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From Nexavar to Zolgensma: Has Indian Compulsory Licensing Law Evolved?

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ABSTRACT

The compulsory licence issued in India in 2012 for Bayer's cancer drug Nexavar remains the seminal instance of section 84 of the Patents Act, 1970 in action. The case is frequently read in India either as proof that patient health trumps patent rights or as an unusual intrusion on pharmaceutical innovation. Neither reading is complete. This article asks whether Indian compulsory licensing law has advanced from Nexavar to Zolgensma, the extremely expensive one-off gene therapy for spinal muscular atrophy. The law has advanced in doctrine and in procedure, but it has not changed in terms of remedy. Nexavar affirmed the independent justiciability of the three grounds in section 84, and assessed affordability by reference to the public rather than to the patentee's preferred pricing framework. The later applications concerning dasatinib and saxagliptin made the process more evidence based. Litigation arising from the pandemic indicated that sections 92 and 100 are available in emergencies, while negotiation and voluntary licensing remained the executive's preferred approach. Zolgensma shows the point at which this framework fails. Compulsorily licensing a patent conveys no knowledge of how to manufacture a product built on viral vector technology, and it supplies neither cell lines, quality systems, clinical data and regulatory approval nor the financing needed to purchase the therapy. The argument advanced here is that the Indian scheme is now a workable bargaining and arbitration mechanism for reproducible products, but that it lacks any settled connection with the technological and financial institutions that advanced therapies require. Evolution now demands a coherent process that links those institutions.

Keywords: *compulsory licensing, Patents Act 1970, Nexavar, Zolgensma, access to medicines, gene therapy, rare diseases*

I. INTRODUCTION

From Nexavar to Zolgensma, the object of pharmaceutical patent policy changes. Nexavar, or sorafenib tosylate, is a small molecule cancer drug that an experienced Indian generic manufacturer could produce once the patent obstacle was removed. Zolgensma, or onasemnogene abeparvovec, is a weight-based, one-time treatment that delivers a functional copy of the SMN1 gene using an adeno-associated virus vector. The first problem was one of

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price, supply and permission. The second combines price and permission with know-how, biopharmaceutical manufacturing, cold chain logistics, specialised administration, safety surveillance and public financing.[1]

This distinction raises more than a comparison of list prices. Compulsory licensing under Indian law is not an authority to reduce the price of a life-saving medicine at large. It authorises specified uses of one or more Indian patents, subject to grounds, procedure, remuneration and the availability of a licensee capable of working the invention. No decision under section 84 comparable to Nexavar has yet been made in relation to Zolgensma.[2] The question is whether a framework built around conventional medicines has matured enough to deal with an advanced therapy in which the obstacles are not only patents.

The answer proposed here is a limited one. The Indian framework has developed doctrinally, with Nexavar supplying the interpretation of the reasonable requirements of the public, of a reasonably affordable price and of working in the territory of India. It has developed procedurally, requiring genuine efforts at voluntary licensing and product specific evidence, and routing appeals to the High Courts rather than to a specialised tribunal. In its remedial function, however, the framework has not matured. No further licence has been granted in order to open a market; the executive continues to rely on voluntary mechanisms; the disclosure requirements that made working easier to assess have been relaxed; and the patent system remains unconnected to technology transfer and financing.

The disparity has a constitutional dimension. The Supreme Court has located a duty to secure life and to provide health services in Article 21, while accepting that the allocation and management of resources are governmental functions.[3] Compulsory licensing is one means by which that obligation can be balanced against temporary patent rights. It is neither automatic under the right to health nor a substitute for a health system. Progress should therefore not be measured by the sheer number of licences granted, without regard to whether they are used.

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[1] U.S. FOOD & DRUG ADMIN., *FDA Approves Innovative Gene Therapy to Treat Pediatric Patients with Spinal Muscular Atrophy, a Rare Disease and Leading Genetic Cause of Infant Mortality* (May 24, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-innovative-gene-therapy-treat-pediatric-patients-spinal-muscular-atrophy-rare-disease; EUROPEAN MEDS. AGENCY, *Zolgensma: EPAR Medicine Overview*, https://www.ema.europa.eu/en/medicines/human/EPAR/zolgensma.

[2] WORLD INTELLECTUAL PROPERTY ORGANIZATION, *An International Guide to Patent Case Management for Judges* ch. 6.10 (India), https://www.wipo.int/patent-judicial-guide/en/full-guide/india/6.10 (recording that compulsory licences are hardly ever issued in India and that the single instance concerned a cancer drug).

[3] *Paschim Banga Khet Mazdoor Samity v. State of West Bengal*, (1996) 4 SCC 37 (India); *State of Punjab v. Mohinder Singh Chawla*, (1997) 2 SCC 83 (India).

