

# News Analysis: Big Pharma cries foul upon India court decision

*Editor's Note: The broad daylight scandal of gouger industries like Big Pharma, energy, etc., is common and inherent in US society, where one of the most savage and cynical forms of capitalism reigns practically unopposed. Now, as The New York Times reports ([Low-Cost Drugs in Poor Nations Get a Lift in Indian Court](#)), an Indian court has sided with the public in a matter of critical interest, something rarely seen in America, despite the fact that populist senator Estes Kefauver exposed the drug industry racket as a public enemy in the 1950s, and nothing much has changed since (Cf In a Few Hands). One of the things that Kefauver systematically demonstrated was precisely that much of new drug R&D expense was actually underwritten by taxpayer allocations, with most of the hard part of the R&D conducted in government and academic facilities, even if the profitable selling of the drugs was later handed over to Big Pharma. If that is not a sweet backroom deal, what is?*

*While on the topic, we should keep in mind that the US is one of the few countries in the entire world where we can witness both the President and Congress move in unison to block a measure that would have allowed volume discounts to government agencies. Canada and many other capitalist nations don't dare go that far openly injuring the public interest, but here, where the ruling cliques have little to fear from the largely passive if not politically comatose masses, they do it every day, with almost total impunity. One more thing: Observe in the select comment thread we have included how public opinion, except for some likely shill for the drug industry or misguided libertarian, is overwhelmingly against Big Pharma and anxious to see it*

*forcefully reined in, or kicked out of the game of for-profit medicine altogether, where it really belongs in a truly rational and decent society.—P. Greanville*

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## Low-Cost Drugs in Poor Nations Get a Lift in Indian Court



Big Court Ruling Favors Generic Drugs: The Times's Katie Thomas explains why a ruling in India favoring generic drugs has rippling effects around the world.

By [GARDINER HARRIS](#) and [KATIE THOMAS](#)

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NEW DELHI – People in developing countries worldwide will continue to have access to low-cost copycat versions of drugs for diseases like H.I.V. and cancer, at least for a while.



Rafiq Maqbool/Associated Press

While advocates for the pharmaceutical industry argue that fairly liberal rules on patents spur innovation, a growing number of countries are questioning why they should pay high prices for new drugs.

Production of the generic drugs in India, the world's biggest provider of cheap medicines, was ensured on Monday in a ruling by the Indian Supreme Court.

The debate over global drug pricing is one of the most contentious issues between developed countries and the developing world. While poorer nations maintain they have a moral obligation to make cheaper, generic drugs available to their populations – by limiting patents in some cases – the brand name pharmaceutical companies contend the profits they reap are essential to their ability to develop and manufacture innovative medicines.

Specifically, the decision allows Indian makers of generic drugs to continue making copycat versions of the drug Gleevec, which is made by [Novartis](#). It is spelled Glivec in Europe and elsewhere. The drug provides such effective treatment for some forms of leukemia that the Food and Drug Administration approved the medicine in the United States in 2001 in record time. The ruling will also help India maintain its role as the world's most important provider of inexpensive medicines, which is critical in the global fight against deadly diseases. Gleevec, for example, can cost as much as \$70,000 a year, while Indian generic versions cost about \$2,500 a year.

The ruling comes at a challenging time for the pharmaceutical industry, which is increasingly looking to emerging markets to compensate for lackluster drug sales in the United States and Europe. At the same time, it is facing other challenges to its patent protections in countries like Argentina, the Philippines, Thailand and Brazil.

“I think other countries will now be looking at India and

saying, 'Well, hold on a minute – India stuck to its guns,' ” said Tahir Amin, a director of the Initiative for Medicines, Access and Knowledge, a group based in New York that works on patent cases to foster access to drugs.

In trade agreements – including one being negotiated between the United States and countries in the Pacific Rim – the drug industry has lobbied for stricter patent restrictions that would more closely resemble protections in the United States.

Gleevec is widely recognized as one of the most important medical discoveries in decades. In a televised interview, Ranjit Shahani, vice chairman of the Indian subsidiary of Novartis, said that companies like Novartis would invest less money in research in India as a result of the ruling. “We hope that the ecosystem for intellectual property in the country improves,” he said.

India exports about \$10 billion worth of generic medicine every year. India and China together produce more than 80 percent of the active ingredients of all drugs used in the United States.

