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# Intellectual Property Rights Protection in International Investment: Legal Risks and Strategic Responses for Multinational Companies

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#### **Abstract**

Against the backdrop of ongoing globalisation and the rapid development of the digital economy, the protection of intellectual property rights (IPRs) has become a key factor in the overseas investment decisions of multinational companies (MNCs). This paper first reviews the evolution of international IPR regimes and their essential status in investment agreements. It then takes the *Eli Lilly v Canada* case as a core example to deeply analyse three significant difficulties currently faced in the protection of IPRs in cross-border investment: first, the uneven enforcement of laws across countries, which leads to inconsistent effectiveness in IPRs protection; second, the vague, outdated, and insufficiently adaptive provisions in existing investment and trade agreements, which fail to cover emerging technological fields effectively; third, the divergence between the application of international agreements and domestic legal systems, which increases legal uncertainty and compliance costs for multinational enterprises. Finally, the paper puts

forward recommendations from both state and corporate perspectives, including strengthening international cooperation, improving the dynamic adjustment mechanisms of agreements, and urging enterprises to establish localised IPR strategies and compliance management systems. The article emphasises the need to construct a more coordinated, efficient, and forward-looking international IPR governance system to balance the protection of innovation with national sovereignty and corporate interests.

## Keywords

Intellectual property rights (IPRs); multinational companies (MNCs); investment agreements; legal uncertainty; Eli Lilly v Canada

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## 1 Protection of IPRs

#### 1.1 Overview of IPRs Protection

#### 1.1.1 Evolution

Since the nineteenth century, the expansion of international commerce and the growth of multinational companies (MNCs) have facilitated the strengthening of local intellectual property rights (IPRs) regimes and the conclusion of international IPR agreements.1 At the multilateral level, global intellectual property protection has evolved through a series of key instruments. These include the Paris and Berne Conventions, which laid the foundations for the multilateral system of IPRs protection, increasing international investors' confidence; the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which came into force in 1995 and significantly strengthened international IPRs protection; as well as the 2007 Development Agenda adopted by the World Intellectual Property Organization (WIPO), marking a shift in policy focus towards "respect for intellectual property".2 Additionally, provisions concerning the protection of IPRs have been increasingly incorporated into regional trade agreements over time, including the North American Free Trade Agreement (NAFTA), which entered into force in 1994. This regional framework evolved into the United States-Mexico-Canada Agreement (USMCA) in 2018, which further reinforced IPRs protection, particularly in the

<sup>&</sup>lt;sup>1</sup> Patricio Sáiz and Rafael Castro, "Foreign Direct Investment and Intellectual Property Rights: International Intangible Assets in Spain over the Long Term" (2017) 18 Enterprise & Society 849.

<sup>&</sup>lt;sup>2</sup> Louise Greunen and Iva Gobac, "Building Respect for Intellectual Property—the Journey toward Balanced Intellectual Property Enforcement" (2020) 24 The Journal of World Intellectual Property 167.

pharmaceutical sector.<sup>3</sup> Parallel developments occurred in bilateral investment treaties (BITs), such as the 2003 China-Germany BIT<sup>4</sup> and the United States' 2012 Model BIT<sup>5</sup>, which reflect a broader trend of incorporating IPRs protection into investment treaty frameworks.

#### 1.1.2 Significance

The legal recognition of IPRs as protected investments forms the foundation of these rights' significance in international investment law (IIL). IPRs are increasingly recognised as a form of protected investment in international investment agreements (IIAs). Both the USMCA Article 14.1 and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) Article 9.1 explicitly include IPRs within the scope of assets eligible for investment protection, enabling foreign investors to seek treaty remedies such as fair and equitable treatment or safeguards against expropriation.<sup>6</sup> A similar approach was adopted in *PSEG v Turkey*, where the applicable BIT expressly listed intellectual and industrial property as protected investments, further

<sup>&</sup>lt;sup>3</sup> Ronald Labonté and others, 'USMCA (NAFTA 2.0): Tightening the Constraints on the Right to Regulate for Public Health' (2019) 15 Globalization and Health 1, 12.

