the First Amendment. However, the Supreme Court justices differed in their justification of the affirmation.

Matal v. Tam (cont'd.)

Justice Alito, joined by Chief Justice Roberts, Justice Thomas, and Justice Breyer, invalidated the disparagement clause on First Amendment grounds. Alito explained that in order for speech to be limited by the government, the limitations on the speech must be drawn narrowly to advance a "substantial interest." Alito concluded that the disparagement clause sweeps too broadly because it applies to all disparaging trademarks, including those that disparage racists or sexists.

Justice Kennedy, joined by Justice Ginsburg, Justice Sotomayor, and Justice Kagan, believed that the disparagement clause should be subject to a more searching review, on the ground that it amounts to "viewpoint discrimination" – singling out some message for less favorable treatment based on the views that they express. This set of justices believes that the applicant should be able to register a "positive or benign" trademark, but "not a derogatory one." However, while Tam believed that the trademark is for the betterment of society, the USPTO did not and rejected his application, using its viewpoint to make that decision. Kennedy concluded that the USPTO should have issued the trademark registration based on Tam's viewpoint on the trademark.

Molon Motor and Coil Corporation et al. v. Nidec Motor Corporation

On May 11, 2017, the U.S. District Court for the Northern District of Illinois Federal Court ("District Court") allowed Molon Motor and Coil Corporation et al. ("Molon") to sue Nidec Motor Corporation ("Nidec") for trade secret misappropriation entirely based on the improper taking of trade secrets by a Molon former employee.

Molon is a maker of bespoke motors and gearmotors, and sued Nidec for trade secret misappropriation after Manish Desai ("Desai"), a former Molon employee, allegedly downloaded Molon's designs and technical data, quit employment at Molon, then switched employers to Nidec. Before leaving Molon, Desai downloaded dozens of files containing Molon's trade secrets.

Nidec moved to dismiss the trade secret claims, arguing, among other things, that the Defend Trade Secrets Act ("DTSA") did not apply because the alleged acts occurred prior the effective date of the DTSA.

The District Court stated that downloading files onto a flash drive was not something Desai ordinarily did during the term of his employment. By doing so, Molon had grounds for suspicion that Desai took the information to use at Nidec, a competing company. The District Court used the "inevitable disclosure" doctrine, which allows a plaintiff to "prove a claim of trade secret misappropriation by demonstrating that the defendant's new employment will inevitably lead him to rely on the plaintiff's trade secrets."

The District Court considered in evaluating whether the facts justified this inference: "1) the level of competition between the former employer and the new employer; 2) whether the employee's position with the new employer is comparable to the position he held with the former employer; and 3) the actions the new employer has taken to prevent the former employee from using or disclosing trade secrets of the former employer." The District Court found that 1) Molon and Nidec were serious competitors in the custom motor market; 2) Desai, former head of quality control of Molon, would use his Molon's trade secrets to perform his duties at Nidec; and 3) the District Court was silent in regards to if Nidec had done anything to prevent Desai from using or disclosing the trade secrets of Molon. Thus, the District Court allowed Molon to go forward with its DTSA claim.

AIPLA Legislative Proposal for Rewriting 35 U.S.C. §101

The American Intellectual Property Law Association ("AIPLA") recently introduced a legislative proposal for rewriting 35 U.S.C. § 101. The AIPLA believes that the current framework of §101 has an adverse impact on innovation and places the United States at risk of falling behind the patent systems of other countries. The proposal eliminates the two-part test established by the U.S. Supreme Court under *Alice* for subject matter eligibility for patent protection. The AIPLA proposal is very similar to an amendment proposed recently by the Intellectual Property Owners Association ("IPO"). The proposed §101 amendments are as follows:

"Inventions Patentable

*[AMENDED] (a) Eligible Subject Matter.—Whoever invents or discovers any ~~new~~ ~~and~~ useful process, machine, manufacture, composition of matter, or any useful improvement thereof, ~~may~~ ~~obtain~~ **shall be entitled to** a patent therefor, subject **only** to the conditions and requirements ~~of~~ set forth in this title.*

[NEW] (b) Sole Exceptions to Subject Matter Eligibility.—A claimed invention is ineligible under subsection (a) only if the claimed invention as a whole exists in nature independent of and prior to any human activity, or can be performed solely in the human mind.

NEW] (c) Sole Eligibility Standard.—The eligibility of a claimed invention under subsections (a) and (b) shall be determined without regard to the requirements or conditions of sections 102, 103, and 112 of this title, the manner in which the claimed invention was made or discovered, or whether the claimed invention includes an inventive concept."

Staas & Halsey Attorneys Speak at the 3rd Annual IP Strategy Summit

This past May 2017, Staas & Halsey partners Richard A. Gollhofer and Mehdi Sheikerz and senior associate Stephen McClure presented "Drafting Patent Claims to Avoid 35 U.S.C. §101 Rejections" at the 3rd Annual IP Strategy Summit in Seattle, Washington on May 3, 2017. The presentation was part of the firm's ongoing efforts to inform Applicants about recent patent subject matter eligibility (SME) decisions by the courts and recent SME guidance developments at the U.S. Patent and Trademark Office (USPTO).

