
Jacob R. Osborn

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A VIEW OF THE HIERARCHY OF PATENT RIGHTS, TRIPS, AND THE CANADIAN PATENT ACT

Jacob R. Osborn

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I. INTRODUCTION

Many have appropriately criticized international law as being vague and ambiguous.\(^1\) Though arguably applicable to other areas of law, international law is particularly subject to interpretive criticism because

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International law is a body of vague rules for the attention of the political scientists and the amusement of the law student not much interested in law. It should not be confused with real law, which, as Mr. Justice Holmes pointed out, is "the articulate voice of some sovereign or quasi-sovereign that can be identified."

Id. (quoting S. Pac. Co. v. Jensen, 244 U.S. 205, 222 (1917) (Holmes, J., dissenting)).

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of the broad terms in which international legal provisions are generally defined.\(^2\) When a substantive issue is interpreted under international law, one is frequently left with the notion that the judicial interpreters developed the legal dicta in support of the arrived-at legal determination based on the desire to effectuate a particular outcome.\(^3\) Often, this situation may arise in the context of an international judicial body considering whether a national legal provision is in conformity with an international agreement.

In general terms, it is not always the best legal argument that wins international disputes. In certain international disputes, beyond proffering seemingly flawless legal arguments favoring the interpretation of the international law in a party’s favor, an advocate may be wise to offer policy arguments as to why the legal interpreters should favor a specific interpretation. In addition, if the legal interpreters have preconceived notions regarding the most desirable policy to advance, alternative means should be considered to effectuate the desired outcome.

Accordingly, a legal advocate should consider various methods of using the legal system to his advantage. For instance, one might consider advancing a “historical analysis” approach to interpreting the terms within an international agreement. In this way, rather than accepting the textual basis for international laws as standing on its own merits, one could more properly view the law in context of the intentions and historical significance surrounding its formulation.

In this paper, Section I introduces the international dimension of intellectual property with respect to the Trade Related Aspects of Intellectual Property (TRIPS) Agreement and the Dispute Settlement Understanding for resolving conflicts thereupon. Section II proceeds to examine two facets of the Canadian Patent Act: the Regulatory Review


\(^3\) See Fred Rodell, *Woe Unto You, Lawyers!* 50 (1939).

But a non-lawyer, untrained in legal logic and trying to find a definition of Consideration that made sense to him, might well put the whole business completely in reverse. He might say that, so far as he can see, Consideration is what there is when a court upholds a promise and what there isn’t when a court refuses to uphold a promise. In other words, the whole question of whether a court is going to say there is Consideration or not comes down to a question of whether the court is going to uphold the promise or not. And though, to a lawyer, such a notion would amount to blasphemy, there is no doubt at all that from a practical standpoint the apparently naïve non-lawyer is exactly right.

_Ibid._
Exception and the Stockpiling Exception. While the international judicial authority determined that the Regulatory Review Exception was in conformity with TRIPS, the authority also found the Stock Piling Exception in violation of Article 30 of the TRIPS Agreement. Finally, Section III offers an alternative, historical approach to construing TRIPS, based on the substantive rights granted in United States patent law, and consistent with the interpretation of “limited exceptions” embodied by the Stock Piling Exception of the Canadian Patent Act.

II. THE INTERNATIONAL DIMENSION OF INTELLECTUAL PROPERTY

Intellectual property is commonly understood to be a distinct type of legal monopoly over a creation of the mind, both artistic and commercial, and the corresponding fields of law. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works, discoveries and inventions, and words, phrases, symbols and designs, in order to create incentives for development. Although common types of intellectual property include copyrights, trademarks, patents, industrial design rights, and trade secrets, the primary focus of this article will be with respect to substantive patent requirements under the international framework known as the TRIPS Agreement.

Traditionally, intellectual property has been a function of national law. In other words, the protection of intellectual property rights has traditionally been entirely within the realm of national law. Although this continues to be the case, the TRIPS Agreement provides rules requiring national governments to ensure a certain minimum level of protection for patents, copyrights, industrial designs, trademarks, business secrets, and similar matters.

