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Indian Legal Framework in Shaping Patents Regime in the Healthcare Sector vis-à-vis Securing Right to Public Health[4]

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Abstract

The patents regime in healthcare sector and its tussle with right to public health is a long controversial saga. The crux of matter which is debated focuses upon providing patent rights that reduces the accessibility of cost-effective healthcare services, particularly in developing country. The counter point to this has remained that providing patent allows nurturing of research and development in the healthcare sector, which promotes the healthcare industry to take initiatives to tackle various health related problems and provide better treatment.

According to the rival opinions presented in the aforesaid, the centre of the issue is health, therefore it is necessary to discuss the corresponding rights of citizens and duties of the government to make healthcare industry favourable.

Keywords: patent, healthcare, right to health, pharmaceutical industry, global value chain.

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Indyjskie ramy prawne dotyczące kształtowania reżimu patentowego w sektorze opieki zdrowotnej vis-à-vis zabezpieczenia prawa do zdrowia[5]

Streszczenie

Reżim patentowy w sektorze opieki zdrowotnej i jego zmagania z prawem do zdrowia publicznego to długa kontrowersyjna saga. Przedmiotem dyskusji jest zapewnienie praw patentowych, które zmniejszają dostępność opłacalnych usług opieki zdrowotnej, szczególnie w krajach rozwijających się. Przeciwieństwem tego pozostaje fakt, że patentowanie pozwala na pielęgnowanie badań i rozwoju w sektorze opieki zdrowotnej, co sprzyja podejmowaniu przez sektor opieki zdrowotnej inicjatyw mających na celu rozwiązywanie różnych problemów zdrowotnych i zapewnianie lepszego leczenia.

Zgodnie z przedstawionymi we wspomnianym wyżej konkurencyjnymi opiniami, w centrum problemu jest zdrowie, dlatego konieczne jest przedyskutowanie odpowiednich praw obywateli i obowiązków rządu, aby branża zdrowotna była korzystna.

Słowa kluczowe: patent, opieka zdrowotna, prawo do zdrowia, przemysł farmaceutyczny, globalny łańcuch wartości.

[5] Badania wykorzystane w artykule nie zostały sfinansowane przez żadną instytucję.

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The Rights of Citizenry in View of Access to Healthcare vis-à-vis Innovation Framework

PART 1: India's International Commitments and Situation of Conflict

In this part the objective is to depict India's international commitments through treaties and conventions which led to situation of conflict between Access to Healthcare and facilitating patent process in the healthcare sector.

It is well established fact that right to health is now a fundamental right which traces its origin, evolution and development under article 21 of the Constitution of India.

However, as the paper focuses largely upon the Indian context it must not be mistaken that rift between right to health and patent regime is limited to India, rather it would be appropriate to say that the rift between the same has flown from the international context, which will be established in this paper by referring to necessary international obligations upon India and the manner in which such obligations were responded. Hence it is material to bring into light the international background under this section.

The right to health under Article 21 of Indian Constitution is not an alien concept, as its traces its roots and history to the UDHR[6] wherein under Article 25 it was stated that everyone has the right to standard living and adequate for health and well-being. It can be said that although Article 25 was merely a form of declaration, in actual terms it laid down the foundation for the right to health which imposes responsibility upon the state to secure right to health for its citizens. Later, various international covenants were passed such as the International Covenant on Economic, Social and Cultural Rights[7] (ICESCR). The ICESCR was subject to progressive realisation based on the capacity and material resources of the nations. There were various other international instruments. However, to maintain the brevity and to remain within the contours of the topic, it is necessary not to reiterate all those international covenants at this juncture.

However, even after being signatory to several international instruments related to the right to health the same was not ratified into Indian laws in letter and spirit

6 Universal Declaration on Human Rights 1948.

7 Article 12 of the Covenant for Right to Health.

due to the socio-economic condition of the country. Yet, the constitution makers of our country were visionary enough to inculcate the provision for respect towards international treaty and obligation in the constitution itself under the Directive Principles of State Policy. Article 51 states that India must foster respect towards international treaty and obligation.

