Right to Health: An Analysis of the IPR Regime and Subsequent Growth Opportunities

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Abstract

The growth of Intellectual property Rights (Hereinafter referred as IPR) over the last decade has been exponential, which makes the importance of legislations governing such rights all the more paramount. Compulsory Licensing falls under the ambit of such legislations. A Compulsory license, under a broad umbrella, provides that the proprietor of a patent or copyright licenses the utilization of their rights against payment either predefined by the jurisdiction of law or decided upon, through some sort of assertion or arbitration. Basically, under the above-mentioned consideration, an individual or organization trying to utilize another's protected innovation can do so without looking for the rights holder's assent, and pays the rights holder a set expense for the same. With the continual growth of Intellectual Property Rights (IPR) in the last decade, the relevance of Compulsory Licensing in India has reached the very forefront. We have gone into a brief history of the origins of Compulsory Licensing in India has reached the very forefront. We have gone into a brief history of the origins of Compulsory Licensing in the field of pharmaceuticals, and its transformation over time, and how it has become a cogent and vital cog in our modern legislations. We have, throughout the entirety of this paper, pointed out the benefits of Compulsory licensing of pharmaceuticals from an Indian perspective, and how it helps build our economy, and how it helps us to run parallel along with the developed nations. The Paris Convention for the Protection of Industrial Property of the year 1833, was one of the first of its kinds which talked about the issue at hand under the gamut of IPR. India, however signed the amended provisions of the same, more than a century later; in 1998. We have highlighted how these improved legislations, which are in accordance with the International Standard, prove that India has evolved to be ‘technologically -sound’. The same, as a result are a testimony to India being able to cope up with other developing and developed-countries. There have been many controversies in India, surrounding these improved legislations, even though they were in consonance with the International agreements.

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4 Leah Chan Grinvald, A tale of two theories of well-known mark., Vanderbilt Journal of Entertainment and Fall, 2010
We have talked about how India has developed its laws governing the issuance of such patents, prior to The Agreement on Trade-Related Aspects Of Intellectual Property Rights (TRIPS), how it has undergone a period of transition, and how it has moulded its existing laws to suit TRIPS. This has significant importance in the field of pharmaceuticals, because firstly, it helps in the improved access of such pharmaceutical products to the global masses, which further aids in the execution of the idea of everyone having a “Right to Health”\(^5\). Secondly, improved legislations like these help us in building and stabilizing our economy. The so mentioned legislations help the pharmaceutical firms in India to expand our markets outside of Indian dominions, and secure markets on a global scale. This paper points forth as to why Compulsory Licensing is relevant in the present-day context, and how by acceding to such International agreements, India has become a real force in the pharmaceutical market abroad.

AN INTRODUCTION TO COMPLUSORY LICENSING

In this day and age, protection of IP rights has gained new ground, and is gaining even more relevance with each passing day. Patents are issued for new inventions, which benefit the masses at large. Inevitably, there follow many laws and regulations which govern the issuances of licenses to gain access to these protected patents. As far as licenses go, there are essentially two types of patents: Voluntary and Compulsory Licenses. This paper will deal only with the effects and the repercussions, vis-a-vis the Growth and Evolution of Compulsory Licensing in India.

The idea of ‘Right to Health’ has been propagated by many public health activists for quite some time. This Right to Health, essentially signifies that all people are entitled to a right to gain access to medicines, and are entitled to a minimum standard of health, and can’t be deprived of such an access simply on the grounds of Economic status, Cultural and/or Social differences. This ‘Right to Health’ comes at a price, as the issuance of patents to pharmaceutical products, leads to an increase in the costs of these products. This, in turn, affects the wide range of accessibility to the overall population. When we talk of compulsory licensing, we attempt to draw a very fine line of demarcation between economic benefits and the idea of a ‘Right to Health’.

This line of distinction can only be achieved through Compulsory Licensing. It acts as the bridge that joins these two variants together. On one hand, it bolsters industries, and their overall economy. On the other hand, it also ensures that people get access to the required pharmaceuticals. It acts like a “necessary evil” - something that must be avoided, keeping in mind the welfare of the entire general mass. This concept is in consonance with the Welfare Economic Theory as propounded by Adam Smith. The portion of compulsory licensing will be covered in the later stages of this paper. This essential compromise can only be reached through the intervention of legislative laws.

