

# *Gimme Shelter*

Safe Harbor in the United States and Europe

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# Disclaimer

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This is not legal advice.

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# Background

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## 35 U.S.C. § 271

### INFRINGEMENT OF PATENT

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

. . .

(e)

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . *solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.*



**THE "SAFE HARBOR"**

# Supreme Court Denies Cert. in *Momenta II*

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## Higher Scrutiny for Post-Approval Acts

*Amphastar Pharm. Inc. v. Momenta Pharm., Inc.* (S. Ct. Dkt. No. 15-1402).

- Question Presented:
  - “Whether the Safe Harbor protects a generic drug manufacturer’s bioequivalence testing that is performed only as a condition of maintaining FDA approval and is documented in records that must be submitted to the FDA upon request.”
- Certiorari Denied on Oct. 3, 2016.
  - Leaves undisturbed CAFC holding in *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610 (Fed. Cir. 2015) (“*Momenta II*”).
  - Implemented a heightened standard of scrutiny on whether post-approval activities are covered by the Safe Harbor.

# Agenda

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## What we'll cover

- Genesis of the Safe Harbor
- Decisions leading to *Momenta I and Momenta II*
- Protection for pre- and post-approval conduct
  - Supplying active ingredients
  - Stockpiling drug inventory
  - Using research tools
- Bolar Exemption (EU)
  - EU Research exemption
- Bolar Exception (Canada)



# The Safe Harbor

**FISH.**

# Genesis of Safe Harbor

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## Addresses Limited Research Exemption in the U.S.

- Competitors can begin selling an otherwise infringing product on the day a 'blocking' patent expires.
- Marketing of pharmaceuticals regulated by FDA under the Federal Food, Drug, and Cosmetic Act.
  - Requires that drug manufacturers comply with various statutes, regulations, and guidelines before market approval is granted.
- *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), delayed availability of generics by allowing a patentee to maintain market exclusivity long after blocking patent(s) expired.
  - Court found Bolar infringed when it used Roche's patented substance prior to expiration of the blocking patent to prepare FDA submission to enable Bolar to market its own version of the drug after the Roche patent expired.
  - Court: "[T]ruly narrow" experimental use exception limited to experiments to satisfy idle curiosity, or for strictly philosophical inquiry. *Id.* at 863.

# Genesis of Safe Harbor

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## Hatch-Waxman Act Overruled *Roche*

- Congress created 35 U.S.C. § 271(e)(1) to specifically overrule *Roche*:
  - “It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.”
- Expedited FDA approval to get generic drugs to market immediately following expiration of any blocking patents.
- Safe Harbor also applies to branded products (pharmaceuticals, medical devices, follow-on biologics, and biosimilars)
  - Not limited to generics.

# Genesis of Safe Harbor

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## Section 156 Provides Symmetry

- Congress also enacted 35 U.S.C. § 156, which extends the life of patents claiming FDA-approved product or a method of making/using that product.
- Note: § 271(e)(1) covers “patented inventions”- no limitation on scope.
  - Balanced rights of patentees and generic manufacturers.
  - Research tools — patented inventions that are used in drug development, testing, and screening — are not subject to regulatory approval and thus are not extendable under section 156.
- Because these two sections were simultaneously enacted, some courts have cited the lack of symmetry between them to exclude research tools from the Safe Harbor.
  - If a patent is not extendable, it is not subject to the Safe Harbor, and thus, alleged infringers are not protected by § 271(e)(1).

# Supreme Court *Integra* Decision

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## Safe Harbor is Broad

In *Merck KGaA v. Integra Life Sciences*, 545 U.S. 193 (2005), the Supreme Court stated:

“[T]he statutory text [of § 271(e)(1)] makes clear that it provides a **wide berth** for the use of patented drugs in activities related to [FDA] approval.”

