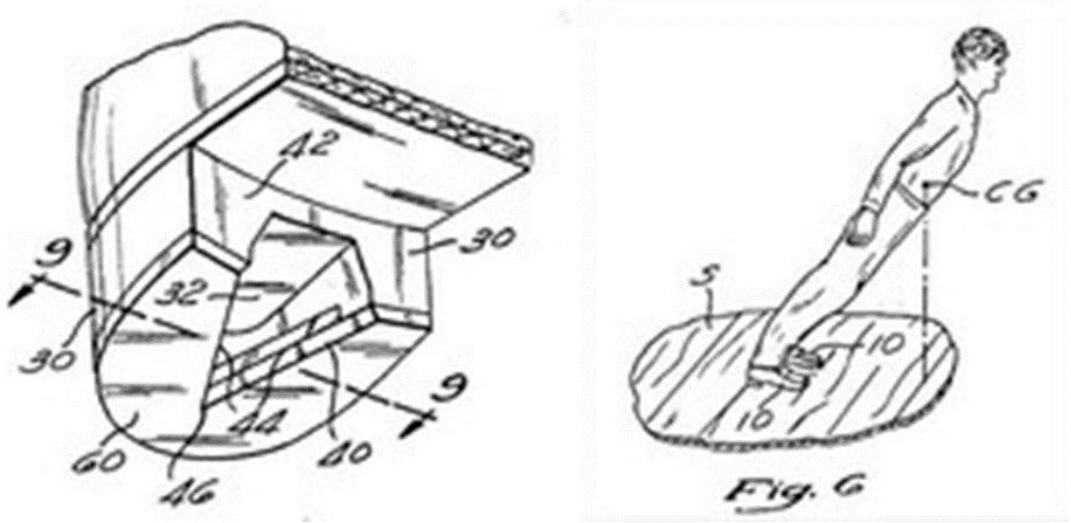
Important Concepts and Caselaw

Swapna Sundar

What can be patented

LANDMARK CASES



US Patent 5,255,452, Jackson, et al
Method and means for creating anti-gravity ***illusion***

3. THE INVISIBLE BIKE HELMET

Designed by two Swedish students, Hövding is a stylish neck collar that contains an airbag helmet that inflates in the case of an accident. The new invention is available in select stores in Europe - and no doubt we'll be "seeing" more of Hövding in the near future.

Hövding: Before and after (Niklas Carlsson)

Nicholson paving case

Invention not placed in public use by public experimentation

- Nicholson sought to patent a process for a system of pavement using wooden blocks and sued the City of Elizabeth, NJ for infringement. City claimed that he had publicly used the system for 6 years. Court found that he had been testing it in private conditions.

- Nicholson put down a section of his new pavement on a turnpike operated by a private corporation in which Nicholson was a shareholder and officer in 1848 in order to test its durability and the public's response to it.

Anticipation

- "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Anticipation

Verdegaal Bros. v. Union Oil Co. of California, "When a claim covers several compositions, generically or as alternatives, the claim is deemed anticipated if any of the structures /compositions within the scope of the claim is known in the prior art. (Urea-sulphuric acid liquid fertilisers) – use of earlier batch as ‘heel’.

Brown v. 3M (claim to a system for setting a computer clock to an offset time to address the Year 2000 (Y2K) problem; a system that offsets year dates in only 2-digit formats anticipates the claim “at least one of 2-digit, 3-digit, or 4-digit" representations

Richardson v. Suzuki Motor Co., The elements must be arranged as required by the claim, but identity of terminology is not required. – alternate shock mount/criss-cross full floater

Anticipation – multiple reference

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35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

- Prove the primary reference contains an "enabled disclosure;" *In re Donohue*, claims were rejected over a publication in view of two patents.

- The publication disclosed the claimed compound structure
- the patents taught methods of making compounds of that general class.

The court held that the publication taught all the elements of the claim and thus motivation to combine was not required.

Anticipation extrinsic

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- Extrinsic evidence may be used to explain but not expand the meaning of terms used in the anticipating reference.

In re Baxter Travenol Labs. Baxter invented a blood bag system incorporating a bag containing DEHP (Di-2-ethylhexyl phthalate). The examiner rejected the claims over

a technical progress report by Becker which taught the same blood bag system without expressly disclosing DEHP but disclosing the commercial blood bag system as "very similar to Travenol's.

"Extrinsic evidence (depositions, declarations and patentees admissions) showed that commercial blood bags contained DEHP. PHOSITA would have known that "commercial blood bags" meant bags containing DEHP.

Anticipation

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- Show that a characteristic not disclosed in the reference is inherent.

Continental Can Co. USA v. Monsanto Co., accommodates situations in which the common knowledge of technologists is not recorded in the reference.

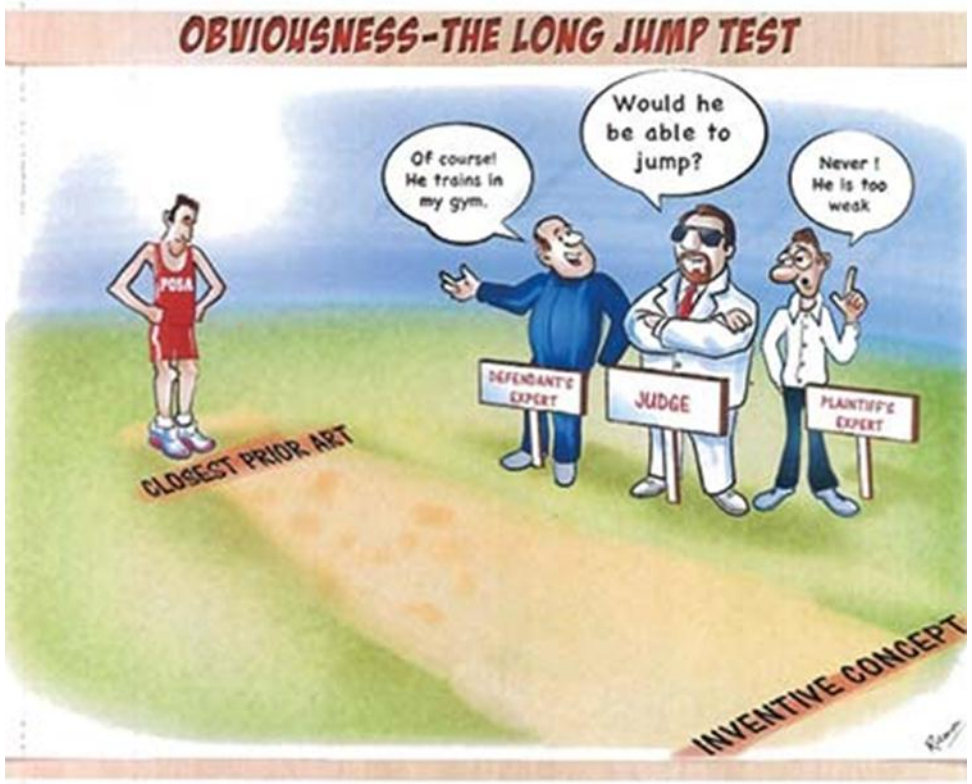
Atlas Powder Co. v. IRECO, Inc., Two prior art references disclosed blasting compositions containing water-in-oil emulsions + identical ingredients in overlapping ranges. The only element of the claims not present in the prior art was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that emulsions would inevitably and inherently have "sufficient aeration“.