5. See generally, 2 JAY DRATLER & STEPHEN McJOHN, INTELLECTUAL PROPERTY LAW: COMMERCIAL, CREATIVE, AND INDUSTRIAL PROPERTY Chs. 5-7 (Law Journal Press 1991); TIMOTHY P. TRAINER & VICKI E. ALLUMS, PROTECTING INTELLECTUAL PROPERTY RIGHTS ACROSS BORDERS, Ch. 1 (Thomson Reuters/West 2008).
6. See WORLD INTELLECTUAL PROPERTY ORGANIZATION, INTRODUCTION TO INTELLECTUAL PROPERTY: THEORY AND PRACTICE, Ch. 1 (Kluwer Law International Ltd. 1997).
7. See ARTHUR MILLER & MICHAEL DAVIS, INTELLECTUAL PROPERTY: PATENTS, TRADEMARKS, AND COPYRIGHT IN A NUTSHELL, Ch. 1 (West Group, 2000).
8. See, e.g., DONALD CHISUM, CHISUM ON PATENTS, Appendix 5, Regulations under the PCT (2009).
A. **TRIPS Framework**

The Uruguay Round Agreement on TRIPS conducted within the framework of the General Agreement on Tariffs and Trade ("GATT") came into effect in 1995. This multilateral agreement established by the World Trade Organization (WTO) created substantive and procedural obligations meant to be binding on all WTO signatories. The WTO is currently comprised of 153 member states, each member as diverse as the body of law that they are governed by.

On its face, the TRIPS Agreement recognizes the need to reduce distortions and impediments to international trade, the need to promote effective and adequate protection of intellectual property rights, and the need to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. Dissatisfaction with international intellectual property agreements and the variance of rights afforded to inventors prompted developed countries to pressure developing countries for the inclusion of intellectual property rights during the Uruguay Round Negotiations.

With respect to patents, the TRIPS Agreement defines the subject matter covered, establishes the rights conferred, and creates the minimum duration of protection. Although member countries may provide more extensive coverage than is required by the TRIPS Agreement, TRIPS is properly understood to be the minimum standards to which each member must adhere.

B. **The Dispute Settlement Understanding**

An international agreement such as TRIPS is largely ineffective without an appropriate mechanism for enforcement. Accordingly, the

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11. Id. at 22.
15. Mota, supra note 9, at 534-35.
16. Id. at 535.
17. Some suggest that the World Intellectual Property Organization (WIPO), a specialized agency of the United Nations that administers the Paris and Berne Conventions among other intellectual property conventions, would be better suited to enforce intellectual property mechanisms. However, because the enforcement body for WIPO is the International Court of
WTO established a Dispute Settlement Body (DSB) under the Dispute Settlement Understanding (DSU) as a mechanism for enforcement of the provisions of TRIPS. Under the DSU, any of the 153 member states of the WTO may request a consultation with the DSB when a violation of the TRIPS Agreement is perceived. If the dispute is not resolved, the member state alleging a violation may request that a panel be established to hear and determine the dispute. Furthermore, the WTO may impose trade sanctions against other member states that refuse to comply with adverse decisions rendered by the panel established under the DSU.

The panel established by the DSU is similar to a trial court in that each party presents a case, and then a determination is made by the panel with respect to the alleged violation of TRIPS. As of March 2008, twenty-three requests for consultations under claimed TRIPS violations had been made through the dispute settlement process. Although most of the twenty-three disputes were resolved under mutually agreed settlements, a handful proceeded to the panel stage where they were determined by an appellate body.

III. THE CANADIAN PATENT ACT UNDER FIRE

In April 2000, the WTO panel considered whether two provisions of Canada’s Patent Act conformed to the TRIPS Agreement. While the Appellate Body found that Canada’s Regulatory Review Exception was in accordance with TRIPS, the Appellate Body also found that Canada’s Stockpiling Exception violated Article 30.

In relevant part, the panel considered whether two provisions of the Canadian Patent Act were in accord with TRIPS Articles 27.1, 28.1, 30, and 33. Article 27.1 simply requires that the grant of a patent should not be discriminated against based on the field of technology. In addition,
Article 33 requires that the term of patent protection shall be no fewer than twenty years from the filing date of the patent application.\textsuperscript{27}

Article 28.1 provides the core rights that a patent shall confer:

A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product.\textsuperscript{28}

While Article 28.1 provides the core rights that a patent shall confer, Article 30 provides an exception to the exclusive rights of Article 28.1. According to 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.\textsuperscript{29}

Thus, in order for a member state to provide an exception to the exclusive rights of making, using, offering for sale, selling, or importing for these purposes, a three-part test is to be applied. The three prongs of the test are that: (1) the exception must be limited; (2) the exception must not unreasonably conflict with the normal exploitation of the patent; and (3) the exception must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

A. The Regulatory Review Exception

The panel considered whether two distinct provisions of the Canadian Patent Act were in compliance with TRIPS.\textsuperscript{30} The first

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\textsuperscript{27} Id. at Art. 33 (“The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”).

