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Experimental Use Defense to Patent Infringement: Scope, Limitations, and Implementation by Common Law vs. Statute

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Today's faculty features:

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Experimental Use Defense to Patent Infringement: Scope, Limitations, and Implementation by Common Law vs. Statute

Strafford Webinar

November 24, 2020

mbhb McDonnell Boehnen Hulbert & Berghoff LLP

Outline of the talk

- Three types of experimental use exceptions
  - To avoid the public use bar under 35 U.S.C. § 102(b) and § 102(a)(1)
  - Under the Hatch-Waxman Act 35 U.S.C. § 271(e)(1)
  - Common law research exemption

- Proposals for legislative codification of research exemption

- Effects of COVID pandemic
- Research Exemption outside U.S.

- Future prospects and considerations




Experimental Use Exception to Public Use Bar

35 U.S.C. § 102(b)

A person shall be entitled to a patent *unless*:

. . .

b) the invention was *patented* or *described* in a printed publication in this or a foreign country, or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . .

35 U.S.C. § 102(a)(1)

NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

(1) 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 . . .

Definition of Public Use

- The technology was used in circumstances such that it was accessible to the public
- Public use *vs*. hidden use: not the same (public need not recognize a witnessing)
  - Used in public, but not seen by public
  - Commercial use = public use
- Permission of another to use without restriction is a public use

Definition of Public Use

- A single public use is sufficient
- Use of process by inventor to commercialize product constitutes a public use, even if process secret

- Contrast with secret use of process by third party -- not a public use under § 102(a)

Experimental Use Exception to Public Use

- For the one-year grace period is to permit the inventor to perfect the invention - sometimes testing “on site” is required
- Device must not yet achieve desired goal
- Inventor must retain control and access
  - Control over mattress tests: *Atlanta Attachment v. Leggett*
  - Some CAFC judges admit case law is confused
- Payment by customer may be OK
- Contract for testing under confidentiality may be helpful

Judicial Antecedents

- *City of Elizabeth v. American Nicholson Pavement*, 97 U.S. 126 (1878)

- Wooden pavement on a street in Boston
- Set out for over a year so effects of traffic could be determined and invention perfected

- Inventor inspected almost daily" and "examine[d] the pavement," "walk[ed] over it," "striking it with his cane, and making particular examination of its condition"

- Also evidence of inquiring from passers-by about their opinion

Principles

- Inventor's motive, behavior, and actions important
- Experimental use found generally when a) it tests a feature of the invention and b) the testing is directed to determining whether the invention will work for its intended purpose
- On the other hand, if the use is primarily commercial or directed to commercial questions (such as marketing), the exception does not lie and public use more than one year before filing is a bar to patentability

Legal Questions

- Must be a public use that would raise a patentability bar before experimental use exception question is raised
- Provides a basis for the PTO or a court not to consider the public use to preclude patentability
- Whether the experimental use exception applies is a question of law - *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423 (Fed. Cir. 1996)
- Various expressions of facts used to make legal determination

Factors Indicative of Experimental Purpose

ClockSpring, L.P. v. Wrapmaster, Inc. (Fed. Cir. 2009)

1. the ***necessity*** for public testing
2. the amount of ***control*** over the experiment retained by the inventor
3. the nature of the invention
4. the length of the test period
5. whether ***payment*** was made
6. whether there was a ***secrecy*** obligation
7. whether ***records*** of the experiment were kept

8. who conducted the experiment
9. the degree of ***commercial exploitation*** during testing
10. whether the invention reasonably requires evaluation under actual conditions of use

11. whether testing was systematically performed
12. whether the inventor continually monitored the invention during testing
13. the nature of contacts made with potential customers

Continued Viability Recent example

- *Polara Engineering Inc. v Campbell Co*. (Fed. Cir. 2018)
- Invention: an accessible pedestrian signal system ("APS") tested in public
- Evidence Polara monitored the operation of the system and modified the system when necessary.
- No charge to municipalities where tested, confidentiality requirements varied, system could not be understood by observation
- Under these circumstances, lacking contemporaneous record keeping of the experiments did not doom the defense.