The term ‘Compulsory Licensing’, essentially refers to the grant of permission by a government to a particular enterprise who is seeking to use the intellectual property of its proprietor without his/her consent. Such a license requires the sanction of the government, and requires for the compensation of money, or resources in lieu to the proprietor of such Intellectual Property. It encompasses many licenses including pharmaceuticals and other inventions related to public health, but the scope of such licenses is potentially widespread as they apply to any technological invention or discovery, which is beneficial to the masses, and is of tangible benefit.6

Over the last few years, we have seen the growth of IP laws and treaties reach new heights, and continue to gain even more relevance with each passing year, most notably in the developing countries. Some of the few prominent treaties are those of that of the TRIPS7 (Trade Related Aspects of Intellectual Property) Agreement and the Doha Convention8, which will be covered through the entirety of this paper. The TRIPS Convention is an agreement wherein the participating members of the WTO (World Trade Organization) resolve for stringent measures to protect IP rights.

Inevitably there are people who vent their disagreement towards such acts of legislation or treaties for that matter. Such people disagree to it on the grounds that they would have astute Health- Impacts on the people concerned. To this measure, TRIPS requires the developing countries to issue patents for pharmaceutical products, which indirectly connotes to the limited

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6 35 U.S.C. §101
8 WTO, Ministerial Declaration of 14 November 2001, WT/MIN (01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration]
access for the beneficiaries in such countries to less-expensive versions of the newly developed medicines. In the view of some, it will diminish incentives for a ‘novel’ innovation.

They are of the opinion that compulsory licenses would necessarily lead to the diminishing of incentives for firms and other concerned bodies to conduct healthy research, which, in turn, would be detrimental to the long-term goals of the overall development of the nation. There are others who believe that the issuance of such licenses will further the cause of public health in general, and also help in technology transfer.

The fundamental question remains-Can the developing be made to harmonize their IP laws in accordance with that of the developed nations? The essence of establishing such a convention was to ensure that the developing countries could frame their IP laws in conformity with that of the developed countries. The TRIPS objective now borders upon new multinational harmonization, and to progress along the lines of its implementation and its enforcement. This Convention, *prima facie*, aims to unite all the members of the WTO to establish common ground rules to manage Intellectual Property Rights in their countries, which will in turn aid the betterment of free flow of public health goods in the Global Economy. The clash between economic development, and the protection of rights of public health was pretty evident in the days prior to such a convention.

The consumer ideally wanted a less-controlled market, while manufactures wanted exclusive control over their products. This exclusive control led to an increase in the prices of the products, which made it less accessible to the masses, and put the entire public health in jeopardy. This is where the importance of such a convention is brought to the forefront. The TRIPS Convention aims to bridge this gap existing between these two variants.

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13 See, e.g., Liza Porteus Viana, US Lawmakers Seek to Fuel International IP Enforcement Activities, INTELL. PROP. WATCH, Nov. 8, 2007
14 Prescription Drugs, supra note 4, at 6-7.
Firstly, the competition increases, and it keeps the manufacturing companies on their toes.\textsuperscript{15} It directly challenges the exclusive rights granted to the patent user.\textsuperscript{16} Secondly, the element of misuse of such control is nullified to a large extent. This is obviously, just conjecture, as things could go the other way as well. The consumers want a less controlled market, while the many proficient IP law experts are of the notion that it leaves sufficient “wiggle room” in it for the developing countries, and if pressurised from an external source\textsuperscript{17}, they could completely discard such laws and agreements bound by the Convention, by invoking its flexibilities.\textsuperscript{18} This comes in the backdrop of allowing the developing countries a “transition period” to frame laws that are in accordance with the TRIPS Convention. India didn’t need any such transition period, as it seamlessly eased into the system. This sort of a system aided India’s cause, as it has a capacity to implement these laws in accordance to local needs. Compulsory Licensing has effectively been executed in India, and this paper aims to develop a nexus between the past and present India, and how ‘Make in India’ scheme launched by the government paves way for India becoming the third largest pharmaceutical market in terms of Incremental Growth. In addition, India being the largest provider of generic drugs globally, with a share of twenty percent in the global economy.