\textsuperscript{28} Id. at Art. 28.1.

\textsuperscript{29} Id. at Art. 30.

\textsuperscript{30} See European Cmty. v. Canada, supra note 4, at ¶ 8.1.
provision, known as the Regulatory Review Exception, provided that it would not be infringement for a person to construct, use, or sell the patented invention for uses related to the development and submission of information required by the law.\(^{31}\) In practice, the Regulatory Review Exception allowed third parties such as generic drug companies to make, use, or sell the patented product during the term of the patent without the consent of the patent owner. As recognized by the panel, this type of exception is an important advantage to generic drug manufacturers, because usually, a generic manufacturer is required to spend from two to four years in the development of its regulatory submission.\(^{32}\) If the generic drug company was unable to gather this information during the applicable period of the patent, because the generic drug company would be unable to compete with the original patent holder until the regulator review process concluded, it would effectively extend the market exclusivity of the original patent holder by a period of two to five years. The text of §55.2(1) of the Canadian Patent Act stated,

> 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 a law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.\(^{33}\)

In the United States, the Regulatory Review Exception is commonly known as a *Bolar* Exception, named after the U.S. case *Roche Products v. Bolar Pharmaceutical*.\(^ {34}\) In 1984, the United States Court of Appeals for the Federal Circuit determined that Bolar was prohibited from using a chemical patented by Roche in experiments to determine its bioequivalence to Valium, in order to obtain FDC approval for its generic version of Valium.\(^ {35}\) The U.S. court rejected the argument that the use by Bolar constituted an "experimental use," because Bolar ultimately intended to sell its generic product after patent expiration, and therefore had a business as opposed to an experimental purpose.\(^ {36}\) In

\(^{31}\) *Id.* at ¶ 2.1.

\(^{32}\) *Id.* at ¶ 2.5.


\(^{35}\) *See Roche Prods.*, 733 F.2d 858.

\(^{36}\) *Id.* at 863. The Court of Appeals for the Federal Circuit additionally noted that apparent policy conflicts between statutes such as the Food and Drug Act and the Patent Act should be decided by Congress and not the courts. *Id.* at 863-64.
response, Congress passed a law permitting use of the patented products in experiments for the purposes of obtaining FDA approval.\(^{37}\)

Thus, at the time of the panel report, the United States also had a statutory regulatory review exception. In addition, after the conclusion of the TRIPS Agreement, four other WTO Members—Argentina, Australia, Hungary and Israel—also adopted legislation containing regulatory review exceptions.\(^{38}\)

A layperson may suppose that the panel would consider that various signatories of the WTO recognized the Bolar Exception in compliance with TRIPS, and therefore arrive at the simple legal conclusion that the Bolar Exception was in compliance with the broad “limited exceptions” provision of TRIPS.\(^{39}\) Rather, the panel issued a 200-page report\(^{40}\) finding that the Canadian Regulatory Review Exception was in fact a limited exception, did not conflict with a normal exploitation of patents, and did not prejudice the legitimate interest of affected patent owners within the meaning of Article 30.\(^{41}\) With respect to interpreting “limited exception,” the panel noted, “As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded.”\(^{42}\) Thus, Canada’s Regulator Review Exception was found to be consistent with the provisions of TRIPS.

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38. Jackson, supra note 22, at 1014. Furthermore, both Japan and Portugal adopted interpretations of existing patent law which confirmed exemptions for regulatory review submissions, either in the interpretation of “experimental use” or in similar patent exceptions. Id. at 1014-15.
39. See FRED RODELL, WOE UNTO YOU, LAWYERS! 7 (1939).
   Briefly, the Law is carried on in a foreign language. Not that it deals, as do medicine and mechanical engineering, with physical phenomena and instruments which need special words to describe them simply because there are no other words. On the contrary, law deals almost exclusively with the ordinary facts and occurrences of everyday business and government and living. But it deals with them in a jargon which completely baffles and befuddles the ordinary literate man, who has no legal training to serve him as a troth. Id.
41. See European Cmtyys. v. Canada, supra note 4, at 158.
42. Id. at ¶ 7.45. The Panel also noted that:
   Even though regulatory approval processes may require substantial amounts of test production to demonstrate reliable manufacturing, the patent owner’s rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of resulting final products.
A VIEW OF THE HIERARCHY OF PATENT RIGHTS