\* \* \*

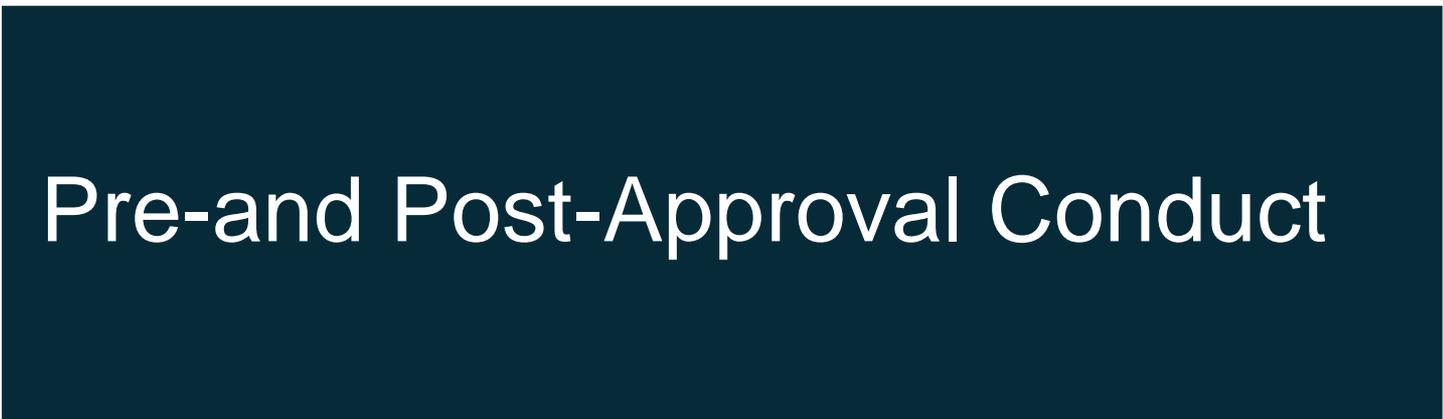
“[W]e think it apparent from the statutory text that § 271(e)(1)’s exemption from infringement extends to **all** uses of patented inventions that are **reasonably related** to the development and submission of **any** information to the [FDA]. This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process.”

*Id.* at 202 (emphasis on “any” in original).

# Burden of Proof – Use of Safe Harbor

## Plan Ahead

- Section 271(e)(1) is an affirmative defense, and defendant has burden of establishing it.
  - Plaintiff–patentee is entitled to conduct discovery to test allegations set forth by the defendant. *Ventrassist Pty Ltd. V. Heartware Inc.*, 377 F. Supp. 2d 1278, 1286-88 (S.D. Fla. 2005).
- Detailed records regarding “infringing” conduct to establish Safe Harbor protection are necessary.
  - Supreme Court in Merck stated “[e]ach of the accused activities must be evaluated separately to determine whether the exemption applies.” *Merck*, 545 U.S. at 200.
- If one intends to rely on Safe Harbor, plan ahead.
  - To counter allegation of induced infringement, opinion of counsel on non-infringement is admissible and negates “specific intent” required for inducement under § 271(b).
  - Will an opinion of non-infringement due to Safe Harbor demonstrating a good-faith belief in non-infringement suffice?
- Important in pharma/biotech industry as many allegations of infringement are based on inducement of method-of-treatment patents.
  - If one is protected by the Safe Harbor, i.e., a good-faith belief in non-infringement – even if incorrect – is that entity liable while its good faith belief exists?



# Pre-and Post-Approval Conduct

# Momenta I — Pre-Approval Conduct

## CAFC Broadly Interprets Scope of Safe Harbor

- *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.* 686 F.3d 1348, 1358 (Fed. Cir. 2012) (*Momenta I*).
  - FDA required Amphastar to test each commercial batch (post approval) before sale.
  - Amphastar used Momenta’s patented assay (research tool), although other tests available.
    - No need to select non-infringing alternative.
  - Court held use was protected by Safe Harbor because resulting information was “necessary both to the continued approval of ANDA and to Amphastar’s ability to market the generic drug.”
    - Distinguished *Classen Immunotherapies, Inc. v. Biogen Idec.*, 659 F.3d 1057, 1070 (Fed. Cir. 2011), in which the Federal Circuit held that Safe Harbor “does not apply to information that may be *routinely* reported to the FDA, long after marketing approval has been obtained.”
    - Amphastar’s post-approval activities sheltered because they were conducted to satisfy the FDA’s specific requirements and thus were “anything but ‘routine.’”
  - The court did not rest its decision on the fact that the assay was a research tool.
  - Court also held that actual submission of information to the FDA was not necessary.