THE EVOLUTION OF INDIA’S PATENT LEGISLATION

India’s pre TRIPS era

The concept of issuing pharmaceutical patents was first initiated by the British, during the colonial era.\textsuperscript{19} Over time, the system of issuing patents evolved, and over the next few decades, India witnessed a sharp fall in the production of -patents on medicines.\textsuperscript{20} One of the more famous legislations that followed was the Patents Act, 1970. This came in the backdrop of the exorbitant prices charged by the firms on pharmaceutical products, something which the

\begin{thebibliography}{99}
\bibitem{reichman} J.H. Reichman, \textit{The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries}, 32 CASE W. RES. J. INT’L L. 441, 458-59, 461 (2000)
\end{thebibliography}
common people could not afford to buy.\textsuperscript{21} This was the result of the continuing dominance of the foreign pharmaceutical firms who controlled almost 70\% of the local market.\textsuperscript{22}

This consequently allowed India\textsuperscript{23} to transform and develop itself into one of the more functional pharmaceutical industries on the global scale. This created space for the local pharmaceutical companies to dive into the local market, and increase their overall share of the Indian Market. This resulted in the dwindling of shares by the foreign firms, who were now held in their steps. As a result, Indian firms became more technically sound and sophisticated knowing that they could ward off attention from the foreign firms, they started developing new processes for drug production, and also became skilled in reverse-engineering.\textsuperscript{24}

\textbf{INDIA’S AGE OF TRANSFORMATION (1995-2005)}

\textbf{TRIPS Agreement in India Hits A Roadblock}

India added a new dimension to its International IP Law, when it became a member of the WTO, and accepted The TRIPS Agreement. This agreement came into force in 1995.\textsuperscript{25} The TRIPS Agreement revolved around the idea that the supremacy and the overall stability of the developed nations, vis-à-vis, the USA, Japan, Europe depended upon them ensuring ample protection of IP rights outside their dominions, especially in the developing countries.\textsuperscript{26} The TRIPS Convention also ensured that for the countries to be part of the WTO, they had to be a part of the TRIPS agreement.\textsuperscript{27} This, specifically, underlined the “single undertaking” nature of the WTO.

The TRIPS Agreement has stirred a lot of controversy, as it requires patents on pharmaceutical products, which was something that the developing nations did not adhere to at that time.\textsuperscript{28} This didn’t go down well with the developing nations as it affected their shares in the local

\textsuperscript{21} STAFF OF S. COMM ON THE JUDICIARY, SUBCOMM. ON ANTITRUST AND MONOPOLY, 87TH CONG. IST SESS., REP. No. 448 (June 27, 1961) 41 tbl.19
\textsuperscript{22} SUDIP CHAUDHURI, THE WTO AND INDIA'S PHARMACEUTICALS INDUSTRY: PATENT PROTECTION, TRIPS, AND DEVELOPING COUNTRIES 1, 29 (2005)
\textsuperscript{24} Dilip G. Shah, Generic to Innovative: Transition of Indian Pharmaceutical Companies, 5 PHARMA FOCUS ASIA 13, 14 (2007).
\textsuperscript{25} The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005
\textsuperscript{26} Susan K Sell, Private Power, Public Law: The Globalization Of Intellectual Property Rights, Berne Convention for the Protection of Literary and Artistic Works art. 33, Sept. 9, 1886
\textsuperscript{28} Carlos M. Correa, Patent Rights In Intellectual Property and International Trade: The TRIPS Agreement 227
Issuing of patents meant that the prices of the pharmaceutical products would go up, and which render them incompetent to function in such conditions. The only upside that was presented to it was the fact that it would lead to pharmaceutical innovation. By allowing the innovators to block competition, and therefore, lead to a greater appreciation of their ideas, IPR’s can act as incentives for initiating further investment in research and development.