B. The Stockpiling Exception

The second provision considered by the panel, known as the Stockpiling Exception, provided that it would not be infringement for a person to make, construct, or use the invention during the applicable period, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires. The text of §55.2(2) stated:

It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires.\(^{43}\)

In effect, this statute provided for any generic drug company in Canada to perform the acts of making, constructing, and using the patented invention during the last six months of the patent term without authorization of the patent holder.\(^{44}\) In contrast to the Regulatory Review Exception, Canada was the only country in the world to allow for such a Stockpiling Exception.\(^{45}\)

Notably, the Stockpiling Exception was part of the Canadian Patent Act Amendment Act, which entered into force in February 1993, more than a full year before the 1994 TRIPS Agreement.\(^{46}\) However, contrary to the Regulatory Review Exception, the Stockpiling Exception of Canada’s Patent Act was found to violate Canada’s obligations under TRIPS because it was not a “limited exception” under Article 30.\(^{47}\) According to the panel, with no limitations upon the quantity of production, the Stockpiling Exception removed the patent protection entirely during the last six months of the patent term, including additional commercial and market benefits via a short period of extended market exclusivity after the patent expires.\(^{48}\) The panel determined that “limited exception” referred to “the exclusive rights,” and therefore must

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Id.

44. See European Cmty's v. Canada, supra note 4, at ¶ 4.2.
45. Id. at ¶ 4.2.
46. Id. at ¶ 4.6.
47. Id. at ¶¶ 7.33 – 7.36.
48. Id. at ¶¶ 7.34 – 7.35.
be read to connote a narrow exception, one which makes only a small diminution of the rights in question.49

Having determined that Canada’s Stockpiling Exception was not a “limited exception,” the panel found it unnecessary to consider whether the Stockpiling Exception was in accord with the second and third prongs of the test.50

C. Interpretation of Limited Exceptions

The panel decision was inconsistent on various levels, and as a result, has been widely criticized.51 In plain terms, the panel determined that the Stockpiling Exception was not limited because the patent rights of Article 28.1 include indirect rights occurring after the term of the patent, such as the market benefits during the short period of extended market exclusivity after the patent expires. However, although the same thing could be said for the Regulatory Review Exception, the panel made no mention of this fact.

In addition, while the panel considered all three prongs of the test in parallel when deciding the fate of the Regulatory Review Exception, the panel only considered the first part of the test with respect to the Stockpiling Exception. This piecemeal interpretation effectively limited the decision to “limited exceptions,” rather than appropriately considering the impact of the statute on the normal exploitation of the patent and the possible prejudice of the legitimate interests of the patent owner. It is difficult to imagine how these two prongs would have varied from the analysis applied to the Regulatory Review Exception, except that the analysis may have varied in favor of Canada.

Ironically, it may be that Canada did not appeal the panel decision to the Appellate Body because the Stockpiling Exception was much more limited than the Regulatory Review Exception. It is likely that the Regulatory Review Exception is actually more beneficial to the generic drug companies than the Stockpiling Exception. For instance, it may take a generic company many years to comply with the regulatory review established by the government if the statutory exception would have been found to be invalid. These many years could have adverse

49. Id. at ¶ 7.30.

50. Id. at ¶ 7.38. The second and third prongs of the test are: (2) the exception must not unreasonably conflict with a normal exploitation of the patent, and (3) the exception must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Id. at ¶¶ 7.51, 7.60.

affects on getting the generic drug to the market quickly, thereby *de facto* prolonging the length of the patent holder's rights.

If the Stockpiling Exception would have been determined to be in compliance with TRIPS and the Regulatory Review Exception conflicting with TRIPS, the result is that the Stockpiling Exception would not have been as beneficial to the generic drug companies as the Regulatory Review Exception. Although the generic drugs would have been able to more quickly enter the market with stockpiled supplies, in most instances it would not take a generic drug company as long to manufacture the drug as it would to complete the regulatory review process required by the government.

