

## **Ensuring Access to Medicines in Frame of the Right to Share in Scientific Advancement and its Benefits**

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**Abstract** A significant role in providing access to medicines is rightfully played by legal norms regulating intellectual property protection. The pharmaceutical sector stands out among other industries in terms of implementation of various mechanisms of intellectual property rights protection, which guarantee the possibility to recover economic losses due to tremendous investments in R&D. However, intellectual property protection mechanisms trigger the rise of medication costs, which significantly influence state expenditures and limit patient's access to treatment. At the time of scientific achievements access to medicines is directly linked with the right "to enjoy the benefits of scientific progress and its applications". It means that initiatives implemented by international organizations and national healthcare policies should contain balanced approach between the interests of the society and pharmaceutical producers in order to protect public and private interests.

**Keywords:** • right to health • access to medicines • patent protection • compulsory licensing • TRIPS •

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## 1 Introduction

The concept of “access to medicines” is defined by the United Nations Millennium Development Goals (MDG) Task Force as the availability and affordability of essential medicines in private and public health facilities or other points of sale that are within an hour's walk from the homes of the population.<sup>1</sup> The Lancet Commission estimated that ensuring access to basic package of 201 essential medicines (378 dosage forms) in all low and middle-income countries requires between US\$77,4 and \$151,9 billion (or \$13 to \$25 per capita). But the majority of low-income countries (LICs) and 13 out of 47 middle-income countries spend less than \$13 per capita on pharmaceuticals (Wirtz, 2016: 1881).

Ensuring universal access to medicines is an important aspect of the UN agenda and healthcare policy of every country despite its income level. However, it should be noted that currently there is no established regulatory mechanisms at international and national level, which can guarantee equal access to high quality medicines for the whole population. The WHO Working Group on Access to Medicines of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines pointed out six most important barriers limiting access to existing medicines including, inter alia, international standards for the protection of intellectual property rights, as well as policies, stimulating R&D in the pharmaceutical area.

The need to develop cooperation with pharmaceutical companies in order to provide access to essential medicines was recognized as one of the strategic elements for achieving the internationally agreed Millennium Development Goals (MDGs). Access to medicines is identified as one the UN Sustainable Development Goals. The goal 3.8 specifically mentions the importance of “access to safe, effective, quality and affordable essential medicines and vaccines for all” as a central component of Universal Health Coverage (UHC), and Sustainable Development Goal 3.b emphasises the need to develop medicines to address persistent treatment gaps.<sup>2</sup>

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<sup>1</sup> Millennium Development Goal 8. Delivering on the Global Partnership for Achieving the Millennium Development Goals. MDG Gap Task Force Report. United Nations New York, 2008, p. 35.

<sup>2</sup> UN GA Doc. A/RES/70/1.

The purpose of the conducted research was to analyze the controversial role of intellectual property rights protection mechanisms in driving research and development (R & D) and creation of new medicines and at the same time limiting access in low and middle-income countries. The article accesses current trends in R&D and its influence on bringing innovation to clinical practice and analyses the influence of international treaty provisions in patent protection on access to medicines. The authors bring up the correlation between provisions in intellectual property protection and the right to enjoy the benefits of scientific progress guaranteed by the main human rights protection treaties. Additional focus is made on the compulsory licensing mechanism, its role in expanding access to medicines and the perspective of its implementation in Russian Federation.

## **2 R&D as a key driver of access to medicines**

One of the main drivers of ensuring the availability of medicines is to maintain an adequate level of investment in R & D. In the last decade, there has been a negative trend in the development of new medicines. Only a small share of the molecules in the R&D pipeline will enter the pharmaceutical market, and only a few will be able to recoup investments (Ecorys, 2009). In 1998–2014 only 12% of medicines in clinical trials, successfully passed the registration procedure.<sup>3</sup> The cost of R&D is rapidly growing. In 2010, the cost of bringing the new medicine to the market was about \$ 1.3 billion, compared to \$ 138 million in 1975 (Di Masi, Hansen, Grabowski, 2003: 151–185; Di Masi, Grabowski, 2007: 469–479).<sup>4</sup> Thus, over the past 35 years, the cost of research has increased almost 10-fold. The ratio between the volume of investment in the research area and the volume of sales is five times higher among pharmaceutical companies than among average US manufacturing company.<sup>5</sup> The process of medicine development is time-consuming, risky, and extremely expensive, intensifying the importance of the intellectual property protection. A significant role in providing access to medicines is rightfully played by legal norms in the field of intellectual property protection. In 2011, the World Intellectual Property Organization (WIPO) defined intellectual property protection as an important mechanism for stimulating