<sup>&</sup>lt;sup>4</sup> Agreement between the Government of the People's Republic of China and the Government of the Federal Republic of Germany on the Encouragement and Reciprocal Protection of Investments (signed 1 December 2003, entered into force 11 November 2005), art 1(1)(d), <a href="https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/736/download">https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/736/download</a> accessed 17 December 2025.

<sup>&</sup>lt;sup>5</sup> Carlos Correa and Jorge E Viñuales, "Intellectual Property Rights as Protected Investments: How Open Are the Gates?" (2016) 19 Journal of International Economic Law 111.

<sup>&</sup>lt;sup>6</sup> United States-Mexico-Canada Agreement (USMCA) (signed 30 November 2018, entered into force 1 July 2020) art 14.1, <a href="https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between">https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between</a> accessed 17 December 2025.

Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) (signed 8 March 2018, entered into force 30 December 2018) art 9.1, <a href="https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/text-texte/index.aspx">https://www.international.gc.ca/trade-commerciaux/agr-acc/cptpp-ptpgp/text-texte/index.aspx</a> accessed 17 December 2025.

illustrating this broader interpretive trend. Scholars have similarly observed that many IIAs today define "investment" in a way that encompasses IPRs, allowing investors to invoke treaty obligations in defence of their IP assets. This evolving recognition reinforces the legal basis for protecting the intellectual property of foreign investors under international law. It offers companies a more reliable means of safeguarding their intangible rights across borders.

Beyond their legal status, IPRs play a pivotal economic role in international investment. Adequate IPR protection is crucial for global investment and has a direct impact on the legitimacy and security of transnational investment. Compliance with host country laws is a prerequisite for obtaining protection.<sup>9</sup> By combating counterfeiting and piracy, IPRs protection promotes market competition and consumer rights, and is a key driver of innovation and economic growth. The Anti-Counterfeiting Trade Agreement (ACTA) underlines the value of effective enforcement of IPRs for global economic growth and fair competition. International IP treaties also recognise the role of IP in economic development.<sup>10</sup> Accordingly, effective protection mechanisms drive technological innovation, attract foreign investment, promote trade and economic development, and thus enhance competitiveness in international markets.<sup>11</sup>

<sup>&</sup>lt;sup>7</sup> PSEG Global Inc. and Konya Ilgin Elektrik Üretim ve Ticaret Limited Sirketi v Republic of Turkey, ICSID Case No. ARB/02/5 (19 January 2007); P Sean Morris, "Intellectual Property Investment Functions and the Legal Characteristics of Privatization" (2023) 11 American University Business Law Review 313.

<sup>&</sup>lt;sup>8</sup> Simon Klopschinski, Christopher S Gibson and Henning Grosse Ruse-Khan, *The Protection of Intellectual Property Rights under International Investment Law* (OUP 2021) 21-22.

<sup>&</sup>lt;sup>9</sup> Correa and Viñuales (n 5) 91–92.

<sup>&</sup>lt;sup>10</sup> Greunen and Gobac (n 2) 172.

<sup>&</sup>lt;sup>11</sup> Paul Noon, Glauco De Vita and Lindsey Appleyard, "What do we know about the impact of intellectual property rights on the foreign direct investment location (country) choice? A review and research agenda" 2019, 33 Journal of Economic Surveys 669.

Notwithstanding these benefits, IPRs protection must be balanced against competing public interests. The significance of IPRs protection under IIL lies in its role as a normative framework that balances innovation incentives with the regulatory autonomy of states. The TRIPS Agreement exemplifies this duality. On the one hand, Article 27 establishes minimum standards for patent protection. On the other hand, Article 8 affirms the right of Member States to adopt necessary measures to protect public health and other societal interests.<sup>12</sup> The balancing mechanism was affirmed in *Philip Morris v Uruguay*, which highlighted the role of IP law in mediating between investor rights and the regulatory authority of the state. The tribunal invoked the police powers doctrine under customary international law to uphold the legitimacy of Uruguay's public health measures involving IP, even though such a doctrine was not explicitly codified in the applicable investment treaty.<sup>13</sup> It is also clarified that the Paris Convention does not confer a positive right to use a trademark, and that Article 20 of the TRIPS Agreement cannot be interpreted as implying such a right. Instead, this provision merely prohibits unjustifiable encumbrances on the use of trademarks and does not amount to a grant of an affirmative right of use.<sup>14</sup> Accordingly, the case demonstrates that the application of international IP law in investment arbitration must account for public policy objectives, rather than serve solely as a basis for investor claims.