Post-AIA Considerations

- Congress showed no intention of changing the standards of acts barring patenting or exceptions thereto *The Medicines Co. v. Hospira*
- Inclusion of “or otherwise available to the public” not intended to change meaning of the statutory bars (public use, on-sale)

- First inventor to file changes consequences of public use protected by experimental use, because a competitor could observe and modify enough to avoid derivation determination

- Less incentive under modern practice (provisional applications, 20-year patent term)




Experimental use under the Hatch-Waxman Act “Safe Harbor”

mbhb McDonnell Boehnen Hulbert & Berghoff LLP

Hatch-Waxman Act

- Drug Price Competition and Patent Term Restoration Act of 1984
  - Responsive to two patent term distortions:
    - Regulatory approval of patented drug (patentee can't use drug during patent term until approved)
    - Regulatory approval of generic (competitor couldn't test drug until expiration of patent)
- Remedy:
  - Patent term extension ≤ 5 years to patentee (35 U.S.C. § 156)
  - § 271(e)(1) exemption

35 U.S.C. § 271(e)(1)

- Important but limited applicability
- 35 U.S.C. § 271(e)(1)
  - It shall not be an act of infringement to make, use, offer to sell or sell within 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….

35 U.S.C. § 271(e)(1)

- Statutory Interpretation
  - "Patented Invention"
    - All inventions, not limited to drugs
    - *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990)(Class I and/or Class II medical devices)

- "Federal law which regulates … drugs"
  - *Any* federal law containing provisions that apply to drugs

Merck v Integra (2005)

- Supreme Court reversed Federal Circuit restriction that precluded sage harbor for activities related to identifying drug candidates
- Safe harbor not limited to activities directed to traditional FDA approval process
- Requires "reasonable basis for believing that the activities will produce the type of information that is relevant to FDA approval"

35 U.S.C. § 271(e)(1)

- "Reasonably Related"
  - An activity is *reasonably related* to seeking FDA activity if "it would have been reasonable, objectively, for a party in defendant's situation to believe that there was a *decent prospect* that the use in question would contribute (*relatively directly*) to the generation of the kinds of information *likely to be relevant* in the process by which the FDA would decide to approve the product."
    - *Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269, 1280 (N.D. Col. 1991), *aff'd*.,_991 F.2d 808 (Fed Cir. 1993)

35 U.S.C. § 271(e)(1)

- Exemption not lost if …
  - Results obtained from exempt use not ultimately used
    - Often not sure whether amount and extent of data that will be necessary for regulatory submission
  - Engage in non-infringing activities
    - Can use results from an exempt activity for purposes other than obtaining regulatory approval, even commercial purposes
    - Congress well aware of commercial underpinnings; could have prevented such use but did not.
    - Congress's main intent was to bring drugs to market faster

35 U.S.C. § 271(e)(1)

- Two step analysis:
  - Is activity otherwise infringing?
    - If no, irrelevant to applicability of exemption
  - Is activity a use reasonably related to obtaining regulatory approval?

35 U.S.C. § 271(e)(1)

- Examples
  - Drug "stockpiling" permitted - required to demonstrate ability to produce commercial quantities - *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202 (D. N.J. 1994)
  - Stockpiling for purposes of entering the market not exempt - *Biogen, Inc. v. Schering AG*, 954 F. Supp. 391 (D. Mass. 1996)

35 U.S.C. § 271(e)(1)

- Exports of a patented compound (to Japan) to test alternative manufacturing method held exempt, *Amgen, Inc., v. Hoechst Marion Roussel, Inc*., 46 U.S.P.Q.2d 1906 (D. Mass 1996)
  - Because FDA approval was required for the alternative method and FDA guidelines contemplated use of a reference standard sample from one manufacturing process to evaluate the effects of alterations in the manufacturing process
  - But, making and exporting for foreign regulatory approval not exempt

35 U.S.C. § 271(e)(1)

- Product safety testing held exempt even though data not submitted to FDA, performed at concentrations unacceptable to FDA, and conducted for European regulatory purpose, *Amgen, Inc., v. Hoechst Marion Roussel, Inc.*
  - tests relevant to confirm purity and safety for use in clinical trials, which trials would produce data for submission to the FDA sufficient for exemption

35 U.S.C. § 271(e)(1)

- Generation of three commercial-scale production batches held exempt, *Amgen, Inc., v. Hoechst Marion Roussel, Inc.*
  - objectively likely to generate useful information, even though the results were later discarded or abandoned for reasons unrelated to FDA approval

35 U.S.C. § 271(e)(1)

- Limited testing of plasma sterilizer (medical device) to collect data for FDA approval exempt, *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019 (Fed. Cir. 1997)
  - Ct. rejected Plaintiff's argument that actual purpose of tests was for commercial promotion.
  - Statute does not look to *underlying purposes* or *attendant consequences* of activity as long as use is reasonably related to FDA approval. Statutory language allows use of data for more than FDA approval.