India, consequently, objected to the TRIPS Agreement, and all of its patent provisions, as did all of the local pharmaceutical firms. On being faced with the threat of having to leave the WTO if it didn’t adhere to the TRIPS Agreement, India finally acceded to it. TRIPS Agreement required that the issuance of compulsory licensing should be “predominantly” within the local markets only.

Article 31 of this Agreement was a slight deviation from this general rule, as it allowed the issuance of compulsory licenses by the government to third parties under four conditions: (a) Situations of National Emergency (b) Situations involving commercial non-public use (c) Where there is an inherent need to correct anti-competitive practices (d) Involving dependant patents. TRIPS inherently aims to bridge the fine gap between the interests of consumers and the manufacturers. This article added many flexibilities as to the issuance of compulsory licenses, though it still left terms like “National Emergency” undefined, which led to many ambiguities, thus leaving the provisions of the agreement in utter uncertainty. As a matter of fact, there were doubts as to whether India could avail these flexibilities under this article, and whether or not, it would have to declare a state of National Emergency to invoke this particular statute.

Effects of The TRIPS Agreement on India: An Overview

Between the periods of 1995-2005, as a direct response to the imminent threat that was looming, that is the loss of the local market, due to the increase in prices of the pharmaceutical products, the local firms turned their attention outside India. They turned towards exports and
R&D (Research and Development) in the developed nations. This was aptly pointed out by the Organisation of Pharmaceutical Producers of India (OPPI)\textsuperscript{36}.

Indian companies, however, could not manage to enter the American Market because of their stringent regulatory barriers. This, however, was temporary, as the Indian firms gained valuable expertise in navigating patents and soon they were to hold 20-50% of all the applications of drug approval in the US. \textsuperscript{37} This massive turnover has resulted in India gaining a significant advantage in trade affairs. \textit{“It has become one of the largest suppliers of pharmaceuticals formulations in the world”}.\textsuperscript{38}

This is in stark contrast to what the condition was prior to the TRIPS Agreement. Foreign exports now formed a bulk of the revenue of the local firms, than the local sales. This, in turn, will lead to greater foreign investment. As per the WHO, "Developing countries bear the brunt of the problem" and "poverty, and the lack of an official supply chain, are major factors in creating markets for counterfeit products"\textsuperscript{39}. By using India’s third world patent system in line with that of the Western countries, India gained legitimacy and positive attention. The R&D Sector also improved drastically under the TRIPS Agreement.

One of the ramifications that have followed is that \textit{“Indian firms involved in Research and Development have focused on the diseases prevalent in the developed countries other than those specific to India”}.\textsuperscript{40}

This economic development brought the complete and utter disregard of public health to the forefront, as public health activists raised the issue of the conflict between the two sections.\textsuperscript{41} Many NGO’s, the WHO, and other organizations began to study and analyse the relationship between economic development, and the overall public health. The HIV crisis,
acted as the epicentre for the medicine campaigners, who propagated the idea that TRIPS acted as a barrier to the access of generic AIDS medicines in the developing countries.\textsuperscript{42}

The efforts of the health activists reaped awards as the Doha Convention ensured that the issuance of compulsory licenses extended to that of the developing countries as well, also known as the countries who did not have the resources to manufacture medicines or pharmaceutical products, could now get access to such products, by means of a compulsory license.\textsuperscript{43}

The Doha Declaration was held in Doha, on November 14, 2001. It shifted the focus from that of the developed countries to that of the developing countries, as it moved a step further towards promoting and looking out for the overall benefit and welfare of the entire global population at large. It aimed to promote an increased access to medicines and, consequently support and aid the overall public health.

It allowed the issuance of compulsory licenses to those countries which lacked the resources to manufacture their own pharmaceutical products. The Doha Convention went a long way in alleviating the distressing conditions in the third-world countries.\textsuperscript{44} It, however, failed in its objective to clarify the term “national emergency”, which being a vague term, could be construed so as to benefit the developed nations.\textsuperscript{45}

To put things into perspective, in the light of all the ambiguities mentioned in the TRIPS Agreement, India put forward its Revised Act in 2005. India was attributed with the assertion that developing countries required a “Transition Period”.\textsuperscript{46} India, had to file their patent applications, in accordance with the “Mailbox Provision”, when the 2005 changes came into effect.\textsuperscript{47}

