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STRENGTHENING DESIGN PATENT PORTFOLIOS: STRATEGIES FOR MEDICAL DEVICE COMPANIES

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INTRODUCTIONS

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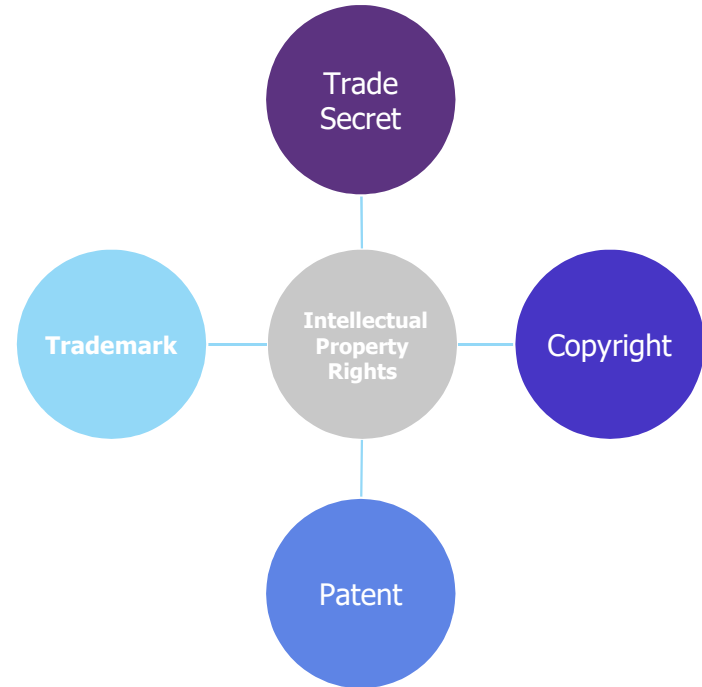
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INDUSTRIAL DESIGNS FOR MEDICAL DEVICES

Intellectual Property

- Creations of the mind that the law protects from unauthorized use.
 - Trade Secrets
 - Copyrights
 - Trademarks
 - Patents
 - Utility Patents
 - Product, Process, or Machine
 - Design Patents
 - Ornamental Appearance/Industrial Design



Industrial Design

- Industrial design is the process of applying ornamental design to useful articles of manufacture



Med Device IP Trends

- Growth and changes in design patent law
- Design patent enforcement at the border
- Future of medical device patent litigation
 - High-tech and medical industries continuing to merge
 - Expected to lead to more patent disputes (start-up v. legacy mentality)
- ITC investigations are more frequent and an effective tool
 - New Federal Circuit decision strengthens impact of ITC rulings
- Increasing trade secret litigation
 - Litigation is fueled by employees rapidly moving to new companies

UNDERSTANDING DESIGN PATENTS

Consider Design + Utility Filing Strategy

- Innovative technical features may not be easy to imitate and infringement not easily detected
- Utility protection is time consuming and may not even be available
- Competitor may be happy to provide inferior product that looks like the real thing
- Distinctive design features are easily imitated and infringement is easily detected
- Function does not bar design protection

Design Patents

- Protects ornamental features of a useful article
- Referred to as industrial, community, or registered designs outside of the U.S.
- Protection rights are defined by the drawings
- Registration is required
- Narrower than utility, similar in ways to trademark, and broader and more powerful than copyright
- Functional elements permitted, but can not claim a “primarily functional” design

Design Patents Continued

- Foreign priority filing deadline is 6 months from first filing
- Domestic priority can be claimed in the U.S. to utility applications but not provisional application
- Average time to registration is 1-2 years but can be expedited
- Term is 15 years from grant (14 yrs. for patents filed before 5/13/15)
- Ownership – resides with the inventor unless contracted to otherwise
- Infringement standard is Ordinary Observer test

Written Description

In re Owens (Fed. Cir. 2013)

parent



Fig. 1

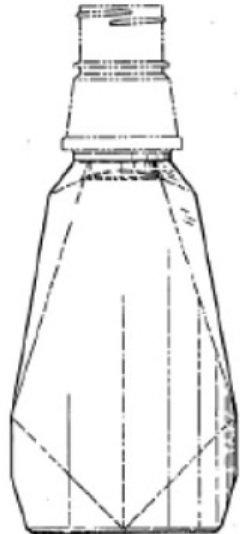


Fig. 2



continuation



Fig. 1

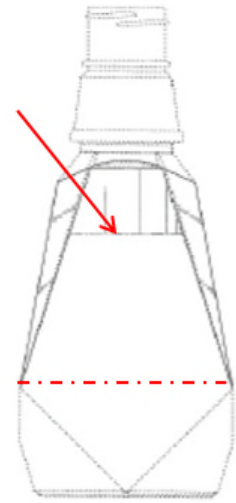
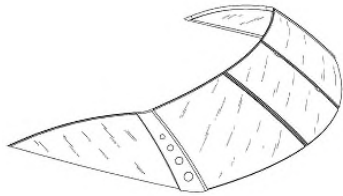