35 U.S.C. § 271(e)(1)

- The extreme: *Bristol-Myers Squibb Company, v. Rhone-Poulenc Rorer, Inc*, 2001 U.S. Dist. Lexis 19361 (S.D.N.Y. 2001)
  - Infringement claim based on use of three patented intermediates in production of thousands of taxol analogs to screen for anti-cancer activity, a use far "upstream" of obtaining regulatory approval
  - Held: objectively reasonable to believe a "decent prospect" that use of intermediates would contribute to generation of information likely relevant to FDA

Post-approval activities

- Unsettled area of the law
- Two divergent cases (and Supreme Court so far refused to grant cert to resolve):
- *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011)
- *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc*. (686 F.3d 1348) (Fed. Cir. 2012).

Classen Immunotherapies, Inc. v. Biogen IDEC

- Claims of dubious patent eligibility directed to post-immunization testing for chronic immune-related disorders (adverse event monitoring)
- Majority held that such activities, which were not submitted to FDA nor required to be for approval were outside the scope of the safe harbor

- Plain meaning statutory interpretation as the basis

- Judge Moore dissents on restricting scope to pre-approval activities submitted to FDA

Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.

- Post-approval activities directed to determining drug purity standards with regard to fragmented heparin preparations
- Majority did not interpret statute to be limited to pre-approval activity

- Nor to activities required by FDA for approval
- Use of "any activity" in the statute included acts performed after approval

- fact that information not submitted remedied by FDA requirement for record keeping




Common law research exemption

Common law research exemption

- Origins*: Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813)
- Infringement should not lie for someone "who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."

- *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813)
- Distinguished between uses "with an intent to . . . profit" and those for the mere purpose of philosophical experiment or to ascertain the verity and exactness of the specification."

Common law research exemption

- Pre-Federal Circuit case law consistent with these principles
  - *Standard Measuring Mach. Co. v. Teague*, 15 F. 390 (C.C.D. Mass. 1883) (making a machine to illustrate an improvement did not infringe the pioneering patent)
  - *Akro Agate Co. v. Master Marble Co*., 18 F. Supp. 305 (N.D. W. Va. 1937) (experimental use of a patented marble-making machine is not infringement because "marbles were not commercially sold")
  - *Dugan v. Lear Avia, Inc*., 55 F. Supp. 223, 229 (S.D.N.Y. 1944), aff'd, 156 F.2d 29 (2d Cir. 1946) (experimental use is not infringement because the defendant had not "sold any" of the experimental product)
  - *Chesterfield v. United States*, 159 F. Supp. 371 (Ct. Cl. 1958) (uses "for testing and for experimental purposes" are not infringement)

Federal Circuit takes a different approach

- Federal Circuit restricts scope of common law research exception
- *Roche v. Bolar* (Fed. Cir. 1983): pre-Hatch-Waxman (believed to be impetus for enactment), held it was infringement for a generic drug company to perform drug development that infringed innovator's patents; commercial activity prohibited
- *Embrex, Inc. v. Serv. Eng'g Corp*. (Fed. Cir. 2000): academic research involving methods for inoculating chickens *in ovo*; and testing devices for that purpose
- Federal Circuit found no research exemption applied because although performed by academicians a clear commercial purpose

Federal Circuit effectively abolishes common law research exemption

- *Madey v. Duke Univ*. (Fed. Cir. 2002)
- Academic use of prior professor's invention
- Court acknowledged the existence of a common law research exemption but construed narrowly
- Limited to "for amusement, to satisfy idle curiosity or for strict philosophical inquiry"
- Status as a university insufficient to satisfy these requirements
- Court finds that the "business" of the university is to teach and train students, to obtain funding from granting agencies, and the perform research some of which can have commercial applications
- These aspects are more than amusement, idle curiosity, or philosophical inquiry

