

A STUDY TO REVIEW THE IMPORTANCE OF INTELLECTUAL PROPERTY RIGHTS IN CLINICAL RESEARCH

Rajesh Kumar*¹, Krishan Pal², Anju Pal³

¹Research Scholar, Dept. of Biotechnology, Shri Venkateshwara University, Gajraula, (UP) – India.

²Department of Biotechnology, Shri Venkateshwara University, Uttar Pradesh, India

³Scientist, Medicinal and Aromatic Plants, K.V.K. Haridwar G.B.Pant University of Ag. & Technology, Pantnagar, Uttarakhand, India

Article Received on
05 July 2015,

Revised on 29 July 2015,
Accepted on 24 Aug 2015

***Correspondence For
Author**

Rajesh Kumar

Research Scholar, Dept. of
Biotechnology, Shri
Venkateshwara
University, Gajraula, (UP)
– India.

ABSTRACT

This article describes the modern world growth and importance of intellectual property rights given to pharmaceutical organization in the field of clinical research. Clinical trials cost (an average of \$2.6 billion) is well known and success rate is very low. Approximately 5 to 10 thousands experimental molecules considered every time, only five in 5,000, or 10%, of the drugs that begin preclinical testing ever make it to human testing. Typically, only one will gain Food and Drug Administration (FDA) approval for human usage, after an average of 10-15 years of research and development process. Drug research and development leads to the discovery of tomorrow's life-changing and life-saving new medicines. Clinical Research intellectual property (IP)

protections, such as patents and data protection, provide the incentives that spur research and development. They help ensure that the innovative clinical research companies that have invested in life-saving medicines have an opportunity to justify their investments. Intellectual property protections also help companies secure the resources for future investments in research, giving hope to patients who await tomorrow's innovative medicines. Intellectual property policies play key necessary role to support future R&D investment. These policies provide incentives that spur biopharmaceutical innovation, leading to new treatments and eventually generics and biosimilar drugs. Intellectual property rights are one of the most important aspects of clinical research.^[1-10]

KEYWORDS: Intellectual property right, Clinical research, Drug, Patents.

INTRODUCTION

IPR: According to WIPO (World Intellectual Property Organization) Intellectual property (IP) refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce.

It is now a known fact that IP plays a vital role in the modern economy. IPR is a strong tool which protects investments, time, money, effort which were invested by the creator of an idea/product, as IPR grants the creator an exclusive right for a certain period to fully utilize the creation. This results in the economic development by promoting a healthy environment towards new ideas and creations. (Chandra Nath Saha & Sanjib Bhattacharya 2011).

IP is divided into two categories

- 1) Industrial property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and
- 2) Copyright, which includes literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs. Rights related to copyright include those of performing artists in their performances.

How and Why IP Protection Works

There are three key elements for an effective intellectual property system:

- It must provide fair and effective incentives for innovation
- It must provide innovators certainty regarding their rights
- It must offer patent holders strong enforcement tools for defending infringed patents

Without intellectual property rights, competitors could simply copy biopharmaceutical innovations as soon as they were proven safe and effective, offering their own versions without investing the time and money to develop the medicines. Innovators in the biopharmaceutical industry could lose the ability to recoup their substantial investment in new drug development, making it more challenging to find funding.

Reasonable intellectual property protection is essential to sustain the U.S. biopharmaceutical sector's continuing investments in new research and development. At the most fundamental level, IP rights give America's biopharmaceutical research companies a chance to fund research into new treatments for our most costly and challenging diseases.

Intellectual Property Rights Clause

1.1[Subject to clause [CONFIDENTIALITY CLAUSE], each party shall give full disclosure to the other of all Background Intellectual Property owned or licensed by it which is relevant to the Project.]

1.2 All Background Intellectual Property is and shall remain the exclusive property of the party owning it (or, where applicable, the third party from whom its right to use the Background Intellectual Property has derived).

1.3 Subject to clause 1.4, Foreground Intellectual Property shall vest in and be owned absolutely by the party creating or developing the Technology in respect of which it arises. To the extent that either party sub-contracts performance of any Project, that party shall ensure that any Foreground Intellectual Property arising from the work of its sub-contractor shall be assigned to it absolutely.