Fig. 2

Prosecution History Estoppel

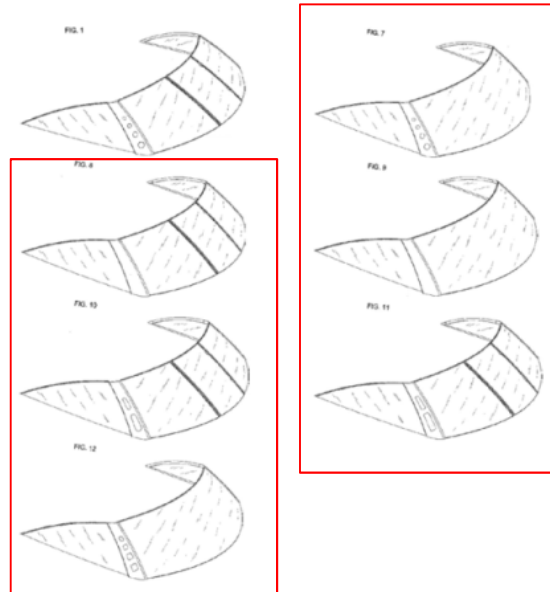
- *Pacific Coast Marine Windshields Ltd. v. Malibu Boats, LLC et al*, No. 2013-1199 (Fed. Cir. 2014)



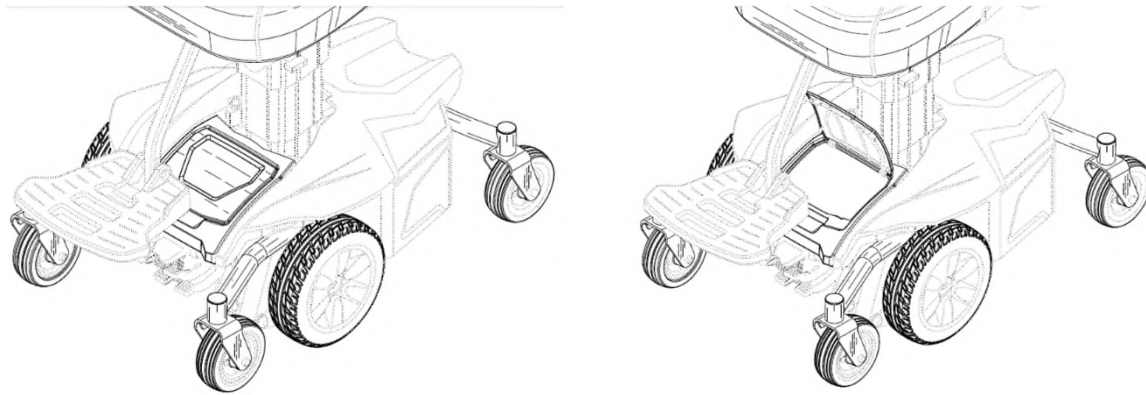
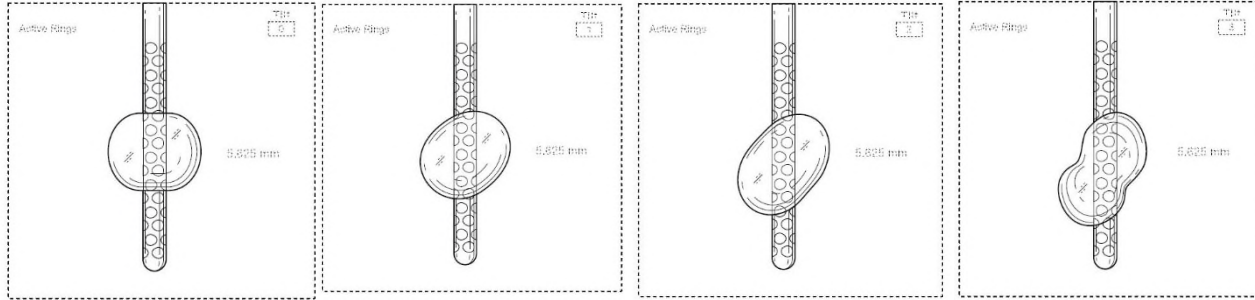
The '070 Patent