Obviousness §103

PHOSITA is a legal fiction defined in the Patent Act of the United States, based on

- educational level of the inventor;
- type of problems encountered in the art;
- prior art solutions to those problems;
- rapidity with which innovations are made;
- sophistication of the technology; and

educational level of active workers in the field



Obviousness

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution to obtain predictable results;

(C) Use of known technique to improve similar devices

(D) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(E) Known work in one field of endeavour may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(F) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Structural obviousness

the motivation of PHOSITA to make a claimed compound, expecting compounds similar in structure will have similar properties

In re Merck & Co., Inc., 1986, claimed and prior art compounds used in a method of treating depression expected to have similar activity because the structural difference between the compounds involved a known bioisosteric replacement. A skilled artisan would have expected the known tricyclic compound, amitriptyline.

In re Dillon, 1991, The tri-orthoester fuel compositions of the prior art and the claimed tetra-orthoester fuel compositions would have been expected to have similar properties based on structural and chemical similarity between them and as both the prior art and applicant used the orthoesters as fuel additives.

Formulation

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Unigene Labs. and Upsher-Smith Labs v. Apotex, 2011: Unigene's reissued patent covers its Fortical calcitonin nasal spray developed in response to Novartis's Miacalcin calcitonin nasal spray. Novartis product used BZK to enhance absorption along with, polysorbate 80, phenylethyl alcohol and benzyl alcohol. Unigene's patent contained citric acid to enhance absorption.

In 2006, Apotex filed an ANDA to import a generic version of Unigene's spray. Unigene sued for infringement. Apotex’s obviousness defense was struck down by Fed.Cir.

The court determined that the citric acid in Unigene serves as a substitute for BZK and that at the time of invention, it was not an obvious substitute for BZK.

Process

"A process yielding a novel and nonobvious product may nonetheless be obvious; conversely, a process yielding a well-known product may yet be nonobvious." TorPharm, Inc. v. Ranbaxy Pharmaceuticals, Inc., (Fed. Cir. 2003)

Brouwer, "highly fact-specific by design“ to be assessed on a case-by-case basis. Ochai: flexibility

Process of chemically reducing one novel, nonobvious material to obtain another novel, nonobvious material was held obvious because the reduction reaction was old. In re Albertson (CCPA 1964)

In re Kuehl

In re Kuehl, (CCPA 1973) Process of cracking hydrocarbons using novel zeolite catalyst found to be patentable even though catalytic cracking process was old. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties." PHOSITA would not only have to able to predict the outcome of using ZK-22, but also find it obvious to use ZK-22 which was not predictable until the invention.

Obviousness-type double patenting

Applicants are barred from obtaining multiple patents covering the same invention. There are two types of double patenting:

- statutory double patenting, which prohibits a later patent from covering the identical invention,

- and obviousness-type double patenting, which prevents a later patent from covering a slight variation of an earlier patented invention.

Sun Pharma v Eli Lilly

Eli Lilly's Patent No. 4,808,614 related to Gemzar – which claims both gemcitabine itself, a method of using it to treat viral infections, as well as discloses using gemcitabine to treat cancer. Patent No. 5,464,826 claims a method of treating cancer comprising administering a therapeutically effective amount of gemcitabine.

The applications leading to both the '614 (exp. 2010) and '826 (exp. 2012) patents were filed on the same day, December 4, 1984. The '614 was a continuation-in-part of application No. 473,883 which did not disclose using gemcitabine to treat cancer.

TSM test

Winner Int'l Royalty Corp. v. Wang, (2000), there must be a suggestion or teaching in the prior art to combine elements shown in the prior art in order to find a patent obvious.

Non-obviousness grant of patent requires more than simple novelty. Thomas Jefferson's 1813 letter: changing material to "chain, rope, or leather" was insufficient for patentability. Patent Act of 1952, in part, to reduce the impact of non-obviousness on patentability and to eliminate the flash of genius test.

KSR v Teleflex

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Teleflex, Inc. sued KSR International, claiming that KSR products infringed Teleflex's patent on connecting an adjustable vehicle control pedal to an electronic throttle control. KSR argued that the combination of the two elements was obvious, and the claim was therefore not patentable.

The district court ruled in favour of KSR. Federal Circuit reversed in January 2005.

On April 30, 2007, the Supreme Court reversed the judgment of the Federal Circuit, holding that the disputed claim 4 of the patent was obvious.

Federal Circuit had rigidly applied the "teaching-suggestion-motivation" (TSM) test.

Graham Factors

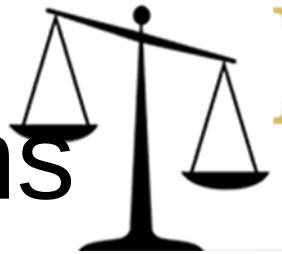
Obviousness depends on the following factual determinations

(Graham V. John Deere, Supreme Court 1966):

1. the scope and content of the prior art;
2. the differences between the prior art and the claims at issue;
3. the level of ordinary skill in the art at the time the invention was made; and
4. objective evidence of non-obviousness, if any.”