The presentation included a brief review of the *Alice Corp. v. CLS Bank* decision and eight subsequent Federal Circuit decisions that found patent eligibility through March 2017. This provided the background for a discussion of several hypothetical examples of possible claim amendments that may be deemed by USPTO examiners to comply with the current SME.

RICHARD A. GOLLHOFER

MEHDI SHEIKERZ

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Staas & Halsey Attorney Presents at the Knowledge Group Trademark Webinar

On June 21, 2017, Staas & Halsey trademark attorney Alexander Butterman was a panelist in a trademark law webinar sponsored by The Knowledge Group which was entitled, Best Practices in Protecting Your Brand and the Fundamentals of Trademark Law: A 2017 Perspective.

Alexander Butterman joined panelists Barnard Madsen (Fillmore Spencer LLC) and John McKeown (Goldman Sloan Nash & Haber LLP) in presenting an overview of modern day trademark law with an emphasis on practical insights and recommended best practices for mark owners to follow. Mr. McKeown began the webinar discussing the basics of branding and brand protection; Mr. Butterman followed with an overview on the process of selecting, clearing the availability of, and protecting a trademark or service mark both domestically and internationally; and Mr. Madsen reviewed trademark enforcement procedures and pitfalls to avoid.

A recording of this approximately 1.5 hour trademark webinar is presently available for purchase for US$99 on the website of the webinar provider, The Knowledge Group by clicking HERE. The webinar might qualify for 1.5 Continuing Education or Continuing Legal Education credit hours for U.S. attorneys.

ALEXANDER H. BUTTERMAN

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Summer in Washington, D.C.

The glorious days of summer have finally arrived in D.C. All the plants are in bloom and all the tourists are blooming with excitement as they go forth from museum to museum to monuments to restaurants, and finally to hotels. So much to see, hear, taste, and explore. Washington, D.C. has it all.

Photo on right: U.S. Capitol in the summer with garden in full bloom.

Photo on left: U.S. White House in the summer at dusk.

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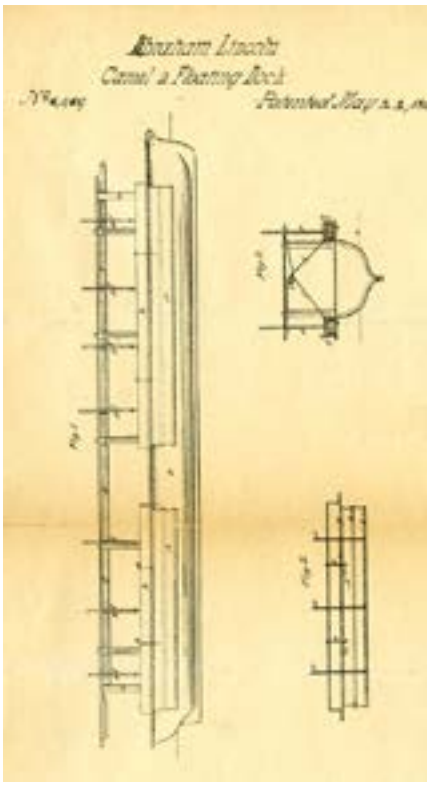
Celebrity Patent Inventor: President Abraham Lincoln



How many U.S. presidents have been granted patents in the U.S.? **ONE.** Who was the U.S. president granted this patent? **Abraham Lincoln**. Before he was President and before his pivotal role in the U.S. Civil War, Abraham Lincoln was an inventor. In his youth, Abraham Lincoln was employed on flatboats hauling freight down rivers like the Sangamon, Mississippi or Ohio. On many occasions, Lincoln noted that the boats would get stuck on sandbars and the crew would have to unload cargo to get boats over sandbars. Lincoln, known for his mechanical and solution-finding mind, set out to invent an apparatus that would lift boats over sandbars and other obstructions and alleviate waste of time, energy, and money by boat crewmembers. So while a Congressman, Lincoln with the help of mechanic, Walter Davis, created a model of his invention. In March of 1849, he submitted his patent application to the USPTO for review.

Stated in his patent application, Lincoln wrote “Be it known that I, Abraham Lincoln, of Springfield, in the County of Sangamon, in the State of Illinois, have invented a new and improved manner of combining adjustable buoyant air chambers with a steamboat or other vessel for the purpose of enabling their draught of water to be readily lessened to enable them to pass over bars, or through shallow water, without discharging their cargoes; and I do hereby declare the following to be a full, clear, and exact description thereof, reference being had to the accompanying drawings making a part of this specification.”

Although the USPTO granted U.S. patent 6,469 on May 22, 1849, Lincoln’s invention was never utilized. The original model created by Lincoln and a replica created for public display can be found at the Smithsonian’s National Museum of American History in Washington, D.C.

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