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US and Canadian Law on Compulsory Licensing of Intellectual Property Rights

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Abstract. The relevance of scientific research lies in the fact that the article explores the theoretical and legal issues of the compulsory licensing in American and Canadian law. Compulsory licensing is a mechanism that allows the state or third parties to use intellectual property (IP) objects without the consent of the copyright holder, but with compensation. This tool is used to balance the interests of copyright holders and society, especially in cases where IP monopoly may impede access to important technologies, medicines or cultural goods. This article discusses the specifics of US and Canadian compulsory licensing legislation, as well as their practical application.The leading method of researching the problem was the deductive method, which made it possible to study the legal and social nature of the processes of using compulsory licensing in American and Canadian law. The article uses inductive method, method of system scientific analysis, comparative legal and historical methods. The leading method behind the problem is to justify the concept of carefully study of judicial practice (on the example of specific court cases) and legislation of US and Canadian compulsory licensing.The author of the article made the following conclusions. First, the convergence of US and Canadian approaches to compulsory licensing may facilitate more efficient use of this mechanism. Second, U.S. enforcement licensing jurisprudence demonstrates the importance of this tool in protecting competition and the public interest. Examples of court decisions such as United States v. Line Material Co. and eBay Inc. v. MercExchange, L.L.C., illustrate how compulsory licensing can be used to provide access to important technologies and medicines. However, its application comes with certain challenges, such as legal barriers and economic consequences. Further development of judicial practice in this area will depend on global challenges and changes in international law. Third, Canada's enforcement licensing jurisprudence demonstrates the importance of this tool in protecting the public interest, particularly in the area of access to medicines. Examples of court decisions such as Apotex Inc. v. Merck & Co. and Eli Lilly and Co. v. Canada, illustrate how compulsory licensing can be used to provide access to important technologies and medicines. However, its application comes with certain challenges, such as legal barriers and economic consequences.

Keywords: Antitrust regulation, Compulsory licensing, Copyright holder, Intellectual activity, License, Patent, Recording license.

1. INTRODUCTION

In the *US*, compulsory licensing is limited by strict conditions, making it difficult to enforce. Compulsory licensing can reduce incentives for innovation, especially in the pharmaceutical industry. The use of compulsory licensing can be controversial with other countries, especially in the context of international trade. It is important to note that in the United States, compulsory licensing is rarely used and mainly in cases related to antitrust regulation or public interest. For example, during the COVID-19 pandemic, the possibility of compulsory licensing of vaccine patents was discussed, but such measures were not taken.

In the United States, compulsory licensing is governed primarily by patent law. Unlike other countries, the United States does not have a general law on compulsory licensing [6]. However, there are separate mechanisms that can be considered as forms of compulsory licensing, including:

Antitrust: In cases where patents are used to limit competition, courts may require the copyright holder to grant licenses to third parties. For example, in United States v. Line Material Co. (1948) The U.S. Supreme Court upheld the state's right to interfere with patent rights to protect competition.

Bayh-Dole Act: This act allows the federal government to require licensing of patents created with government funding if the copyright holder does not ensure their practical application.

In the field of copyright, compulsory licensing is used in limited cases, such as: *mechanical licenses* (in accordance with section 115 of the Copyright Act, copyright holders of musical works are required to grant licenses to record and distribute their works after the first release), b) *digital broadcasting* (for example, section 114 of the Copyright Act provides for mandatory licensing for digital broadcasting of musical works) [3].

Canadian law provides greater opportunities for compulsory licensing compared to the United States. According to section 65 of the Canadian Patent Act, compulsory licensing can be granted in the following cases: a) insufficient use of the patent in Canada; b) the right holder's refusal to grant a license on reasonable terms; c) public interests such as access to drugs or technology.

2. METHODOLOGICAL BASE

The leading method of researching the problem was the deductive method, which made it possible to study the legal and social nature of the processes of using compulsory licensing in American and Canadian law. The article uses inductive method, method of system scientific analysis, comparative legal and historical methods. The leading method behind the problem is to justify the concept of carefully study of judicial practice (on the example of specific court cases) and legislation of US and Canadian compulsory licensing.

Compulsory licensing is governed by international agreements such as the TRIPS Agreement (Agreement on

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Trade-Related Aspects of Intellectual Property Rights), [1]which sets minimum standards for IP protection. [2]According to article 31 of TRIPS, compulsory licensing is permissible subject to certain conditions, including: preliminary negotiations with the copyright holder (except in extraordinary circumstances; payment of adequate compensation; limited license term.