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II. THE LEGAL ARCHITECTURE: FLEXIBILITY WITH CONDITIONS

A. TRIPS and the public health baseline

The TRIPS Agreement does not make the compulsory licensing of patents unlawful. Under Article 31 a member may authorise use of a patented invention without the authorisation of the right holder where the authorisation is considered on its individual merits, where efforts to obtain a voluntary licence on reasonable commercial terms have failed within a reasonable period, and where the authorisation is non-exclusive and limited in scope and duration.[4] Prior negotiation may be waived in a national emergency, in circumstances of extreme urgency, for public non-commercial use, and to remedy practices found to be anti-competitive.

The Doha Declaration dispelled any suggestion that these safety valves subordinate public health to the patent monopoly. Members of the World Trade Organization recognised that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, that each member has the right to grant compulsory licences and the freedom to determine the grounds on which they are granted, and that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency.[5] Article 31bis later established a dedicated export route for countries without sufficient manufacturing capacity in the pharmaceutical sector, which India implemented through section 92A.[6]

These rules set a floor. They leave domestic institutions to work out affordability, public need, evidence, procedure and the relationship between importation and local production.

B. The Patents Act and its graduated toolkit

Section 83 supplies the interpretive constitution for Chapter XVI. Patents are to encourage inventions and their working in India rather than to secure a monopoly over imports; they should facilitate the transfer of technology and contribute to social welfare; and they should not impede the protection of public health or be used to keep medicines from being available at reasonably affordable prices.[7] These are not free standing causes of action, but they guide the Controller in exercising the licensing powers that follow.

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[4] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299.
[5] WORLD TRADE ORGANIZATION, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, paras. 4, 5(b)-(c) (adopted Nov. 14, 2001).
[6] Protocol Amending the TRIPS Agreement art. 31bis, Dec. 6, 2005, WT/L/641; The Patents Act, No. 39 of 1970, s 92A (India).
[7] The Patents Act, No. 39 of 1970, s 83 (India).

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Section 84 provides the general, applicant driven route. At any time after three years from the date of grant of a patent, any person interested may apply on any one of three grounds: that the reasonable requirements of the public have not been satisfied; that the patented invention is not available to the public at a reasonably affordable price; or that the patented invention is not worked in the territory of India.[8] The grounds are disjunctive, although an applicant may establish more than one. In considering the application the Controller takes into account the nature of the invention, the time elapsed since the grant, the measures taken by the patentee to work the invention, the ability of the applicant to work the invention to the public advantage, the applicant's capacity to bear the risk, and whether the applicant has made efforts to obtain a licence on reasonable terms, a period that ordinarily need not exceed six months.[9]

Sections 89 and 90 make the liability rule operational. A licence should secure that the invention is worked to the fullest extent and without undue delay, while not unfairly prejudicing a person who has developed an invention in India. The remuneration must be reasonable; the licensee must work the invention to the best advantage and earn a reasonable profit; and the article must be made available to the public at reasonably affordable prices.[10] A compulsory licence is not a confiscation. The Act also provides for faster public access. Section 92 allows the Central Government to notify a national emergency, a circumstance of extreme urgency or a case of public non-commercial use, after which the ordinary opposition procedure may be abridged. Section 100 confers a right of use by or for the government on negotiated or judicially settled terms, and in an emergency the notification may follow the authorisation.[11] Section 90 bars a licensee from importing the patented article unless the Central Government, satisfied that it is necessary in the public interest, directs the Controller to authorise the import.[12] The problem is not one of power but of the absence of a protocol for choosing among and combining these options.

III. NEXAVAR AS THE DOCTRINAL BASELINE

A. The Controller's order

Bayer held Indian Patent No. 215758, granted on 3 March 2008, for a class of compounds that included sorafenib tosylate, sold as Nexavar for advanced kidney and liver cancer. Natco approached Bayer for a voluntary licence on 6 December 2010, offering to sell a month's

[8] *Id.* s 84(1).
[9] *Id.* s 84(6) and explanation.
[10] *Id.* ss 89-90.
[11] *Id.* ss 92, 100.
[12] *Id.* s 90(2)-(3).

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therapy for less than Rs. 10,000, and Bayer refused on 27 December 2010. After the expiry of three years from the date of grant, Natco applied under section 84 on 29 July 2011.[13]

The factual contrast was striking. Bayer's price was about Rs. 2,80,428 for a month of therapy. Natco offered Rs. 8,800 for the 120 tablets that constitute a month's course. The Controller estimated the number of patients in India who needed the drug, compared that estimate with Bayer's supply, and concluded that the reasonable requirements of the public had not been satisfied.[14] The licence granted on 9 March 2012 was non-exclusive and non-assignable, capped Natco's price at Rs. 8,880 for a pack of 120 tablets, required the drug to be supplied free of cost to at least 600 needy and deserving patients each year, and fixed a royalty of six per cent of net sales.[15]

Affordability entered the order in a way that acknowledged that research has value. The royalty preserved the patentee's return, while the price condition measured accessibility to the public. The order examined the patentee's obligation to supply, rather than treating any sale at all as curing the default.