# *Momenta I* — Pre-Approval Conduct

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## Chief Judge Rader Argues for Limited Scope in Dissent

- Argues that Safe Harbor won approval from diverse group of stakeholders with competing interests because it was limited in time and only applied to experimentation and not commercial sales:
  - “Nowhere in the legislative history can this court find a hint that an ‘infringer’ could continue to use its competitor’s patented method in manufacture of each commercial batch for contemporaneous sale.”
- Former Chief Judge’s views are instructive because he was involved in Act’s legislative history during tenure on Senator Hatch’s staff.
- Legislative history may not support ongoing use of patented research tools to support post-approval commercial sales.
- Chief Judge Rader has always viewed research tools as outside the scope of the Safe Harbor.

# Momenta II — Post-Approval Conduct

## More Critical Analysis in the Post-Approval Context

- In *Momenta II*, CAFC reconsidered *Momenta I* decision and excluded Amphastar’s use of the patented assay from Safe Harbor because it was a “habitual” or “regular” part of the production process and not related to obtaining FDA approval.
- Post-approval conduct will only be exempted if it is truly “required” by the FDA — studies to obtain or supplement an existing filing or to modify an existing drug label.
  - “The routine record retention requirements associated with testing and other aspects of the commercial production process contrast with non-routine submissions that may occur both pre- and post-approval, **such as the submission of investigational new drug applications (“INDs”), new drug applications (“NDAs”), supplemental NDAs, or other post-approval research results.** . . . The routine quality control testing of each batch of generic enoxaparin as part of the post approval, commercial production process is therefore not reasonably related to the development and submission of information to the FDA, and it was clearly erroneous to conclude otherwise.” *Momenta II*, 809 F.3d at 621.

# Momenta II — Post-Approval Conduct

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## Pre-Momenta Cases Agree

- Post-approval studies on the effect of food on the drug's bioavailability resulting in a change to its drug label were exempt because the studies “expedit[ed] development of information for regulatory approval” and therefore, were not “routine.” *Classen Immunotherapies, Inc. v. King Pharmaceuticals, Inc.* 981 F. Supp. 2d 415, 421 (D. Md. 2013).
- Even though *Momenta* involved a research tool, its reasoning applies to all post-approval conduct.
- The *Momenta I* “FDA required” analysis is essentially gone because the FDA did *require* the testing of each batch before it could be sold.
  - See Coggio and Vogel, “Federal Circuit Limits Safe Harbor for Post-Approval Conduct,” IP Law 360 (Nov. 17, 2015).

# Examples of Exempt Activities

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## Section 271(e)(1) Applies to . . .

- ITC actions – *Amgen, Inc. v. Int’l Trade Comm’n*, 519 F.3d 1343 (Fed. Cir. 2008).
- Medical devices (Types I, II and III) – *Abtox, Inc. v. Exition Corp.*, 122 F.3d 1019 (Fed. Cir. 1997).
- Manufacture of patented items, most of which were used to generate data for the FDA – *Intermedics, Inc. v. Venitritex, Inc.*, 755 F. Supp. 1269 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993).
- Submission of data to foreign regulatory agencies, where data are also submitted to the FDA - *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202 (D.N.J. 1994).
- Use of patented product to develop alternative FDA-approved manufacturing process - *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998).
- Use of FDA-generated data to prepare patent applications. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 WL 1512597 (S.D.N.Y. 2001).

# Examples of Non-Exempt Activities

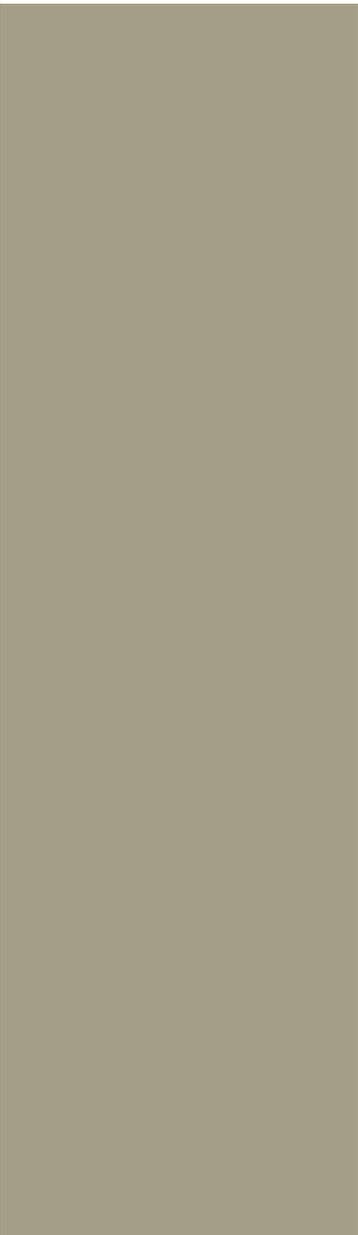
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## Section 271 (e)(1) Does Not Cover . . .