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<sup>3</sup> Tufts Center for the Study of Drug Development (CSDD). Cost of developing a new drug. Briefing. Boston, Mass.: CSDD. November 2014.

<sup>4</sup> See also Global Health Technologies Coalition and Policy Cures, Saving Lives and Creating Impact: Why Investing in Global Health Research Works (Washington DC: GHTC, 2012). Available: <http://www.ghtcoalition.org/files/Savinglivesandcreatingimpact.pdf>.

<sup>5</sup> USCBO (2006) Research and Development in the Pharmaceutical Industry, Congress of the United States, Congressional Budget Office.

innovation, allowing to harmonize the interests of private investment with the preferences of the society.<sup>6</sup>

The pharmaceutical sector stands out among others in terms of implementation of various intellectual property rights protection mechanisms, including patents and data exclusivity, in order to ensure the return on investment in R&D (Taylor, Silberston, 1973: 294). Surveys conducted in 1986 and 2000 showed that pharmaceutical, biotechnology, and chemical industries rely more heavily on patents than other industries.<sup>7</sup>

For example, in most cases, the time between the filing of a patent application and the registration of a medicinal product exceeds 10–15 years, so the companies do not have enough time to recoup investments before patent loss. The lack of sufficient level of state funding in R&D is compensated by the provision of various preferences to pharmaceutical companies. In many countries, applicant companies are guaranteed a special data protection period in which other manufacturers cannot use similar data to apply for registration of their medicines to provide compensation for R&D costs. In the European Union (EU), patent protection for a registered medication can be extended under Article 63(2) of the European Patent Convention (EPC) and Regulation (EC) 469/2009 by means of a Supplementary Protection Certificate<sup>8</sup> (SPC).<sup>9</sup> The maximum lifetime of an SPC is 5 years, counted from the end of the patent term.

The harmful influence of patent protection on essential medicines is widely discussed in terms of limitation patients' access. There is lot of data stating that intellectual property protection mechanisms trigger the rise of medications costs, which significantly influence state expenditures and limit patient's access to treatment. At the same time it should be noted that out of the 375 items on the 2013 WHO MLEM, 95% are off-patent, meaning that these medicines patents have expired and that generic equivalents are likely available (Reed, 2016: 4).

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<sup>6</sup> WIPO (2011a), World Intellectual Property Report, Geneva, WIPO.

<sup>7</sup> This difference in reliance on patents is decreasing. See Cohen et al., 2000, Mansfield, 1986.

<sup>8</sup> OJ L 152, 16. 6. 2009, p. 1–10.

<sup>9</sup> See more at Storz, 2012: 25–41.

### **3 The role of patent protection in ensuring access to medicines**

Patent protection guarantees the possibility for companies to maintain a high level of investment in R&D, to recover economic losses due to investments that do not lead to the creation of a market product. However, it should be noted, that the procedure for issuing a patent is based on the know-how disclosure, allowing other entities to use this technology in the future after patent protection loss.

For many years, product patents were not granted to pharmaceutical products, even in high-income countries. For instance, Japan did not issue product patents for drugs until 1976, Switzerland waited until 1977 to introduce patents covering pharmaceutical products. By the end of the 1980s, at least forty developing countries provided no patent protection for pharmaceuticals. Spain, Portugal, Greece, and Norway granted product patents to pharmaceuticals since 1992 (Lanjouw, Cockburn, 2000).