In Monday’s decision, India’s Supreme Court ruled that the patent that Novartis sought for Gleevec did not represent a true invention. The ruling is something of an anomaly. Passed under international pressure, India’s 2005 patent law for the first time allowed for patents on medicines, but only for drugs discovered after 1995. In 1993, Novartis patented a version of Gleevec that it later abandoned in development, but the Indian judges ruled that the early and later versions were not different enough for the later one to merit a separate patent.

Leena Menghaney, a patient advocate at Doctors Without Borders, said that the ruling was a reprieve from more expensive medicines, but only for a while.

“The great thing about this ruling is that we don’t have to

worry about the drugs we're currently using," Ms. Menghaney said. "But the million-dollar question is what is going to happen for new drugs that have not yet come out."

Others decried the ruling, saying it was further evidence that India does not respect the intellectual property rights of pharmaceutical companies. Last year, India granted what is known as a compulsory license to a generic drug manufacturer to begin making copies of [Bayer's cancer drug Nexavar](#), and revoked Pfizer's patent for another [cancer drug, Sutent](#). Both companies have appealed the decisions.

"It really is in our view another example of what I would characterize as a deteriorating innovation environment in India," said Chip Davis, the executive vice president of advocacy at the Pharmaceutical Research and Manufacturers of America, the industry trade group. "The Indian government and the Indian courts have come down on the side that doesn't recognize the value of innovation and the value of strong intellectual property, which we believe is essential."

Anand Grover, a lawyer who argued the case on behalf of Cancer Patients Aid Association in India, said the ruling confirmed that India had a very high bar for approving patents on medicines.

[Gardiner Harris](#) reported from New Delhi, and [Katie Thomas](#) from New York.

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"What is happening in the United States is that a lot of money is being wasted on new forms of old drugs," Mr. Grover said. Because of Monday's ruling, "that will not happen in India."

In the United States, companies can get a new patent for a drug by altering its formula or changing its dosage. The

companies contend that even minor improvements in medicines – changing a pill dosage to once a day instead of twice a day – can have a significant impact on patient wellness. But critics say a majority of drug patents given in the United States are for tiny changes that often provide patients few meaningful benefits but allow drug companies to continue charging high prices for years beyond the original patent life.

They point to AstraZeneca, for example, which extended for years its franchise around the huge-selling heartburn pill Prilosec by slightly altering the chemical structure and renaming the medicine Nexium. Amgen has won so many patents on its expensive erythropoietin-stimulating drugs that the company has maintained exclusive sales rights for 24 years, double the usual period. A result of this practice is that the United States pays the highest drug prices in the world, prices that only a tiny fraction could afford in India, where more than two-thirds of the population lives on less than \$2 a day.

While advocates for the pharmaceutical industry argue that fairly liberal rules on patents spur innovation, a growing number of countries are questioning why they should pay high prices for new drugs. Argentina and the Philippines have passed laws similar to the one enacted in India, placing strict limits on patents. And Brazil and Thailand have been issuing compulsory licenses for AIDS drugs for years under multilateral agreements that allow such actions on public health grounds.

As the economies of emerging markets grow, the countries' refusal to pay higher premiums for newer drugs could significantly reduce the money needed for innovation. The drug industry makes more than a third of its sales in the United States, a dependence that many in the industry fear is unsustainable, especially since sales of prescription drugs actually dropped in the United States in 2012, according to the research firm IMS Health. Sales in emerging markets like

Brazil and China are expected to account for 30 percent of global pharmaceutical spending by 2016, up from 20 percent in 2011, according to IMS Health.

The United States government has become increasingly insistent in recent years that other countries adopt far more stringent patent protection rules, with the result that poorer patients often lose access to cheap generic copies of medicines when their governments undertake trade agreements with the United States. Washington is currently negotiating the terms of a new Pacific Rim trade agreement, called the Trans-Pacific Partnership, which might be completed later this year. The pharmaceutical industry has lobbied the United States to require other countries to enforce tougher patent restrictions, although the details are still being worked out.

Gardiner Harris reported from New Delhi, and Katie Thomas from New York.

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## Related

- [India Ink: The Novartis Patent Case: The Full Supreme Court Ruling](#) (April 1, 2013)
- [India Ink: Health Care Advocates Cheer Supreme Court Decision](#) (April 1, 2013)

## Comments (Selected comments for purposes of discussion)

Share your thoughts.