Bayer V. Watson, Fed. Cir., 2018 – when Bayer’s Vardenafil (Levitra) was approved, Pfizer’s Viagra, Eli Lilly’s Tadalafil (Cialis) were in the market. Levitra was uncoated ODT with use of sorbitol and mannitol. The district court held that the PHOSITA would not be motivated to form ODT. Fed. Cir. Held that rarity of ODT formulations in the field are not relevant.

Non-obviousness indications



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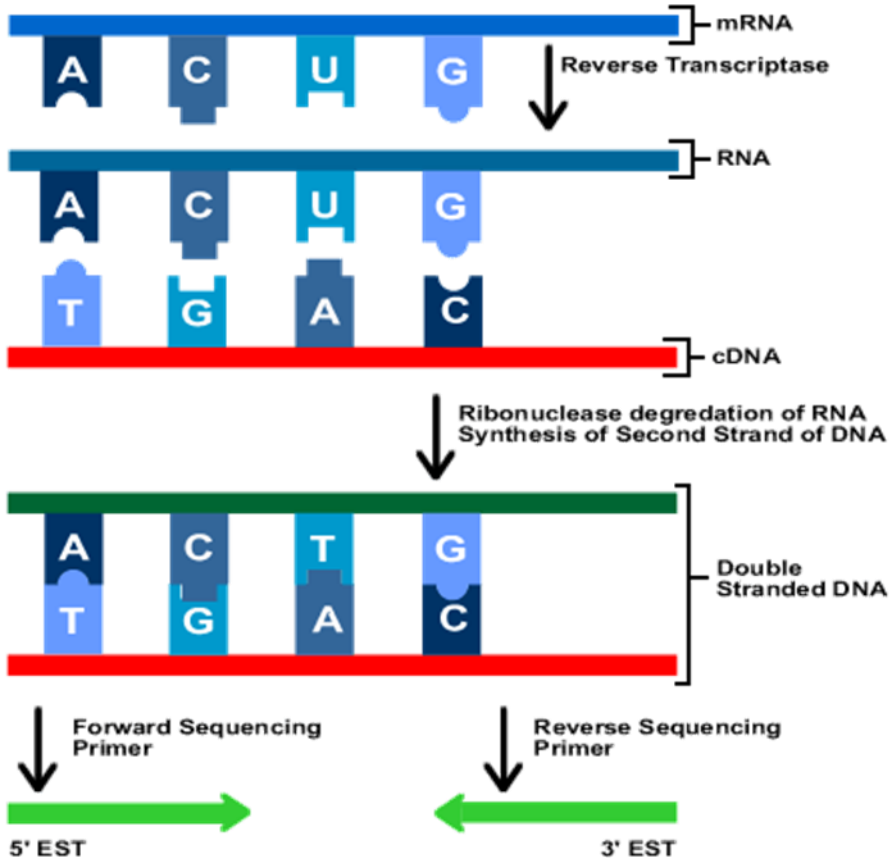
- Environmental Designs, Ltd. v. Union Oil Co. of Cal., (Fed. Cir. 1983) considering scepticism or disbelief before the invention as an indicator of non-obviousness;

- Allen Archery, Inc. v. Browning Mfg. Co., (Fed. Cir. 1987) considering copying, praise, unexpected results, and industry acceptance as indicators of non-obviousness

Utility

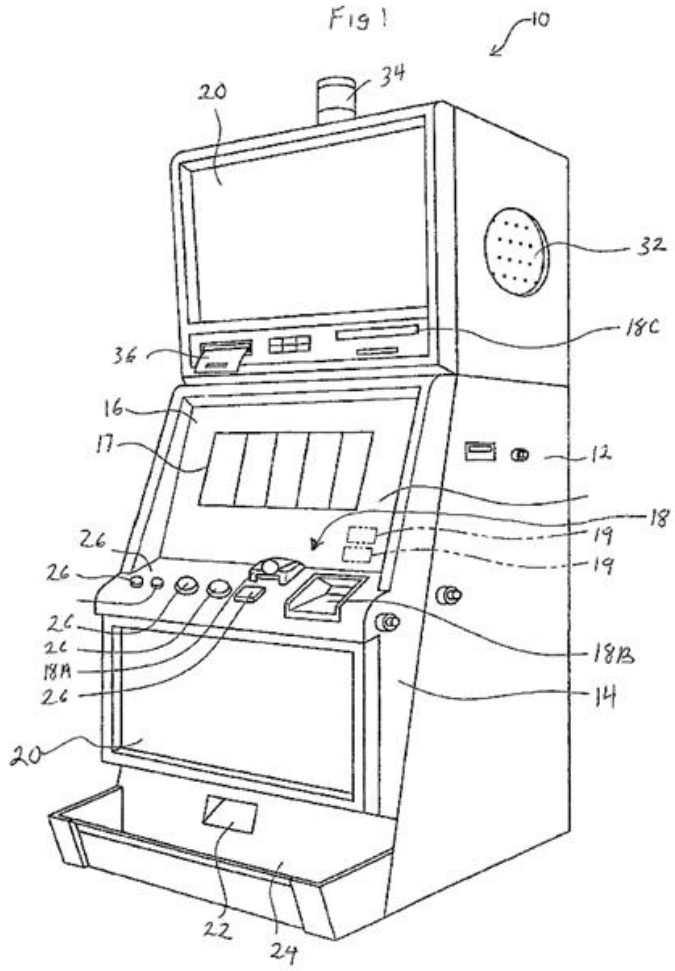
- Brenner V. Manson (1966) - novel process for making a known steroid did not satisfy the utility requirement because the patent applicants did not show that the steroid served any practical function.
- Nelson V. Bowler (1980) - Practical utility - one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public – expressed gene sequence tags



Utility diluted

- **Juicy Whip, Inc. v. Orange Bang**, Inc. dealing with a juice dispenser that arguably deceived the public into believing that the liquid seen in the attached reservoir was that which was being dispensed

- **Gambling**: multiple pull single token slot machine and method thereof



Natural characteristics utility

Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948): Kalo got patents on packaged mutually non-inhibitory rhizobia species for inoculation into the roots of leguminous plants and for the process. Held not patentable as: “qualities of these bacteria…are manifestations of laws of nature”; “aggregation of species”

ISOLATES: The first patent for a human product was granted on March 20, 1906 for a purified form of adrenaline. It was challenged and upheld in **Parke-Davis v. Mulford** [2] Judge Hand argued that natural substances when they are purified are more useful than the original natural substances.