The first formal multilateral patent treaty, the 1883 Paris Convention for the Protection of Industrial Property, imposed a set of global norms in intellectual property protection, but it also left significant room to use intellectual property to pursue national goals. States retained the discretion to determine the duration of a patent under national law and to exclude certain fields of technology from patentability.

It is important to note that the introduction of international patent protection standards did not lead to the emergence of an “international patent” which can be valid in several countries. Patents are issued based on national legislation provisions or at a regional level it happens with European patents according to European Patent Convention. It means that the necessary balance of interests in the field of intellectual property protection is formed at the state level, while the international legal documents establish general principles and create a national legal regulation system.

Article 4 of the Paris Convention of 1883 establishes mutual independence of patents for one invention in different countries. This principle was introduced by the Additional Act to Convention adopted at the revision Conference of Brussels in 1900 and Washington in. The article stipulates that patents applied for in the various countries of the Union shall be independent of patents obtained for the

same invention in other countries. The spirit derived from the principle of independence and national treatment, requires that each member apply its domestic law in its territory independently and a foreigner who is granted patent and trademark by a member state enjoy the equal benefit to its domestic national (Wu, 2006: 329). In context of pharmaceutical patents, it means that a patent for pharmaceutical technology issued in one country cannot be used to prevent competition from generic medicines in countries where patent protection is not available for this medicine.

Unified general principles and minimum standards for the protection of IP were set out in The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS emerged from the Uruguay Round of trade negotiations in 1994. All WTO members are legally required to bring their domestic legislation into conformity with the terms of TRIPS, subject to any exceptions or waivers agreed upon by WTO Members.

It should be noted that TRIPS Agreement contains provisions, which could be used to promote the right to health. For instance Article 8(1) formulate principles, which provide countries with an opportunity to formulate or amend their laws and regulations necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development.

The principles mentioned above are realised through a number of provisions, commonly referred to as "flexible" provisions, such as parallel import, exception of patent rights, patentability criteria, compulsory licensing, which can be implemented in accordance with the specifics of national legislation to ensure access to medicines. It is worth noting that the applicable TRIPS flexible mechanisms are consistent with the World Health Organization's (WHO) Global Strategy for Health, Innovation and Intellectual Property, which encourages R&D aimed at combating diseases affecting the economic and social development of low-income and middle-income countries.<sup>10</sup>

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<sup>10</sup> Document of the World Health Conference 61.21. Global strategy and plan of action on public health, innovation and intellectual property, 2008.

The right of countries to implement TRIPS flexibilities was confirmed in the Doha Declaration on TRIPS and public health. The scope of the Declaration is not limited to the impact of patents on public health, but applies to all intellectual property rights that are within the scope of the TRIPS Agreement, such as test data protection. Moreover, the declaration is valid for any public health problem and epidemic in order to protect public health and enhance access to medicines for poor countries.<sup>11</sup>

More critical for public health and protection of the right to health are provisions contained in bilateral or regional trade agreements, which often include mutual commitments to implement IP regimes that go beyond TRIPS minimum standards. They cause pressure on developing countries to increase the levels of IP protection in their own regimes, based on standards in developed countries. Trade agreements put sharp restrictions on the use of flexibilities related to patent scope and quality and may forbid countries, from excluding patents on new uses or methods of treatment. They also restrict the grounds on which countries may grant compulsory licences and strengthen data exclusivity requirements (Roffe, Spennemann, 2006: 75–93).

The existing challenges in intellectual property protection, R&D investments level and undeveloped legal mechanisms, granting access to medicines justify the necessity to balance regulations in order to protect public and private interests. This idea has been repeatedly reaffirmed by the UN, which set out the priority to ensure protection of intellectual property rights and access to achievements of scientific progress.

#### **4 Intellectual property protection and the right to enjoy the benefits of scientific progress**

Access to medicines is directly linked with the right “to enjoy the benefits of scientific progress and its applications”. In 1947, the Committee on the Theoretical Foundations of Human Rights, convened by UNESCO to develop the basic concepts of the Universal Declaration of Human Rights (UDHR), recognized the human right to access technical and cultural achievements of civilization.