<sup>&</sup>lt;sup>12</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299 (entered into force 1 January 1995), arts 8, 27.

<sup>&</sup>lt;sup>13</sup> Philip Morris Brand Sàrl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v Oriental Republic of Uruguay ICSID Case No. ARB/10/7 (8 July 2016); Emmanuel Kolawole Oke, "International Intellectual Property Law as Applicable Law in Investment Disputes" (2025) ICSID Review - Foreign Investment Law Journal 187.

<sup>&</sup>lt;sup>14</sup> Ibid. 181.

Simultaneously, Article 20.6 of the USMCA reinforces the spirit of the Doha Declaration on the TRIPS Agreement and Public Health by expressly stipulating that obligations under this chapter shall not prevent Parties from adopting legitimate measures to protect public health, and shall be interpreted and implemented in a manner supportive of public health objectives. <sup>15</sup> This formulation not only affirms the institutional flexibility regarding public interests under the TRIPS Agreement, but also establishes an interpretative framework for reconciling IPRs protection obligations with national regulatory autonomy. It demonstrates that public health regulations and intellectual property investment protections are not inherently incompatible but instead require balanced accommodation within the treaty framework. Consequently, multinational enterprises can more effectively assess policy risks within a relatively stable legal environment and accordingly adjust their global investment allocation strategies.

#### 1.1.3 Manifestations

A key driver of IP reform has been the inclusion of enforceable IP provisions in a growing number of trade and investment agreements. These agreements specify the obligations of the parties and require enhanced IPR protection.<sup>16</sup>

The TRIPS Agreement establishes three criteria for the granting of patents: novelty, inventiveness, and industrial application. Although minimum standards are established, these terms are not clearly specified, resulting in flexibility in interpretation and legal differences between countries.<sup>17</sup> In addition,

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<sup>&</sup>lt;sup>15</sup> USMCA, art 20.6 (n 6).

<sup>&</sup>lt;sup>16</sup> Mercedes Campi and Alessandro Nuvolari, "Intellectual Property Rights and Agricultural Development. Evidence from a Worldwide Index of IPRs in Agriculture (1961-2018)" (2020) 57(4) The Journal of Development Studies 650.

<sup>&</sup>lt;sup>17</sup> Pratyush Nath Upreti, "The Role of National and International Intellectual Property Law and Policy in Reconceptualising the Definition of Investment" (2021) 52 IIC - International Review of Intellectual Property and Competition Law 107.

the TRIPS Agreement emphasises, through Articles 7 and 8, that IPRs should contribute to economic well-being and take into account the socio-economic development of the country.<sup>18</sup>

Furthermore, the CPTPP reflects the interests of all parties and enhances legal certainty for IP holders in the region by adjusting the provisions of the original the Trans-Pacific Partnership Agreement (TPP).<sup>19</sup> Meanwhile, the USMCA strengthens regional and bilateral relations and promotes the digital economy through digital trade and IPRs protection provisions.<sup>20</sup>

In the following section, I will explore three aspects of the question of whether IIAs protect IPRs and, in so doing, examine the impact of IPRs protection on MNCs' investment decisions. To deepen the analysis, I will use *Eli Lilly v Canada*<sup>21</sup> as a central case throughout the discussion to help illustrate the key points of the issue and its practical implications for MNCs' investment behaviour.