1. 

- Eleanore1946
- Old Bridge NJ

The US Big Pharma goes deaf whenever it's a matter of possible loss of profits. First of all, taxpayers in the US fund much of the R&D. Look at the for what it really is...Taxpayers helping Big

Pharma to research and develop drugs, Big Pharma then going “entitlement” to billions in profits when they received assistance from the very people they will savage with unaffordable prices of drugs taxpayers already paid for with their tax dollars...Smell the extortion yet?

It’s time to see clearly what the costs of this so-called “expensive” R&D really is. And...India is telling the US the truth that Big Pharma doesn’t want to hear...our prescription drugs are unnecessarily expensive. The proof of that is how India for more than 2 decades has been able to R&D drugs at 1/10th the cost in the US. So...what’s the real rank odor in Big Pharma? How about those unnecessarily high salaries at the top? Are they in line with the same jobs in India? You bet not.

Novartis got what they deserved... the truth. Now, they are balking...because they are not thinking of producing drugs people can actually afford...they are only concerned about their next million dollar bonuses.

▪ [April 2, 2013 at 8:33 a.m.](#)



2.

- bnc
- Lowell, MA

The drug industry is psychopathic! Between the high-cost drugs it pushes and the deadly side-effects of all the others, I’m glad I’m not taking any of those pills – and I will make every effort to find alternatives before I sign my obituary over to them.

▪ [April 2, 2013 at 8:33 a.m.](#)



3.

- so costly
- nj

What does the Affordable Care Act do to assist patients here in the US with the costs of their drugs? Due to a 50% co-pay with my health insurance, I can’t afford some of my medications.

▪ [April 2, 2013 at 8:33 a.m.](#)



4.



- jwdzzz
- 02653

Research in pharmaceuticals, like energy (oil, gas,solar, etc.) should be taken over by governments and not be a for-profit, patentable business.

- [April 2, 2013 at 8:33 a.m.](#)



5.

- gmt
- Tampa

What good are these life saving drugs if you can't afford them? This re-patenting medicine is fueled by greed. Tell it like it is. This country has a system where only the rich and mighty – or very good insurance – get access to the latest medicines. I have no sympathy for companies like Allergan and Novartis which make money hand over fist. I had to buy Restasis from India because the price here was prohibitive. Both these companies and the FDA need to be more realistic. If the FDA was so rigorous, why did it approve medications that ended up causing harm and after years were pulled, those so-called aspirin substitutes. If big pharma would stop advertising and the billions it spends on that, they'd save enough to put a realistic price tag on these medicines.

- [April 2, 2013 at 8:33 a.m.](#)



6.

- RegExpert
- USA

Lot of people have a misunderstanding as to what has happened here. India is not saying that they don't respect the patent system. In this case Novartis did not patent Glivec originally in India when they originally patented it in US and EU.

So when Novartis filed for an imatinib patent in India, it was for a different polymorph of the drug, which it hoped would be patentable chemical matter. The Indian patent office disagreed in 2006, saying that this was merely a reformulation of an existing compound (which had been approved in the U.S. in 2001), and rejected the application. Read this link for an excellent analysis:

<http://seekingalpha.com/article/1313001-novartis-loses-the-glivec-patent..>

This was a clear case of ever greening by Novartis. Novartis thought Indians can be hoodwinked!!!

- [April 2, 2013 at 8:33 a.m.](#)

7.



▪ SJose

▪ Kwt

I am not qualified to comment on the good or bad of this decision. But being a person who has lived in India, Middle East, Europe and Africa, I know this:

My BP medicine in India 30 tabs= USD 4.00

Same medicine but branded/patented in Middle East// Europe= circa. USD 30.00

That is agreeable.

But look at the plight of this poor patient in an African Country

Same medicine but branded/patented in Middle East// Europe= circa. USD 48.70!!!!!!!

Imagine that country has worst poverty levels like India and only the elite could definitely afford this medicine which is prescribed for daily intake. Now I submit the case for pros and cons.

▪ [April 2, 2013 at 8:33 a.m.](#)



8.