It is likely that the panel arrived at the above interpretation of TRIPS simply because Canada was the only member state with a prior Stockpiling Exception. Justifying the panel decision on the grounds that Canada was the only member state with a prior Stockpiling Exception may have made more sense than interpreting the word "limited" in the context of exclusive market rights. In short, one is left wondering how the panel determined the broader of the two limitations to be the sole limited exception.

**IV. THE HIERARCHY OF PATENT RIGHTS**

The rights included in TRIPS Article 28.1 are to prevent third parties from: (1) making; (2) using; (3) offering for sale; (4) selling; or (5) importing for these purposes, the patented invention.52 These five, distinctive rights are inherently hierarchical. A historical analysis of these distinctive rights suggests that they have not always been treated the same under legal jurisdictions. In addition, the modern-day application of widely accepted curtailments to these rights further suggests that they are not all to be treated equally in every respect.

In promoting the arts and sciences, it is generally understood that for the public utility obtained by disclosure of the invention, the patentee is granted a limited monopoly in order to profit from the invention.53 In exchange for his invention and the knowledge imparted by his disclosure of the invention, the reward bestowed on the inventor can be readily summarized as the ability to exclusively profit from his invention. Essentially, a system that affords the exclusive right to profit in exchange for disclosure of invention partially dispenses to the free market the ultimate value of the compensation for actualizing an

52. TRIPS Agreement, *supra* note 10, Art. 28.1.
53. WORLD INTELLECTUAL PROPERTY ORGANIZATION, *supra* note 6, at Ch. 1.
invention. By way of example, the monetary amount that the public is willing to pay for the invention, absent the traditional free-market decrease in price due to competition, is the price that the inventor may charge for his patented invention.

Assuming, arguendo, that the right to profit from the invention is a primary benefit conferred to inventors in our current patent system, then one must consider why rights, other than the right to exclude others from selling the invention, are included in the modern formulation of patent laws. In conceptual terms, it is apparent that the right to sell the invention is most directly linked to the value of compensation for actualizing the invention. However, the rights to make, use, offer for sale, or import the invention may or may not be directly related to the ability of the patentee to exclusively profit from his invention.

In summary, “secondary” rights (i.e., rights tangential, but possibly related to the right to profit) are likely included in modern patent laws in order to ensure the right of the inventor to profit from his invention remains fully undiminished. As an illustrative example, if someone were to offer to sell an invention patented by another, this offer for sale may or may not have an effect on the bottom-line price, which the patentee may obtain for his invention. First, the offer for sale may be at a much higher price than the price at which the patentee sells his patented invention, thus eliciting a rejection of the offer and consumer understanding that the patentee indeed offers the invention at the best price. In theoretical free-market analysis, there is unlikely to be an economic difference to the bottom-line economic benefit of the patentee between the situations where: (1) the consumer understands that a patentee is the exclusive provider of the good; and (2) the consumer understands that a patentee is the lowest price provider of the good.\textsuperscript{54} However, if the offer for sale is at a price much lower than the price at which the patentee sells his invention, the consumer may choose to forego purchase of the good from the patentee, because the patentee does not offer the good at the lowest price. Therefore, in some instances, it is possible that an “offer for sale” has a direct effect on lowering the exclusive right to profit of the patentee.\textsuperscript{55}

\textsuperscript{54} By way of example, this hypothetical assumes a theoretically efficient market based on full consumer knowledge of the prices of goods.

\textsuperscript{55} It is also possible that a consumer could purchase the first good he finds on the market, regardless of price. This could also have an effect on the right of the inventor to exclusively profit. Also, note that an “offer for sale” during the end years of a patent term could delay a consumer’s purchase, to cause him to wait until the non-patent holder may enter the market.
Assuming that the goal of the patent system is to reward the patentee by providing him the right to exclusively profit from his patented invention during the length of the patent term in exchange for the disclosure and eventual public utility of the invention, one would expect to find curtailments to the "secondary" rights bestowed to the patent holder in cases where his profit is unaffected. As expected, in situations where the right of the inventor to monopolistically profit from his invention remains unimpaired, historical analysis reveals that governing bodies are most comfortable with legislating curtailments to secondary rights.