B. Appellate consolidation and important limits

In March 2013 the INTELLECTUAL PROPERTY APPELLATE BOARD upheld the licence and raised the royalty to seven per cent.[16] It moderated what appeared to be the Controller's understanding of working as manufacture alone. Importation may amount to working, but whether it does depends on the nature of the article, the reasons why local manufacture is not possible, the extent of the importation and the evidence led by the patentee. That issue became central when the Bombay High Court took up the case.

In *Bayer Corporation v. Union of India* the High Court declined to disturb the concurrent findings that Natco had genuinely sought a voluntary licence, that the reasonable requirements of the public were not satisfied and that Nexavar was not available at a reasonably affordable price.[17] The Court rejected the argument that a patient assistance programme established public availability at an affordable price: charity that depends on selection and discretion is not the same as availability at a price. It stressed that the public interest is a crucial consideration where

[13] *Natco Pharma Ltd. v. Bayer Corp.*, C.L.A. No. 1 of 2011 (Controller of Patents, Mar. 9, 2012) (India); *Bayer Corp. v. Union of India*, 2014 (60) PTC 277 (Bom) (India) (Writ Petition No. 1323 of 2013, decided July 15, 2014).
[14] *Natco Pharma Ltd.* (n 13) (findings on price, patient numbers and supply).
[15] *Natco Pharma Ltd.* (n 13) (terms and conditions of the licence).
[16] *Bayer Corp. v. Union of India*, OA/35/2012/PT/MUM (I.P.A.B. Mar. 4, 2013) (India), https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/Bayer%20Corporation%20Vs.%20Union%20of%20India%20and%20Others%20IPAB%202013.pdf.
[17] *Bayer Corp.* (n 13) (Bombay High Court, on the three grounds and on the patient assistance programme).

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a medicine is concerned, and described patent law as a balance between the inventor and the public.

On working, the Court kept to a case by case approach. Importation is not irrelevant, but the patentee must explain why, in the circumstances, importation amounts to adequate working. Bayer led no evidence about why there was no Indian manufacture and only limited importation.[18] That standard is more nuanced than a local manufacturing requirement and stricter than a rule that any importation suffices.

The Supreme Court dismissed Bayer's special leave petition on 12 December 2014, declining to intervene on the facts while keeping questions of law open.[19] The procedural point matters. The Bombay judgment is the reasoned decision, and the dismissal of the petition against it did not confer constitutional status on all of its findings.

C. What Nexavar did and did not settle

Nexavar established that section 84 is a real remedy rather than a theoretical construct, that its conditions can be established through market evidence, and that a licence may combine price control, royalty, patient supply, territorial limitation and quality obligations. It did not establish a presumption that every costly medicine is unaffordable, a numerical threshold of affordability, or a rule that manufacture must always take place in India.

Long after Nexavar, it remains the only compulsory licence granted for a pharmaceutical patent under section 84.[20] The absence of a second grant does not by itself show a doctrinal retreat, since few applications have reached the decision stage. It does indicate that Nexavar never became a settled regulatory pathway.

IV. After Nexavar: doctrinal discipline, administrative reticence

A. The failed applications

The first lesson after Nexavar came from the attempt by BDR Pharmaceuticals to obtain a licence for dasatinib, patented by Bristol Myers Squibb. The Controller refused to proceed because BDR had not made a genuine effort to obtain a voluntary licence. A single request followed by an inadequate response to the patentee's queries did not satisfy section 84(6)(iv).[21]

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[18] *Bayer Corp.* (n 13) (Bombay High Court, on working and importation).

[19] *Breaking News!! SC Dismisses Bayer's SLP Against India's First CL*, SPICYIP (Dec. 12, 2014), https://spicyip.com/2014/12/breaking-news-sc-dismisses-bayers-slp-against-indias-first-cl.html.

[20] WORLD INTELLECTUAL PROPERTY ORGANIZATION (n 2).

[21] *In re BDR Pharmaceuticals International Pvt. Ltd.*, C.L.A. No. 1 of 2013 (Controller of Patents, Oct. 29, 2013) (India), https://spicyip.com/wp-content/uploads/2017/07/CLA1of2013.pdf.

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An applicant must negotiate on commercially sensible terms and show that the negotiation failed.

The 2015 application by Lee Pharma concerning saxagliptin, then held by AstraZeneca, failed for a different reason. There was insufficient evidence that the reasonable requirements of the public were unmet, that the price was not reasonably affordable or that the invention was not worked, particularly where alternative therapies in the same class were available at comparable prices.[22] Not every part of that analysis was convincing, but the institutional message was clear: the moral force of Nexavar cannot substitute for product specific evidence.

Together these decisions produced a more disciplined section 84. An applicant must identify the relevant patent, the affected population, the extent of need and supply, comparative prices and substitutes, its own technical and financial capacity, the justification for its proposed price and its efforts to obtain a voluntary licence. This discipline prevents opportunistic applications. It also makes access depend on information that is usually held by patentees or scattered across patent, regulatory, procurement and clinical databases.