In *Eli Lilly v Canada*<sup>22</sup>, Eli Lilly, an American pharmaceutical company, challenged the Canadian federal court's revocation of two of its patents for failing to meet the "utility standard" under the Patent Act.<sup>23</sup> Eli Lilly argued that the "promise doctrine" applied by the court unreasonably breaches the international patent standards defined by NAFTA and the TRIPS Agreement. However, the

<sup>&</sup>lt;sup>18</sup> Ivan Stepanov, "Economic Development Dimension of Intellectual Property as Investment in International Investment Law" (2020) 23 The Journal of World Intellectual Property 739.

<sup>&</sup>lt;sup>19</sup> CPTPP (adopted 8 March 2018, entered into force 30 December 2018) UNTS 56101 vol 3337.

 $<sup>^{20}</sup>$  Joshua P. Meltzer, 'The United States-Mexico-Canada Agreement: Developing Trade Policy for Digital Trade' (2019) 11 Trade L & Dev 253.

<sup>&</sup>lt;sup>21</sup> Eli Lilly and Company v Canada, ICSID Case No UNCT/14/2, Final Award (16 March 2017).

<sup>&</sup>lt;sup>22</sup> Ibid.

<sup>&</sup>lt;sup>23</sup> Brook K Baker and Katrina Geddes, "Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines - Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement" (2015) 23 Journal of Intellectual Property Law 38.

tribunal rejected Eli Lilly's claim, ruling that the Canadian legal standards did not breach NAFTA.<sup>24</sup>

# 1.2 Examples of Challenges in IPRs Protection within Investment Agreements and Their Impact on MNCs

#### 1.2.1 Differences in Enforcement of Laws

Globally, there are significant discrepancies in the enforcement of IP laws across countries, which undermine the coherence of IPRs protection and increase the uncertainty of IPRs protection for MNCs. Especially between developing and developed countries, the former often have reservations about rigorous IPR regulations in the initial phases of economic development, fearing that they might inhibit economic growth and lead to weak enforcement. In contrast, developed countries tend to adopt strict laws to prevent technological spillovers and malicious imitation. Such discrepancies may expose MNCs to the risk of inadequate IPRs protection in specific markets.<sup>25</sup> The TRIPS Agreement establishes universal standards for IPRs protection, allowing countries to flexibly implement these standards in accordance with their own laws and national conditions, leading to differences in the level and manner of enforcement. Not only does the agreement give judges a wide margin of discretion, but it also does not impose complete global harmonisation of laws, thus recognising and enabling diversity in the strength of implementation and specific measures taken

<sup>&</sup>lt;sup>24</sup> Lisa Diependaele, Julian Cockbain and Sigrid Sterckx, "Eli Lilly v Canada: The Uncomfortable Liaison between Intellectual Property and International Investment Law" (2017) 7 Queen Mary Journal of Intellectual Property 292.

<sup>&</sup>lt;sup>25</sup> Shiue-Hung Lin and Leslie Wu, "Intellectual Property Rights and Law Enforcement in Developing Countries" (2021) 35 Economic Research-Ekonomska Istraživanja 143.

by countries.<sup>26</sup> However, such discrepancies have weakened the coherence of IPRs protection and undermined the actual effectiveness of protection on a global scale.

Eli Lilly v Canada<sup>27</sup> highlights global distinctions in the enforcement of IP law. The Canadian court revoked two pharmaceutical patents of Eli Lilly for failing to meet the "utility standard".<sup>28</sup> Eli Lilly argued that by invalidating its patents through changes in patent law, the Canadian government had violated its legitimate patent rights and breached NAFTA and other relevant international IPRs protection treaties.<sup>29</sup> This case demonstrates that discrepancies in the interpretation and enforcement of patent laws in different countries add to the uncertainty and challenges of global IPRs protection for multinational corporations and reflect the inconsistency of international standards, which expose companies to a more complex legal environment.