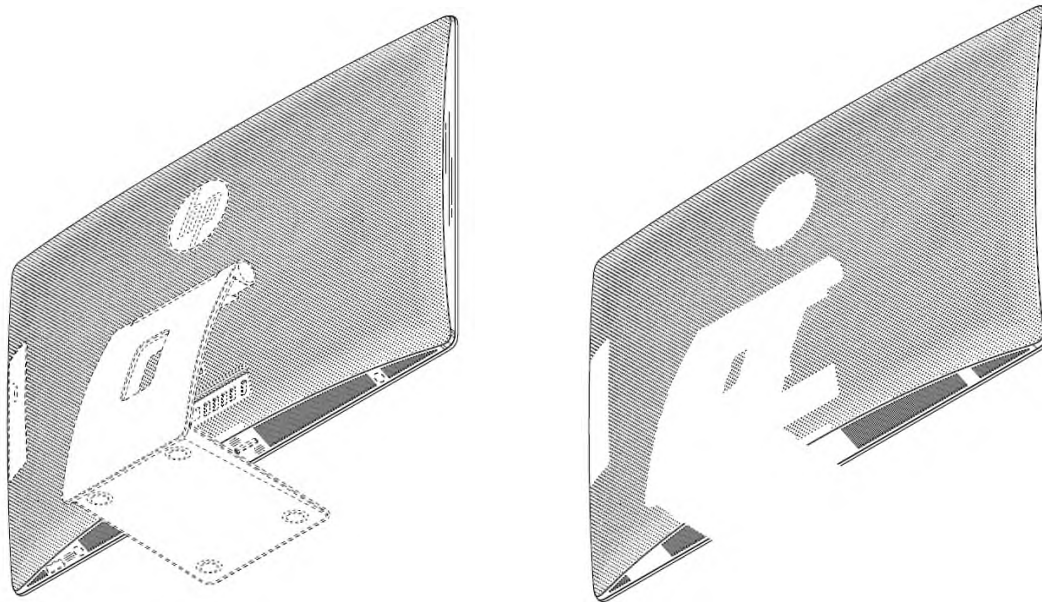
The Accused Malibu Windshield



Protecting User Interfaces and Movement



Foreign Filing Considerations



Claim Scope

- *Simpson Strong-Tie Co. v. Oz-Post Int'l (dba OZCO Building Prods.)*, 2019 WL 6036705 (N.D. Cal. Nov. 14, 2019)

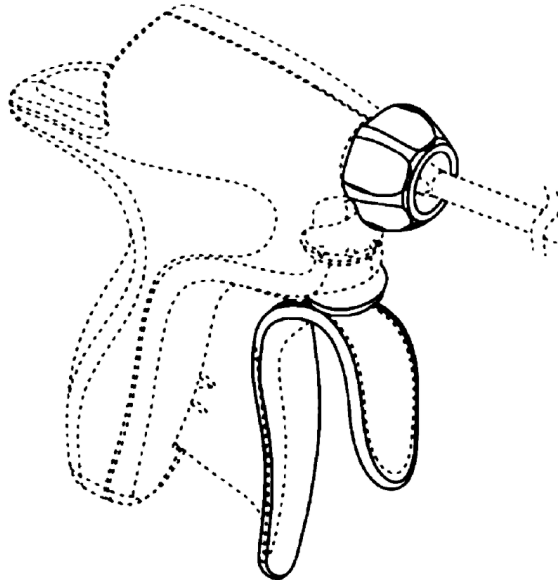


PROTECTING REPLACEMENT PARTS

Protect Replacement Components: Function

Ethicon Endo-Surgery, Inc. v. Covidien, Inc., 796 F.3d 1312 (Fed. Cir. 2015)