- Manufacturing patented products in the U.S. for shipment to foreign regulatory authorities - *NeoRx, supra*.
- Use of product for foreign clinical trials where no indication that results would be submitted to the FDA - *NeoRx, supra*.
- “Basic research” - *Merck KGA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

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- Activity must in some way relate to potential FDA approval of drug (device), supplemental approval, or label modifications.



# Supplying Active Ingredients (API)

# Supplying Active Ingredients

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## Pre-Approval OK

- API suppliers are not ANDA filers as they do not “submit” the ANDA. But can they be liable for inducement?
- There had been some confusion in the law. *Compare Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*, 267 F. Supp. 545, 548-49 (N.D. W. Va. 2003), with *Shire LLC v. Mylan Inc.*, 202 WL 2072665 (D.N.J. June 7, 2012).
- Safe Harbor protects third party that supplies active pharmaceutical ingredient (API) to a generic filer. *Shire LLC v. Amneal Pharm.*, 802 F.3d 1301, 1310 (Fed. Cir. 2015).
- But if a supplier does more, it can be sued.

# Supplying Active Ingredients

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## Post Approval is Trickier

- If supplier will provide commercial API quantities *after* approval, it may be liable for inducement.
  - In *Smithkline Beecham Corp v. Geneva Pharmaceuticals, Inc.*, the court permitted Smithkline to sue third party Sumika, which would manufacture and sell the generic product *after* FDA approval. 287 F. Supp. 2d 576, 585-86 (E.D. Pa. 2002).
- Some decisions have held the corporate relationship between the ANDA filer and the API supplier can make both liable as “submitters.”
- *Astra Zeneca Pharmaceuticals LP v. Aurobindo Pharma Ltd.*, 2009 WL 483131 (D. Del. Feb. 25, 2009) (employee of U.S. company signed on behalf of parent); *Wyeth v. Lupin, Ltd.*, 505 F. Supp 2d 303 (D. Md. 2007) (parent and wholly-owned U.S. subsidiary both liable).
  - See Coggio and Vogel, “Safe Harbor Protects Supplier of Active Ingredient for ANDA,” IP Law 360 (Sept. 29, 2015).



Stockpiling

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# Stockpiling — Support in Case Law?

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## Case(s) Condemning Stockpiling are Distinguishable

- *Biogen, Inc. v. Schering AG, Biogen*, 954 F. Supp. 391 (D. Mass. 1996).
  - Court held that Biogen’s “substantial and expensive effort” — including more than \$24 million spent stockpiling — was not protected by Safe Harbor. *Id.* at 395-96.
  - Here, Biogen – the plaintiff/alleged infringer in a D.J. Action - argued that the Safe Harbor did not apply in order to maintain subject matter jurisdiction.
- Cases hold protected conduct is flexible, given unpredictable nature of the FDA approval process.
  - Manufacturing and sale of alleged infringing medical devices to support clinical trials protected because parties often do not know what information will be needed to secure FDA approval. *Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269, 1280, 1289-90 (N.D. Cal. 1991).

# Stockpiling — Support in Case Law?

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## Case Law Analogies

- Stockpiling of “launch-quantity inventory” from 4<sup>th</sup> commercial-scale lot — in excess of 3 lots necessary to secure FDA approval — is protected. *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202 (D.N.J. 1994).
- Comm'l batches neither regulated by / submitted to FDA protected because they were objectively likely to generate useful information, even if results later discarded for reasons unrelated to FDA approval. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.* 3 F. Supp. 2d 104, 108, 110 (D. Mass. 1998).
  - “The exemption is not so ephemeral that it will be lost as a result of conduct which postdates the making, using, or selling of the patented product. The retention of the [not yet approved generic] following its manufacture is not an activity that could constitute infringement under section 271(a).”
- This aligns with *Merck KGaA v. Integra Life Sciences*, 545 U.S. 193, 202 (2005) where SCOTUS found Safe Harbor provides wide berth of protection.