Differences in the strength of enforcement of IPR laws may have a direct impact on the internationalisation strategy choices of MNCs. As an illustration, United States firms usually co-operate through licensing in countries with stronger enforcement in order to reduce transaction costs and use local enforcement agencies to deal with infringement issues. In contrast, in countries with weaker enforcement, firms prefer to set up affiliated subsidiaries to control and protect IPRs and avoid market risks. Such strategic adjustments reflect the adaptability of firms to different market legal environments.<sup>30</sup> The contrast

<sup>26</sup> Xavier Seuba, *The Global Regime for the Enforcement of Intellectual Property Rights* (Cambridge University Press 2017) 97.

<sup>&</sup>lt;sup>27</sup> Eli Lilly v Canada (n 21).

<sup>&</sup>lt;sup>28</sup> Baker and Geddes (n 23).

<sup>&</sup>lt;sup>29</sup> Diependaele, Cockbain and Sterckx (n 24) 283.

<sup>&</sup>lt;sup>30</sup> Nikolaos Papageorgiadis, Constantinos Alexiou and Joseph G Nellis, "International Licensing Revisited: The Role of Copyright and Trademark Enforcement Strength" (2016) 19 European Journal of Innovation Management 268.

between South Africa and Uganda further illustrates this point. South Africa provides strong enforcement support through the Counterfeit Goods Act<sup>31</sup>, which enables firms to protect IPRs effectively. Whereas Uganda lacks specialised legislation, and although the Anti-Counterfeit Bill is moving forward, existing laws and enforcement mechanisms remain inadequate, resulting in limited enforcement effectiveness and increased market risk.<sup>32</sup> The enactment of the Anti-Counterfeiting Bill would be expected to define a clearer legal framework, thereby potentially reducing market risks for MNCs and enabling more predictable IPRs protection strategies. This disparity highlights the fact that distinctions in IPR protection and enforcement have essential implications for the internationalisation strategies of MNCs. In countries with weaker enforcement, firms are exposed to greater market risks and may encounter counterfeit products that erode brand and market share. In addition, higher legal and regulatory costs make MNCs more cautious when investing abroad, weighing legal risks against market uncertainty.

# 1.2.2 Gaps in Agreements

Existing international trade and investment agreements often contain gaps, such as provisions that are overly broad and lack specificity. As the number of bilateral and multilateral trade agreements increases, they tend to cover a wide range of elements, not just specifically addressing the protection of IPRs. Hence, it reflects the lack of IPRs protection of the agreements themselves, which increases the risk of investment by MNCs. Such problems may lead to discrepancies in various countries' understanding during the implementation process, thereby

<sup>&</sup>lt;sup>31</sup> Counterfeit Goods Act 37 of 1997 (South Africa).

<sup>&</sup>lt;sup>32</sup> V Ferguson and M Schneider, "Enforcement of Intellectual Property Rights in Africa" (2015) 10 Journal of Intellectual Property Law & Practice 277-278.

weakening the actual protection of IPRs.<sup>33</sup> Moreover, in the face of emerging technologies and business models, these agreements may be overwhelmed by the difficulty of adapting to such uncertainty and diversity, thus failing to ensure adequate protection of IPRs.

Eli Lilly v Canada<sup>34</sup> also shed light on the potential issues of IPRs protection in international trade agreements. Eli Lilly argued that Canada's "promise doctrine" violates international patent standards established by NAFTA and the TRIPS Agreement. However, the tribunal upheld Canada's position, finding that Canada's legal practices were consistent with its international obligations.<sup>35</sup> This judgment demonstrates that there is a certain amount of flexibility in international agreements to respond to differing legal standards and levels of enforcement between countries. However, this reveals that these agreements may lack sufficient uniformity in protecting IPRs.

Taking TPP as an example, Chapter 18, as the core content of IPRs protection, exposes the problems of complexity and ambiguity in practice. These problems have led to increased legal uncertainty and increased compliance costs for governments and stakeholders. In addition, the cumbersome and vague legal language in the provisions often causes member states to encounter difficulties in understanding and fulfilling their specific obligations, leading to inconsistencies in the implementation process. <sup>36</sup> Consequently, this inconsistency undermines the certainty of MNCs' overseas investment, thereby increasing

<sup>33</sup> Mireille van Eechoud, "Bridging the Gap: Private International Law Principles for Intellectual Property Law" (2016) 2016 Nederlands Internationaal Privaatrecht 717.