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<sup>11</sup> The Doha Declaration on TRIPS and Public Health Ten Years Later: The State of Implementation. Policy brief 7 No. 7, 1 November 2011.

The right “to share in scientific advancement and its benefits” is recognized in (UDHR, Article 27) and was further emphasised as a treaty obligation “the right of everyone... to enjoy the benefits of scientific progress and its applications” in the ICESCR Article 15.1(b). However, the normative content of the “right to science” as articulated in the UDHR and the ICESCR has been less defined than many other rights, including the right to health.

This right has also been formulated in regional instruments for the protection of human rights, in particular in Article 13(2) of the American Declaration of the Rights and Duties of Man 1948, Article 14(1)(c) of the Protocol Additional to the American Convention on Human Rights in the Field of Economic, Social and Cultural Rights, 1988 (the "San Salvador Protocol") and in Article 1 of Protocol No. 1 to the Convention for the Protection of Human Rights and Fundamental Freedoms, 1952 Year (European Convention on Human Rights). The role of scientific achievements in access to quality health care services and essential medicines was affirmed in the Universal Declaration on Bioethics and Human Rights (UDBHR, 2005), an authoritative but non-binding international law document. The right to benefit from scientific progress has also been applied by domestic courts in law suits to ensure access to affordable medicines.<sup>12</sup>

The ICESCR formulates the right of every person to use the results of scientific progress and their practical application in Article 15.1 (b), as well as the right to protect moral and material interests arising from any scientific work in Article 15.1 (c), without an explicit definition of the content and scope of these rights, which creates problems for their interpretation and application. In other words, it can be understood as while Article 15.1 (b) establishes the right of all patients to have access to medicines, the provisions of Article 15.1 (c) protect the rights of companies to receive profit from the developed medicines.

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<sup>12</sup> E.g., NA et al v. Ministerio de Sanidad y Asistencia Social, Supreme Court of Justice of Venezuela, Case No. 14.625, Judgment of 14 August 1998; Cruz del Valle Bermudez y otros c. Ministerio de Sanidad y Asistencia Social, Supreme Court of Justice of Venezuela, Case No. 15.789, Judgment No. 916 (15 July 1999); López y otros c. Institute Venezolano de los Seguros Sociales (IVSS), Supreme Court of Venezuela (Constitutional Chamber), Judgment No. 487 (6 April 2001). See discussion in Elliott et al., 2006: 64–68.

UN CESCR in General Comment No 17 has clarified that a company may, of course, have a legal claim, under relevant provisions of intellectual property law, to profits generated from the use and sale of that invention as property that it has acquired, but as noted by the Committee, there is no right of the company to any particular form of protection for such material interests from human rights perspective.<sup>13</sup> The position of CESCR was also reaffirmed in the report of the Special Rapporteur on Cultural Rights as a basis for the implementation of other fundamental human rights, including the right to medicines.<sup>14</sup> Although only States have a responsibility to comply with the provisions of the ICESCR, it is vital to consider the responsibility of the private sector, in the implementation of the rights recognized in article 15 of the ICESCR.

The need to maintain a balance of public and private interests has been repeatedly documented in the UN documents. In particular, in the "Norms on the Responsibility of Transnational Corporations and Other Enterprises in the Field of Human Rights", the United Nations Sub-Commission on the Promotion and Protection of Human Rights recognized that, while States bear the primary responsibility for the promotion, respect and protection of human rights, "transnational corporations and Other enterprises ... are also responsible for promoting and securing ... human rights. "

## **5 The role of compulsory licensing in expanding access to medicines**

In particular, flexible provisions include the use of the compulsory licensing mechanism used by public authorities to grant a patent licence. However, before a government decides to issue a compulsory license, there are several technical and procedural requirements under the TRIPS Agreement that must first be satisfied. In the case of issuing a compulsory license, the patent holder must receive sufficient compensation in form of royalties. According to Article 31 of the TRIPS compulsory licence can only be issued in cases of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use," where the issuing government does not need to demonstrate an initial

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<sup>13</sup> UN Committee on Economic, Social and Cultural Rights, General Comment 17: The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (Article 15(1)(c), of the Covenant), UN Doc. E/C.12/GC/17 (2006), para. 10.