# Stockpiling — Support in Case Law?

## Stockpiling Without Infringing Sales Inflicts No Harm?

- *In Aktiebolag v. Andrx Pharmaceuticals, Inc.*, 695 F. Supp. 2d (S.D.N.Y. 2010) alleged infringer did not seek Safe Harbor protection.
  - Before trial ANDA defendant Andrx produced 78 commercial batches worth over \$400 million.
  - Court found product infringed and deferred Andrx’s claim that batches were protected under Safe Harbor.
    - Andrx then destroyed all the commercial batches.
  - In damages phase, Andrx conceded batches were not exempted by the Safe Harbor.
  - Court excluded the testimony of Astra’s damages expert because the expert improperly derived her conclusions from projected sales — not actual sales — and awarded no damages because Astra was not economically harmed:
    - “[Astra’s expert’s] analysis suffers from several flaws. First and foremost, it does not calculate a reasonable royalty based on manufacture alone, which is the sole act of infringement here. . . . [Astra’s expert also] does not suggest any harm to Astra from Andrx’s manufacture of product alone. [The] report, being wholly divorced from events subsequent to the hypothetical negotiation date, particularly the fact that Astra concededly suffered no harm as a result of the infringement, is thus properly excluded under Rule 702.” Transcript of Sept. 20, 2013 Proceedings at 35, 38, No. 1:99-cv-09887 (Dkt. 239)
- Not clear what damages — if any — the court would have awarded had Astra’s expert properly addressed “damages” or if the stockpiled products had been sold.

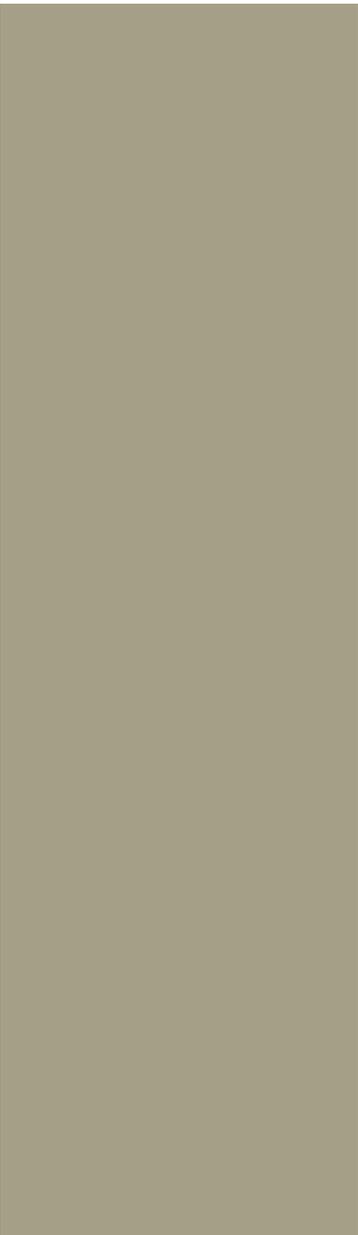
# Stockpiling — Support in Legislative History?

## Congress Aimed to Give *Immediate* Access to Drugs

- Act's legislative history demonstrates that goal of Safe Harbor was to give the public immediate access to generic products after patent expiration.
  - It is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but preventing of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.

\* \* \*

- [The Committee on Energy and Commerce] reasoned that without [§ 271(e)(1)] generic manufacturers would be required to engage in . . . bioequivalency tests after the expiration of the patent. This would result in delays of about two years after the expiration of the patent before a generic could go on the market.
- Goal can be achieved by allowing generic to prepare to enter the commercial market immediately after any blocking patent expires by stockpiling the product.
- Goal of Safe Harbor is to facilitate introduction of competing product "as soon as... legally permissible." *Teletronics Pacing Sys. Inc. v. Vendritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992); See also *Teva Pharmaceutical USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007).
- See Coggio and Vogel, "Is Stockpiling Protected by the Hatch-Waxman Safe Harbor," IP Law360 (Nov. 21, 2014).