Ethicon's Patented Design



Covidien's Accused Design

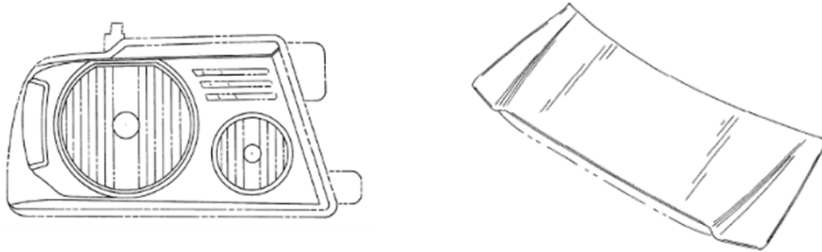


Protect Replacement Components: Function

- *Automotive Body Parts Association ("ABPA") v. Ford Global Technologies, LLC*, Case No. 2:15-cv-10137 (E.D. Mich. Feb. 20, 2018)
 - ABPA sued Ford, seeking a declaratory judgment of invalidity or unenforceability of design patents
 - ABPA “effectively ask[ed] this Court to eliminate design patents on auto-body parts”
 - Though Ford had not moved for summary judgment, the district court announced its intention to enter judgment in favor of Ford *sua sponte* pursuant to Federal Rule of Civil Procedure 56(f)(1)
- *ABPA v. Ford*, 930 F. 3d 1314 (Fed. Cir. July 23, 2019)
 - Federal Circuit affirms summary judgment that ABPA was not entitled to declaratory judgment of invalidity or unenforceability as to Ford’s design patents

Protect Replacement Components: Function

- ABPA argued that auto body parts are functional, thus not eligible for design patent protection
- Headlamp and hood of a truck are inherently functional



- However, the court disagreed
- Although functional, the ornamental look of these parts matters
- Thus, design patent protection is possible

Protect Replacement Components: Function

- Take advantage of the current design patent environment
- Functional products are (often) entitled to design patent protection
- Potentially expand the scope of these patents by depicting *unclaimed* functional features, particularly if the accused product typically has this feature

Protect Replacement Components: Defenses

- Federal Circuit rejected ABPA's argument that design patents are unenforceable under the doctrine of exhaustion and the related repair doctrine
- Patent exhaustion: sale of a patented product can prevent the patent owner from asserting the patent against that **same product** in the future
- Repair doctrine: allows the owner of a patented product to repair that **same product** without incurring any infringement liability

Protect Replacement Components: Defenses

- ABPA argued that these doctrines should also be broadened, just like design patent rights have been broadened
 - ABPA argued that when the F-150 truck is sold, design patent rights are exhausted and the **design patent** cannot be asserted against any product
 - ABPA argued that the repair doctrine allows owners to purchase replacement parts, even if a **design patent** covered the OEM part
- Federal Circuit reconfirmed that exhaustion and repair doctrines are not avoided by the sale of the patented article

Protect Replacement Components: Summary

- Scope of design patent rights has expanded
- Role of functionality in design patents have changed
- Defenses to infringement have not been expanded
- Balance of equities favors design patent holders and makes litigation more difficult for accused infringers
 - Note: our strategies for defense against an allegation of design patent infringement are covered separately

REASSESSING ENFORCEMENT STRATEGIES

Reassess Enforcement Strategy

- Business goal: stop infringers, maintain market share, and receive monetary compensation—all in a timely and financially efficient manner
- Typical legal strategy: utility patent lawsuit in district court and/or a utility patent infringement action before the International Trade Commission (ITC)
- However, the recent Federal Circuit rulings in *Swagway v. ITC* along with the proposed Counterfeit Goods Seizure Act of 2019 legislation may result in new enforcement strategy

Reassess Enforcement Strategy

- Non-patent matters decided by the ITC typically have a preclusive effect
- Federal Circuit recently addressed – and possibly altered – the outcome of this issue
- Initially held that, like patent disputes, there was no preclusive effect
- However, the Federal Circuit then *removed* the preclusivity portion of its opinion
- Removal is not a holding that ITC rulings have preclusive effect
- But, it does strengthen the argument that ITC rulings will be given significant weight—and possibly even a preclusive effect—by a district court
 - *Swagway, LLC v. ITC*, 934 F.3d 1332 (Fed. Cir. 2019)

Reassess Enforcement Strategy

- Implement *Swagway* ruling by filing an ITC action based on non-patent intellectual property rights, such as its trade dress rights
- This ITC action would likely be less expensive than a traditional utility patent dispute
- If successful at the ITC, the result would be an importation ban