<sup>14</sup> Report of the Special Rapporteur in the field of cultural rights, Farida Shaheed The right to enjoy the benefits of scientific progress and its applications. A/HRC/20/26. 2012.

attempt to obtain the patent holder's authorization before issuing a compulsory license.

It is a common perception that a compulsory license is issued when there is an emergency in the country. However, the Doha Declaration in the Article 5b specifies the right of each WTO member to determine independently the grounds for issuing a compulsory license, as well as to formulate criteria for a situation recognized as an emergency or a circumstance of extreme necessity (Coriat, Orsi, d' Almeida, 2006: 1033–1062). Moreover, Members adopted the decision on “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” on August 30, 2003, which allowed to provide compulsory licensing for the purpose of export in countries with insufficient manufacturing capacity, which would be unable to benefit from the compulsory licensing provisions.

In order to establish harmonized decision procedure for the granting of compulsory license for export purposes to eligible importing countries in need of such products, the EU established Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 “On compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.”

Within the framework of TRIPS, there are no criteria for determining sufficient compensation, which leaves possibilities for states to make decisions on their own. The decision to issue a compulsory license and the amount of compensation may be reviewed in a judicial or other established manner by government agencies. According to Article 31 (k) of the TRIPS, the amount of compensation to the patent owner is determined taking into account the amounts established by violations of the competition law.

To determine the value of royalties, the patent owner must use the recommendations formulated by international organizations. Due to their simplicity, guidelines prepared by WHO jointly with the United Nations Development Program (hereinafter: UNDP) were used more often for these purposes.

Routine use of compulsory licenses is not consistent with the intent of TRIPS, because it provides only short-term solutions that risk undermining long-term needs, and, rather than enhancing access, could instead discourage the introduction of new medicines (Desai, 2016: 32). It should be noted that despite the existence of provisions allowing the use of compulsory licensing in the legislation of foreign countries, this mechanism is very rarely used. The possibility of applying compulsory licensing is an important argument in negotiations with manufacturers about price decrease, and the use of this mechanism itself is an extreme measure.

## **6 Perspectives of compulsory licensing mechanism in Russian Federation**

The Constitution, as the fundamental law of the Russian Federation, enshrines the right of everyone to health protection. It is emphasized that medical care in state and municipal healthcare institutions is provided to citizens free of charge at the expense of the state budget. It is important to note that the right to drug provision is not enshrined in the provisions of the Constitution of the Russian Federation, in particular, this aspect is not specified in the context of protecting the rights of the most vulnerable categories of citizens: elderly, children, disabled.

The annual report of the Commissioner for Human Rights in the Russian Federation notes that the main problem in ensuring the realization of the right to health is the access to medical care. In particular, it is emphasized that one of the main problems for the last years remains the provision of essential medicines in the regions of the Russian Federation.<sup>15</sup> The use of compulsory licensing in the interests of defence and security with an adequate compensation to the patent holder is allowed under Article 1360 of the Civil Code of the Russian Federation.<sup>16</sup> It should be noted that the article does not provide any special provisions in relation to pharmaceuticals. However, it should be noted that drugs are considered as an important element of national security under “Strategy of the National Security of Russia until 2020.”<sup>17</sup> The updated version of the Strategy

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<sup>15</sup> The Annual 2017 Report on the activity of the High Commissioner for Human Rights in the Russian Federation. URL: [http://ombudsmanrf.org/upload/files/docs/lib/104441\\_lite.pdf](http://ombudsmanrf.org/upload/files/docs/lib/104441_lite.pdf).

<sup>16</sup> Civil code of the Russian Federation. Part 4. No. 230 18. 12. 2006 /. [http://www.consultant.ru/document/cons\\_doc\\_LAW\\_64629/e05f16f41f651fc9c162999e5b59776e21e8b591/](http://www.consultant.ru/document/cons_doc_LAW_64629/e05f16f41f651fc9c162999e5b59776e21e8b591/).