# Research Tools

# Research Tools — Support in *Momenta II*

## *Momenta II* Allows for Coverage of Research Tools?

- *Momenta II* Court, in explaining the breadth of the exemption, stated:
  - Despite the broad contours of the [Safe Harbor] exemption, some activities are outside its protection. . . . [R]esearch tools or devices that are not themselves subject to FDA approval **may** not be covered. *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265-66 (Fed. Cir. 2008) (emphasis added).
- Use of the word “may” at odds with citation of *Proveris*, where CAFC seemingly held that research tools are not covered by Safe Harbor because the patent-at-issue could not be extended.
- If *Momenta II* Court believed that research tools were not covered under the Safe Harbor, analysis could have ended.
  - But Court instead excluded Amphastar’s quality control tests from the Safe Harbor because they were a “habitual” or “regular” part of the production process.
- *Proveris* is contravened by earlier decision in *Abtox, Inc. v. Exitron Corp.*, 131 F.3d 1009 (Fed. Cir. 1997), which held that statutory symmetry between Sections 271(e)(1) and 156 for research tools was **not** required for Safe Harbor. This decision should have controlled.

# Research Tools — Need Statutory Symmetry?

## Supreme Court and CAFC Do Not Require Symmetry

- In *Eli Lilly and Co. v. Medtronic, Inc.*, the Supreme Court recognized that exceptions could exist where research tool patents would be subject to Section 271(e)(1), even though the controlling patent was not extendable under Section 156:
  - “[T]here may be some relatively rare situations in which a patentee will obtain the advantage of a [§ 156] extension but not suffer the disadvantage of the [§ 271 (e)(1)] noninfringement provision, and others in which he will suffer the disadvantage without the benefit.”
- *Abtox* stated that in *Eli Lilly* “the Supreme Court command[ed] that statutory symmetry is preferable but not required.”
- Years later, *Proveris* excluded research tools from Safe Harbor because of lack of symmetry.
  - Earlier *Abtox* decision should control until overruled *en banc*.
- Some district court decisions do not require symmetry. See, e.g., *Classen Immunotherapies Inc. v. Shionogi, Inc.* 2014 WL 323941 (D. Md. 2014); *Teva Pharm. USA, Inc. v. Sandoz Inc.*, 2013 WL 3732867, at \*7 (S.D.N.Y. July 16, 2013).
- Other courts require symmetry between the two sections. See, e.g., *Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, 2014 WL 794811, at \*11-\*12 (S.D. Cal. Feb. 27, 2014).

# Research Tools — Legislative History

## Act's History does not Address Commercial Sales

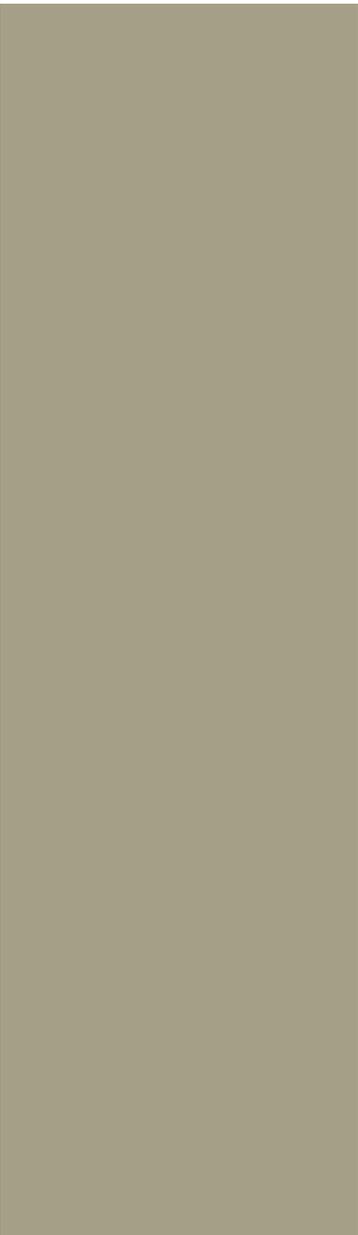
- *Momenta II* could align with legislative history if Court acted to protect Momenta from the impact of lost sales through Amphastar's royalty-free use of research tool.
- CAFC has not yet addressed what would happen if FDA mandated that generic manufacturer use a specific patented method or no alternative, non-patented methods were available.
- In his dissent in *Integra Lifesciences I, Ltd. v. Merck KGaA*, Chief Judge Rader argued that research tools should not be covered under the Safe Harbor.
  - Rader also opined that when deciding whether something is a research tool, the focus should be on how a patented compound or method is being used, not how it is claimed. 496 F.3d 1334, 1351-52 (Fed. Cir. 2007) (Rader, J., dissenting).
  - Significantly, the purpose of § 271(e)(1) was to permit a “**limited** amount of testing” so generic companies could establish bioequivalence. Thus, the nature of the interference with the rights of a patentee was “**not substantial**.” (legislative history).
  - See Coggio, “Research Tools and the Hatch-Waxman Safe Harbor,” 33 *Biotechnology Law Report* 1 (2014).