It must also be noted that apart from the international obligations to secure right to health, the Constitution of India also had the similar feature under the Directive Principles of State Policy such as Article 39I which directs the state to secure health of workers, Article 42 directs the state to just and humane conditions of work and maternity relief, Article 47 casts a duty on the state to raise the nutrition levels and standard of living of people and to improve public health.

All these duties of state to secure health as well as to honour the international obligation was kept under realm of DPSP, as India was a newly independent country facing acute shortage of basic resources. However, with the passage of time the judiciary felt the need through its interpretation that DPSP and Fundamental rights must be read harmoniously to fulfil the constitutional aspirations of the country and vision of the constitution makers.

At this stage, it is also imperative to refer to the India's international obligation towards patenting in the healthcare sector, as it would not be wise to discriminate between the international commitments of the country.

India was signatory to the GATT (General Agreement on Tariffs and Trade),[8] however, was not able to fulfil all its obligation as the GATT favoured developed countries rather than helping the developing countries. It was seen as the attempt by developed countries to have command over patent regime of developing countries who are already facing issues related to non-accessibility of medicines and poor public healthcare infrastructure. Later, in 1995 the TRIPS agreement was adopted by the World Trade Organization (WTO) and India being the member of the WTO had no other option than conforming to TRIPS. However, India took a firm stand against the inclination of TRIPS towards developed nations and obtained a 5-year transition period for implementing TRIPS in its national law, which was followed by an extension of another 5 years. This meant that India was able to secure 10 years of grace period for complying with its international commitments of the patent regime in the healthcare sector.

Now, considering the international commitments of India as discussed in the above paragraphs in respect of the right to healthcare and facilitating innovation

[8] India acceded to the GATT on 8 July 1948, and became a founding member of the World Trade Organization on 1 January 1995. As a result, India joined the TRIPS Agreement on 1 January 1995. On 7 September 1998, India joined the Paris Convention.

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framework in the patent regime of the healthcare sector, it can be understood that how difficult the situation would have been, and it even remains as of today in terms of reconciling both of the commitments.

This situation of conflict was not only based on the international obligation rather was also now the part of inviolable fundamental rights enshrined under the Indian Constitution. The Right to Health was deemed to be part and parcel of Article 21 of the Indian Constitution[9] in view of the India's international commitment and DPSP,[10] whereas facilitating patent process in the healthcare sector could be related with Article 19(1)(g) of the Constitution which talks about the freedom of trade and profession as India started to adopt TRIPS under its municipal law in a phased manner.

The way in which TRIPS was adopted in view of the patent in healthcare and how the balance was maintained with right to health shall be analysed in the next part.

PART 2: The Pathway Towards Adopting TRIPS and Securing Right to Health

India followed Articles 70.8 and 70.9 of the TRIPS agreement and introduced the system of 'mailbox' and 'exclusive marketing rights', respectively. These two concepts allowed India to efficiently process the patents application related to healthcare sector during the transition phase of 10 years.

The mailbox system provided a mechanism for filing of the patent applications which can be considered as if same is filed from the date India entered into the TRIPS agreement and the patent can be granted upon satisfaction by the competent authority from such a date. The exclusive marketing rights allowed until the time the patents applications are examined. The controller of patents was simply required to inquire as to whether the application submitted for a patent is under the category of patent or not or whether it falls under criteria wherein no patent rights can be granted. Considering these two factors the exclusive marketing rights would be granted to the applicant.

Upon completion of the transition period of 10 years in the year 2005, India had complied with the norms of TRIPS under its municipal law. However, there remained and even remains loopholes which are not intended to violate the international commitment rather is based on the socio-economic condition of the country and other obligations which are on priority to be fulfilled.

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9 Francis Coralie Mullin v. The Administrator, Union Territory of Delhi AIR 1981 SC 746.

10 Bandhua Mukti Morcha v. Union of India, AIR 1984 SC 812.

The Amendment of 2002 was the initiating step towards complying with the standards of patents as formulated under TRIPS. Section 3 of the Patents Act (1970) was drafted and enacted in the light of Article 27.1 of the TRIPS agreement which says that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.