3. RESULTS

In Canada, compulsory licensing in the field of copyright is governed by the Copyright Act. For example, section 70.1 provides for mandatory licensing for the translation of literary works if the copyright holder has not provided a translation within a certain period. Canada actively uses compulsory licensing to ensure access to medicines. For example, in 2007, the Government of Canada issued a compulsory license to manufacture generic antiretroviral drugs for export to Rwanda. This was done as part of amendments to the Patent Act, which allow the issuance of compulsory licenses for the export of drugs to developing countries [4].

Let's dwell on the legislation and judicial practice of some US states on compulsory licensing in the disposal of rights to the results of intellectual activity.

1. *The case of United States v. Line Material Co. (1948)* is one of the first examples of compulsory licensing in the United States. [3]In this case, the US Supreme Court considered the legality of agreements between patent holders that limited competition in the electrical market. Line Material Co. and Southern States Equipment Corp. entered into an agreement to mutually license patents, which led to the creation of a monopoly. The U.S. Supreme Court upheld the state's right to interfere with patent rights to protect competition. The court ruled that the use of patents to create monopolies could be restricted and ordered the copyright holder to grant licenses to third parties.[4]

2. *The case United States v. Glaxo Group Ltd. (1973).* Glaxo Group Ltd. held a patent for the antibiotic ampicillin and refused to grant licenses to other manufacturers, which led to the monopolization of the market. In this case, the court ordered Glaxo Group Ltd. to grant licenses for the production of the antibiotic ampicillin, citing antitrust laws. The court ruled that the use of patents to limit competition was unacceptable and ordered the copyright holder to grant licenses on reasonable terms.

3. *The case of eBay Inc. v. MercExchange, L.L.C. (2006)* [5]is an important precedent in patent law. MercExchange, L.L.C. filed suit against eBay Inc. for patent infringement of online auction technology. The trial court refused to issue an injunction, which allowed eBay to continue using the technology, paying compensation. The US Supreme Court ruled that courts should not automatically issue injunctions in cases of patent infringement. This decision opened the possibility for compulsory licensing, as copyright holders may be required to grant licenses instead of obtaining an injunction.

4. *The case Microsoft Corp. v. Motorola Inc. (2012).* [6]Motorola Inc. held the patents required for communications standards and required Microsoft Corp. to pay high licensing fees. Microsoft has filed a lawsuit alleging that Motorola is violating its obligations to grant licenses on reasonable and non-discriminatory terms (FRAND). In that case, the court ruled that Motorola Inc. must grant licenses to its patents necessary for communication standards on reasonable and non-discriminatory terms (FRAND). This case illustrates the importance of compulsory licensing in the field of standard technologies.[7]

5. *The case Apple Inc. v. Motorola Mobility Inc. (2014).* [8]Motorola Mobility Inc. held the patents required for communications standards and required Apple Inc. to pay high licensing fees. Apple has filed a lawsuit alleging that Motorola is violating its FRAND license obligations. In that case, the court ruled that Motorola Mobility Inc. must grant licenses to its patents necessary for communication standards on reasonable and non-discriminatory terms (FRAND). This case also illustrates the importance of compulsory licensing in the field of standard technologies.[9]

The main regulation governing compulsory licensing in Canada is the Patent Act. Under section 65 of the Act, compulsory licensing may be granted in the following cases: under-use of a patent in Canada, refusal of the copyright holder to grant a license on reasonable terms, public interest such as access to drugs or technology.

In the field of copyright, compulsory licensing is governed by the Copyright Act. For example, section 70.1 provides for mandatory licensing for the translation of literary works if the copyright holder has not provided a translation within a certain period.

Canada is a party to the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), which sets minimum standards for IP protection. According to article 31 of TRIPS, compulsory licensing is permissible subject to certain conditions, including preliminary negotiations with the copyright

[1]https://docs.cntd.ru/document/902340087
[2]https://rospatent.gov.ru/ru/docs/interdocs/trips
[3]For more details, see:https://supreme.justia.com/cases/federal/us/333/287/
[4]https://ballotpedia.org/UNITED_STATES_v._LINE_MATERIAL_CO._ET_AL._(1948)
[5]See details: https://supreme.justia.com/cases/federal/us/410/52/
[6]See details: https://law.justia.com/cases/federal/appellate-courts/ca9/14-35393/14-35393-2015-07-30.html
[7]https://patentlaw.jmbm.com/2012/10/microsoft-v-motorola-district.html
[8]См. подробнее: Motorola Mobility, Inc. v. Apple Inc., In the Matter of Certain Wireless Communication Devices, Portable Music and Data Processing Devices, Computers and Components Thereof, ITC Inv. No. 337-TA-745, 2010-10-6.
[9]https://www.lexology.com/library/detail.aspx?g=ae374ceb-85d9-44c6-9325-991ce7e3e1d6

holder (except in extraordinary circumstances), payment of adequate compensation and a limited license period.