B. The pandemic and the unused emergency architecture

The pandemic returned sections 92 and 100 to judicial discourse. In April 2021 the Delhi High Court directed the Central Government to engage with manufacturers and patent holders in order to increase the supply of critical medicines, and observed that if voluntary licences proved insufficient the government should not hesitate to resort to compulsory licensing on payment of appropriate compensation.[23] The Supreme Court asked the Union to state its position on compulsory licensing and government acquisition in relation to vaccines and essential medicines, on the footing that the use of intellectual property must be related to manufacturing capacity and availability.[24]

In the event, India did not invoke section 92 domestically. It relied instead on negotiated scale up, voluntary licences, procurement and regulation. The experience cuts both ways. Voluntary scale up can be rapid where originators work with Indian partners and capable facilities exist. At the same time, the absence of any compulsory licence during so clear a public health emergency shows that legal possibility is not the same as administrative capacity.

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[22] *In re Lee Pharma Ltd.*, C.L.A. No. 1 of 2015 (Controller of Patents, Jan. 19, 2016) (India); Devika Agarwal & Radhika Agarwal, *Indian Patent Office Rejects Saxagliptin Compulsory License Application*, 11 J. INTELL. PROP. L. & PRAC. 565 (2016).

[23] *Rakesh Malhotra v. Government of NCT of Delhi*, W.P. (C) 3031/2020 (Delhi H.C. Apr. 20, 2021) (India).

[24] *In re Distribution of Essential Supplies & Services During Pandemic*, Suo Motu Writ Petition (Civil) No. 3 of 2021 (S.C. Apr. 30, 2021) (India), https://api.sci.gov.in/supremecourt/2021/11001/11001_2021_35_301_27825_Judgement_30-Apr-2021.pdf.

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Political commitments were also contested. In March 2016 reports claimed that Indian officials had privately assured a United States industry body that compulsory licensing would not be used for commercial purposes. The MINISTRY OF COMMERCE AND INDUSTRY denied the allegations, and access to medicines organisations warned that any such commitment would defeat the legislative intent of the public health safeguards in the Act.[25] Official practice is therefore not one of formal renunciation but of controlled exceptionalism.

C. Changes in information and appeals

Two institutional changes matter for future cases. The first concerns Form 27, the statement of working of a patent. The Patents (Amendment) Rules, 2020 simplified the form and narrowed what had to be disclosed.[26] The Patents (Amendment) Rules, 2024 then reduced the filing frequency from once a year to once in respect of every period of three financial years, the statement to be furnished within six months of the expiry of each such period.[27] Section 146(1) still allows the Controller to call for information, but routine public information will now lag. For a therapy that serves a small and rapidly changing patient group, an interval of three years consumes most of the available window.

The second reform came through the Tribunals Reforms Act, 2021, which abolished the INTELLECTUAL PROPERTY APPELLATE BOARD and transferred patent appeals to the High Courts.[28] High Courts bring constitutional and commercial expertise, and specialised intellectual property divisions can help. The absence of a standing technical appellate forum nevertheless means that capability will vary across jurisdictions. Neither change alters the criteria under section 84, but each affects how a future applicant proves and appeals a case.

These changes support an ambiguous verdict on evolution. Procedure has become more precise and appeals more clearly located; courts have shown themselves willing to treat compulsory licensing as a legitimate legal strategy; but real time transparency about working has diminished, and no protocol for emergency decision making has been established.

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[25] Devika Agarwal & Radhika Agarwal, *The Dismal History of Compulsory Licences in India*, KLUWER PATENT BLOG (Apr. 21, 2016), https://legalblogs.wolterskluwer.com/patent-blog/the-dismal-history-of-compulsory-licences-in-india/ (recording that the Ministry of Commerce and Industry had denied the allegations in a March 2016 press statement); MEDECINS SANS FRONTIERES, *MSF Responds to Media Reports on Indian Government's Verbal Assurance to US Groups to Discontinue the Use of Compulsory Licence* (Mar. 15, 2016), https://msfsouthasia.org/msf-responds-media-reports-indian-governments-verbal-assurance-us-groups-discontinue-use-compulsory/.

[26] The Patents (Amendment) Rules, 2020, Gazette of India, pt. II sec. 3(i) (Oct. 19, 2020) (India).

[27] The Patents (Amendment) Rules, 2024, r. 131(2), Gazette of India, pt. II sec. 3(i) (Mar. 15, 2024) (India); OFFICE OF THE CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADE MARKS, *Frequently Asked Questions on Form 27* (Aug. 26, 2024), https://ipindia.gov.in/writereaddata/Portal/News/1001_1_Final_FAQs_Form-27_26thAugust2024.pdf.

[28] The Tribunals Reforms Act, No. 33 of 2021, ch. VIII (India).