The next in the line is the most important amendment related with the instant topic which was made in 2005. The section 5 of the Patents Act (1970) was omitted which prohibited grant of patent for substance to be used as food, medicines or drugs or substance related to chemical processes.[11]

Then India started its journey towards product as well as process patents, which was in negation to its firm stand prior to the TRIPS agreement during the GATT. India has strictly followed the law of not granting a product patent considering the affordability and accessibility of the medicines. It must be noted that the Ayyangar Committee's report[12] was also against the product patent as it was of the clear view that granting of product patent shall confer monopolistic rights in the hands of pharmaceuticals giant and the poor Indians shall suffer due to non-affordability of the high-priced medicines. At this juncture it would be compelling to quote the words of Smt. Indira Gandhi, the former Prime Minister of India. She stated in the World Health Assembly 1982 that 'The idea of a better ordered world is one in which medical discoveries will be free of patents and there will be no profiteering of life and death.'

As now, the patent was allowed in the healthcare sector, started the saga of a rift between commercially driven patent rights and the socially driven right to health.

As India had now complied with TRIPS and process as well as product patents were also allowed, it was of utmost importance that citizens of a developing nation such as India is not made to remain aloof of the medicines, as it is a very well--known fact that pharmaceutical companies use the patent rights to fix high prices of medicines which reduces its affordability and accessibility.[13] India, being the country who have followed the mixed pattern of economy and has a socialistic vision when it comes to health of its citizen, shall always keep the interest of the community on a higher pedestal than the interest of the individual. The proponents

11 Section 4 of the Patents (Amendment) Act (2005).

12 Report on the revision of the patent law, Rajagopal Ayyangar Committee, September 1959, http://nopr.niscair.res.in/bitstream/123456789/2027/1/JIPR%2013%285%29%20414-423.pdf (access: 17.08.2022).

13 G. Dutfield, *Intellectual Property Rights and the Life Science Industries: Past, Present and Future*, 2nd ed. Singapore 2009, pp. 315–316.

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of human rights also believe the same: that patent rights are never fundamental rights and the interest of public at large comes first.[14]

Considering part 1 of this paper, it can be inferred that India did not have only one obligation under TRIPS to be fulfilled. However, as most developing countries were interested in TRIPS it became much more highlighted and appeared to have a character of super imposition as the obligation which must be complied *in toto* expeditiously. Undoubtedly, IPR protection was used as a means for developed countries to gain supremacy in the world of advancement.[15]

In the light of all the commitments and healthcare infrastructure of India, TRIPS had to be read with Article 21 and Article 14 of the Indian Constitution, as it must be remembered that in India the state's highest duty is to protect its citizens.[16]

However, the above discussion must not create a conception that TRIPS was made solely for the developed nations and has only led to the less affordability and poor accessibility of medicines in India. The critical analysis of TRIPS shows that it has acted like a boost to the private healthcare sector. After the TRIPS regime, the private players were motivated to take up medicinal and drug-based research in the developing countries. The private players got the opportunity and motivation to indulge in finding the treatment for the disease mainly prevalent in the third world developing countries.[17] It must be noted that developing countries face various kind of disease which are not known or less talked about in the developed nations. Such diseases are also referred as 'neglected disease.'[18]

Considering the benefits of the post-TRIPS regime, it is stated that the fight against grant of patent was never the issue. It appeared as the position over which lot of debates and deliberations were held but in reality, the issue was whether the private rights which are granted in form of patents to the pharmaceutical corporations is returned back to the society in form of social benefits. Till the balance between private rights and social benefits are maintained the issue remains stable and tranquilised. However, as soon as the balance gets tilted towards either side the issue springs into action.

However, developing countries especially Indian has remained reluctant to the fact that TRIPS has more of positive benefits. It has been continuously argued

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14 Ibidem, note 7.

15 C. Oh, *Trade-Related Aspects of Intellectual Property Rights and Pharmaceuticals*, https://www.globalpolicy.org/component/content/article/209/43854.html (access: 18.08.2022).