In United States law, the same rights as those enumerated in Article 28.1 are currently codified in 35 U.S.C. § 154. Some have appropriately criticized the textual basis of TRIPS as derived from the laws of developed countries. In fact, analysis of the language of TRIPS suggests that much of the text was copied from U.S. law at the time of the drafting of TRIPS. Therefore, if much of the basis of the textual significance was extrapolated from U.S. law, it may then be appropriate to consider whether the United States considers a hierarchy of significance to these rights.

A. 1770 - 1836

U.S. law did not always provide for each of these five distinctive rights. In the United States, the first Patent Act of 1790 contained only three of these rights—the rights to make, use, and vend—for the limited duration of fourteen years. As a remedy, the 1790 Patent Act provided for jury-assessed damages and forfeiture of the infringing items to the patent holder. Shortly thereafter, in 1793, the Patent Act was revised.

56. "Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States . . . ." 35 U.S.C. § 154(a)(1) (2002).


58. "... and thereupon granting to such petitioner or petitioners, his, her or their heirs, administrators or assigns for any term not exceeding fourteen years, the sole and exclusive right and liberty of making, constructing, using and vending to others to be used, the said invention or discovery . . . ." Patent Act of 1790, Ch. 7, 1 Stat. 109-112 (April 10, 1790) (current version at 35 U.S.C. § 154 (2002)).

While the 1793 revision did not affect the exclusive rights granted to the inventor, it provided protection exclusively for U.S. citizens, modified the types of infringement that warranted a remedy, and revised the compensation to be granted in the event of infringement. A remedy was warranted in three distinct cases. The first case was when any person makes the thing invented; the second case was when any person devises and uses the thing invented; and the third case was when any person sells the thing invented. Remarkably, simply using the invention did not rise to the level of infringement. In addition, offering to sell the invention did not rise to the level of infringement.

The exclusive remedy provided to the patent holder was that the infringer should pay a sum at least three times the price of which the patentee has usually sold or licensed the patented item. Thus, the modern notion of an injunction was deleted from the final wording of the Patent Act of 1793.

As can be seen, from an early point in patent law history, it is clear that a great emphasis was placed on the monetary reward that the patentee was granted in exchange for his disclosure of the invention. This historical emphasis is consistent with the modern incentive-based justification for our patent system. In fact, an infringer could simply

And be it further enacted, That if any person or persons shall devise, make, construct, use, employ, or vend within these United States, any art, manufacture, engine, machine or device, or any invention or improvement upon, or in any art, manufacture, engine, machine or device, the sole and exclusive right of which shall be so as aforesaid granted by patent to any person or persons, by virtue and in pursuance of this act, without the consent of the patentee or patentees, their executors, administrators, or assigns, first had and obtained in writing, every person so offending, shall forfeit and pay to the said patentee or patentees, his, her or their executors, administrators or assigns such damages as shall be assessed by a jury, and moreover shall forfeit to the person aggrieved, the thing or things so devised, made, constructed, used, employed or vended, contrary to the true intent of this act, which may be recovered in an action on the case founded on this act.

Id.


61. Id.

62. Id.
elect to infringe the patent and sell the patented invention if he were willing to compensate the patent holder at a rate of three times the price at which the patent holder sells the invention. Moreover, importation or an offer to sell the invention did not even rise to the level of infringement. The 1793 Patent Law included that a third party would infringe the patent by devising and using the patented invention, not by merely using the invention. Taken in context, this language was likely incorporated to prohibit the infringer from circumventing the intentions of the law by selling something other than the patented invention itself (e.g., services and use of the patented invention to the benefit of his customers).

B. 1836—Current

The Patent Laws were again revised in 1836, but did not vary significantly from the language used in the eighteenth century—this included the rights to make, use, and vend. While the 1836 Patent Laws included only a remedy of monetary damages, not until 1870 were the Patent Laws revised to again include a remedy for an injunction. As an equitable remedy, the injunction allowed the court to prohibit the infringement from occurring in the future, in situations where monetary damages were unable to solve the problem.