Let's take a closer look at the legislation and judicial practice of Canada on compulsory licensing in the disposal of rights to the results of intellectual activity.

1. *The case of Apotex Inc. v. Merck & Co. (2002)* [10]is one of the best-known examples of compulsory licensing in Canada. [11]Apotex Inc., a Canadian pharmaceutical company, applied for a compulsory license to manufacture generic drugs of the drug losartan, the patent for which belonged to Merck & Co. The court granted Apotex's application, citing public interest and the need to ensure access to medicines at affordable prices. to section 65 of the Patent Act, which allows compulsory licences to be granted in case of under-utilisation of a patent. The court also considered public interests, such as the need to ensure access to medicines at affordable prices. The case is one of the most prominent examples of compulsory licensing in Canada. It illustrates how compulsory licensing can be used to provide access to important medicines.

2. *The case of Eli Lilly and Co. v. Canada (2017).* [12]In this case, Eli Lilly challenged the Canadian government's decision to grant a compulsory license to manufacture olanzapine generics. Eli Lilly argued that the decision violated its patent rights. The court confirmed the validity of the license, citing section 65 of the Patent Act and the public interest [1]. The court ruled that compulsory licensing is permissible in cases where it is necessary to ensure access to medicines. [13]This case illustrates the importance of compulsory licensing to ensure access to medicines. [14]It also confirms that the public interest can prevail over the rights of patent holders [2].

3. *The case Canada (Commissioner of Patents) v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning (1966)* is a classic example *of* compulsory licensing in Canada. In this case, the court considered an application for a compulsory license to produce the antibiotic tetracycline. The copyright holder, Farbwerke Hoechst, did not ensure sufficient use of the patent in Canada. The court granted the application for a compulsory license to produce the antibiotic tetracycline, citing insufficient use of the patent in Canada. The court also took into account public interests, such as the need to ensure access to important medicines. This case set an important precedent for subsequent decisions on compulsory licensing. It illustrates how compulsory licensing can be used to provide access to important technologies and medicines.

4. *The case Bayer Inc. v. Canada (Attorney General) (1999).* [15]In this case, Bayer Inc. challenged the Canadian government's decision to issue a compulsory license to manufacture generics of the drug ciprofloxacin. [16]Bayer argued that the decision violated its patent rights. The court upheld the validity of the license, citing the public interest and the need to ensure access to medicines.

The court ruled that compulsory licensing is permissible in cases where it is necessary to protect the public interest. This case illustrates the importance of compulsory licensing to ensure access to medicines. It also confirms that the public interest can prevail over the rights of patent holders.[17]

5. *The case AstraZeneca Canada Inc. v. Apotex Inc. (2014).* [18]Apotex Inc. applied for a compulsory license to manufacture generic esomeprazole, the patent for which belonged to AstraZeneca Canada Inc. Apotex argued that AstraZeneca did not provide sufficient use of the patent in Canada. The court granted Apotex's application, citing section 65 of the Patent Act, which allows compulsory licenses to be issued if a patent is underutilized. The court also considered public interests, such as the need to ensure access to medicines at affordable prices. This case illustrates how compulsory licensing can be used to ensure access to important medicines. It also confirms that the public interest can prevail over the rights of patent holders.[19]

Problems arising in this area can be conditionally classified into: a) legal barriers (the process of obtaining a compulsory license can be complex and lengthy, which makes it difficult to apply), b) economic consequences (compulsory licensing can reduce incentives for innovation, especially in the pharmaceutical industry); c) international disputes (the use of compulsory licensing can cause disputes with other countries, especially in the context of international trade).

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[10]See details: https://files.slaw.ca/cases/apotex_2012-01-18.pdf

[11]Merck Frosst Canada & Co. held the rights to a patented drug called norfloxacin. In the early 1990s, Apotex Inc. applied to the Minister of Health for a Notice of Compliance (NOC). Apotex alleged that it would not infringe Merck's patent as it would either use norfloxacin raw material acquired by a third company, Novopharm Ltd., under a license from Merck, or it would produce norfloxacin by a method that would not infringe the patent. Merck filed two applications to prohibit the Minister from issuing an NOC to Apotex.