# Summary

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## Safe Harbor Has Limits

- Safe Harbor is a defense that must be proven by defendant.
- Safe Harbor is very broad. It covers drugs, biologics, medical devices, and possibly research tools. The vast majority of reported decisions have found that the Safe Harbor applies.
- Safe Harbor applies where a drug maker/researcher has “a reasonable basis for believing” that a patented compound “may work.” Certainty is not required.
- Research must be “reasonably related” to “development and submission” of information to the FDA. Information can be used for other purposes without losing protection, e.g., marketing, foreign filings, etc.
- Actual “submission” to the FDA of documents underlying protected research is not required.
- Validation batches are covered — particularly important for biologics.
- Basic research is not protected.
- Stockpiling may be protected.
- Limited post-approval activities can be protected, even if drug is commercialized.



Europe and Canada

**FISH.**

# Bolar Exemption— EU Safe Harbor

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## Bolar Exemption Varies Among Member States

- Article 10(6) of EU Directive on Community Code relating to medicinal products for human use, known as the Bolar Exemption, protects activities carried out to support drug marketing approval:
  - “Conducting the necessary studies and trials . . . and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.”
- Bolar Exemption limited to studies and trials necessary for obtaining generic EU marketing approval in Belgium, Germany, Ireland and the Netherlands.
  - But broader scope of trials — for originator and generic approval — should be exempted in Denmark, France, Italy, the UK, and Spain.
- Trials to obtain marketing authorizations outside the EU do not constitute patent infringement in Denmark, France, Germany, Italy, Spain, Switzerland, or the UK.
  - But exemption is limited to trials for EU-wide approval in Belgium, Ireland, and the Netherlands.

# Bolar Exemption— UPC to Harmonize

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## UPC Targeted for Dec. 2017 Despite Brexit

- Legal uncertainty about the scope and interpretation of Bolar Exemption across the EU given (i) limited national case law and (ii) lack of guidance from the European Court of Justice, which interprets all EU Directives.
- Establishment of the Unified Patent Court (UPC) will help harmonize the Bolar Exemption across the EU.
  - UK government plans to ratify the agreement while the UK is still part of the EU.
  - UPC now targeted to open in December 2017.

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- In Canada, the Bolar Exception shields activities done to generate information reasonably related to the development and submission of information required for regulatory approval.
  - Includes drug approvals in both Canada and other countries.
  - Bolar Exception can protect both pre- and post-approval activities as long as there is no commercial aspect to the work.

# EU Research Exemption

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## Much Broader Protection for Basic Research in EU

- In *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), the Federal Circuit held that research exemption only shelters acts done for “amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”
- Many EU countries have a stand-alone basic research exemption, i.e., research to increase the wealth of scientific knowledge is protected, i.e., “basic research.”
  - In France, Germany, the Netherlands, Spain, and the UK, only research ‘on’ patented subject matter (i.e., to understand or improve the invention) is protected.
    - In UK, Bolar Exemption allows the use of a patented research tool in trials to support regulatory approval.
  - In Italy and Belgium, the research exemption is broader and permits both research ‘on’ patented subject matter as well as research ‘with’ patented subject matter (i.e., using the invention for commercial-type activities).

# Questions?

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For further reading, see <http://www.fr.com/fish-litigation/survey-of-the-safe-harbor-in-the-united-states-and-europe/>.

Coggio and Vogel, “Safe Harbor in the United States and Europe,”  
Pharmaceutical Law & Industry Report, 14 PLIR 47 (Dec. 2, 2016).

# Thank you.

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