Infringement §271

Whoever without authority makes, uses, offers to sell, or sells, imports

…actively induces infringement

…offers to sell, sells or imports a component of a patented machine, manufacture, combination or composition or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, shall be liable as contributor infringer.

(e)(1)It shall not be an act of infringement…solely for uses reasonably related to the development and submission

Infringement

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- Filing a 505(j) ANDA/505(b)(2) application for a patented drug or use of drug
- Seeking approval of biological product

Until eBay v. MercExchange (2006), plaintiffs routinely sought, and were granted, injunctions prohibiting infringement of their patents.

- Injunctive relief
- Damages or monetary relief when there is commercial manufacture, sale
- 3XDamages
- Reasonable Royalty
- Attorney fees when infringement when Hatch-Waxman Act

LANDMARK CASES

Patents Involved in Apple v.s. Samsung Patent War

Apple 15 | 12 SAMSUNG

MOTOROLA

vs in 2010

US7812828
US7663607
US7920129

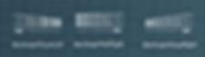
Multipoint touch screen

US7456893

Touch screen patent

US7864163
US7469381
US6493002
US7853891

GUI operating patent



Phone Control/Operation

US7577460
US7079871
US7069055
US7698711

Design patent

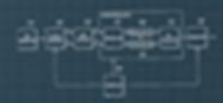
USD627790
USD617334
USD604305
USD618677
USD593087
USD622270
USD504889

Programming inferfaces

US7844915

Data transmission/coding

US7050410
US7386001
US7675941
US7362867
US7447516
US6928604
US7200792



patsnap 智慧芽

Contributory infringement

In **Wallace v. Holmes**, (CC Conn.1871) Patent a new burner for an oil lamp and claimed in combination with standard fuel reservoir, wick tube, and chimney necessary for a properly functioning lamp.

A competitor began to market a rival product including the novel burner but not the chimney. This did not amount to direct infringement, because the competitor had not replicated every single element of the patentee's claimed combination. The court held that there had been "palpable interference" with the patentee's legal rights, because purchasers would be certain to complete the combination, and hence the infringement, by adding the glass chimney. The court permitted the patentee to enforce his rights against the competitor who brought about the infringement, rather than requiring the patentee to find and sue all the innocent purchasers who technically were responsible for completing the infringement.

Inducement to infringement

Limelight Networks, Inc. v. Akamai Technologies, Inc. (2015): Limelight directed or controlled its customer's performance of the method steps it did not itself perform.

Henry V. A.B.Dick: Henry sold ink to buyers of A.B.Dick's patented machine which came with a license condition that only Dick's ink be used. Henry sold with intent that the buyer should infringe on the license conditions of Dick's machine.

Defenses

LANDMARK CASES

Non-infringement: to prove infringement, patentee must show that each and every limitation of the asserted claim is present in the accused product, either literally or equivalently. [TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc., 529 F.3d 1364 (Fed. Cir. 2008)] This is known as the “all elements rule”.

Attack the validity of the Patent and claims. Even if patent is determined to be valid, the Plaintiff must prove that every element of at least one claim was infringed.

Prior commercial use – 35 USC 273; Exhaustion of rights

Safe Harbour

Research for "purely philosophical" inquiry is not an infringement, but research directed to commercial purposes is infringing. 1813 decision in Whittemore v. Cutter, Justice Story wrote that the intent of the legislature could not have been to punish someone who infringes "merely for [scientific] experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.“

Hatch-Waxman process – Where research is directed toward obtaining approval of the Food and Drug Administration (FDA) for introduction of a generic version of a patented drug

Experimental use

In **Roche Prods., Inc. v. Bolar Pharm. Co**.(1984) held that scientific inquiry that has "definite, cognizable, and not insubstantial commercial purposes" did not qualify as experimental use. Bolar used ‘valium’ to test bioequivalence of its generic version.

In **Embrex, Inc. v. Service Engineering Corp**. (2002)that the experimental use defense applied only to actions performed "for amusement, to satisfy idle curiosity, or strictly for philosophical inquiry."

Bolar Exception

Roche Products V. Bolar Pharmaceutical Co. (Fed. Cir. 1984). Roche was the assignee of the rights, expiring in 1984 in prescription sleeping pill "Dalmane" – U.S. Patent No. 3,299,053 (the '053 patent), which expired on January 17, 1984 - Novel 1 and/or 4-substituted alkyl 5-aromatic-3H-1,4-benzodiazepines and benzodiazepine-2-ones

In early 1983, Bolar decided to market a generic drug equivalent to Dalmane after patent expiry. Bolar immediately began its effort to obtain federal approval and to prove bio-availability. Took steps to acquire flurezepam HCl for studies on stability, dissolution rates, bio-equivalence etc. required for ANDA filing.

Bolar Exception

Roche complained before Distt. Ct. that testing 6 m before expiry constituted infringement. Does the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute infringement?

Held: Tests, demonstrations, and experiments which are in keeping with the legitimate business of the alleged infringer are infringements for which experimental use is not a defense

3X - Polaroid Corp. v. Eastman Kodak Company (1990)

LANDMARK CASES

7 years before producing its first commercial instant photography product, Kodak retained a patent law firm to conduct patent clearance studies. The attorneys considered over 250 Polaroid and non-Polaroid patents in the technology and rendered over 67 written and many other oral opinions on the patents. After the Court entered an injunction, Kodak withdrew from the instant camera market—and has not since re-entered this market.

Even though the attorneys' advice simply turned out to be incorrect concerning a few of the patents, a finding of willful infringement was avoided.