THE PATENT EXPERIMENTAL USE EXCEPTION AROUND THE WORLD

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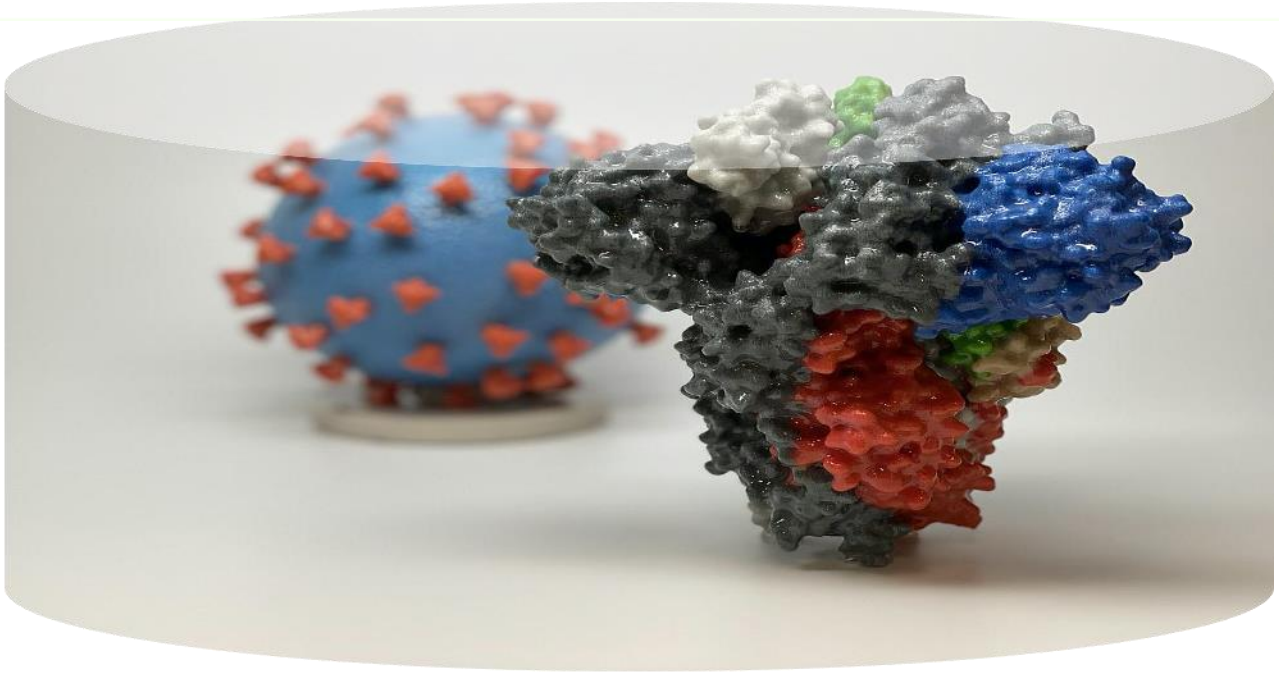

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OVERVIEW

- Worldwide, the experimental use exception is one of the most common exceptions to patent infringement
- The law of patent experimental use in other countries is often distinctly different from that of the United States
- Statutory approaches to experimental use exceptions are common
- Canada, United Kingdom, France, Germany, Japan, China, India, and the Gulf Cooperation Council ("GCC") are explored

IMPORTANT FACTORS

- In general, salient factors may include:
  - Privacy
  - Commerciality
  - Nature of experimentation
    - Experimentation *on* or *with* patented invention?
  - Scope of experimentation
    - Exclusively for experimentation?
  - Purpose of experimentation
    - Elucidating properties of the invention?
    - Verifying sufficiency of patent disclosure?
    - Verifying claimed invention actually works?
    - Determining validity of patent claims?
    - Determining what behaviors would infringe?
    - Improvement of invention?

LEGAL BASIS

- *Canada - Patent Protection of Pharmaceutical Product* case (WTO Dispute Settlement Panel, WT/DS114/13 | 18 August 2000) appears to have endorsed experimental use exception
  - We may take as an illustration one of the most widely adopted Article 30-type exceptions in national patent laws - the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement.