1.4 To the extent that any Foreground Intellectual Property arises or is obtained in respect of Technology developed by the parties jointly or otherwise than solely by either party, It shall be jointly owned in equal and undivided shares by the parties. If any such jointly-owned Foreground Intellectual Property is registrable,

[A] shall be responsible –for, the filing and prosecution of applications for registration on behalf of the parties and in their joint names in such countries as the parties agree in writing. [A] shall be responsible for the maintenance and renewal of any such registrations in such countries, subject to

[B] co-operating in the provision of all necessary assistance, information and instructions and bearing an equal proportion of any fees and costs, including reasonable agents and lawyers' fees, in relation to such registrations, provided that:

(a)if only one party wishes to apply for registration in any country or countries, the party wishing to apply may do so [at its sole cost and expense] on behalf of both parties and in their joint names, and the party not making such an application shall provide the party making the application with all necessary assistance, information, and instruction;

(b)neither party shall amend or abandon any registration in respect of which the parties are jointly registered without the other party's written consent; and (c)the party making an application for registration shall consult with the other party at reasonable intervals concerning the application for and maintenance of such registration.

1.5 Each party shall immediately give written notice to the other party of any actual, threatened or suspected infringement of any party's Background Intellectual Property or Foreground Intellectual Property, whether jointly or solely owned, or any unauthorized use of any party's Technology.

Current Forms of Intellectual Property in Clinical Research

A. Patents

The patent laws are enacted by Congress pursuant to its power under Article I, section 8, clause 8 of the Constitution. The patent statute, Chapter 35 of the U.S. Code, further defines patent rights.

Rights

A patent gives the owner the right to exclude others from making, using, selling, offering for sale or importing the claimed invention in the United States.^[11] The grant of a patent, however, does not give the inventor the right to practice the invention. In fact, the inventor may have to comply with other laws and regulations, such as those promulgated by the FDA.

Duration: A patent lasts for 20 years from the date of filing.^[12] After a patent expires, the patent is dedicated to the public.

Policy

Obtaining this right to exclude for 20 years, or as some would define it a limited monopoly, is a strong and powerful right, but it is not without its costs. In return for this right, the inventor must disclose his invention, including the manner and process of making and using it, so that one of ordinary skill in the art would be able to make and use the invention.^[13] In addition, the inventor must set forth the best mode of carrying out the invention.^[14]

Patents value in Clinical Trials

Assuming that all of the statutory requirements are met, patent law could protect new chemical entities and new drugs, new formulations of drugs, methods of manufacturing chemicals or drugs, and methods of using the chemicals or drugs. Thus, patents may be obtained from clinical trial results that indicate a new use or method of using a drug. However, the underlying studies are not generally protected by patent law. In fact, the patent law makes an exception that allows others to engage in clinical research without violating a

patent.^[15] In an effort to balance this exception, Congress provided that the filing of a Paragraph IV certification for either ANDAs or NDAs is an act of infringement.^[16]

The patent laws also recognize that the time to get a drug approved by the FDA can be considerable and can decrease the value of the patent because by the time the drug is approved there is considerably less time to enforce the patent. To further encourage disclosure of inventions, a patent term extension may be granted for those compositions or processes that are subject to regulatory review by the FDA pursuant to the FDCA.^[17] The term of the patent may be extended if it has been subject to a regulatory review period before commercial marketing or use.^[18] The patent is thereby extended by the amount of time equal to the regulatory review period that occurs after the patent issues, less periods of time where the applicant was not acting diligently in the review process.^[19] However, the grant of such extension shall not exceed 14 years.^[20]

B. Trademarks^[21]

Trademark law, unlike patent and copyright law, has both federal and state laws that dictate its scope, rights, and enforcement. The Federal trademark law, the Lanham Act,^[22] describes the scope of federal protection afforded to trademarks. Congress enacted the Lanham Act under its power to regulate interstate commerce. States also have their own statutes and/or common law doctrine that govern trademarks.

Rights

A trademark gives the owner the right to exclude others from using the mark or a colorable variation thereof in connection with the sale, offering for sale, distribution or advertising of goods or services that is likely to cause confusion, mistake or deception^[23] or dilutes the trademark.^[24] A trademark owner can lose its rights if the mark becomes generic, if the rights have been abandoned, or if the trademark was obtained through fraud.^[25]

Duration

Trademarks can exist for an infinite length of time. A trademark ceases to exist if the mark becomes generic, if the rights have been abandoned, or if the trademark was obtained through fraud.^[26]

Policy

Trademarks are generally justified as providing a benefit to the public and providing incentive to owner to maintain consistent quality in his product. The public is benefited by

being able to quickly and efficiently identify and distinguish products. Additionally, consumers benefit by receiving goods or services that have a consistent quality.