Doctrine of Equivalents

LANDMARK CASES

holds a party liable for patent infringement even though the infringing device or process does not fall within the literal scope of a patent claim, but nevertheless is equivalent to the claimed invention

In the US, the doctrine is applied to individual claim limitations, not to the invention as a whole and is limited by prosecution history estoppel.

The difference between the limitation in the accused device and the limitation literally recited in the patent claim may be found to be "insubstantial on the basis of the triple identity test:

It performs substantially the same function

In substantially the same way

To yield substantially the same result

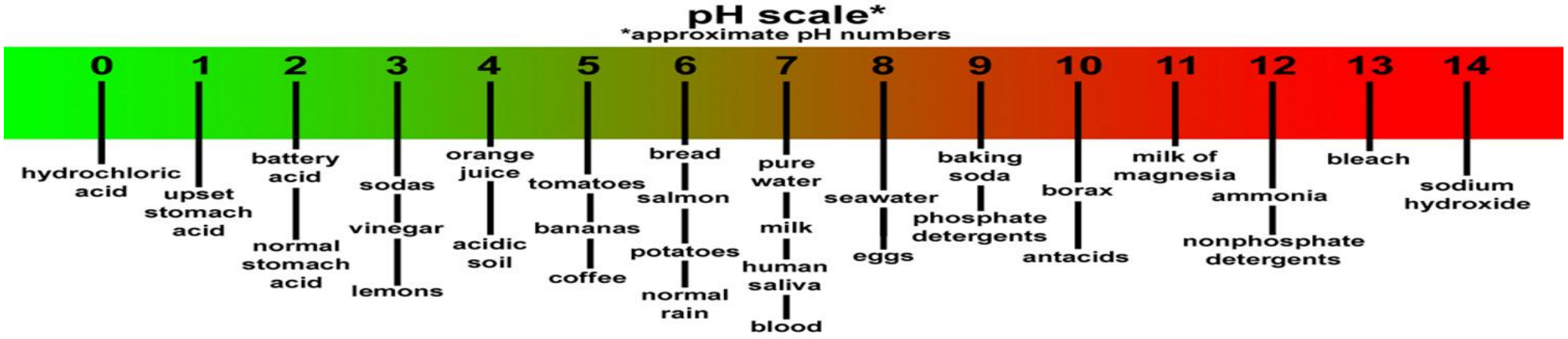
Graver Tank v. Linde Air (1950)

The plaintiff Linde Air Products Co. owned a patent for an electronic welding process, and sued defendants including the Graver company for infringing the patent. The defendants asserted that they were not infringing the patent because the patented welding process used a welding composition made of alkaline earth metal silicate and calcium fluoride (usually expressed as silicates of calcium and magnesium), while the purported infringers substituted a similar element, manganese, for the patentee's magnesium. The United States district court found infringement, and the Court of Appeals affirmed the infringement claim.

Warner-Jenkinson Co. v. Hilton Davis Chem. Co. (1997)

LANDMARK CASES

Hilton Davis had developed an "ultrafiltration" process to purify dyes. By amendment he specified that a solution used in the process must have a pH level between 6.0 and 9.0, to avoid overlap with prior art which specified lower limit of 9.0; plaintiff was unable to explain why the amendment stated a lower level of 6.0. The defendant had developed a process using a solution with a pH level of 5.0, which was outside the range of the plaintiff's patent. Held estopped.



Festo Corpn. V SMC (2002)

LANDMARK CASES

- Any amendment that narrows the scope of a claim for any reason related to statutory requirements will give rise to estoppel.
- Once claim is limited, the scope of coverage will not extend beyond literal terms

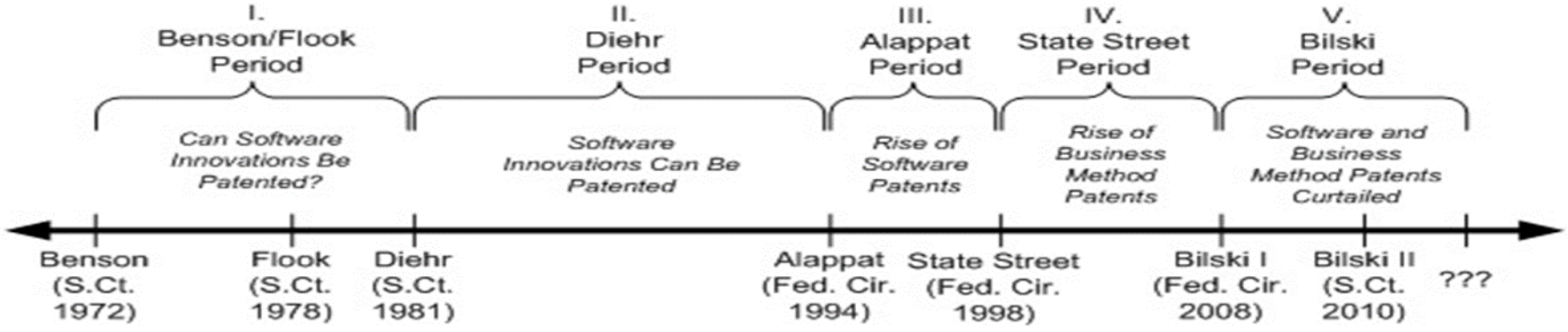
- Festo – magnetisable sleeve; sealing ring at each end of piston
- SMC – non-magnetisable sleeve, sealing ring at only one end

Software patent trilogy

LANDMARK CASES

Gottschalk v. Benson method of programming a general-purpose digital computer using an algorithm to convert binary-coded decimals into pure binary numbers.

Held the discovery was un-patentable since it was no more than abstract mathematics; would preclude others from using the abstract mathematical principles. Court's decision did not preclude patenting of software, only patentability where the only useful characteristic was an algorithm.



Software trilogy

Parker v. Flook method of calculating alarm limits by using a "smoothing algorithm" to make the system responsive to trends but not momentary fluctuations in process variables (such as temperature).

Held Where a patent was sought on an implementation of a principle (the algorithm), the implementation itself must be inventive for a patent to issue. Since that was not so, the Court held unpatentable.