LEGAL RECOGNITION

- Text of WTO-TRIPS appears to authorize experimental use exceptions in national patent laws
  - Article 30. Exceptions to Rights Conferred
    - Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

COUNTRIES WITH EXCEPTION

- WIPO has identified 113 countries with an experimental use exception in their “legal framework”
  - The most prominent of these include:
    - Argentina, Australia, Brazil, Canada, China, European Union members (including France, Germany, Italy, and Spain), Israel, Mexico, New Zealand, Norway, South Korea, Russia, Saudi Arabia, Switzerland, Thailand, Turkey, and the United States
  - In addition to common law, Australia, Canada, and New Zealand have codified the exception in statute

CANADA

- Under the *Budget Implementation Act, 2018, No. 2*, the Parliament of Canada enshrined in statute a broad experimental use exception to patent infringement
- This amended the *Patent Act*, adding new §55.3
- Section 55.3 became effective on December 13, 2018
- Previously, experimental use had largely been a creature of common law

CANADA (I)

- Section 55.3
  - (1) An act committed for the purpose of experimentation relating to the subject-matter of a patent is not an infringement of the patent.
  - (2) The Governor in Council may make regulations respecting
    - (a) factors that the court may consider, must consider or is not permitted to consider in determining whether an act is, or is not, committed for the purpose set out in subsection (1); and
    - (b) circumstances in which an act is, or is not, committed for the purpose set out in subsection (1).
- Also applies to Certificate of Supplementary Protection (CSP)
- Applies prospectively to any action or proceeding that not finally decided by December 13, 2018

CANADA (II)

- A *Bolar*-esque provision already existed in the *Patent Act*
  - Section 55.2(1)
    - It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

CANADA (III)

- Previously, §55.2(6) of the *Patent Act* provided:
  - It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.
- In light of §55.3, §55.2(6) now provides:
  - For greater certainty, subsection [55.2](1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose.

CANADA (IV)

- New section 55.3 may distinguish between
  - Private or noncommercial activities; and
  - Activities carried out exclusively to conduct experiments related to particular patent claims
    - It may be that the experimental use exception applies in both noncommercial and commercial settings
- We await judicial decisions interpreting new §55.3, amended §55.2(6), and §55.2(1)

CANADA (V)

- Previously, experimental use exception largely defined by *Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp.* (1971), 1971 CarswellNat 388, 2 C.P.R. (2d) 193 (S.C.C.). [Micro Chemicals]
  - Case dealt with experimentation carried out in preparation of obtaining a compulsory license
  - Court found the following to be important factors to consider:
    - Amount produced, entrance into commerce, profits, damage to patent owner, bona fide nature of the activities

CANADA (VI)

- *Merck & Co., Inc. et al v. Apotex Inc.*, 2006 CarswellNat 1119, 2006 FC 524, 53 C.P.R. (4th) 1(F.C.), affirmed on this issue 2006 CarswellNat 3206, 2006 FCA 323, 55 C.P.R. (4th) 1(F.C.A.) and *Teva Canada Limited v. Novartis AG*, 2013 FC, reinforced that it is not infringement to
  - Make or use for experimentation or testing without intent to commercialize; or
  - Improving a claimed invention

UNITED KINGDOM

- Section 60(5)(b) of the *Patents Act of 2004*
  - An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -
  - [...]
  - (b) it is done for experimental purposes relating to the subject matter of the invention;
  - [...]

FRANCE

- Article L613-5(b) of the *Intellectual Property Code* (version of September 7, 2018)
  - Article L613-5
  - Les droits conférés par le brevet ne s'étendent pas:
  - [...]
  - b) Aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;
  - [...]
  - Article L613-5
  - The rights conferred by the patent do not extend:
  - [...]
  - b) To acts performed carried for experimental purposes that are related to the subject-matter of the patented invention;
  - [...]

GERMANY

- Section 11(2) of the Patent Act (amended October 8, 2017)
  - Sektion 11
  - Die Wirkung des Patents erstreckt sich nicht auf
  - [...]
  - 2. Handlungen zu Versuchszwecken, die sich auf den Gegenstand der patentierten Erfindung beziehen;
  - [...]
  - Section 11. The effect of a patent shall not extend to:
  - [...]
  - 2. acts done for experimental purposes relating to the subject-matter of the patented invention;
  - [...]

JAPAN

- Article 69(1) of the *Patents Act No. 121 of 13 April 1959* (amended July 10, 2015)
  - Article 69. Limitations of patent right
  - (1) A patent right shall not be effective against the working of the patented invention for experimental or research purposes.
  - [...]

CHINA

- Article 69(4) of the *Patent Law of the People's Republic of China* (amended on December 27, 2008)
  - Article 69. The following shall not be deemed to be patent right infringement:
  - [...]
  - (4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation.
  - [...]

INDIA

- Section 47 of the *Patent Act No. 39 of 20 April 1970* (last amended in 2005)
  - Section 47. Grant of patents to be subject to certain conditions.
  - The grant of a patent under this Act shall be subject to the condition that -
  - [...]
  - (3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupil;
  - [...]