Trademarks value in Clinical Trials

There is very little in the clinical trial process that would be protected by trademark law. The only possible areas where trademark protection would be available would be for the trademarked name of the drug and in some rare instances, services that would be provided with a drug that was offered (i.e. if for example a mark were attached to a way of administering chemotherapy that was in a specific simulated environment). However, the brand name of a drug is usually not used in the actual clinical trial. In fact the technical name of the drug is frequently not revealed to the subject^[27] or not revealed to either the subject or the investigator.^[28] Once the drug is on the market, however, the trademark protection of a drug is valuable.

C. Copyrights

The copyright laws are enacted by Congress pursuant to its power under Article I, section 8, clause 8 of the Constitution. In turn, Congress has enacted the Copyright Statute.^[29]

Rights

Copyright protection consists of a bundle of rights including the right to distribute copies and the right to create derivative works.^[30] Copyrights protect the owners from unauthorized use of the copyrighted work. Copyrights do not protect uses which are considered fair uses.^[31] Copyrights do not protect the owner if another individual develops the exact same work or a substantially similar work provided that the new work was developed independently.

Duration

A copyright will last for the life of the author plus 70 years and for those works that are works made for hire, the copyright will last for 95 years from the shorter of the date of first publication 120 years from creation.^[32]

Policy

The policy reasons generally given to justify granting copyrights include: (1) protections and benefits afforded to the author; (2) public benefits; and (3) other economic benefits. Those protections and benefits afforded to the author include the incentive to create the work, the right to control one's creation, prestige, and leverage for negotiations. The public benefits by

having more access to both more obscure works and the “blockbuster” works. Finally other economic benefits include encouraging publisher investment and allowing for transactions and bargaining occurring between authors and publishing companies.

Copyrights value in Clinical Trials

The copyright laws protect various aspects of the clinical trial process. Copyright law protects any reports or publications of clinical results, to the extent that they are expression.. Moreover, to the extent that any forms are designed for administration of the clinical trial process, those forms may be copyrightable. A copyright may exist in the labeling of the drug. Copyrights in the clinical trial arena are problematic because (1) copyrights will not protect the underlying data; (2) ownership and control of publication is difficult and (3) copyright protection may be unenforceable. First, to the extent that copyright protection is granted, it does not protect the underlying data. Second, conflict over ownership and control of copyrights will be greatest with respect to trial protocols, study reports and forms created for clinical trial data collection. The sponsor may only retain ownership and control of these works if (1) the sponsor’s employees create or co-create these works; (2) the sponsor’s contract with the CRO and/or investigator contains a works made for hire provision; or (3) the sponsor subsequently purchases the copyright. Some CROs and investigators, especially those that are affiliated with academic institutions, refuse to allow an employee of the sponsor to work with them as a co-author and will not agree to sign a work-made-for hire agreement. Moreover, they frequently have explicit clauses retaining publication rights to the study they are performing. A sponsor that wants to maintain ownership and control is therefore forced to go to a site, often those not affiliated with academic institutions, to perform their trial. Being forced to use a CRO or investigator that is not affiliated with an academic institution is most problematic where the trial must be done a special population that is only accessible through these particular institutions. Moreover, the sponsor is forced to choose between a prestigious institution and retaining copyright ownership.

Enforcement of copyrights may also be difficult. Although copyrights on labels for drugs may exist, an ANDA applicant will not be held liable for copyright infringement because the FDA requires that the labels are the same as the labels of the approved drug.^[33] Similarly, incorporating another’s study by reference into a 505(b)(2) or 505(j) application is unlikely to be a source of copyright infringement because there is no copyright in the underlying data that is referred to and to the extent that any copyright protection exists in the submitted

clinical trial, the 505(b)(2) or 505(j) applicant is not copying the work as it is incorporated by reference.

D. Trade Secrets

Trade secrets are protected by state law. The Uniform Trade Secrets Act has either been enacted in original or modified form in most states. Owners of trade secrets are protected from misappropriation of their trade secrets.

Rights

Once the trade secret has been identified or asserted, trade secret law protects against misappropriation. Misappropriation occurs when trade secrets are acquired by improper means or are disclosed or used when the original acquisition was improper.[34] Trade secret law does not protect against acquisition of trade secrets by proper means, including reverse engineering and independent development.