Diamond v. Diehr A method of operating a rubber-moulding press for precision molded compounds with the aid of a digital computer. In this case the Court backed away from the analytic dissection approach, and insisted that patent-eligibility must be decided on the basis of the claim (or invention) considered as a whole, granting the patent. Court studiously avoided stating that Flook and Benson were overruled or limited.

Alice corp v CLS Bank (2014)

Whether computer-implemented, electronic escrow service for facilitating financial transactions covered abstract ideas ineligible for patent protection. The patents were held to be invalid because the claims were drawn to an abstract idea, and implementing those claims on a computer was not enough to transform that idea into patentable subject matter.

- the court stated a test that focused on first identifying the abstract idea or fundamental concept applied by the claim and then determining whether the claim would preempt the abstract idea.[

State Street Bank (1998)

extended patent protection to business methods in its decision in State Street Bank v. Signature Financial Group.

That decision upheld a patent on a “hub and spoke” automated data processing system that used a series of calculations to transfer assets among a pool of mutual funds. The court found the exception to be ill conceived. It stated that it would be inappropriate to prevent an otherwise patentable invention from being issued a patent simply because it is implemented using a computer.

Bilsky v Kappos (2010)

holding that the machine-or-transformation test is not the sole test for determining the patent eligibility of a process, but rather "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101

the Court found that his method of optimizing a fixed bill system for energy markets was an unpatentable abstract idea.

Did not rule out patentability of business methods.

Mayo v Prometheus (2012)

- Personalised medicine
- Prometheus licensed diagnostic kits for treatment with thiopurine drugs for auto-immune diseases to Mayo.
- Mayo began offering its own tests – 3 step process – administering drug, measuring metabolite, being warned that a dose adjustment is required
- Data-gathering + mental step comprising correlation – no step required change in the dosage.
- Mere use of computers does not render it patentable

Patenting of Life

1970s A.M.Chakrabarty of GE developed a genetically improved microorganism that was designed to break down crude oil rapidly; Process granted but not product

In 1980, 8 years after the initial filing, the Supreme Court held that the microorganisms were a new composition of matter, the product of human ingenuity and not of nature's handiwork, and thus a patentable subject matter. – Human intervention test

Chakrabarty and Kellogg for ''Bacteria capable of dissimilation of environmentally persistent chemical compounds," in 1985. Kenneth Hibbard, Paul Anderson, and Mellanie Barker for ''Tryptophan overproducer mutants of cereal crops,'' in 1986. Philip Leder and Timothy Stewart ''Transgenic nonhuman mammals'' in 1988 the ''Harvard Mouse.'

Human Cells

Human cells, expressed sequence tags (ESTs), single nucleotide polymorphisms (SNPs), and cultivation and isolation of stem cells have also been patented.

David Golde and Shirley Quan for ‘‘Unique T-lymphocyte line and products derived therefrom’’ in 1984 for cell line derived from John Moore’s spleen. Ann Tsukamoto, Charles Baum, Ykoh Aihara, and Irving Weissman for ‘‘Human hematopoetic stem cell,’’ isolated human bone marrow stem cells in 1991

Gene Patents are patent on a specific isolated gene sequence, its chemical composition, the processes for obtaining or using it, or a combination of such claims. Gene patents are a part of the broader category of biological patents.

Harvard Oncomouse

LANDMARK CASES

Inventors: Philip Leder, Timothy A. Stewart
Original Assignee: President and Fellows of Harvard College
Current U.S. Classification: 800/10; 435/6.14; 435/317.1; 536/23.5; 800/18
International Classification: C12N 100; C12Q 168; C12N 1500; C12N 500

Patent number: 4736866
Filing date: Jun 22, 1984
Issue date: Apr 12, 1988

Two patents were issued to Harvard College covering methods for providing a cell culture from a transgenic non-human animal (expired Feb 11, 2009) and testing methods using transgenic mice expressing an oncogene (expiring 2016)

Other jurisdictions

Canada

2002: Supreme Court rejected the patent in Harvard College v. Canada, overturning a Federal Court of Appeal verdict which ruled in favour of the patent.

2003: Canadian patent 1,341,442 CA 1341442 was granted to Harvard College amended to omit the "composition of matter" claims on the transgenic mice. Canadian patent law allowed the amended claims to grant under pre-GATT rules and the patent remains valid until 2020.

EPO

1989: refused in by an Examining EPO as EPC excludes patentability of animals per se. 1992 granted on the ground that varieties were unpatentable not animals per se. 2001, hearing on objections, the patent was maintained in amended form. 2006 revoked for failure to pay the fees and to file translated claims.

Assn for Molecular Pathology v Myriad Genetics

- Isolated DNA sequences to diagnose propensity to cancer by looking for mutated DNA sequences. BRCA genes.
- Previously considered composition of matter
- Not inventive and relating to genetic information
- Fed. Cir. Isolated genes do not exist in nature
- Supreme Court held that isolating genes does not make them patentable.

Hatch Waxman Act

- Efficacy: 1962 amendments to FDCA in Response to the THALIDOMIDE issue, first introduced proof of Safety and efficacy requirements.

- Counter the lengthy approval period for innovators Which resulted in de facto shortening of the patent term

- Counter the onerous approval requirements for generics which resulted in “off-patent” drugs with no generic competition
- **Roche v Bolar** was impetus for congressional enactment of the Drug Price Competition and Patent Term Restoration Act, 1984

Section 505 of the Fed. Food, Drug and Cosmetic Act

Describes 3 types of new drug applications

1. Contains full reports of investigations on safety and effectiveness 505(b)(1)
2. Contains full reports of investigations on safety and effectiveness but where some of the information required for approval comes from studies not conducted by applicant 505(b)(2)
3. Contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labelling, quality, performance characteristics and intended use, among other things, to a previously approved product 505(j)

Additional exclusivities

- New Drug Product Exclusivity

NCE (New Chemical Entity): 5 years

  - New active ingredient, new molecules, new salts
  - FDA cannot accept a generic application for 5 years (4 years if a Para IV challenge)
  - Effectively 7 ½ years if there is a Para IV challenge after 4 years