<sup>&</sup>lt;sup>34</sup> Eli Lilly v Canada (n 21).

<sup>&</sup>lt;sup>35</sup> Diependaele, Cockbain and Sterckx (n 24).

<sup>&</sup>lt;sup>36</sup> Kimberlee G Weatherall, "Intellectual Property in the TPP: Not the New TRIPS" (2016) 17 Melbourne Journal of International Law 284.

investment risk and compelling MNCs to adopt more cautious strategies that include thorough assessments of legal risks and costs.

# 1.2.3 Adaptation Issues

The internet and digital economy are rapidly developing, while IPRs protection is lagging in responding to emerging technological areas, which may affect MNCs' incentives to innovate, particularly in the area of copyright protection. As digital content is easy to copy, existing laws have struggled to keep pace with rapid technological advances, resulting in significant gaps in copyright protection in these areas.<sup>37</sup> This maladaptation constrains innovative activity, as IPRs protection, whether too strict or too lenient, can negatively affect the global competitiveness and creative capacity of firms in cutting-edge technologies. For MNCs, the lack of legal protection is particularly pronounced when investing abroad, rendering it impossible to obtain adequate legal support in the global marketplace. This situation significantly constrains their development and innovation potential in emerging technological areas, exacerbating the challenges of international competition. It not only undermines their global competitiveness but also limits their expansion and growth in overseas markets, posing a significant challenge to current overseas investments.

Eli Lilly v Canada<sup>38</sup> demonstrated the adaptability of international agreements to accommodate changes in national laws and the requirements of sovereignty. By upholding Canada's position, the tribunal explained that the NAFTA and TRIPS agreements allow for national scrutiny and invalidation of patents to ensure the fairness and effectiveness of the patent system. This

<sup>&</sup>lt;sup>37</sup> Meltzer (n 20) 257.

<sup>&</sup>lt;sup>38</sup> Eli Lilly v Canada (n 21).

adaptability ensures national autonomy in the management of IPRs, while reflecting the strengths and limitations of international agreements in responding to different legal environments. This ruling has important implications for future trade and investment agreements, while possibly prompting more investors to use arbitration mechanisms to challenge the interpretation of the TRIPS Agreement.<sup>39</sup> What is more, company has established a dangerous precedent by using the ISDS mechanism to challenge foreign patent standards. This behaviour may take IPRs protection beyond the scope of traditional patent law and weaken the country's control over patent law. Although Canadian patent law is designed to prevent excessive patenting and to protect the public interest, Eli Lilly's attempt to turn his view of Canadian patent law into legal requirement was seen as an infringement of national sovereignty. As a result, IPRs protection in international agreements needs to be reasonably limited to ensure that it is justified in the defence of national sovereignty and the public interest. 40 This case therefore highlights the necessity and potential limitations of international agreements in adapting to modern legal challenges.

In the USMCA agreement, although some critical provisions have been made in relation to the IPRs protection in the digital context, such as requiring member States to provide effective online copyright enforcement mechanisms and imposing criminal penalties for circumventing technical protection measures, these provisions are still not sufficiently adaptable in the face of rapidly evolving new technologies and business models.<sup>41</sup> This can lead to challenges in protecting IPRs in practice, particularly as the existing legal

<sup>&</sup>lt;sup>39</sup> Diependaele, Cockbain and Sterckx (n 24) 302.

<sup>&</sup>lt;sup>40</sup> Baker and Geddes (n 23) 54.

<sup>&</sup>lt;sup>41</sup> David A Gantz, "USMCA Provisions on Intellectual Property, Services, and Digital Trade" (2020) Baker Institute Report 3.

framework struggles to keep pace with technologies and market changes. Ensuring that these provisions are sufficiently flexible and forward-looking to respond to rapid evolution in the technological and business environment is therefore key to enhancing IPRs protection.