Duration

A trade secret can exist indefinitely. However, the life of a trade secret can be shortened if the trade secret is disclosed to the public, becomes generally known to the public or the owner fails to take reasonable steps to maintain its secrecy.

Policy

Trade secret protection is frequently justified based on commercial morality and the impropriety of stealing another's property. By protecting a trade secret, the scope of protection is much more limited than those of the patent laws as it does not protect against those who independently create or develop the trade secret. The public benefits from the existence of trade secret law because it provides incentive to develop trade secrets that indirectly benefit the public (i.e. a special mixture of gasoline which cannot be readily ascertained from the final product can be beneficial to the public).

Trade secrets value in clinical trials

Trade secret law does not adequately protect clinical trials because the trade secret law is not uniform throughout the U.S., the competing interests of numerous players within the clinical trial process make reasonable efforts to maintain secrecy difficult, the value of a study may be questionable, maintaining the clinical trial as a secret necessarily does not promote public disclosure and there may be takings issues with respect to 505(b)(2) applications.

First, since trade secret law varies from state-to-state and the drug approval process is federal in nature, there may not be uniformity in the various state's trade secret statutes or the judicial interpretation thereof. Thus, the sponsor may be in a position where he is able to successfully assert that the information in a clinical trial is a trade secret in some states while not being a trade secret in other states. The Texas Appellate Court refused to find that collateral estoppel applied to bar Upjohn from claiming that a trade secret existed in the clinical trial data.^[35] A previous decision by the district court in Utah, prior to dismissal of the case, had found that Upjohn could not claim trade secrets with respect to information in case report forms and technical and statistical reports not authored by Upjohn.^[36] Moreover, unlike patents that establish rights of the owners as compared to the world, trade secret law is often interpreted to reflect the nature of the property as between the two parties involved.^[37] Courts have readily recognized clinical trials as trade secrets where there were improper acts by a competitor.^[38] When a competitor offered to establish honorariums in return for access to a competitor's clinical trial data, the Massachusetts Superior Court was willing to issue a preliminary injunction requiring destruction of clinical trial information that the competitor has obtained, cessation of any communication with the investigators that were performing the clinical trials, and no disclosure of clinical trial information without permission of the sponsor or the court.^[39]

Second, since some CROs and investigators, particularly those that are affiliated with academic institutions, maintain rights to publish information, a court decision could decide that giving this right away is not considered reasonable efforts to maintain secrecy, thus destroying the existence of a trade secret. Clinical protocols were not considered to be trade secrets where published and described extensively in medical literature.^[40] The court then went on to find that two out of three of the investigation drug brochures at issue that revealed clinical trial results were not trade secrets as they were already generally known.^[41] The court went on to note that efforts to maintain secrecy were not reasonable where there was no written agreement between the sponsor and the investigator (even though it was alleged that this was industry custom), the documents were not marked confidential, the material was disseminated to approximately 19 centers, no policy of document retrieval, and there were no letters contesting the investigator's publication of clinical trial information.^[42] The sheer number of people involved that have access to the clinical trial information – the investigators, CROs, IRBs, and patients - make maintaining secrecy a difficult task.

Third, a trade secret requires showing value. For failed studies, the value of the study is questionable. A sponsor would claim that there is value in maintaining that information as a secret as other competitors could waste money on the same futile research. Even so, failing to recognize the failed trial as a trade secret does not encourage its disclosure. For successful trials that are used as the basis for an FDA application much of the information is available under the Freedom of Information Act.^[43] A government agency may withhold disclosure of information if it falls into one of the exceptions, including a trade secrets exception. Data from a clinical trial that is provided to the FDA may be claimed as a trade secret or confidential information where the release would result in an unwarranted invasion of personal privacy.^[44] However, the value of the clinical trial may be determined based on the ability to rely on the study in FDA approval. The court refused to grant motion for summary judgment where there was a genuine issue of material fact – more specifically, the sponsor as well as the FDA claimed that dissemination of the information would cause harm to its competitive position while the defendant claimed that there would be no substantial economic harm as the information in the tables used was analyzed to determine the efficacy and safety of Oralet [a narcotic lollipop] and could not be relied upon by a competitor for approval.^[45] Fourth, by allowing trade secret protection of clinical trials, there is necessarily a desire to keep the information obtained in the secret. Thus, the owner of the trade secret is required to balance how much disclosure is necessary to lure potential licensees while maintaining secrecy. If some other form of intellectual property is recognized that encourages the dissemination of types of clinical trials engaged in licensing could be encouraged or even mandated. Moreover, encouraging secrecy of information whether clinical trial results or methodology, encourages a gap between public knowledge disseminated and actual knowledge. Pfizer tried to claim a trade secret by investing in excess of \$20 million and 10 years on developing the most efficient means of developing clinical trials, i.e., the types of patients to use, the dosage sequence, the means for measuring individual reaction, etc., as well as the things to be avoided as not being beneficial to the testing program.^[46] The court refused to grant a preliminary injunction because that information likely did not rise to the level of trade secret status.^[47] Moreover, the court noted that allowing a trade secret in this information would be against public interest because it would promote inefficiency in clinical trials.^[48]