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V. ZOLGENSMA AS A STRESS TEST

A. A different therapeutic object

Spinal muscular atrophy is a neuromuscular disorder caused by a defective SMN1 gene. Zolgensma uses a recombinant AAV9 vector to deliver a functional copy of that gene. The UNITED STATES FOOD AND DRUG ADMINISTRATION approved it in May 2019 for children under two years of age with bi-allelic mutations in SMN1, and the European authorisation is framed by reference to specified SMN1 and SMN2 profiles.[29]

Its clinical importance is significant but not absolute. Trials and observational studies report improved survival and motor milestones, particularly with early administration, alongside adverse effects that require controlled use and monitoring. A 2026 Indian study of thirteen children reported gains in motor milestones together with frequent transaminitis and transient thrombocytopenia, both managed successfully, and three deaths within a month of dosing, two attributed to the severity of the underlying disease and one of undetermined cause.[30] Patent policy must avoid two extremes: the therapy is neither a luxury good nor a costless cure.

Novartis set a United States wholesale acquisition cost of $2.125 million, defending it against the projected lifetime cost of chronic treatment.[31] In India the therapy was for years obtained by import at a reported cost of the order of Rs. 16 crore to Rs. 17 crore, through managed access or through fundraising by families; the Indian regulator granted approval in August 2025, although no Indian price had been announced at the time of that reporting.[32] The Government has exempted drugs for spinal muscular atrophy imported for personal use from basic customs duty and integrated tax, but a tax exemption can do little about a treatment costing crores.[33]

The *National Policy for Rare Diseases, 2021* recognises the underlying problem: orphan medicines may be prohibitively expensive, domestic manufacturing capacity is limited, epidemiological information is inadequate and public funds are stretched. Gene therapy for spinal muscular atrophy falls squarely within the category of therapies that are expensive and

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[29] U.S. FOOD & DRUG ADMIN. (n 1); EUROPEAN MEDS. AGENCY (n 1).

[30] Neelu Desai, Saheli Roy, Franzina Coutinho & Usha Kasar, *Onasemnogene Abeparvovec in Early-Onset Spinal Muscular Atrophy: An Indian Experience*, 29 ANNALS INDIAN ACAD. NEUROLOGY 197 (2026).

[31] NOVARTIS, *AveXis Announces Innovative Zolgensma Gene Therapy Access Programs for US Payers and Families* (May 24, 2019), https://www.novartis.com/news/media-releases/avexis-announces-innovative-zolgensma-gene-therapy-access-programs-us-payers-and-families.

[32] *India Approves Zolgensma, One of World's Costliest Drugs. Why It's Sparked Hope, but Also Concern*, THEPRINT (Aug. 28, 2025), https://theprint.in/health/india-approves-zolgensma-one-of-worlds-costliest-drugs-why-its-sparked-hope-but-also-concern/2730423/.

[33] Notification No. 46/2021-Customs, Gazette of India, pt. II sec. 3(i) (Sept. 30, 2021) (India) (exempting medicines for spinal muscular atrophy and Duchenne muscular dystrophy imported for personal use from basic customs duty and integrated tax); RAJYA SABHA, Unstarred Question No. 1551, *Financial Assistance to Patients with Rare Diseases* (Dec. 20, 2022), https://sansad.in/getFile/annex/258/AU1551.pdf?source=pqars.

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in which patient selection is difficult.[34] Financial assistance was raised to Rs. 50 lakh per patient at a notified Centre of Excellence, and by May 2026 the Government reported fifteen such centres; Rs. 50 lakh nevertheless falls far short of the cost of the treatments now available.[35] The arithmetic reveals the access gap.

B. Applying section 84 hypothetically

An Indian applicant seeking a licence of the patents in force in India would most plausibly make out a *prima facie* case on affordability. A cost of the order of Rs. 16 crore is not affordable to the Indian public, and occasional donations do not make it so. The rejection in Nexavar of charity as an answer to affordability is directly in point. The global managed access programme run by Novartis supplied the therapy free of charge to close to 300 children across forty countries before it closed to new requests in 2024.[36] Such programmes save lives; they confer no legal entitlement and no stable public price.

The reasonable requirements ground would have to be proved. An applicant would need data on the incidence of the condition, eligible age groups, screening rates, physician capacity, the number of units imported, alternative therapies and estimates of uptake. The rare disease policy does not supply comprehensive epidemiological data. That gap does not necessarily assist the patent holder, but Lee Pharma shows that a general claim will not do. The Controller would have to use section 146 and the available regulatory data to construct a reliable denominator.

Working would turn on the facts. Imported supplies for individual patients could amount to adequate working if properly evidenced, since Nexavar does not require domestic manufacture. Sparse supply, the absence of a stable commercial route and the absence of local technology transfer would tell against treating importation as adequate working. In the case of Zolgensma, however, showing that a patent is not worked does not show that the applicant has the capacity and the means to work it.