In the current global economic environment, TRIPS faces challenges in adapting to modern innovation, particularly in the pharmaceutical field. Although TRIPS sets the basic framework for international IPRs protection, its provisions are often rigid when applied to emerging technologies and pharmaceutical innovations. For instance, the TRIPS Agreement imposes rigorous rules on patent standards, which substantially limit the ability of countries to develop more flexible patent protection policies, making it difficult to respond effectively to the needs of modern technological developments.<sup>42</sup> Similarly, the USMCA agreement, while providing some provisions on IPR protection, focuses mainly on the traditional pharmaceutical industry and fails to adequately take into account the new challenges emerging in the modern, digitally driven economy. This reveals that the USMCA lacks sufficiently broad coverage and corresponding responsiveness when confronted with emerging technologies and the digital economy, which in turn affects its applicability.<sup>43</sup> Furthermore, the implementation of guidelines for the examination of pharmaceutical patent applications within the TRIPS Agreement framework highlights the limitations of international agreements in addressing emerging innovation obstacles, as they are incompatible with TRIPS provisions.44

<sup>&</sup>lt;sup>42</sup> Mike Snodin, "Pharmaceutical innovations and obligations under TRIPS" (2017) 12 Journal of Intellectual Property Law & Practice 491.

<sup>&</sup>lt;sup>43</sup> Dan Ciuriak and Robert Fay, "The USMCA and Mexico's Prospects under the New North American Trade Regime" in *Implementing the USMCA: A Test for North America* (Senado de la República 2021) 9.

<sup>&</sup>lt;sup>44</sup> Snodin (n 42).

Collectively, these issues demonstrate that the limited adaptability of international IPR frameworks has gradually evolved into a broader source of legal and operational risks for MNCs investing abroad.

#### 1.3 Recommendations for States and MNCs

#### 1.3.1 Strengthening International Co-operation

Through platforms such as the WIPO and WTO, countries have actively promoted global coherence in IPRs protection. For instance, the WIPO secretariat provides technical and legal assistance to help member States implement IP treaties, optimize national IP law policies, and enhance capacity-building to promote global standardization. These initiatives aim to reduce the legal complexity and uncertainty faced by multinational corporations in different markets. Meanwhile, law enforcement cooperation among countries has been gradually strengthened, especially in cross-border IP infringement cases, through the WIPO platform for information sharing and joint law enforcement, 45 which has enhanced the efficiency of combating infringement, laid the foundation for global IPRs protection, and promoted the development of international trade and innovation environment.

# 1.3.2 Improving the Terms of Agreements

Among the IPR challenges faced by MNCs in their recent overseas investments, improving the terms of agreements is crucial. First, it is recommended that a dynamic adjustment mechanism be introduced into existing trade and investment agreements to ensure that the terms respond promptly to emerging

 $<sup>^{\</sup>rm 45}$  Nirmalya Syam, "Mainstreaming or Dilution? Intellectual Property and Development in WIPO" (2019) 95 South Centre Research Paper 5.

technologies and market changes. This mechanism can mitigate risks associated with lagging agreements by establishing a regular review and revision process for the terms, ensuring the agreement's content aligns with current technological advancements and market conditions. Second, for emerging areas such as artificial intelligence, blockchain, and biotechnology, it is recommended that special IPRs protection clauses be added to the agreement. Through these clauses, the IPRs of these technologies on a global scale can be effectively safeguarded to prevent loopholes caused by insufficient protection in the agreement, thereby better protecting the technological innovation and market interests of MNCs.