[12]See details:https://www.researchgate.net/publication/316071599_Eli_Lilly_v_Canada_The_uncomfortable_liaison_between_intellectual_property_and_international_investment_law

[13] https://patentblog.kluweriplaw.com/2017/04/04/eli-lilly-v-canada-the-first-final-award-ever-on-patents-and-international-invest-ment-law/

[14]Other noticeable examples are Philip Morris v Australia and Philip Morris v Uruguay, regarding Philip Morris' trademarks (both cases are discussed in more detail in section 5.3), and Shell v Nicaragua, also concerning trademarks. See L Vanhonnaeker, Intellectual Property Rights as Foreign Direct Investments: From Collision to Collaboration (Edward Elgar, Cheltenham 2015), 194–200. However, it is possible there are more ISDS disputes involving IRPs which have not been disclosed to the public.

[15]See details:https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Bayer%20Inc%20v%20Canada%201998%20Federal%20Court%20of%20Canada.pdf

[16]This case dealt with the interpretation of the Canadian Food and Drug Regulations, subsection C.08.004.1(1) concerning data exclusivity protection. The Federal Court of Canada (hereinafter "the Court") ruled that the five-year data protection to originator manufacturers is not triggered if the subsequent manufacturer, generally a generic manufacturer, can establish the safety and effectiveness of its product on the basis of bioequivalence or bioavailability studies without the Minister having to consult the confidential data filed by the innovator.

[17]https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/32108/index.do?q=Bayer

[18]See details:https://www.researchgate.net/publication/320257147_AstraZeneca_Canada_Inc_v_Apotex_Inc

[19]https://www.lexpert.ca/archive/astrazeneca-canada-v-apotex/351718

4. DISCUSSIONS

It can be concluded that the US and Canadian compulsory licensing laws reflect different approaches to balancing the interests of copyright holders and society. In the United States, compulsory licensing is rarely used and mainly for antitrust purposes, while in Canada it is actively used to ensure access to drugs and technologies. Both approaches have advantages and disadvantages, and their further development will depend on global challenges and changes in international law.

In Canada, compulsory licensing is regulated by law and applied where necessary to protect the public interest, such as access to drugs or technology. This article examines the legislative basis for compulsory licensing in Canada, as well as examples of court decisions illustrating its application.

In the US, compulsory licensing is not explicitly enshrined in law as in some other countries, however, court practice and antitrust have created precedents that can be considered as forms of compulsory licensing. In the field of copyright, compulsory licensing is used in limited cases, such as:

Mechanical licenses: Under section 115 of the Copyright Act, music copyright holders are required to grant licenses to record and distribute their works upon initial release [5].

Digital broadcasting: Section 114 of the Copyright Act provides for mandatory licensing for digital broadcasting of musical works.

Table 1:

Comparative Characterization of US and Canadian Law		
Aspect	**USA**	**Canada**
Patent law	Limited application, mainly in antitrust cases	Widespread use, especially for access to medicines
Copyright	Mechanical licenses, digital broadcasting	Translations, public interest
Public interest	Rarely used	Actively used to access drugs and technology
International obligations	Corresponds to TRIPS	TRIPS compliant, with a focus on access to medicines

5. CONCLUSION

Based on what is stated in the article, the author of the article made the following conclusions. First, in the face of global challenges such as pandemics and climate change, compulsory licensing can be an important tool for ensuring access to critical technologies. The convergence of US and Canadian approaches to compulsory licensing may facilitate more efficient use of this mechanism.

Second, U.S. enforcement licensing jurisprudence demonstrates the importance of this tool in protecting competition and the public interest. Examples of court decisions such as United States v. Line Material Co. and eBay Inc. v. MercExchange, L.L.C., illustrate how compulsory licensing can be used to provide access to important technologies and medicines. However, its application comes with certain challenges, such as legal barriers and economic consequences. Further development of judicial practice in this area will depend on global challenges and changes in international law.

Third, Canada's enforcement licensing jurisprudence demonstrates the importance of this tool in protecting the public interest, particularly in the area of access to medicines. Examples of court decisions such as Apotex Inc. v. Merck & Co. and Eli Lilly and Co. v. Canada, illustrate how compulsory licensing can be used to provide access to important technologies and medicines. However, its application comes with certain challenges, such as legal barriers and economic consequences.

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