The patent position itself raises questions. Zolgensma rests on a portfolio of licences: exclusive worldwide licences covering the intravenous and intrathecal delivery of AAV9 for spinal muscular atrophy and recombinant AAV vector technology, an exclusive licence for delivery of the SMN gene into the central nervous system, and a non-exclusive licence for self-

[34] MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA, *National Policy for Rare Diseases 2021* (2021), https://rarediseases.mohfw.gov.in/uploads/Content/1624967837_Final-NPRD-2021.pdf.

[35] PRESS INFORMATION BUREAU, GOVERNMENT OF INDIA, *Union Ministry of Health and Family Welfare Inaugurates Two-Day National Conference on Rare Diseases in New Delhi* (May 5, 2026), https://www.pib.gov.in/PressReleasePage.aspx?PRID=2257977.

[36] NOVARTIS, *Zolgensma Global Managed Access Program*, https://www.novartis.com/healthcare-professionals/managed-access-programs/zolgensma-global-managed-access-program-gmap.

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complementary DNA technology.[37] A potential licensee would have to identify the Indian equivalents, their claim scope, ownership, status and unexpired term. Licensing one patent leaves blocking vector, construct, process, assay and use patents intact. Section 88(3) permits the benefit of a licence to be extended to other patents held by the same patentee, but it does not allow the easy consolidation of rights held by several licensors.

C. Why a patent licence may be insufficient

The real difficulty lies in tacit knowledge. Small molecule medicines can usually be characterised, reverse engineered and licensed through equivalence pathways. Viral vector therapy is produced in living systems under tightly controlled processes. Yield, potency, capsid integrity, contamination control, assay development, comparability and batch release all depend on knowledge that may be held as a trade secret. Removing patent protection without transferring manufacturing know-how does not enable production.[38]

Regulation compounds the problem. Another manufacturer would need an approved facility, starting materials, process control, pre-clinical and clinical comparability data, pharmacovigilance and approval under Indian law governing drugs and biologicals. Hospitals would need diagnostic and infusion capability, monitoring of the liver and of blood counts, immunomodulation and follow up. The European regulator's product materials set out the safety conditions that surround the treatment.[39] The Controller may license a patented medicine; the Controller cannot certify that a facility making a biological product is compliant or that a hospital is prepared.

Economies of scale are also inverted. Zolgensma is administered once to a small and urgent group. An entrant faces very large fixed costs spread over few administrations and uncertain demand. Even a zero royalty would not bring its cost structure close to that of an ordinary generic.

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[37] AVEXIS, INC., Annual Report (Form 10-K) (for the year ended Dec. 31, 2017), https://www.sec.gov/Archives/edgar/data/0001652923/000155837018001313/avxs-20171231x10k.htm (describing exclusive worldwide licences from NATIONWIDE CHILDREN'S HOSPITAL and REGENXBIO INC. and a non-exclusive licence from ASKLEPIOS BIOPHARMACEUTICAL, INC. for self-complementary DNA technology); NOVARTIS, *AveXis Enters into Licensing Agreement with Genethon* (Mar. 13, 2018), https://www.novartis.com/news/media-releases/avexis-enters-licensing-agreement-genethon.

[38] Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. INTELL. PROP. L. & PRAC. 1242, 1246-50 (2021); Neil Davey, *Overcoming Patent Barriers to Increase Access to Medicines: A New Path Forward for Compulsory Licensing*, 35 HARV. J.L. & TECH. 689 (2021).

[39] EUROPEAN MEDS. AGENCY, *Direct Healthcare Professional Communication: Zolgensma (Onasemnogene Abeparvovec): Risk for Thrombotic Microangiopathy* (Mar. 18, 2021), https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-zolgensma-onasemnogene-abeparvovec-risk-thrombotic-microangiopathy_en.pdf.

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Finally, access needs a purchaser. Families cannot sustain a market even at a tenth of the innovator's price. Without public or pooled purchasing, outcomes based payment, insurance coverage or regional logistics, a licensee may hold legal authority and still have no viable customers. Zolgensma therefore changes the compulsory licensing question from whether another entity can make and sell the product to who will transfer, validate, purchase, allocate, administer and monitor it.

VI. HAS THE LAW EVOLVED?

A. Doctrinal evolution: yes

Measured by doctrine, the answer is yes. Nexavar turned the open textured grounds of section 84 into a usable analysis. It showed that affordability is public facing, that a patient assistance programme does not answer an unaffordable list price, that supply must be assessed against the appropriate patient population, and that importation must be explained in context. BDR and Lee Pharma went on to establish that negotiation must be genuine and that a case must be made on product specific evidence.

The emergency framework has also been legitimated through interpretation. Orders made during the pandemic accepted that sections 92 and 100 can be combined with fair remuneration and production planning. Nothing in TRIPS precludes such action; the Doha Declaration preserves national choice, and Article 31 requires adequate remuneration and review rather than the right holder's approval.[40] The statutory instruments are flexible enough for ordinary market failure, emergency shortage, public purchase and export.