16 Justice V.R. Krishna Iyer, *Human health and patent law*, "Frontline" 2000, 17(21), pp. 14–27.

17 P. Agrawal, P. Saibaba, *Trips and India's Pharmaceutical Industry*, "Economic and Political Weekly" 2001, 36, pp. 37–87.

18 T.G. Agitha, *Global Governance for Facilitating Access to Medicines: Role of World Health Organization*, "Journal of Intellectual Property Rights" 2013, 18, p. 589.

that even in the pre-TRIPS regime, there existed the provision for process patent which allowed the generic pharma market of India to grow substantially. The product patent regime is meant to increase the dominance of foreign companies in the Indian market. The most pertinent factual argument against the post--TRIPS era is that from 1968 to 1979 the foreign pharma companies filed comparatively fewer patents in India, as in 1968 the total number of foreign patents was 4,248 which came down to 1,010 in 1979.[19] Based on the foregoing fact it has been argued that Indian generic market of medicines allowed affordable medicines securing the right to health.

It has been the most pressing argument of the advocates who oppose the TRIPS regime that Indian being an import dependent country until 1950s, it achieved the target of being a low-cost producer of high-quality pharmaceutical products which not only made it self-reliant but also allowed for the export of Indian medicine amount to turnover in excess of $1.5 billion.[20] The studies of such a nature were mostly made around 2005–2010 when the TRIPS regime was enforced with full authority. It has been advocated that during such period India was already at a good position due to its earlier policy on patenting of drugs and pharmaceuticals under which product patent was not allowed.

It is believed and also stands as the inevitable truth that Indian had proved itself as the pharmacy of the poor in the pre-TRIPS era.[21] India was able to understand the technology and methodology of production of pharmaceuticals and drugs at a great pace and was able to meet the needs of third world under developed nations as well.

In the next part, an attempt has been made to explain the impact that the post-TRIPS regime had on the Indian pharmacy market.

PART 3: The Impact on the Indian Pharmaceutical Market in the Post-TRIPS Regime and Response to This Impact

The two major subjects upon which the impact of TRIPS can be seen on the Indian pharmaceutical industry are the impact of exports and upon Global Value Chain in post TRIPS era.

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19 J.M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, "University of Pittsburgh Law Review" 2007, 68, p. 491.

20 N. Joshi, *Data Protection for Pharmaceutical Products under TRIPS: Data Exclusivity Legislation a Necessary Evil for India*, "Delhi Law Review" 2005, 1, p. 104.

21 *India's Pharmaceutical Industry on Course of Globalisation*, https://www.dbresearch.com/PROD/CIB_INTERNET_EN-PROD/PROD0000000000224095.pdf (access: 18.08.2022).

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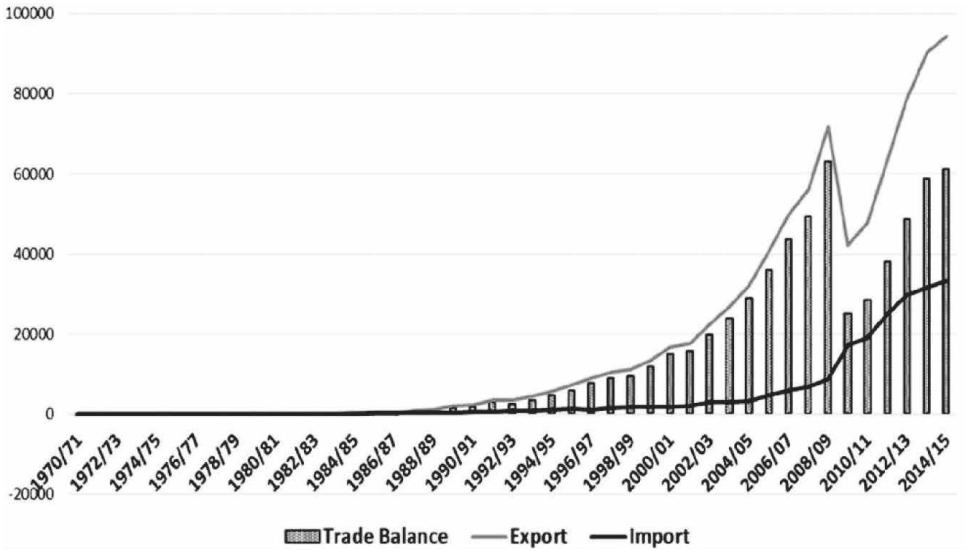
As discussed in the earlier part, during the pre-TRIPS era there was a significant growth of India's export of medicines. Therefore, it is necessary to highlight the issue of India's export of medicines after the enforcement of TRIPS first.