- New product/new use /supplemental exclusivity: 3 years
  - (new clinical studies to support a new indication, formulation, salt, dosage regimen, etc.; enantiomers)

Other exclusivities

- **Orphan Drug** – 7 years without generic competition, but does not prevent generic competition for other approved uses of the drug – myeloma/glioma in adults and muscular dystrophy in kids
- **Paediatric exclusivity** – 505A – sponsor must have written request from FDA; Must report studies to FDA; must fulfil request conditions. – esomeprazole; montelukast; pancrelipase for children. It is an add-on to existing market exclusivity or patent protection.
- **505 (b)(2) exclusivity** – not generic or totally new, changes such as dosage form, strength, delivery mechanism, formulation, combination. *Altoprev TM (Lovastatin)* extended release by Andrx; *Avodart (dutasteride)* benign prostatic hyperplasia for male pattern baldness. *Thalidomid* for cancer - celgene

Patent Linkage

- Generic Marketing Approval is “Linked” to the Expiration of the Pioneer Drug Patent
- If a patent exists, marketing approval will not be granted to a generic until the patent has expired or is found to be invalid.
- Orange Book patent listings: New Drug Application (NDA) must include patent information and the FDA considers the existence of patents as part of the approval process for certain drug applications

ANDA

LANDMARK CASES

- All approved drug products, brand-name and generic are listed in the FDA's Orange Book – Approved Drug Products TE evaluations. Every holder of approved NDA shall list pertinent patents it believes would be infringed if generic drugs were marketed before expiration of the patent
- Sec.viii statement to be filed seeking approval for generic marketing with one of four certifications

Para I - That such patent information has not been filed

Para II - That such patent has expired

Para III - That the generic will not be marketed until expiration of the patent

Para IV - That either the proposed generic drug does not infringe the patent or the patent is invalid

Process

If patent owner brings a patent infringement charge against ANDA filer within 45 days of receiving notice from ANDA filer, FDA suspends approval of the ANDA until

- The court's decision that the listed drug's patent is invalid or not infringed
- Expiry of the patent
- Subject to modification by court, the date that is 30 m from the date the patent owner received notice of Para IV certification

Generic exclusivity

- A reward for challenging the patent associated with an approved pharmaceutical.
- 180-day generic exclusivity period awarded to the first generic applicant to file a para IV
- If ANDA filer loses, he shall convert his appln to a Para III
- No damages are awarded – except attorney fees

Basis for invalidity – anticipation, obviousness, TSM, obviousness, double-patenting

Exclusivity starts – judgement trigger, commercial marketing trigger

Successful defense requirement Mova v Shalala

LANDMARK CASES

FDA approved an application by a drug manufacturer, Mylan Pharmaceuticals, Inc. to market a generic version of micronized glyburide, a drug used to treat diabetes

- Mova Pharmaceutical Corp. had filed an earlier application to market a generic version of the same drug
- Mova's application had not yet been approved, because of a patent infringement suit brought by Pharmacia & Upjohn Company
- Upjohn claimed that Mova's product infringed a patent belonging to Upjohn
- When Mova learned that the FDA had approved Mylan's application, it brought suit relying on 21 U.S.C. 355(j)(5)(B)(iv) (1994), to compel the FDA to delay the effective date of this approval until 180 days after the earlier of the dates that Mova won its suit or began to market its product.

Orange book listing example

Active Ingredient Search Results from "OB_Rx" table for query on "rosuvastatin."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
021366		No	ROSUVASTATIN CALCIUM	TABLET; ORAL	10MG	CRESTOR	IPR
021366		No	ROSUVASTATIN CALCIUM	TABLET; ORAL	20MG	CRESTOR	IPR
021366		Yes	ROSUVASTATIN CALCIUM	TABLET; ORAL	40MG	CRESTOR	IPR
021366		No	ROSUVASTATIN CALCIUM	TABLET; ORAL	5MG	CRESTOR	IPR

Reverse payment

- **Hoechst-Roussel v Andrx** : H-R, the patentee reached a settled with Andrx in respect of once-daily diltiazem product developed by Andrx allegedly infringing upon a formulation patent for Hoechst Marion Roussel's Cardizem CD a once-daily medication for the treatment of hypertension and angina. Andrx developed a second formulation that did not infringe on the Hoechst Marion Roussel patent. Andrx has agreed to market this second formulation and to not market the first. Andrx delayed marketing the formulation until the suit was settled. Hoechst Marion Roussel agreed to compensate Andrx for that delay and will make a final lost-profit payment of approximately $50 million to Andrx. (June 1999)

Para IV strategies

Targets

- Everything
- Blockbusters
- Niche Products
  - – Formulation
  - – Therapeutic Class
  - – Limited API
  - – Limited Sales
- Line Extension

- Market Position
- • First filer
- • Subsequent filer
- – Limited competition
- – Highly competitive market

Most generics interact closely with originator drug manufacturers – sometimes with respect to specific drugs, and at others on more general drug development

Sandoz-Novartis

GREENSTONE - PFIZER

Watson- J&J

Mylan-Merck KGaA Generics Dyson.

1. *Teva*
2. *Mylan*
3. *Sandoz*
4. *Watson*
5. *Greenstone*
6. *Pan Pharma*
7. *Hospira*
8. *Apotex*
9. *Mallincrodt (covidien)*
10. *Dr. Reddy's*

Dr. Reddy's-Merck

Pharma- healthcare

Authorised generics?

ANDAs are filed by generics that have an agreement with originator

✓ not to be sued, but to be supplied with generic copy of drug

✓Both generic and originator benefit without competition or fear of litigation

✓ a long term relationship develops between originator and generic

Pfizer licensed the product to its own Greenstone subsidiary for generic Gabapentin (Neurontin).

Examples of this relationship include:

Paxil (Paroxetine) - licensed by GSK to Par
Prozac (Fluoxetine) - licensed by Lilly to Barr
Augmentin (Co-Amoxiclav) licensed by GSK to IVAX

In February this year Dr. Reddy's announced a similar deal with Merck & Co. for two products Proscar (Finasteride) and Zocor (Simvastatin).