B. Institutional evolution: mixed

Measured institutionally, the picture is mixed. Appeals to the High Courts strengthen constitutional and judicial oversight while dispersing the technical expertise that a single tribunal concentrated, unless specialised benches and scientific assistance fill the gap. Working disclosures have been relaxed at precisely the point at which technical patent portfolios and short clinical windows demand better information. Rare disease policy, Centres of Excellence, customs relief and financial assistance provide the beginnings of a health system response, but they run in parallel with patent administration rather than in concert with it.

Most importantly, India has no mechanism for cooperation between agencies. The PATENT OFFICE knows the claims, the CENTRAL DRUGS STANDARD CONTROL ORGANISATION knows manufacture and safety, the INDIAN COUNCIL OF MEDICAL RESEARCH knows the disease

[40] TRIPS Agreement (n 4) art. 31; *Declaration on the TRIPS Agreement and Public Health* (n 5) para. 5(b).

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registries, the NATIONAL PHARMACEUTICAL PRICING AUTHORITY knows prices and the health departments know delivery. Nothing brings them into a single process.

C. Remedial evolution: largely no

Measured by remedial function, the answer is largely no. A single licence has been granted under section 84 in more than five decades of the Act's operation, and official practice continues to treat compulsory licensing as an exceptional safeguard rather than as an access scheme.[41] The difficulty with exceptionalism is not exceptionalism itself but whether it is tailored and evidence based. A remedy that cannot marshal information, technology, regulatory clearance and procurement may be formally available and practically ineffective.

Zolgensma makes the point. The inherited framework assumes an alternative producer ready to step in once the patent barrier falls. For advanced therapies, an alternative producer needs years of technology transfer and regulatory work before it can produce anything usable. The invention in issue is a composite of patents, know-how, cell banks, data, assays, quality systems and platform licences. Indian patent law can authorise the use of only some elements of that composite. It does not oblige the holder to disclose the complementary know-how, and India has no law providing for the compulsory assignment of trade secrets.

Nor is patent law equipped for questions of distribution. The Drugs (Prices Control) Order, 2013 regulates the prices of scheduled formulations and certain new drugs and confers an extraordinary power to fix prices in the public interest, but it is not a reimbursement scheme for an imported orphan gene therapy.[42] The assistance of Rs. 50 lakh under the rare disease policy is significant and still far below the price of Zolgensma. A successful compulsory licensing process would require allocation, which is an exercise in transparent health technology assessment and budgeting rather than in patent law alone.

The most accurate description is therefore adaptation without transformation. The Indian system has moved from uncertainty to a workable liability rule and a credible bargaining threat. It has not become an access regime for advanced therapies.

VII. A REFORM AGENDA FOR ADVANCED THERAPIES

A. Publish technology sensitive compulsory licensing guidance

Guidance from the PATENT OFFICE, rather than a narrower rule constraining statutory discretion, should set out the evidence expected for pharmaceuticals, biologics and advanced therapy

[41] WORLD INTELLECTUAL PROPERTY ORGANIZATION (n 2); *Natco Pharma Ltd.* (n 13).
[42] Drugs (Prices Control) Order, 2013, Gazette of India, pt. II sec. 3(ii), paras. 4, 19, 32 (May 15, 2013) (India).

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medicinal products. It should state how an applicant is to prove the relevant public, therapeutic alternatives, availability, cost of production, affordability and proposed remuneration. Reasonably affordable should remain a contextual standard, but the Controller should require disclosure of Indian prices, government procurement prices in comparator countries, patient assistance schemes, the expected number of eligible patients and the relationship between price and cost. A government committee once proposed international reference pricing adjusted for Indian incomes; the proposal was imperfect, but it showed that affordability can be reasoned about.[43]

A distinction also needs to be drawn between working in the legal sense and working in the technological sense. Importation may constitute working in defined circumstances. Importers should be required to explain the quantity and duration of the imports, their commercial character and the reasons why manufacture or transfer is not feasible.

B. Create a coordinated public interest pathway

For critical advanced therapies the Central Government should establish a time bound, multi-departmental process before a crisis arises. A designated committee could include the PATENT OFFICE, the CENTRAL DRUGS STANDARD CONTROL ORGANISATION, the INDIAN COUNCIL OF MEDICAL RESEARCH, the DEPARTMENT OF BIOTECHNOLOGY, the DEPARTMENT OF PHARMACEUTICALS, the NATIONAL PHARMACEUTICAL PRICING AUTHORITY, the Centres of Excellence, patient associations and independent manufacturing experts. It would identify the Indian patents and licences, seek information under section 146, determine the patient base and the alternative therapies, assess manufacturing capacity, seek a voluntary package of patents, know-how, data, training and materials, and plan procurement.

If negotiation fails, the committee should recommend the appropriate statutory route. Section 84 suits a competent private applicant able to meet market demand. Section 92 suits an urgent, notified government programme. Section 100 is more direct where the Government itself will procure and distribute through the Centres of Excellence. Section 90(3) allows authorised imports where domestic manufacture is impracticable for the time being. These provisions should be treated as complementary rather than as competing slogans.[44]

Negotiations need a time limit if they are to succeed. The first objective should be a comprehensive voluntary agreement, because cooperation improves both efficiency and safety.