Finally, if clinical trials are considered to be property, then relying on someone else's studies may be considered an improper taking.^[49]

A Non-Comprehensive List of Indicators that may Affect the Strength of Biopharmaceutical IPRs

| | |
|--|---|
| Term of market exclusivity | <ul style="list-style-type: none"> Patent term Market exclusivity provided by regulatory approval Patent/exclusivity extensions to compensate for regulatory review delays Extensions for pediatric investigation Extensions for orphan drugs Extensions for drugs targeting specific diseases |
| Patentability standards | <ul style="list-style-type: none"> Scope of claims Obviousness/inventive step Utility/industrial applicability Novelty (and grace periods) Priority rules |
| Patentable subject matter | <ul style="list-style-type: none"> Products Manufacturing processes Manufacturing intermediates Alternative salts and esters of previously patented compound Use of a product in treating specific diseases Treatment protocols, dosing Packaging/delivery mechanisms Metabolites Naturally occurring substances Genomic or biophysical data Physiological pathways Targets/receptors Transgenic organisms |
| Restrictions on imitators | <ul style="list-style-type: none"> Ability to block “product by process” imports Ability to block testing of production processes Ability to block stockpiling of patented products by generics in advance of patent expiration Ability to block reimportation/parallel trade |
| Obligations of patentees | <ul style="list-style-type: none"> Disclosure requirements (depositing microorganisms or cell cultures, genetic sequences, best mode etc.) Compliance with competition policy (or exemptions) Disclosure of the origin of genetic resources or traditional knowledge |
| Enforcement/challenge mechanisms for all IPRs | <ul style="list-style-type: none"> Preliminary injunctions: availability/standards Presumption of validity Recovery of lost profits |

| | |
|------------------------------------|---|
| | Recovery of “reasonable royalty” Punitive damages: how much, when awarded Judicially applied limitations on enforcement Criminal counterfeiting: penalties, burden of identifying, prosecuting, etc. Incentives to challenge patents e.g. Hatch-Waxman Pre/post grant opposition |
| Trademarks | Protection of brand names Protection of “trade dress” |
| Copyright | Marketing/training materials |
| Data exclusivity | When/if imitators can rely on innovator’s submission of safety/efficacy data When/if imitators can rely on innovator’s submission of manufacturing data |
| Database protection | Proprietary collections/linking of physical, genomic, epidemiological data |
| Special provisions | Government rights in inventions arising from publicly funded research Research exemptions Prior user rights Compulsory licensing in public health emergencies Compulsory licensing for other reasons Exclusive marketing rights under TRIPS |
| Bilateral treaty provisions | Other restrictions or exemptions specific to products of certain countries |

CONCLUSIONS

Intellectual property rights are one of the most important aspects of the clinical research world. Give credit where credit is due, pay for things that require payment, and set an example for others, whether they’re creative professionals or simply consumers.^[51]

Pharmaceuticals are an interesting area. In this area, Patents are the most visible and perhaps most important form of intellectual property, other IP rights also play a significant role. All other IPR include copyright in supporting publications and materials, trademark protection of brands, and administrative mechanisms or sui generis provisions giving proprietary rights in clinical and manufacturing data used to support regulatory approval. Copyright and database protection may also be playing an increasingly important role as research relies increasingly on bio-informatics and other in silico research methods to analyze very large databases of genetic, clinical, and bio-physical data (Cockburn (2005)).^[50]

ACKNOWLEDGMENT

I would like to credit the all sites and reference authors. I have assign all the information in a particular way so that students learn quickly about clinical research Intellectual property rights.