In order to meet with the TRIPS deadline, India passed an ordinance that temporarily brought such laws into force.\textsuperscript{48} "The Indian Pharmaceutical Association (Hereinafter referred to as

\begin{itemize}
\item \textsuperscript{42} James Love, Panel Discussion, AIDS Drugs And The Developing World: The Role Of Patents In The Access Of Medicines, 12
\item FORDHAM INT’L PROP. MEDIA & ENT. L.J. 683, 705 (2002)
\item Radhika Bhattacharya, Are developing countries going too far on TRIPS? A closer look at the new laws in India, American Journal of Law & Medicine, Summer-Fall 2008 Issue
\item WTO, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002)
\item Frederick M. Abott et al., International Intellectual Property in an Integrated World Economy 330 (2007)
\item Id
\item Patents (Amendment) Ordinance, No. 7 of 2004.
\end{itemize}
IPA), which represented the largest local generic firms, insisted that the Revised Act include a new provision which would prevent the patenting of already known substances, as well as the patenting of new forms of known substances.\(^{50}\) Local HIV organizations rallied against such laws, and help protests against the passing of the bill.\(^{51}\) Humanitarian bodies like MSF\(^ {52}\) and representatives from WHO, also pleaded to the government “To make laws that would facilitate access to the medicines and not go beyond the minimum level which was required by TRIPS.”\(^ {53}\)

The ultimate objective of adding the provision of compulsory licensing in the 2005 Revised Act was to provide such a license\(^ {54}\) if (a) “a patent is not worked in India [for] three years after its grant”\(^ {55}\) (b) “reasonable requirements of the public” are not satisfied” (c) “the patented invention] is not available to the public at a ‘reasonably affordable price’\(^ {56}\).”

The Revised Act has further added some provisions to shape the future of India’s pharmaceutical industry. These provisions are (a) the recognition of product patents, not just process patents (b) A twenty-year term from the filing date of applications (c) the availability of patents for industrial application.”\(^ {57}\)

On close examination of the Indian context, we can find many anomalies in the Revised Act. Many undefined and vague terms, such as the requirement to involve in “reasonable” efforts to negotiate with the patent-holders is lost completely in relation to the Indian perspective.\(^ {58}\) Such ambiguities have given rise to many flexibilities, which are of relevance with respect to the developing countries, and their access to pharmaceuticals.

Such a wide analysis of the flexibilities is beyond the scope of this paper. Despite these ambiguities, India has gone on to implement the TRIPS Agreements, as this allows a vast scope of expansive development and flexibility in the area of pharmaceuticals that no other legislation

\(^{50}\) See AmitSen Gupta, Mashelkan Committee Trips Again, People's Democracy, Sept. 20, 2009

\(^{51}\) Interview with Loon Gangte, President, Delhi Network of Positive People, in New Delhi, India (June 20, 2007)

\(^{52}\) MEDICINS SANS FRONTILRES, WILL THE LIFELINE OF AFFORDABLE MEDICINES FOR POOR COUNTRIES BE CUT 5-6 (2005)


\(^{54}\) Sands, Katharine W. Prescription drugs:India values their compulsory licensing provision--should the United States foll., Houston Journal of International Law, Winter 2007 Issue

\(^{55}\) Peter Nunn, India Introduces Product Patents, CHARLES RUSSELL, Apr. 1, 2005

\(^{56}\) Id.

\(^{57}\) See Jeffrey D. Hsi, Patent Law in India Focuses Strongly on R & D, 25 GENETIC ENG’G NEWS 9, 9-10 (2005)

\(^{58}\) Art. 31(b), TRIPS
had ever provided before in the international dominions, remains one of the more go-to topics to research on.

**THE PRESENT SCENARIO IN PHARMACEUTICAL INDUSTRY: MAKE IN INDIA**

“Drugs are a public good and not simply just another commodity: first for their high social value, and then because consumers and prescribers are unable to assess their quality, safety and efficacy.”