[43] DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA, *Report of the Committee on Price Negotiations for Patented Drugs* (2013), https://pharmaceuticals.gov.in/sites/default/files/Comments%20Invited%20on%20Report%20of%20the%20Committee%20on%20price%20negotiations%20for%20patented%20drugs.pdf.

[44] The Patents Act (n 7) ss 84, 90(3), 92, 100.

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C. Address complementary know-how and platform rights

The Government cannot assume that a patent licence amounts to a licence of a factory. Public funding and procurement agreements can make technology transfer, second source capability, training, the availability of reference standards and assays and assured supply into conditions of support. Where public money de-risks development and manufacture, public interest licensing terms should be written in.

For existing products the Government could fund a negotiated acquisition or licence of know-how on confidential terms. Competition law can address particular refusals that are anti-competitive, but it cannot serve as a general technology transfer code. A statutory power permitting court supervised access to critical know-how during a declared health emergency deserves consideration.[45]

Fragmentation of the portfolio also calls for the pooling of licences. The Government could bring platform companies, originators, public research institutions and Indian biologics manufacturers into a field limited pool for spinal muscular atrophy and comparable rare diseases. Pooling would reduce royalty stacking and the risk that one licence leaves a blocking right intact.

D. Restore usable transparency

Patents of critical importance to health require a focused transparency regime. Although the three year Form 27 cycle applies across industries, the Controller should use section 146(1) to require information about volumes of import and production, the number of patients treated, approximate turnover, voluntary licences, unmet orders and the reasons for non-working. Confidential cost information can be withheld while supply information is published.

Patents and products also need to be linked. Applicants for marketing authorisation could be required to declare the patents they consider relevant to their product, process, vector or use, without converting India into a patent linkage system.

E. Build purchaser and delivery systems

For therapies of the Zolgensma type, procurement reform is essential. India should use national price negotiation, confidential rebates within a transparent process, staged or performance linked payment where appropriate, and pooling across States. Health technology assessment should weigh clinical benefit, uncertainty, family burden, savings on chronic treatment, equity

[45] Gurgula & Hull (n 38), at 1250-54.

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and opportunity cost. Decisions and reasons should be published in a form that preserves legitimate commercial confidentiality.

Newborn screening and rapid genetic testing are themselves access measures, because gene therapies work best when given early. Centres of Excellence need funding not only for the therapy but for testing, infusion, management of adverse events, rehabilitation and follow up. The extension in 2025 of research support to pharmaceutical projects in strategic public health priority areas, which include specified rare diseases and precision medicines such as gene therapy, is a useful start.[46] It needs to be supplemented by milestone financing for domestic viral vector platforms and quality assurance capacity.

Regional coordination would improve economies of scale. A facility in India serving only the domestic incidence group may not be economic. A manufacturing and procurement consortium for South Asia, or more broadly for developing countries, consistent with territorial patents and with Article 31bis where needed, would aggregate demand. With its section 92A experience and its manufacturing base, India is a natural candidate, provided that the framework covers technology as well as patents.

VIII. Conclusion

Nexavar remains both an example and a cautionary tale. It shows how the Indian compulsory licensing provisions can address public need, affordability, working, remuneration and licensee obligations without invalidating the patent. The later refusals showed that genuine negotiation is required. The pandemic litigation confirmed that emergency and government use powers are legitimate parts of public health governance.

Zolgensma presents a different analytical unit. Access requires permissions, a qualified manufacturer, a purchaser able to spread risk, early detection, specialist hospitals and surveillance. The Indian cost of Zolgensma, the closure of the global managed access programme and the ceiling on assistance under the rare disease policy together demonstrate the limits of charity.

Indian compulsory licensing law has therefore developed unevenly. Doctrine has developed; political legitimacy has widened; procedure has become stricter. Institution building, transparency and delivery remain weak. The next step should be neither the automatic grant of compulsory licences for every expensive medicine nor indefinite reliance on voluntary methods.

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[46] Press Information Bureau, Government of India, *Call for Proposals Under the Promotion of Research & Innovation in Pharma-MedTech Sector (PRIP) Scheme for Industry & Startup Projects Worth About Rs. 11,000 Crore* (Oct. 1, 2025), https://www.pib.gov.in/PressReleasePage.aspx?PRID=2173970.

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It should be a predictable public interest process that begins with information and negotiation, guarantees remuneration and monitoring, and can proceed through sections 84, 92, 90(3) or 100 as circumstances require.

From Nexavar to Zolgensma, the central point is that compulsory licensing is a legal bridge. For a conventional medicine the bridge may reach an existing generic plant. For a gene therapy the bridge does not yet extend to manufacturing facilities, regulators, hospitals and public purchasers. Indian law will have progressed when those institutions are coordinated before another child's therapeutic window closes.

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