EDITORIAL

Apathy to the power of 3 — the government, judiciary, and pharma companies on patented drug pricing

PRATHIBHA SIVASUBRAMANIAN, VEENA JOHARI, KARUNYAPRIYA MARYAM MATHEWS

On September 28, 2026, the Kerala High Court passed a judgment [1] interpreting Section 100 of the Patents Act (PA), 1970, to mean that the government has the power to manufacture a patented medicine for non-commercial supply to needy patients. However, the judgment provides little or no concrete relief to those without access to expensive medicines and healthcare, as it fails to direct the government to take immediate action to have the medicines manufactured and supplied at low cost or free to patients in need.

The court passed its order on a petition filed in 2022 by a woman suffering from metastatic breast cancer, who was receiving targeted therapy with *ribociclib*, a patented medicine not manufactured in India, and available only through import. She had approached the court as she could not afford the treatment that cost her ₹58,140 per month [ie for a 21-day course[a] of 63 tablets (3 tablets per day)] [1: p 4] [2]. She asked the court to direct the government to either issue a notification granting Indian companies a compulsory licence to manufacture the medicine (under Section 92 of the PA), or to use the invention "for the purposes of the government" (under Section 100), and make it available free under the National Cancer Control Programme to patients like her. She did not live to see the judgment on her petition. However, the court took up the matter *suo motu,* and impleaded others, including another aggrieved patient similarly placed.

In early 2026, the price of this drug was increased by the company to ₹73,065/- per month. The government then waived the basic customs duty on the drug, bringing the price by April 2026 to about ₹67,000/- per month [1, 3]. However, this was actually up from ₹58,140 in 2025. Thus, the waiver of customs duty had no impact on the price, affordability, and accessibility of the drug.

The historic patent challenge on HIV drugs — no lessons learned

Such exorbitant drug prices were also seen in the early 1990s, when the annual price of the cocktail of patented medicines for treating HIV/AIDS was USD 10,000-15,000 [4], completely out of reach for the vast majority of people needing the medicines, worldwide.

Then in early 2000, an Indian generic pharmaceutical company entered the international market, challenging the patents on the medicines, and this brought the annual price of these medicines down to USD 350 per year, or around USD 1 per day [5]. At this price, governments could purchase the medicines and provide them free or at subsidised rates to those in need. People with HIV — including in India — were able to live longer, healthier lives.

The impact of this sharp reduction in the prices of patented medicines should have eventually led to reduction in drug prices overall and greater access to essential medicines. One would have expected this, at least in India, where a generic drug company had taken the bold step of challenging patents to bring down the prices of HIV drugs.

However, more than 25 years later, not much has changed in access to medicines. Treatment for a large number of diseases, especially those like cancer, is still unaffordable. Monopolies on medicines created through patents are still being granted, and people needing such medicines must often choose between death and indebtedness. Many generic pharmaceutical companies which might earlier have challenged patents and manufactured and distributed medicines at a fraction of the cost now prefer to enter into voluntary licensing agreements [6] with the big pharmaceutical companies holding patents, to avoid the burden of litigation that is inevitable with a patent challenge. Without competition between companies manufacturing the same medicine, prices remain high and unaffordable.

The pertinent ethical issues are: the pharmaceutical industry pursues aggressive pricing policies, with unconscionably high profit margins; the government refuses to make medicines accessible through regulation, price control, and subsidies; and the courts do not take decisive action to make both industry and government fulfil their ethical obligations.

What is a "reasonable profit"?

The pharmaceutical industry resists any form of regulation, arguing that its prices are justified by the high costs of research and development of new medicines, and the risks it undertakes when developing new medicines.

The issue of high drug prices and unreasonable profits was raised in a 1970s case in the United Kingdom (UK). The UK Monopolies and Mergers Commission questioned Hoffmann-LaRoche on the excessive pricing of its medicines Valium and Librium [7], stating that such high prices operated against the public interest. Among the concerns the Commission raised were: first, what are the costs to be taken into account to determine the fair price of a drug? Second, what is a "reasonable" level of profit when determining fair prices? While prices should be calculated based on the "reasonable" cost of manufacturing, sales promotion and research, the Commission found that the company had inflated its research expenditure to justify excess profits to an extent that the profits failed to be reasonable. This is a common strategy employed — drive up prices to increase profit margins, and show heavy investment in R&D to justify high prices.

Every business is entitled to a reasonable profit, both as a return on investment and for reinvestment in research, etc. But is it ethical to make huge profits at the cost of people's lives?

In the case before the Kerala High Court, Dr Melissa Barber, a drug costing expert from Yale University, informed the court that a 200 mg tablet of *ribociclib* costs between ₹81 and ₹123 to manufacture, which would amount to between ₹5,100 and ₹7,750 for the 21-day course [1]. Novartis, the patent holder, was selling a tablet of *ribociclib* at ₹1,000, ie, at a profit of more than 800%. How can this be called a "reasonable" profit? Each tablet in that strip carries a margin that no honest accounting of "reasonable profit" can explain. This is not the price of innovation. It is the price of a monopoly.