The Figure 1 as obtained from the Reserve Bank of India (*Handbook on Statistics on the Indian Economy*) shall be relevant material to study the subject matter. The results show the study until 2015. It would be sufficient to analyse the ten-year period of TRIPS, i.e. from 2005 to 2015, as the earlier study on the impact of TRIPS was conducted between 2005 and 2010.

Figure 1. Impact on Pharmaceutical Exports by India post TRIPS



Source: *Handbook on Statistics on the Indian Economy.*

The Figure 1 clearly shows that there has been growth in India's export through pharmaceutical industries even after the implementation of TRIPS. During the 10-year period, the growth has been increasing year by year with a sign of dip in 2009, however, it also gained its pace by the years 2012–2013. Therefore, it would not be appropriate to severely criticise the TRIPS framework solely on the basis of export.

Next, it is also important to understand the concept of Global Value Chain to truly appreciate the impact of TRIPS. The Global Value Chain (GVC) refer to international production sharing, a phenomenon where production is broken into

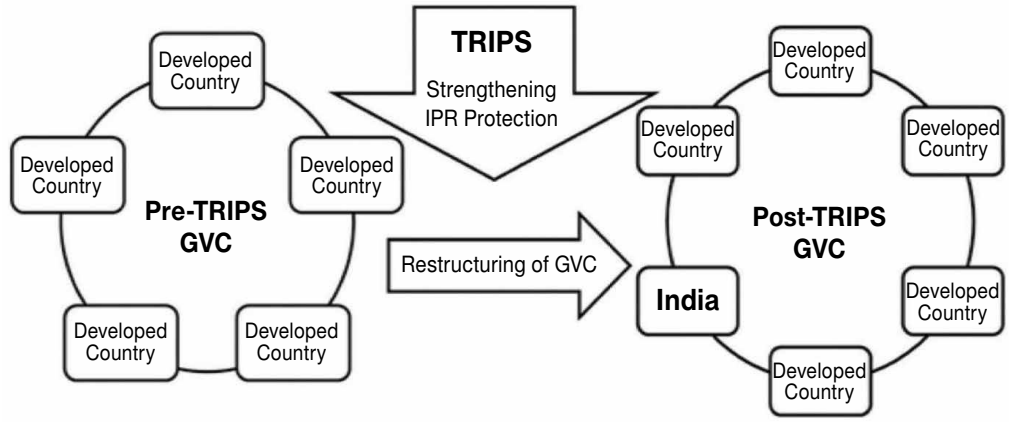
activities and tasks carried out in different countries. In GVCs, the operations are spread across national borders (instead of being confined to the same location).[22]

The Global Value Chain (GVC) before TRIPS was limited to the developed countries only as there was no scope of product patent in India. As now India allows for the product patent option, the global players are interested in operating pharmacy business in India and investing in Research & Development, which was lacking before TRIPS.

Now, the pharmacy companies can easily outsource their research and manufacturing activities to countries like India, as the IPR regime related to patent has attained a certain stage of uniformity post TRIPS. India can effectively utilise the globalisation of pharma industry can be a hub for research and marketing of the medicines and drugs.

The difference between Global Value Chain post and pre-TRIPS is described in a diagram (Figure 2).

Figure 2. The difference between Global Value Chain post and pre-TRIPS



Source: A. Kamiike, *The TRIPS Agreement and the Pharmaceutical Industry in India*, "Journal of Interdisciplinary Economics" 2020, 32(1), pp. 95–113, https://doi.org/10.1177/026010791987557 (access: 21.08.2022).