GCC

- Section 14(1) of the *Patent Regulation for the Gulf Cooperation Council States* (approved by the GCC Supreme Council, 21-22 September 1992)
  - Section 14: The rights under the patent shall not extend to:
  - 1) Acts done particularly for scientific research purposes.
  - [...]

LESSONS

- Most countries have an experimental use exception
- These exceptions *do* differ by country or region
- Following factors tend to be salient:
  - Privacy
  - Commerciality
  - Nature, scope, and purpose of experimentation
- Important to know local patent law
- Excellent source
  - *WIPO Standing Committee on the Law of Patents, REFERENCE DOCUMENT ON RESEARCH EXCEPTION (November 26, 2018)*




Proposals to Resurrect Research Use in U.S.

mbhb

McDonnell Boehnen Hulbert & Berghoff LLP

Proposals to codify research exemption by statute

- Philosophy: necessity and consequences of a research exception
  - An experimental use exception "is not warranted as a matter of law or legal theory, is not consistent with the protection otherwise given the patentee's rights by the courts and may serve as a source of judicial confusion and mischief."

Richard E. Bee, *Experimental Use as an Act of Patent Infringement,* 34 J. PAT OFF. SOC'Y 357 (1957)

- Negative consequences to exception:
  - Devalues the contribution of the patentee to developing innovation
  - Benefit to competitors even if done by noncompetitors like academia
  - Weakens patent enforceability
  - Acceptable if exception beneficiary receive no financial benefit or if commercial entities must pay royalties

Jordan Karp, Note, Experimental Use as Patent Infringement: The Impropriety of a Broad Exemption, 100 YALE L.J. 2169 (1991)

Proposals to codify research exemption by statute

- Acceptable uses:
  - to verify patent claims
  - for comparison to a new technology
  - to gain scientific knowledge
  - for classroom teaching
  - to develop new research tools donated to the public

Michelle Walters, *De Minimus* Use and Experimental Use Exemptions to Patent Infringement: A Comment on the *Embrex* Concurrence, 29 AIPLA Q.J. 509 (2001)

Proposals to codify research exemption by statute

- Research tools:
  - using a patented research tool for its intended purpose; no exception needed
  - using patented subject matter to test the validity of the patent claims; best case for exception
  - is using the patented subject matter to make further advances in the technology in competition with the patent owner; no exception but no injunction, reasonable royalty/compulsory license

Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use,* 56 U. CHI. L. REV. 1017 (1989)

Proposals to codify research exemption by statute

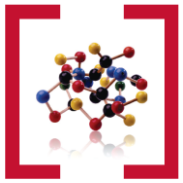
- Research tools:
  - allow universities to use patented research tools for their intended purpose
  - place conditions on how universities can use the results of such research
  - permit unlicensed use of research tools if the research tools were not available on reasonable terms
  - But the researcher must agree to publish the results of the research and to refrain from patenting the results of the research

Rochelle Dreyfuss, Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?, 46 ARIZ. L. REV. 457 (2004);

Proposals to codify research exemption by statute

- Research tools:
  - patented research tools could be used by third parties for their intended research purpose without a license to develop commercial products
  - patentees entitled to reach-through royalties on the products developed with the use of their research tools
  - compulsory licensing for research tool patents, wherein for three to five years, the research tool under exclusive control of the patentee, thereafter the research tool would be subject to compulsory licensing by third parties upon payment of a reasonable royalty to the research tool patentee

Janice M. Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exemption to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1 (2001).



Proposals to codify research exemption by statute

- Avoiding harm to university research:
  - universities and other non-profit research centers have a broad experimental use exemption
  - if a for-profit firm commercializes research undertaken by a non-profit organizations under the exemption, would have to license from the patentee as if the firm had performed the research initially; *or*
  - both non-profit and for-profit organizations can use patented technology for research purposes if the technology has been developed with federally funded research
  - commercialization of federally funded research by firms would require a license if the resulting commercial product or process was covered by the patentee's patent claims

Suzanne T. Michel, Comment, The Experimental Use Exception to Infringement Applied to Federally Funded Inventions, 7 HIGH TECH. L.J. 369 (1992).