A fair pricing policy for essential medicines is required to ensure better public health.

The pharmaceutical industry's ethical responsibility

Big pharmaceutical companies justify high prices by arguing that they provide free medications under patient assistance programmes. What they don't state is that only a limited number of patients are eligible for benefits from such programmes [8]. Furthermore, companies often use marketing strategies offering a few "free" medicines on purchasing a certain quantity of medicines (eg, "buy 3 get 1 free"). Clearly, the industry does not see itself as having any ethical responsibility to make medicines affordable for the general public. The key stakeholder in the healthcare industry is the patient — whose voice is never heard, whose pain is never understood, and whose burden is never shared.

Ethical responsibility of the government

Food, water, shelter, clothing, and medicines are basic essentials for a good life. The 2005 amendments to the Patents Act, 1970, contain provisions which empower the government to ensure that essential medicines — even those under patent — are made available and distributed equitably at affordable prices. However, the last two decades have shown that the government does little or nothing to reduce the cost burden of medicines, especially patented medicines.

The government can control the prices of medicines under the Drug Prices Control Order (DPCO), 2013. However, the DPCO covers only medicines that are off-patent.

In 2013, a committee on patented drug pricing recommended that the government negotiate with pharmaceutical companies to fix the prices of patented medicines. Unfortunately, the Drugs (Prices Control) Amendment Order, 2019, notified on January 3, 2019, amended Paragraph 32(i) of the DPCO, 2013, to exempt any new drug patented under the Patents Act, 1970, from price control for five years [9] from the date of commencement of its commercial marketing in India. In addition to granting exemptions from price control for patented medicines, the government has failed to pursue an active policy or make sustained efforts to regulate their prices and ensure affordability. Such a policy would require disclosure of pricing and cost information, regular monitoring of affordability and availability, and making decisions within clear timelines on issuing of government-use authorisations or compulsory licences when patients report that medicines are unaffordable.

The government must implement price control on patented medicines if patients in India are to get access to these medicines. What prevents the government from taking this step?

The government has effectively legitimised what can be seen as unfair pricing, toeing the line of a pharmaceutical industry focused exclusively on profits. The Indian government generally does not procure patented medicines to be made available at an affordable price; nor does it ensure that they are available free under the public healthcare system. Insurance companies generally do not cover patented medicines.

The court's responsibility

The Kerala High Court's judgment might seem to be pathbreaking. However, while affirming that the government can intervene, in the public interest, to make medicines available at affordable prices (under section 100), the court gave no direction on the immediate action to be taken to make the medicine affordable. Instead, it left the decision to the Centre as a matter of policy. Further, the court required the government to collate data on whether the medicine in question is affordable [1: para 44]. Surely,

it is obvious that a price of ₹67,000 per month is not affordable for most people in India. It may be noted that about 90% of adult Indians earn between ₹6000/ to ₹13,000/- per month [10], and only a small fraction have access to any sort of subsidised care. For most women who require *ribociclib*, such a price would wipe out their incomes as well as their savings (as the cost to them only for *ribociclib* is about ₹8.8 lakhs a year; that does not account for costs of other medicines to be taken along with it, and other healthcare costs), forcing them into debt. Instead of asking the government to issue compulsory licences and cap the medicine price, or directing the company to reduce the price of medicines to make them affordable, the court required evidence to show that the medicines are not affordable.

Where fundamental rights are concerned, especially the right to life and health, the court would be well within its jurisdiction to direct the company and the government to reduce prices and make medicines affordable, but it did neither. The court failed to direct the patent holder to disclose the costs of developing and manufacturing the drug, and the calculation by which they arrived at its price. So, how was justice imparted?

In fact, the Patents Act contains provisions that can facilitate access to affordable medicines thereby reducing people's health expenditure. However, neither the government nor the courts use the provisions present in the law, though they have both the authority and the power to do so.

Under the 2005 amendments to the Patents Act, 1970, when the patented medicine has not been made available at a reasonable, affordable price, the government can issue compulsory licences to local manufacturers (3 years after the grant of the patent) to produce the medicine and make it available at lower prices. However, for the last 20 years, the government has issued only one compulsory licence, for a cancer drug sorafenib tosylate (sold as *Nexavar*). The medicine used to cost patients about Rs 2.8 lakh (₹2,80,428) per month, which was clearly unaffordable. After the compulsory license was issued, the cost came down to ₹8,800/- per month. Although the licence was granted under Section 84 rather than through the "government use" option (under Section 100), this example demonstrated that one can challenge patent exclusivity, and that government intervention can radically alter people's access to medicines, and thereby to better health.

Both these institutions, the government and the courts, have time and again had opportunities to set things right, to address the core concerns of access to medicines and affordable healthcare, which they have failed to do. Approaching the courts is a long-drawn out and costly process, leaving little or no hope for those in distress.