Figure 2 shows that during pre-TRIPS era the only the developed countries were involved in the value chain process however, with introduction of TRIPS in the Indian pharmaceutical economy, India has been made part of the process through globalisation. This ensures more investment in the sector which will not only benefit the healthcare sector but will also open the gates for more employment

[22] *What Are Global Value Chains and Why Do They Matter?*, https://iap.unido.org/articles/what-are-global-value-chains-and-why-do-they-matter (access: 21.08.2022).

and sources of earnings for the Indians, which subsequently makes a better living and increases the financial capacity of an individual through which basic needs such as healthcare can be accessed in a dignified manner.

As it can be seen TRIPS – no matter how much it is criticised for its inclination towards developed countries – also has certain positive impacts on developing countries such as India. The flexibilities that are available under the TRIPS regime must be exercised effectively to extract maximum benefit.

The Attempt to Maintain Balance Between the Patent Regime and Securing Public Health: A Short Analysis and Way Forward

Finally, the reliance must be placed in brief upon the policies of government after 2005 to shape the patents regime in the healthcare sector. The Government of India introduced the National Pharmaceutical Pricing Policy (2012) which had the scheme regarding the price control of drugs in India. This action of the government brought various drugs within the ambit of price control. However, the government was equally aware of the fact that for a nation to prosper it needs to support innovation through research and development and kept patented drugs out of the scheme for the period of 5 years.

However, at the same time, the distinction between patented drugs and non--patented drugs raised question upon the constitutionality of such government action as the drugs included in the list is mostly of essential in character and in the country like India keeping essential drugs away from price control order based upon patentability can prove to be lethal for public health. The right to healthcare being a constitutionally guaranteed right must have been kept at higher pedestal.[23]

The Indian Judiciary has remained highly vocal about the need and importance of access to medical facilities to every citizen of the nation. It has vehemently ruled in the celebrated case of All India Drug Action Network v. Union of India[24] that government must make every effort to provide access to life saving drugs to its citizens.

Based on the policy as discussed and the pronouncement by Hon'ble Supreme Court, it is clear that though India strives to have a robust mechanism for patent driven pharma sector, yet considering the constitutional vision and scheme of India, it would not be viable nor wise to keep patent rights over and above the right to health.

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[23] D. Jain, *Is the National Pharmaceutical Policy, 2012 Really Cheering the Pharma?*, http://www.ijlt.in/archive/volume9/Dipika%20Jain.pdf (access: 21.08.2022).

[24] (2011) 14 SCC 479.

The paper clearly shows that India has stood tall and committed towards its international obligation and has complied with the TRIPS regime with the best of the possibilities considering the national interest, which has no doubt showed progress in the pharma industry.

It would be appropriate to refer the case of Novartis AG v. Union of India and Ors[25] to conclude the paper. The case is of prime importance as it showed the combined efforts of the patent authorities in India as well as Indian Judiciary to protect the national interest of India over any other obligations. The Hon'ble Supreme Court agreed with the decision of patent authority that Section 3(d) of Patents Act (1970) is well within the regime of flexibility as provided under the TRIPS agreement under Article 27(2) which permits members to exclude certain inventions which is necessary to protect public order or morality and to protect human life. The court clearly held that mere trivial changes in the nature of drugs without any actual change in its efficacy would not allow the drug to be patented.

Section 3(d) was upheld by the court as to be constitutionally valid, as it intended to reduce the drug prices and make health care more affordable for the Indian patients which is in absolute conformity with the legal and social ethos of India as well as complies with TRIPS.

Therefore, it can be said that India's approach towards patents under TRIPS has remained balanced to the extent possible in view of the municipal laws of India. The allegation that approach is more titled towards securing public health is not in actual terms an allegation rather should be termed as appreciative efforts of India to secure public health over any other obligations through which not only India's medical needs are met but also various developing and underdeveloped countries are blessed with the practice of reverse engineering which is used for manufacturing generic medicine, as the same is made available at affordable rates. Hence, it can be concluded that India recognises its commitments both in the commercial field and in the field of human rights.

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