Proposals to codify research exemption by statute

The House proposal (1990) would have added 35 U.S.C. § 271(j):

(j) It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention. This subsection does not apply to a patented invention to which subsection (e)(1) applies. H.R. 5598, 101st Cong. § 402 (1990)

Proposals to codify research exemption by statute

Analogous to infringement liability exemption for medical practitioners under 35 U.S.C. § 287(c):

(d)(1) With respect to a scientific researcher performing research in a university of other not-for-profit institution, that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the scientific researcher or against the university of other not-for-profit institution with respect to such research.

Proposals to codify research exemption by statute

As part of the Bayh-Dole Act:

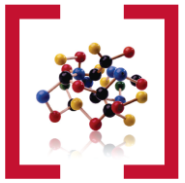
Any patent subject to the provisions of this title, and any license to any such patent granted to any commercial entity, shall be subject to a non-exclusive license to practice the patented invention for non-commercial research purposes by researchers of a U.S. university, non-profit organization, or other scientific research institute.

Kevin Noonan, *A Glimmer of an Idea on an Experimental Use Exemption*, Patent Docs blog, Nov. 7, 2018,https://www.patentdocs.org/2018/11/a-glimmer-of-an-idea-on-an-experimental-use-exemption.html

COVID

- Pandemic has intensified tensions between patent holders, governments, and international organizations
- Doha Declaration provides ability for governments to impose compulsory licenses within the GATT/TRIPS and WTO frameworks for diseases like COVID 19
- Some countries, including Canada, Germany, Israel, Chile, and Ecuador have already passed compulsory licensing legislation or resolutions backing compulsory licensing with respect to any COVID-19 vaccines and therapeutics.
- Alternative: voluntary patent pooling, e.g., under UN-backed Medicines Patent Pool (MPP), which was established in 2010 to expand access to tuberculosis, HIV, and hepatitis therapeutics

Licensing



- "March in" rights under Bayh-Dole Act enable U.S. government to grant licenses based on Federally funded research
- 35 U.S. Code § 203: can require the grantee "to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances" or grant such a license itself
- Never been done and not available for products of privately funded research
- But recent history of industry out-sourcing to universities increases prospects

Licensing

- Also reporting requirements can put patent rights at risk, requires notice of Federal funding on all patents

- Moderna challenged with non-compliance with Bayh-Dole reporting requirements
- 28 U.S. Code § 1498: statute developed for Second World War permits the government to grant non-exclusive licenses to industry for any patent

- Compensation to patentee limited to filing in the Federal Court of Claims
- Limited to “reasonable and entire compensation for such use and manufacture”

- May be applicable to experimental use situations

Questions?

Thank you!

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Experimental use exemption outside U.S.

Generally

- Most countries around the world have an experimental use exception for patent infringement
- No counterpart to exemption for public use because most countries have absolute novelty provisions
- Extent of exemption varies country-to-country but generally more extensive than U.S. exemption
- Exemptions analogous to § 271(e)(1) (termed "Bolar" provisions generally) also recognized in most countries
- Differences involve whether inventions other than drug compounds are included

International Agreements

- TRIPS Article 30: Members *may* provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Europe: Research Use

- Provisions of national law
- Germany: § 11 No.2 of the German Patent Act, wherein "acts done for experimental purposes relating to the subject matter of the patented invention" is exempt from infringement; does not apply to use of patented invention as a research tool
- UK: § 60(5)(b) of the United Kingdom Patent Act, wherein "an act that would constitute an infringement of a patent for an invention shall not do so if it is done for experimental purposes relating to the subject matter of the invention"

Europe: Research Use

- UK: *Monsanto Co. v. Stauffer Chemical Co.* (1985) (RPC 515), U.K. "experimental use" exemption covers activities that seek to generate genuinely new information but not those that seek to verify existing knowledge
- France: Article L. 613-5 of the French Code of Intellectual Property, for "acts done for experimental purposes relating to the subject matter of the patented invention"
- Italy: Article 68 of the Italian Code of Industrial Property, wherein "acts carried out in an experimental manner" are not infringing

Europe: Bolar exemption

- Encompassed by European Union Directives EU Directives 2001/82/EC and 2001/83/EC
- Also contained in national law
- Spain: Article 52, paragraph (b) of the 11/1986 Spanish Patent Act
- Netherlands: Article 53(4) of the Dutch Patent Act

- Generally for obtaining marketing approval for generic medicines, and bioequivalent or biosimilar drugs, in UK, BE, IE, NL, SE, and more broadly in AT, BE CZ, DK, ES, FI, FR, DE, IT, PL, PT, NO, AND CH