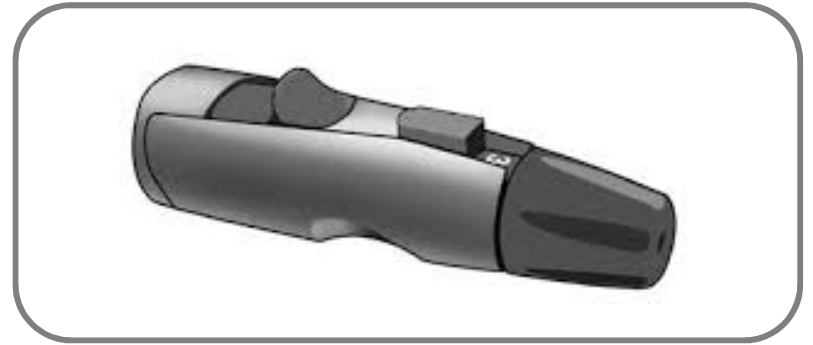
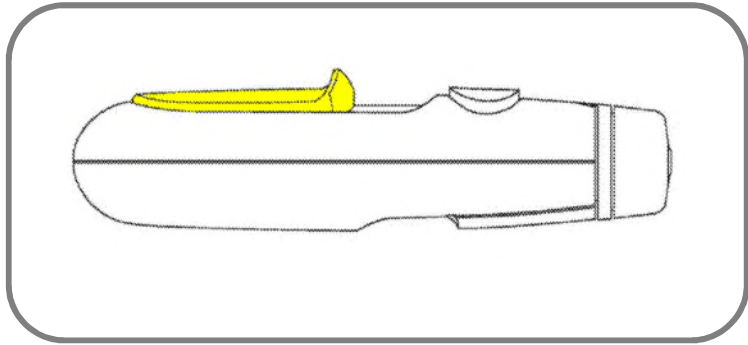
Reassess Enforcement Strategy

- Expand on that success by converting favorable ITC decision into a monetary award and permanent injunction in a district court
- Based on *Swagway*, the district court may even quickly proceed to judgment because the prior ITC decision may be given significant weight, if not complete preclusive effect
- Consider adding patent infringement allegations, particularly design patent allegations
- Design patent dispute is a distinct legal theory from a trade dress dispute, but the court may be inclined to agree that a trade dress infringer is also a design patent infringer
- If successful in expanding the scope of the district court case, seek additional monetary relief against the infringer

Reassess Enforcement Strategy

- Implement in parallel with an enforcement action under the proposed [Counterfeit Goods Seizure Act of 2019 legislation](#), which expands US Customs and Border Patrol authority
 - Currently: CBP has the authority to seize products that infringe copyrights and trademarks
 - Loophole: Counterfeiters import counterfeit products separately from infringing trademark labels
 - Fix: this bill would permit CBP to seize the counterfeit products, if covered by a design patent
- Strategy: if this bill becomes law, seek relief with CBP against design patent infringers for a potentially quicker and cheaper enforcement mechanism
 - Permits a layman (*e.g.*, CPB official) to determine design patent infringement at a (hopefully) high level of accuracy and (relatively) low cost to patent owner

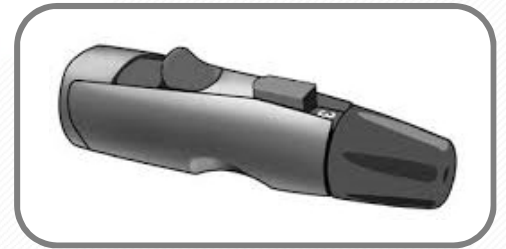
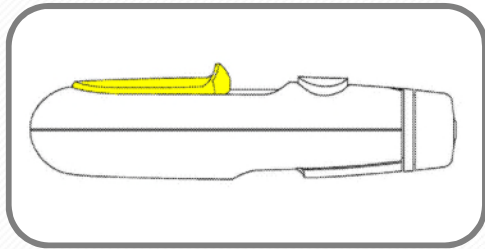
EFFECTIVELY LITIGATING DESIGN PATENTS



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Standard for Design Patent Infringement

Whether the *overall appearance* of the patented design and the accused product would be *substantially similar* to the *ordinary observer* giving *such attention* as a purchaser usually gives *who is familiar with the prior art*.