The Make in India scheme is an initiative launched by the NDA Government led by our honourable Prime Minister Shri Narendra Modi. It is a method of Self Reliance, which aims to bring creativity and innovation by making India self-sufficient in terms of latest technological advancements, thereby reducing dependence on foreign and/or alien agencies for the manufacturing of products. The main idea behind the aforementioned moment of evolution is to prevent the outflow on human capital from the country to foreign nations by making it a global manufacturing hub. This outflow of capital is also termed as Brain-Drain. Make in India pledges to make Indians Job-Creators, and not Job-seekers. “India, too can replicate this by focusing on 'know-why' and 'knowhow' in sectors such as Pharma...which are most effectively expected to give India a competitive edge in order to become a meaningful player in the global supply chain”. Less dependence on foreign capitals would mean a surplus in the Balance of Payments (Hereinafter referred to as BOP), in turn avoiding the condition of disequilibrium in BOP, which is in turn a healthy sign for a developing nation like India.

Speaking statistically, a study titled, Exploring Prospects For Make In India and Made In India, had gone on to show that “The sector directly or indirectly employs about 4 million skilled and unskilled labourers, The sector directly or indirectly employees about 4 million skilled and

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59 Dr. Gro Harlem Brundtland, Director General’s Speech
The National Pharmaceutical Pricing Policy, 2012, which is complementary to Make In India Campaign, has the following as its salient features: 1) The regulation of costs of medications on the premise of the vitality of medications as indicated under the National List of Essential Medicines (NLEM)- 2011, which is in support of “Right to Health”. The regulation of costs of medications on the premise of directing the costs of definitions have been adjusted, in addition to the regulation of costs of medical treatment on the premise of settling the maximum price ceiling of details through Market Based Pricing.63

The Make in India campaign can be regarded as a central important facet in the Union Budget of India, 2015-16, which grants impetus to SETU (Self Employment and Talent Utilization) to be set up as a techno-monetary project, hatching and help project to backing all parts of a new company. In addition to this, Atal Innovation Mission (AIM) is expected to be set up in NITI to give an Innovation Promotion Platform comprising of academicians, and drawing upon national and worldwide encounters to encourage a society of advancement and innovative work.64

A national centre to help develop bulk drugs and facilitate their research is being set up in Hyderabad. An uncanny effort to duty free import of Pharmaceuticals with reference to Indian Standards is proposed to be implemented.65

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64 Ibid

65 Supra 59
CONCLUSION: THE ROAD AHEAD

“But I have promises to keep, and miles to go before I sleep and miles to go before I sleep”. 66

-Robert Frost

Throughout the entirety of this paper, we have aimed to highlight how the domain of Compulsory Licensing in India has seen a drastic evolution with respect to laws that govern the same. The “Make In India” initiative launched by the Central Government forms a strong base of Indian Economy that is apt to serve the superstructure that Indian Economy can rely upon. Through the measures of policy setting and priority setting, Indian Government would be able to fulfil the Role of the State in catering to public health.

The road to global leadership in the field of pharmaceuticals is three fold and can be achieved through: Reviving Manufacturing, Gaining Global Competitiveness and thereby claiming global leadership. 67

The IPR skeleton in India is stable yet flexible which receives its backing from Legal and Judicial legislations. It is also fully consistent with the understanding and considerations by abiding to TRIPS Agreement.

India is committed to broad assortment of overall techniques to revitalize India’s manufacturing sector. Furthermore congregations relating to intellectualisation benefits have been construed and are in the process of implementation to facilitate Foreign Direct Investment (Also known as FDI).

The strength of Indian IPR regime is unquestionable very strong. A vast plethora of awareness programmes are being conducted by the Government in order to acquaint the local producers, in addition to foreign investors to highlight the benefits of Making in India.

“During the last few years, Indian IP offices have undergone major improvements in terms of upgradation of IP legislation, infrastructure facilities, human resources, the processing of IP

applications, computerization, databases, and quality services to stakeholders, transparency in functioning and free access to IP-data through a dynamic website."

It would be correct to say that the present scenario of Indian Legislations has paved innumerable ways to the safeguards of Intellectual Property Rights, along with policies to transform India to be a leader in the field of drugs and pharmaceuticals, thus fulfilling its duty to become the global ambassador in catering the ‘Right To Health’ for all.

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69 Supra 3