- Some countries permit acts directed at market authorization in countries outside the EU

Europe: Bolar exemption

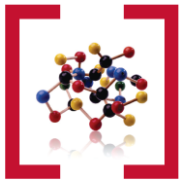
Country	Generic trials	Innovator trials	Phase 4	Non-EU
BE	Yes	No	Yes	No
FR	Yes	Yes	Yes	Yes
DE	Yes	No	Yes	Yes
IT	Yes	Yes	Yes	Yes
ES	Yes	Yes	Yes	Yes
NL	Yes	No	Yes	No
UK	Yes	Yes	Yes	Yes

From Kupecz et al., 2015, Safe Harbors in Europe: an update on the research and Bolar exemptions to patent infringement, *Nature Biotechnology* 33: 710-715

China: Research Use

- Broad research use exception
- Article 69 of the Chinese Patent Law recites "[t]he following shall not be deemed to be patent right infringement: . . . (4) [a]ny person uses the relevant patent specially for the purpose of scientific research and experimentation”
- Has been interpreted to be limited to scientific research and experimentations carried out specifically on the patented technology *per se*. Directed to characterization, improvements, and the effect achieved by patented technology

China: Bolar exemption



- Bolar initially recognized by judicial decisions
- Part of article 69: "[t]he following shall not be deemed to be patent right infringement: . . .(5) [a]ny person produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any other person produces or imports patented drugs or patented medical apparatus and instruments especially for that person

Japan: Research Use

- Also contains broad research use exemption

- Japanese Patent Law § 69(1) provides a general statutory experimental use exception that allows use of any patented invention for experiment or research.

- Japan's general experimental use exception is much broader than the experimental use provisions in the United States and permits more beneficial uses

Japan: Bolar exemption

- Japanese Patent Law § 69(1) also provides the Bolar exemption, albeit not limited to generic drug testing for regulatory approval
- Case law: *Ono Pharmaceuticals* case interpreted § 69(1) encompasses both advancements in technology that "advances" technology and those that do not

Australia: Research Use

- The Intellectual Property Laws Amendment (Raising the Bar) Act 2012. exempts use of a patented invention "for purposes relating to the subject matter of the invention"
- When the predominant purpose is to "gain new knowledge, or test a principle or supposition about the invention"
- Includes:
  - determining the properties of the invention
  - determining the scope of a patent claim relating to the invention
  - improving or modifying the invention
  - determining the validity of the patent or of a patent claim relating to the invention
  - determining whether the patent for the invention would be, or has been, infringed by the doing of an act.

Australia/New Zealand: Bolar exemption

- A somewhat more restrictive exemption
- Australian Patents Act 1990, Section 119A provide exemption for generic drugs
- The Act expressly states that medical or therapeutic devices are not included under the exemption
- New Zealand Patents Act 1953, Section 119A) recites a broader exemption not limited to generic drugs

New Zealand: Research Use

- *Patents Act 2013* provided a research use exemption for the first time as of September 13, 2014
- "[i]t is not an infringement to do an act for experimental purposes relating to the subject matter of an invention (which includes determining how the invention works, its scope, or the validity of the claims, or seeking an improvement of the invention) if that act does not unreasonably conflict with normal exploitation of the invention" – applies to all patents

Canada: Research Use

- Section 55.3 of the Budget Implementation Act of 2018, No. 2, effective Dec. 13, 2018
- "An act committed for the purpose of experimentation relating to the subject-matter of a patent is not an infringement of the patent."
- Additional provisions: 55.2(6) "For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose or in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent."

Canada: Bolar exemption

- Both statutory and common law provisions
- Section 55.2(1) of the Canadian Patent Act:

"It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product."

India: Research Use

- Section 47(3) of the Indian Patent law i.e. Patents Act, 1970 (as amended) ("Act") provides for experimentation / research exemption to patent infringement.
- "Notwithstanding anything in this Act, the making or using of a patented machine or apparatus or other article, or the use of a patented process or the use of an article made by the use of the patented process, machine or apparatus for the purpose merely of experiment or research including the imparting of instruction to pupils and not by way of commercial use, shall not be deemed to constitute an infringement of the rights conferred on a patentee by this Act."

India: Bolar exemption

- Section 107A of the Patent Act of 1970: Certain acts not to be considered as infringement.
- For the purposes of this Act:

(a) any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, [use, sale or import] of any product;

(b)… shall not be considered as an infringement of patent rights

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