People suffer and die when healthcare that could cure them, or at least reduce their suffering, is unaffordable. Healthcare, including access to medicines is a fundamental right. People's access to healthcare ought not to be dependent on their capacity to pay. Those in positions of power, the government, the courts, and the pharmaceutical industry, can set this right, but they respond with apathy, not empathy.

[a]***Note:*** *Ribociclib is taken for about three years for early-stage breast cancer. It is generally taken for 3 weeks (21 days) with one week off the drug, along with hormone therapy, that continues during the week off [2]. In early-stage breast cancer, it is given over a three-year duration, but in more advanced cases, it is continued as long as it is effective.*

Authors: **Prathibha Sivasubramanian** (pratsa2m2023@gmail.com), Senior Researcher, Third World Network, Delhi, INDIA; **Veena Johari** (veenajohari@gmail.com), Lawyers, Courtyard Attorneys, Mumbai, INDIA; **Karunyapriya Maryam Mathews** (karunyapriya23@gmail.com), Lawyers, Courtyard Attorneys, Mumbai, INDIA.

Conflict of Interest: VJ is a Working Editor of the *IJME*.

Funding: None

To cite: Sivasubramanian P, Johari V, Mathews KM. Apathy to the power of 3 — the government, judiciary, and pharma companies on patented drug pricing. *Indian J Med Ethics.* 2026 Oct-Dec; 11(4) NS: 261-264. DOI:10.20529/IJME.2026.065

Submission received: October 15, 2026

Submission accepted: October 30, 2026

Copyright and license

©*Indian Journal of Medical Ethics* 2026: Open Access and Distributed under the Creative Commons license (CC BY-NC-ND 4.0), which permits only non-commercial and non-modified sharing in any medium, provided the original author(s) and source are credited.

References

1. Kerala High Court. *In Re Exorbitant Pricing of Life Saving Patented Medicines.* WP(C) 18999/2022. 2026 Sep 28[cited 2026 Oct 20]. Available from: https://images.assettype.com/barandbench/2026-09-28/ki5gjgef/In_Re_Exorbitant_Pricing_of_Life_Saving_Patented_Medicines.pdf
2. Kalyanikar E. Even after customs exemption in Union Budget, best cancer drugs still far from affordable. *Times of India.* 2026 Feb 4[cited 2026 Oct 20]. Available from: https://web.archive.org/web/20260204031514/https://timesofindia.indiatimes.com/city/mumbai/even-after-customs-exemption-in-union-budget-best-cancer-drugs-still-far-from-affordable/articleshow/127893683.cms
3. Ministry of Finance (Department of Revenue), Government of India. Notification No. 02/2026-Customs. 2026 Feb 01 [cited 2026 Oct 19]. Available from: https://www.indiabudget.gov.in/doc/cen/cus0226.pdf [Ribociclib added to List 3 appended to TABLE I in Notification No. 45/2025 –Customs, 24 October 2025. Also available from: https://courier.cbic.gov.in/ECCS/advisory/2025/Notfi-%2045-2025.pdf].
4. UNAIDS. *UNAIDS: The First 10 Years, 1996–2006.* 2008 May 2[cited 2026 Oct 20] p. 60. Available from: https://data.unaids.org/pub/report/2008/jc1579_first_10_years_en.pdf
5. Khor M. The man who saved millions with cheap medicines. *South Bulletin.* 2013 Jul 5 [cited 2026 Oct 20]; (74):123. Available from: https://

www.southcentre.int/question/the-man-who-saved-millions-with-cheap-medicines/
6. Médecins Sans Frontières. Voluntary Licences and Access to Medicines. Technical Briefing Document. 2020 Oct [2026 Oct 20]. Available from: https://msfaccess.org/sites/default/files/2020-10/IP_VoluntaryLicenses_full-brief_Oct2020_ENG.pdf
7. House of Lords. *F. Hoffmann-La Roche & Co. AG v. Secretary of State for Trade and Industry.* [1975] AC 295 (House of Lords). Available from: https://vlex.co.uk/vid/f-hoffmann-roche-company-792861021
8. Choudhry NK, Lee JL, Agnew-Blais J, Corcoran C, Shrank WH. Drug company-sponsored patient assistance programs: a viable safety net? *Health Affairs.* 2009 May-Jun;28(3):827–834. https://doi.org/10.1377/hlthaff.28.3.827
9. Department of Pharmaceuticals. Order to amend the Drugs (Prices Control) Order, 2013. 2019 Jan 3[cited 2026 Oct 20]. Available from: https://pharma-dept.gov.in/sites/default/files/Gazette%20Notification_DPCO.pdf
10. Jeevan PP. The growing divide: a deep dive into India's inequality crisis. *Sabrang India.* 2024 28 May 28 [cited 2026 Oct 20]. Available from: https://web.archive.org/web/20240615145451/https://sabrangindia.in/the-growing-divide-a-deep-dive-into-indias-inequality-crisis/