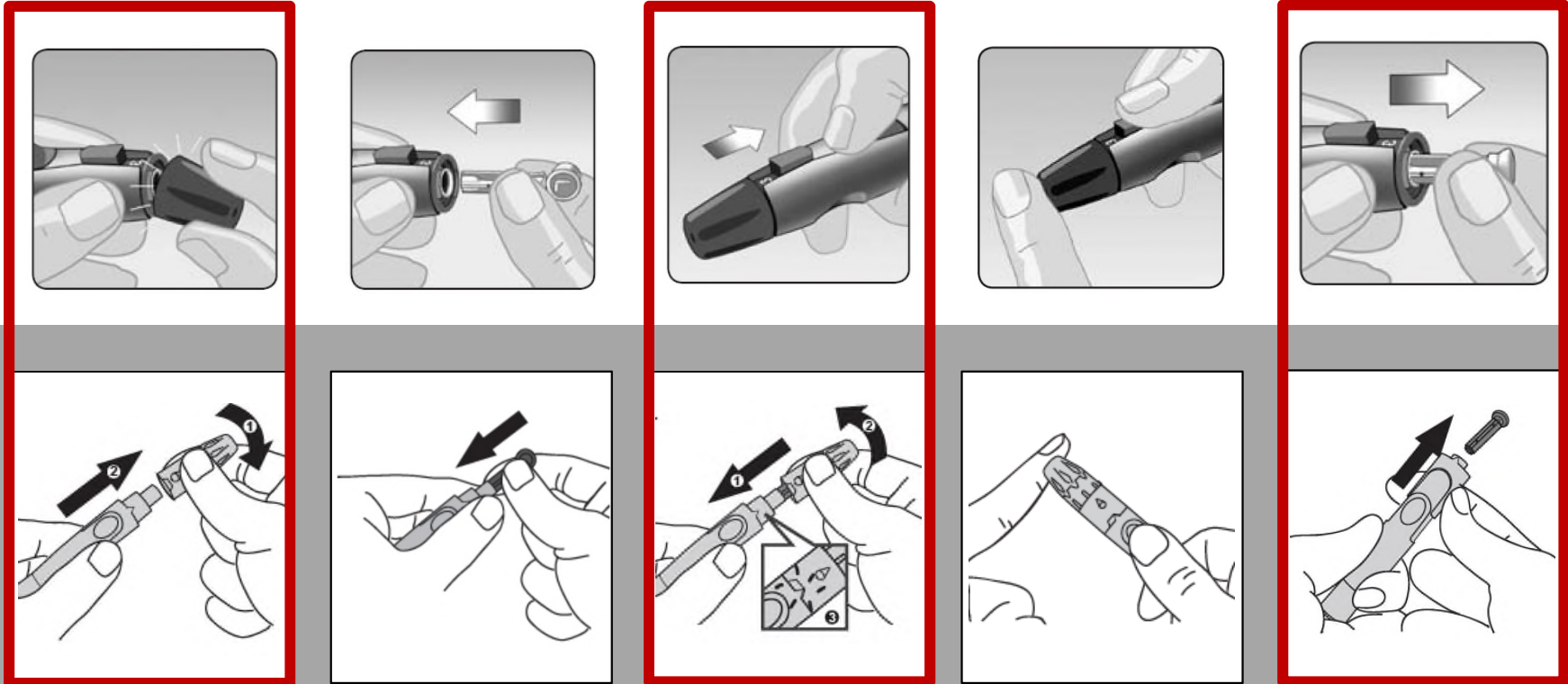


Identify the Overall Appearance from the Outset



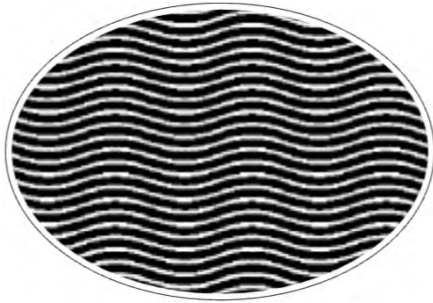
- Who is the *ordinary observer* of the product?
- How many *views* of the product can be seen?
- How much *time* spent looking at the product?
- How much *scrutiny* is applied before purchase?
- What about during the *normal use* of the product?

Account for Differences Between Normal Use



Strategies for Summary Judgment: Infringement

Columbia Sportswear N. Am., Inc. v. Seirus Innovative Accessories, Inc., 942 F.3d 1119 (Fed. Cir. 2019)



No	<i>Logo</i>	Yes
Horizontal	<i>Wave Orientation</i>	Vertical
Varied	<i>Wave Width</i>	Uniform
Large	<i>Wave Size</i>	Small

Strategies for Summary Judgment: Infringement

Columbia Sportswear N. Am., Inc. v. Seirus Innovative Accessories, Inc., 942 F.3d 1119 (Fed. Cir. 2019)

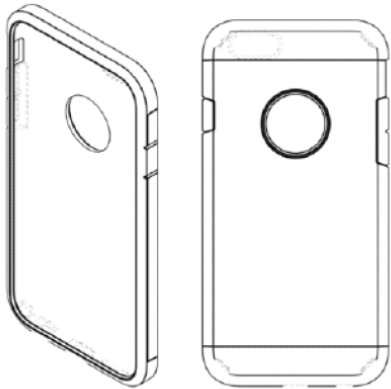


[T]he district court made a finding of fact—whether an element of Seirus’s design would give an ordinary observer a different visual impression than Columbia’s design—over a disputed factual record,” which is “not permitted by Rule 56 and should be resolved by the jury on remand.”