Then, in 1952, the text of the Patent Laws was changed from “the full and exclusive right and liberty of making, using, and vending to others to be used” to “the right to exclude others from making, using, or

63. Patent Act of 1836, Ch. 357, § 14 (1836) (current version at 35 U.S.C. § 284 (1999)). Every such patent shall . . . grant to the applicant or applicants . . . the full and exclusive right and liberty of making, using, and vending to others to be used, the said invention or discovery . . . . And be it further enacted, That whenever, in any action for damages for making, using, or selling the thing whereof the exclusive right is secured by any patent heretofore granted, or by any patent which may be hereafter granted, a verdict shall be rendered for the plaintiff in such action, it shall be in the power of the court to render judgment for any sum above the amount found by such verdict as the actual damages sustained by the plaintiff, not exceeding three times the amount thereof, according to the circumstances of the case, with costs; and such damages may be recovered by action on the case, in any court of competent jurisdiction, to be brought in the name or names of the person or persons interested; whether as patentees, assignees, or as grantees of the exclusive right within and throughout a specified part of the United States.

Id.

64. “. . . and the court shall have power, upon bill in equity filed by any party aggrieved, to grant injunctions according to the course and principles of courts of equity, to prevent the violation of any right secured by patent, on such terms as the court may deem reasonable . . . .” Patent Act of 1870, Ch. 230, 16 Stat. 198-217 (1870) (current version at 35 U.S.C. § 283 (1952)).
In part, the wording of the granting clause was changed to "selling" following language used by the Supreme Court, in order to render the meaning clearer. However, as of 1952, the rights to exclude others from "offering to sell" or "importing" the patented invention remained excluded from U.S. Patent Laws.

Not until the Patent Amendment Act of 1996 did the U.S. Patent Laws supplement the rights of excluding others from "offering for sale" and "importing" the patented invention to the traditional basic rights of making, using, and selling. In fact, prior to the 1996 Amendment, actions other than unauthorized making, using, or selling did not constitute infringement of the patent even though they may have impaired or lessened the patent's economic value. The exclusive right to offer the patented invention for sale extended the scope of the patentee's rights to unauthorized activities that fell short of actual selling, making, or using.

It is possible that the inclusion of "offering for sale" and "importing" in the Patent Act of 1996 was, to a large extent, due to the effects of globalization. In the 1700s and 1800s, it would not have been as likely that an offer for sale could have such a drastic effect on the ability of the patentee to exclusively profit from his invention during the patent term. Presently, a producer of goods is able to use the Internet and modern advertising methods to immediately offer for sale to millions of prospective consumers. Similarly, the sheer number of goods imported into the United States far exceeds those imported earlier in the nation's history. Thus, it is suggested that the inclusion of these "secondary" rights ultimately evolved under the modern theory that the patentee has the exclusive right to profit from his invention during the applicable patent term, although this right to profit may or may not be affected by these "secondary" rights.

C. Modern Day Limitations

The legislative history and modern day limitations placed on patent rights suggest that not all patent rights are to be treated equally.

65. "Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof." Patent Act of 1952, Ch. 14, § 154 (1952) (current version at 35 U.S.C. § 154 (2002)).
66. Chisum, supra note 8, at § 16.02.
67. Id.
68. Id.
69. Id.
Limitations on granting injunctions, the Patent Exhaustion Doctrine, and exceptions for scientific research further suggest that the ultimate right to profit from the patented invention during the patent term is the primary intent of our patent laws. An understanding that the underlying intent of the patent laws is to protect the right of the patentee to exclusively profit from his invention advances the notion of a hierarchical approach to understanding the rights of the patentee.

First, the limitation on the grant of an injunction suggests that a primary purpose in our patent system is to allow the patent holder to exclusively profit from his invention during the patent term. The Supreme Court recently determined in *eBay v. MercExchange* that a four-factor test, historically employed by equity courts in considering whether to award permanent injunctive relief to the prevailing plaintiff, should also apply to disputes arising under the Patent Act. In particular, the court determined that a prevailing plaintiff seeking a permanent injunction must demonstrate that: (1) the plaintiff has suffered an irreparable injury; (2) remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) when considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and (4) the public interest would not be disserved by a permanent injunction. The requirement that monetary damages be inadequate to compensate for the injury is consistent with the general theme that the patent system is ultimately designed to allow the patentee to profit from his invention, unimpeded by competitive market forces. In other words, courts are often complacent with infringing behavior, as long as the patentee is economically rewarded the value of his patent.

Second, a prong of the Patent Exhaustion Doctrine places a limit on the right to exclude others from “using” the patented invention, consistent with the theme of allowing the patentee to profit from his invention. According to the Patent Exhaustion Doctrine as interpreted by the Supreme Court, a person lawfully purchasing and using a patented product during the original patent term has a right to continue such use during any extension of the patent. The Supreme Court noted, “in the essential nature of things, when the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its...