Apotex Inc. v. Daiichi Sankyo, Inc., Nos. 2014-1282, 2014-1291 (Fed. Cir. Mar. 31, 2015)

- Daiichi listed two patents covering Benicar® No. 5,616,599, covers the active ingredient of the drug, and expires on April 25, 2016 with pediatric exclusivity and No. 6,878,703, covers methods of treatment, and expires on November 19, 2021.
- In April 2006, Mylan filed an ANDA with a paragraph IV certification that both the ’599 and ’703 patents were invalid or not infringed by Mylan’s proposed generic drug. In July 2006, for reasons that remain unexplained, Daiichi disclaimed all claims of the ’703 patent, as permitted under 35 U.S.C. § 253. Daiichi then sued Mylan for infringing the ’599 patent.
- Apotex, Inc. sued Daiichi for a declaratory judgment of non-infringement of a Daiichi-owned, but Daiichi-disclaimed, patent.

Purdue Pharm. Products v. TWI Pharms., No. 12-5311 (D.N.J.)

- Purdue holds the NDA for Intermezzo®, a drug used to treat middle-of-the-night insomnia. Four patents are listed in the Orange Book in connection with the NDA. By the time TWi filed its ANDA, four other ANDAs had already been filed and presumably at least one of those is entitled to 180-day exclusivity. Purdue sued TWi on only two of the patents, and granted TWi a covenant not to sue on the other two. TWi filed a DJ counterclaim for noninfringement of all four Orange Book-listed patents.
- TWi's DJ counterclaim is important because it "could potentially trigger the first ANDA filer's 180-day exclusivity period. This would have the effect of expediting TWi's ability to market its generic version of Intermezzo®."

COUNTER GENERIC STRATEGY

AstraZeneca received FDA approval to market Omeprazole (exp. In 2001) in US in 1989, as Prilosec®. By 1999, AstraZeneca's product became one of the most widely
prescribed drugs of any kind in the world, with sales of some $6.1 billion annually. In 1999 AstraZeneca commenced suit against four generic pharmaceutical manufacturers after ANDA filing and in 2000 against 4 more.

In 1995, the company decided to create a strategy to overcome losses due to patent expiry.

What would the outcome be?
How can this strategy work?

US Patent 4255431 on omeprazole - racemic mixture

Evergreening

Purple as symbolics of dependable magic Distress resolution, fear reduction

WO patent 94/27988 on esomeprazole – s-enantiomer

"the purple pill"

Counter generic strategies

- the most popular strategy is the launch of new product formulations (82%)
- defensive pricing (70%) lowering prices or renegotiating purchasing contracts to fight generics
- dependence on overall franchise strength and increased marketing and promotion

- ATORVASTATIN: Ranbaxy has 180 days of exclusivity on the market due to a settlement with Pfizer - launched generic atorvastatin; competition Lipitor, and an offering from Watson Pharmaceuticals, which is selling an authorized generic version on behalf of Pfizer.

Pfizer strategy

- special contracts and increased product promotion, to ensure consumers will find it easy and affordable to remain with Lipitor for six months.
- deals to ensure benefits for links in the pharmaceutical value chain. Pharmacy benefit managers have received discounts on Lipitor
- customers co-pays have dropped to $4 through a Pfizer program that provides a discount card.
- Pfizer has assured Congress that insurance companies are also seeing these discounts though no numbers have been given

Abbot strategy: Fenofibrate (TRICOR)

- Abbott dominates in the US despite the existence of generic fenofibrate & questions regarding the drug's efficacy in reducing cardiovascular risk. Abbott's successful market dominance can be attributed to 2 factors:
  - The sequential launch of branded reformulations that used only bioequivalence data in NDA. These reformulated products showed no improvement in patient outcomes but made substitution with older generic formulations impossible.
  - Taking advantage of FDA 30-month stay, Abbott used this time to produce and market their next-generation product before the generic version of the previous-generation drug could be approved. Lacking the extensive sales force of major pharmaceutical companies, generic drug makers could not compete.
- Abbott has been the target of anti-trust lawsuits, including a class action suit in 2005 by the Louisiana Wholesale Drug Company, and various patients and states. All of these lawsuits were ultimately settled out of court and cost Abbott $300 million, a figure that amounts to less than 4% of total sales to date of their fibrate franchise.

Thank you for your attention

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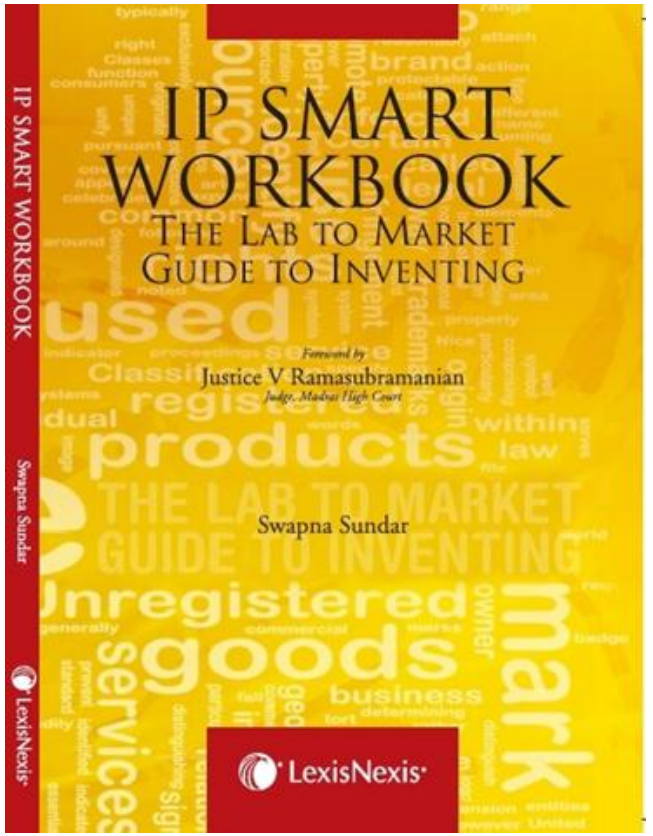

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