# 1.3.3 Business Coping Strategies

Due to the complexity of IP laws in various countries, companies should ensure that their legal teams work closely with business strategy and R&D departments in the early stages of a project to fully exploit and protect the value of IPRs, as well as effectively identify global IPRs to avoid legal risks in the marketplace. 46 Through cross-functional collaboration, companies can identify and mitigate potential legal risks while better leveraging IP. Simultaneously, it is essential to raise the awareness of IPRs protection within the company, which is conducive to safeguarding the overall quality of the company. Therefore, it is recommended that the company's legal department conduct regular legal training and counselling to raise employees' awareness of IPRs protection. Moreover, the company can regularly invite IP experts to provide professional counselling, helping management gain a deep understanding of national IPR regulations before making strategic decisions. Meanwhile, management can leverage the

<sup>&</sup>lt;sup>46</sup> William W Fisher and Felix Oberholzer-Gee, "Strategic Management of Intellectual Property: An Integrated Approach" (2013) 55(4) California Management Review 175.

company's potential talents by inviting them to strategic seminars or providing training courses. This aims to enhance their focus on IPRs protection and strategic thinking, enabling a comprehensive response to related issues.<sup>47</sup> Through these measures, companies can effectively improve their overall competitiveness while strengthening their ability to cope with the uncertainty of IPRs protection in different markets.

Beyond internal management and training, companies must also align their IPR management with external legal realities across jurisdictions. Companies should adopt sovereign-aware IPR strategies. This entails tailoring patent portfolios and enforcement approaches to specific legal jurisdictions. For instance, in markets with volatile patent jurisprudence or weak enforcement, companies should prioritize defensive measures such as trade secrets and technological protection measures, while strategically reserving patent-based strategies for more predictable regimes. This calibrated approach goes beyond mere compliance, it constitutes a proactive legal risk management strategy that responds to the fissures and adaptations within the international IPR governance system discussed throughout this paper.

Before entering a new market, conducting in-depth "freedom to operate" analysis is a crucial legal due diligence step. This process, which involves analyzing local patent searches and prior art, is essential for identifying the very types of legal risks materialized in cases like Eli Lilly, where a divergence in the "utility" standard led to patent revocation. A thorough understanding of the local law enforcement environment and a commitment to strict compliance are

<sup>&</sup>lt;sup>47</sup> Marcelo Negri Soares and Marcos Eduardo Kauffman, "Industry 4.0: Horizontal Integration and Intellectual Property Law Strategies in England" (2018) 16 Revista Opinião Jurídica (Fortaleza) 280.

<sup>&</sup>lt;sup>48</sup> Fisher and Oberholzer-Gee (n 46) 160.

fundamental to avoiding infringement disputes and ensuring that a company's operations are built on a stable legal foundation from the outset.<sup>49</sup> Therefore, by having a comprehensive understanding of local legal requirements, companies can not only ensure that they operate legally in latest markets and safeguard their IPRs. Simultaneously, they can reduce the risk of potential legal disputes, gain a competitive advantage in the new market and achieve long-term stable development.

#### 2 Conclusion

This paper has systematically examined the key challenges faced by MNCs in protecting their IPRs in the course of overseas investment. It reveals how disparities in national enforcement, loopholes in agreement design, and the limited responsiveness of current regimes to technological change can significantly affect the legal certainty and strategic decisions of MNCs. The *Eli Lilly v Canada*<sup>50</sup> case demonstrates how divergent national interpretations can undermine the consistency and reliability of international investment treaties. In response, this paper advocates for strengthened international legal coordination through platforms such as WIPO and WTO, and for the incorporation of dynamic and technology-responsive clauses in future agreements. On the corporate side, MNCs are encouraged to establish cross-functional IPR management systems, enhance legal awareness through internal training, and design tailored compliance strategies based on local legal environments. In sum, the protection of IP in global investment requires a nuanced balance between innovation incentives and national sovereignty, supported by a forward-looking and

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<sup>&</sup>lt;sup>49</sup> Fisher and Oberholzer-Gee (n 46) 178.

<sup>&</sup>lt;sup>50</sup> Eli Lilly v Canada (n 21).

integrated legal framework that ensures a stable and equitable environment for international business. In light of the foregoing analysis, it is essential to assess whether the ongoing evolution of IP provisions can offer a more coherent and predictable framework for IPRs protection. Future research could further explore how MNCs adapt their strategies in response to such legal and policy developments, and how continued reform of IP provisions may reshape the legal landscape governing cross-border IPRs protection.