71. *Id.*
use, he receives the consideration for its use and he parts with the right to restrict that use. The article . . . passes without the limit of the monopoly . . . .\textsuperscript{74} This limit on the right to exclude others from “using” a patented invention is consistent with the patentee’s right to profit from his invention.

The argument for a hierarchical approach to patent rights is further supported by the exceptions that are carved out to modern patent laws. Throughout history, in situations where the “secondary” rights are found to have no bearing on the right of the patent holder to profit from his invention, exceptions have been made. The experimental use exception to patent infringement is an example of such exceptions.\textsuperscript{75} Although this doctrine suffered a serious setback in the case of Madey v. Duke University,\textsuperscript{76} competing views have arisen over the significance of the experimental use doctrine in application to particular areas of technology.\textsuperscript{77} In general terms, the experimental use privilege allows a researcher to use a patented invention without permission from or compensation to the patent owner.\textsuperscript{78} However, the use must be “merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the invention to produce its described effects.”\textsuperscript{79} The curtailment on the exclusive right of the patent holder to preclude others from “using” the patented invention for experimental use seems consistent with the theme of the patentee to be compensated from his invention. In this situation, the experimental use of the invention is not a threat to the competition for sales of the patented invention by the patent holder.

\textsuperscript{74} Id. at 456.


It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) 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 or veterinary biological products.

\textsuperscript{76} The Federal Circuit held that the experimental use privilege does not apply to activities that are “in keeping with the alleged infringer’s legitimate business”—even though the business of the defendant, Duke University, was nonprofit research. Madey v. Duke University, 307 F.3d 1351, 1362 (2002).

\textsuperscript{77} JOHN R. THOMAS, SCIENTIFIC RESEARCH AND THE EXPERIMENTAL USE PRIVILEGE IN PATENT LAW, CRS REPORT FOR CONGRESS, at 2 (Oct. 28, 2004).

\textsuperscript{78} Id. at 6.

Both the historical interpretation and the modern application of patent law suggest that the over-reaching objective of compensation of the patent holder is the main intention and purpose of the patent laws. Put in simplistic terms, in exchange for the right to compensation not subject to ordinary competitive market forces, the patentee agrees to disclose his invention to the public.

D. Hierarchical Application to TRIPS

In interpreting TRIPS, the panel ultimately rejected the EC’s position that “limited exceptions” measures the curtailment of the patent owner’s rights by counting the number of legal rights impaired by an exception. The panel also rejected Canada’s argument that the curtailment of the patent owner’s legal rights is “limited” just so long as the exception preserves the exclusive right to sell to the ultimate consumer during the patent term. In support of the rejection, the panel suggested that:

implicit in the Canadian argument is a notion that the right to exclude sales to consumers during the patent term is the essential right conveyed by the patent, and the rights to exclude “making” and “using” the patented product during the term of the patent are in some way secondary.

The panel did not find support for creating a hierarchy of patent rights within the TRIPS Agreement because, “if the right to exclude sales were all that really mattered, there would be no reason to add other rights to exclude ‘making’ and ‘using.’” As shown by historical analysis and common sense application of the exceptions to patent law provisions, the panel was correct that the right to exclude sales is not all that really matters. Rather, the right of the patentee to exclusively profit from the patented invention during the term of the patent is what really matters. Under this proper analysis, the panel may have found support for creating a hierarchy of patent rights within the TRIPS Agreement.

V. CONCLUSION

In all likelihood, the inclusion of the rights of making, using, offering for sale, and importing are secondary to the overall right to

80. European Cmtns. v. Canada, supra note 4, at ¶ 7.32.
81. European Cmtns. v. Canada, supra note 4, at ¶ 7.33.
82. Id.
83. Id.
profit from the invention, and the closely related right to sell the patented invention. In any given situation, these secondary rights may or may not be directly linked to the right of the patent holder to be exclusively compensated for his invention. In order to guarantee that the patent holder is fully empowered to exclusively profit from his invention during the length of the patent term, history suggests that it is necessary to include these secondary rights into the set of rights given to the patent holder, at least in some form. However, inclusion of these secondary rights into modern patent laws should not completely remove the rights from the context in which they are given, especially when interpreting international law provisions. Courts, judicial interpreters, and legal advocates would be wise to understand patent rights in the context of history, by taking a hierarchical approach to patent rights.