REFERENCES

1. <http://www.phrma.org/innovation/intellectual-property>
2. http://www.wipo.int/export/sites/www/ip-development/en/economics/pdf/wo_1012_e_ch_5.pdf
3. http://www.wti.org/fileadmin/user_upload/wti.org/7_SECO-WTI_Project/Publications/Managing%20IP%20over%20clinical%20test%20data_Andanda_forthcoming%20in%20the%20journal%20of%20IP%20and%20competition%20Law.pdf
4. <http://www.jli.edu.in/blog/intellectual-property-rights-iprs-and-its-importance/>
5. http://www.edctp.org/fileadmin/documents/EDCTP_Intellectual_Property_Rights_Policy.pdf
6. <http://www.research.uky.edu/ip/IPGuide5.pdf>
7. http://www.un.org/millenniumgoals/pdf/Think%20Pieces/11_ips_science_innovation_technology.pdf
8. <http://study.com/academy/lesson/what-is-intellectual-property-law-definition-and-rights.html>
9. <http://www.phrma.org/research-development-process>
10. <http://ca-biomed.org/pdf/media-kit/fact-sheets/cbradrugdevelop.pdf>
11. 35 U.S.C. § 154.
12. 35 U.S.C. § 154.
13. 35 U.S.C. § 112.
14. 35 U.S.C. § 112.
15. 35 U.S.C. § 271(e)(1) exempts acts of making, using, selling, offering for sale or importing a patented invention solely for uses reasonably related to the development of the submission of information under Federal law that regulates drugs.
16. 35 U.S.C. § 271(e)(2)(A).
17. 35 U.S.C. §155.
18. 35 U.S.C. § 156 (a)(4).
19. 35 U.S.C. § 156(c).

20. 35 U.S.C. § 156(c)(3).
21. This paper uses the term trademarks to refer to trademarks and servicemarks collectively.
22. Title 15, U.S.C.
23. 15 U.S.C. § 1114(1).
24. 15 U.S.C. § 1125.
25. 15 U.S.C. § 1064.
26. 15 U.S.C. § 1064.
27. This is considered a single-blind study.
28. This is a double-blind study.
29. Title 17, U.S.C.
30. 17 U.S.C. § 106.
31. 17 U.S.C. § 107. Fair use is usually applicable in news reporting and educational settings.
32. 17 U.S.C. § 302.
33. See *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000) (No copyright infringement where label for generic version of Nicorrete gum was same).
34. *Id.* at (2).
35. *Upjohn Co. v. Freeman*, 906 S.W. 2d 92, 101 (1995 Tex. App.).
36. *Id.* at 102 citing *Grundberg v. Upjohn*, 137 F.R.D. 372, 394-395. (D. Utah 1991)).
37. See *International News Service v. Associated Press*, 248 U.S. 215 (1918) (where news is deemed to be property as between the two parties but not as against the world).
38. See *Transkaryotic Therapies, Inc. v. Bain & Co., Inc.*, 2002 Mass. Super. Lexis 73, (2002).
39. *Id.*
40. *Hoffman-LaRoche Inc. v. Yoder*, 950 F. Supp. 1348, 1359 (S.D. Ohio 1997).
41. *Id.* at 1360.
42. *Id.* at 1361-1365.
43. 5 U.S.C. § 552(b).
44. *Public Citizen Health Research Group v. Food and Drug Administration*, 953 F. Supp. 400, (D.D.C. 1996)
45. *Id.* at 402-403.
46. *Pfizer Inc. v. ICI Americas Inc.*, 1984 Del. Ch. LEXIS 566, 12.
47. *Id.* at 15-17.
48. *Id.* at 17-18.

49. See *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984) (regulatory takings found where submission of information under the Federal Insecticide, Fungicide, and Rodenticide Act were done confidentially and then subsequent applicants were allowed to rely on those studies); See also Citizen's Petition filed by Pfizer Inc. and Pharmacia Corp at <<http://www.fda.gov/ohrms/dockets/dailys/01/Jul01/073001/cp00001.pdf>> (reliance on another's clinical trials without permission for a 505(b)(2) application is an unconstitutional takings).
50. Rachel Kreppel [CLINICAL TRIALS: A NEW FORM OF INTELLECTUAL PROPERTY?]
51. <http://www.smashingmagazine.com/2010/11/why-intellectual-property-rights-are-so-important/>