Strategies for Summary Judgment: Invalidity

Spigen Korea Co. Ltd. v. UltraProof Inc. et al., 955 F.3d 1379 (Fed. Cir. 2020)



Yes	<i>Outer Shell</i>	No
Yes	<i>Circular Aperture</i>	No
No	<i>Triangular Ridges</i>	Yes

Strategies for Summary Judgment: Invalidity

Spigen Korea Co. Ltd. v. UltraProof Inc. et al., 955 F.3d 1379 (Fed. Cir. 2020)



We determine that a genuine dispute of material fact exists as to whether the [prior art design] is basically the same as the [patented design] and hence, a proper primary reference. We thus reverse the district court's grant of summary judgment of invalidity and remand for further proceedings.








Strategies: Patent Infringement Damages



Utility Patents



Design Patents

	Utility Patents	Design Patents
Reasonable Royalty		
Patentee's Lost Profits		
Disgorgement of Infringer's Profits		

Profit Disgorgement

Whoever during the term of a patent for a design, without license of the owner,

- (1) **applies** the patented design, or any colorable imitation thereof, to any **article of manufacture** for the purpose of sale, or
- (2) **sells or exposes for sale** any **article of manufacture** to which such design or colorable imitation has been applied

shall be liable to the owner to the extent of his **total profit**, but not less than \$250, recoverable in any United States district court having jurisdiction of the parties.

Nothing in this section shall prevent, lessen, or impeach any other remedy which an owner of an infringed patent has under the provisions of this title, but he shall not twice recover the profit made from the infringement.

35 U.S.C. § 289



Profit Disgorgement



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Arriving at a damages award under § 289 thus involves two steps.

First, identify the "article of manufacture" to which the infringed design has been applied.

Second, calculate the infringer's total profit made on that article of manufacture.

Samsung Elec. Co., Ltd. v. Apple Inc., 137 S. Ct. 429, 435 (2016)



Step 1: Identify the Article of Manufacture

General Rule

Patentees may recover the total profit from the sale of any article *embodying* the patented design; recovery is not limited to the apportioned profits attributable to the patented design.

Strategy: Elect Lost Profits/Reasonable Royalty to Recover Conveyed Sales



Step 1: Identify the Article of Manufacture

Multi-Component End Products

If patented design is distinct component of larger article of manufacture, patentee may need to apportion, or apply the Entire Market Value Rule, if recovering profits from larger product.

Strategy: Tie the Claimed Design to Product as a Whole

The scope of the claimed design, including the drawing and written description.

Whether the design is conceptually distinct from the product as a whole

The relative prominence of the design within the product as a whole.

The physical relationship between the patented design and the rest of the product

Step 2: Calculate the Infringer's Profits

General Rule

$$\{ \textit{Pre-Tax Sales of Article of Manufacture} \} - \{ \textit{Costs} \} = \textbf{Total Profits}$$

Deductible Costs

- Infringer has the burden to show qualifying *variable costs* (i.e., costs that vary with sales levels) plus some *fixed expenses* (i.e., overhead and other costs that tend not to vary with sales levels).
- Fixed costs not necessary for the production or sale of the infringing product are not deductible.

No Double Recovery for Design and Utility Patent Infringement

General Limitation

If patentee elects to recover the infringer's profits under § 289 for design patent infringement, it cannot also recover a reasonable royalty for utility patent infringement for same accused product.

Strategy: Seek Different Awards for Different Damages Periods



No Enhancement of Disgorged Profits

General Limitation

If patentee elects to recover the infringer's profits under § 289, enhanced damages for willful infringement cannot be awarded because enhancement is only limited to the *patentee's* damages.

Strategy: Seek Enhanced Damages for Non-Patent Claims

Damages for non-patent claims—*e.g.*, trade dress infringement under the Lanham Act—can be enhanced based on the same accused product pursuant to other non-patent laws.



QUESTIONS?

A vibrant, futuristic digital cityscape. The scene is composed of glowing, pixelated buildings and streets in various colors like orange, yellow, pink, and blue, set against a dark background. The perspective is looking down a long, straight street that recedes into the distance. The buildings are made of glowing dots and lines, creating a sense of depth and perspective. The overall atmosphere is one of a high-tech, digital environment.

Presentation Takeaways

- 1) Design patents are playing an increasingly important role in med device IP portfolios.
- 2) Medical devices have functional features, and may include replaceable, single-use components, which may be protected by design patents.
- 3) While the end product of a med device design patent—a few words and some drawings—is seemingly simple, care should be given to the filing and enforcement strategy to maximize protection.
- 4) New enforcement strategies are flexible and efficient for design patent owners
- 5) Develop an effective litigation strategy well before claim construction by identifying the ordinary observer and purchasing environment from the outset of the case.
- 6) Maximize damages award by seeking profit disgorgement for high-margin devices and lost profits/reasonable royalties for low-margin devices or convoyed sales.