<sup>17</sup> Decree of the President of the Russian Federation, 12 May 2009 No. 537 “National Security Strategy of the Russian Federation to 2020.”

approved by the President of the Russian Federation in December 2015 emphasizes the need to create conditions for the development of the pharmaceutical industry, overcoming technological dependence on foreign suppliers, as well as ensuring the availability of high-quality, effective and safe medicines for citizens of the Russian Federation.

The Civil Code of the Russian Federation also allows the use of compulsory licensing in situation of product deficit on the market for 3 years and the patent owner's refusal to enter into a license agreement (Article 1362). The total amount of payments for such a license must be established in a court decision not lower than the price of the license, determined in comparable circumstances.

In 2016, Federal Antimonopoly Service of Russia drafted a law to expand the grounds for issuing a compulsory license, empowering the authority of Russian Government to issue a compulsory license in the interests of defence, security and healthcare protection of citizens. However, this proposal did not find support from the majority of federal ministries. Thus, according to the head of Russian Patent Office, this mechanism is redundant and dangerous for the development of local pharmaceutical industry. Ministry of Economic Development noted that the proposed regulation contradicts the principles laid down in Russian legislation for the protection and enforcement of intellectual property rights, and may also reduce innovation and patent activity in Russia, as well as limit technology transfer.

## **7 Concluding remarks**

The conducted research has shown that initiatives implemented by international organizations are not fully in line with the interests of society and pharmaceutical manufacturers. Certainly, the presence of unified standards for the protection of intellectual property rights guarantees the ability of companies to maintain a high level of funding for R&D activities to compensate economic losses resulting from investments that do not lead to the creation of a medicine. A high level of protection of intellectual rights is one of the key conditions for the successful development of an innovative economy and attracting direct international investment into the country.

Currently the regulation guaranteeing access to medicines is not unified and is influenced by other branches of law including IP protection provisions. In order to ensure universal access to medicines as significant component of reaching sustainable development goals identified by UN, it is critical to systematize existing mechanisms regulating access to medicines.

As the first step, to ensure sustainable access to medicines is to establish unified approach to issuing compulsory licenses in various regions of the world, as the current situation creates an imbalance in the interests of both producers and the state as a guarantor of citizens' rights to medicines. As a possible solution, it is necessary to consider creating an "International Expert Group on Compulsory Licensing" within the framework of the WTO, whose activities will be aimed at establishing the necessary level of royalties to compensate for the manufacturer's investments, as well as ensure the affordability of the necessary drugs. The WTO Dispute Settlement Body according to general rules and procedures resolves disputes arising on compulsory licensing issues. This model is not effective in a situation with compulsory licensing, since pharmaceutical manufacturers cannot act directly as a party to a complaint in case of a dispute at the level of royalties. In addition, the existing approach is criticized by developing countries, because of their low financial capacity and the inability to provide a sufficient level of legal support.

The second major step is to set up transparent rules for identifying clear amounts for royalties. Existing manuals for determining the amount of royalties do not always provide an adequate amount of compensation. Taking into account that TRIPS does not establish the mandatory criteria for determining the amount of compensation, it's worth creating a special Expert group in frame of WTO, which should develop various approaches to determining the necessary amount of royalties to ensure the necessary level of flexibility in making such decisions. As part of the proposed procedure, manufacturers wishing to challenge the size of royalties should provide information on the amount of investment in medicine development, the disease burden, and the ability to pay for therapy in the country. The members of the Expert group should have a sufficient level of qualification in matters of patent law and pharmaceutical regulation. In addition, the principle of geographical representation must be respected.

Finalizing the conducted research, it has to be stated, that there is a direct correlation between intellectual property rights protection mechanisms and the right “to enjoy the benefits of scientific progress and its applications, which justifies the need to maintain a balance of public and private interests within regulatory acts, which currently establish only general principles of regulation.

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