Biography



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John is a patent lawyer who focuses on implementing intellectual property programs for clients involving mechanical and life science technologies. Clients turn to John for counsel on patent portfolio management, patent strategy, product clearance, patentability analyses, and patent challenges including *inter partes* reviews. John also provides support for patent litigation, prepares and negotiates technology agreements, and works with clients on venture capital financing, merger and acquisition agreements, initial public offerings, and IP due diligence.

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Scott is a patent litigator with jury and bench trial experience in US District Courts, *inter partes* review (IPR) experience before the US Patent and Trademark Office (USPTO), and appeal experience before the Federal Circuit. Scott counsels both established companies and startup ventures on intellectual property matters. He also actively works on pro bono immigration and nonprofit intellectual property matters.

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Ehsun concentrates his practice on litigation involving patents, trade secrets, and related intellectual property matters throughout the United States. He handles all phases of litigation from inception through trial and post-trial appeals. Ehsun also represents clients in patent trials conducted before the Patent Trial and Appeal Board (PTAB), including *inter partes* review proceedings established by the 2011 America Invents Act. His cases have involved a diverse range of technologies including inkjet printers, smartphone software, semiconductor chips, medical devices, and biometric systems.

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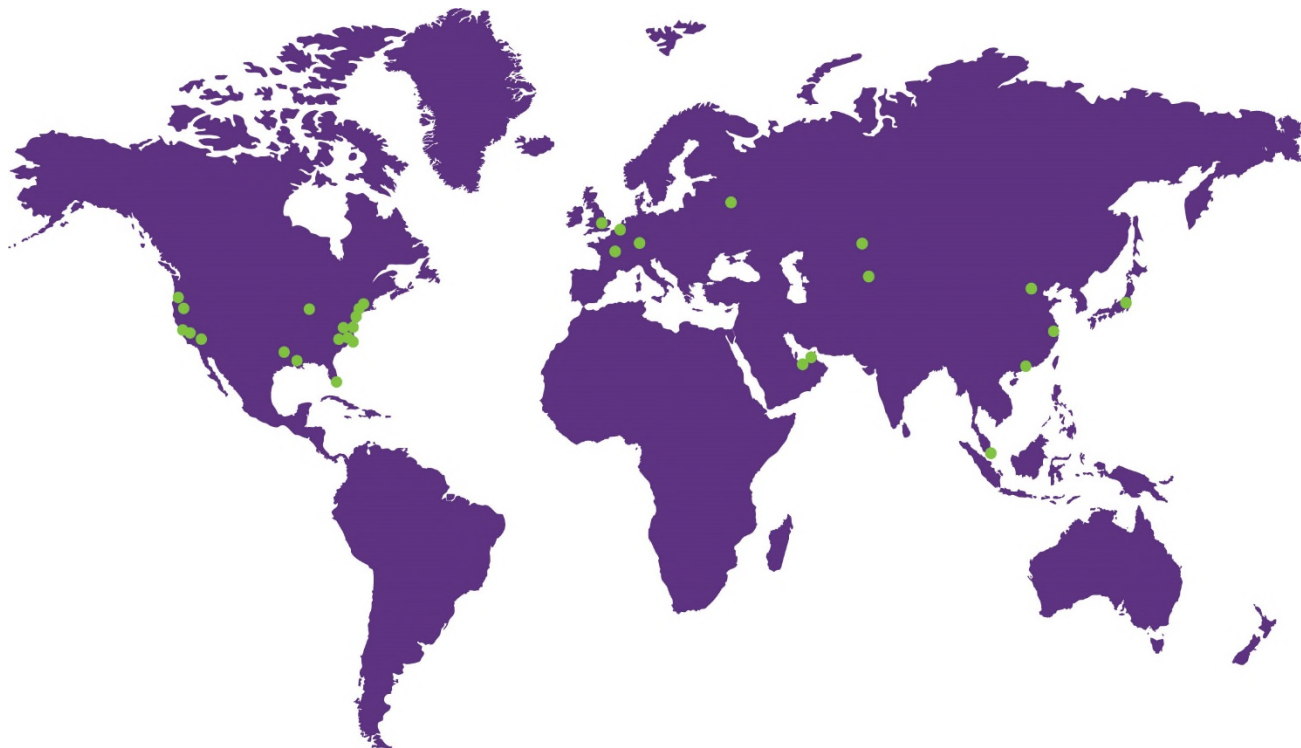
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