▪ Steve Goddard

▪ London

There are several, complex issues to address and resolve. And this is not going to be achieved overnight. While there is the need for companies to retain profits to reinvest in future product development, that itself needs more scrutiny. How much of the profit from drug patents is being reinvested in r and d? And how much is being returned to shareholders? How good and efficient is the company's governance? How much profit is taxed at source to benefit the overall tax pool for the public and how much profit is being generated in low to no tax jurisdictions, which is of no benefit. That's a particularly thorny issue in the UK right now. And there's the ethical issues. How much governmental aid and assistance towards the r and d was granted to the patent holders either nationally or under a federal US or European wide assisted system? Therefore, why so much protectionism when, in reality, that patent is partly or wholly already in public ownership to varying degrees? When people are dying or going blind or losing their faculties because regional and national deployment of new drugs has become unaffordable, you cannot blame any one, whether a government or not, for sidestepping or applying very strict interpretation of the legislation. Shakespeare's Shylock, of Merchant of Venice fame, falling on his 'pound of flesh' comes to mind.

- [April 2, 2013 at 8:32 a.m.](#)



9.

- V P Kochikar
- Bangalore

\$70,000 for the patented version vs. \$2500 for the generic version??

This difference is just too stark, particularly considering that the product has been in the market for 10-12 years – normally any product pays off development costs much earlier than that. The conclusion that Novartis is over-charging appears inescapable (albeit perhaps understandable, given that a business will generally try to maximise profits).

Here's another conclusion that's inescapable: A patent regime that allows the company to make such unreasonable profits must be broken. However, that's a more complex problem to fix.

In this situation, the best fix may be to work towards a compromise that allows Novartis access to the huge markets in the emerging economies, at a reasonable price. There are many price points between 70,000 and 2,500 – at least one must be acceptable to both parties !

- [April 2, 2013 at 8:32 a.m.](#)



10.

- Devendra Misra
- India

The way Novartis is behaving ,is extremely arrogant ,By the way ,the drug in question has not been developed by Novartis ,

- [April 2, 2013 at 8:31 a.m.](#)



11.

- VED from VICTORIA INSTITUTIONS
- DEVERKOVILA

I can only pity the 'poor' fools who support these type of nonsensical events based on a very superficial understanding of the 'poor' nations. Actually there is nothing poor about India other than

the fact that the national government and the feudal languages keep a major section of the population in dire circumstances. Almost 100 % of the national resources and wealth are looted by the officialdom and the ruling classes.

As to medical care, it is a daylight heist. Even if these so-called 'life-saving' drugs are made dirt cheap, it will move through a series of marketing groups and medical establishments who stand to make a fortune.

About the Court in India supporting a theft, well, the judicial officers also wallow in riches in terms of pay, perks and pension. So, their so-believed altruistic actions are just mere eyewash. The nation is current engaged in looting and exploiting its own majority population. In between, it is attempting to loot other nation companies also, in guise of acting like a Robin Hood. But then Robin Hood was not an Indian judicial officer, but the direct opposite.

- [April 2, 2013 at 8:31 a.m.](#)



12.

- bobyong
- MA

Good! this is great news for the rest of the world who can't afford the exorbitant prices the robber pharmaceutical companies charge. I am so sick of hearing that they need 50.00 per pill to subsidize research, that is a bunch of lies, why won't the US force these selfish companies to do research for diseases like Aids, hep C etc? Why won't the USA force these companies to lower the prices on these life saving drugs? If you're rich you live, if you're poor you die? Something wrong with that picture? I work in the medical field and am sick and tired of the medical industry here in the USA and elsewhere ignoring the poor and forcing all of us to pay way too much for healthcare.

- [April 2, 2013 at 8:30 a.m.](#)



13.

- William M. Shaw
- Shreveport, LA

Copyright and patent laws have been abused for many years. The late Aaron Swartz could be the poster-boy martyr for a campaign against the meretricious idea of "intellectual property." Academia, Silicon Valley, Hollywood and Big Pharma are all part of a cabal who have teamed up to use governmental powers

in order to make money off other people's ideas. Ideas should be in the public domain. There shouldn't be a race to the patent office. Free diffusion of knowledge should trump the greed of mere profiteers.

- [April 2, 2013 at 8:30 a.m.](#)



14.

- June
- Charleston, SC

The US protects corporate profits while India & other countries protect their citizen's health. The fact that the US taxpayers pay the highest prices for drugs means US taxpayers subsidize the development of drugs & the profits for the pharmaceutical industry. This is exactly as Congress intends as they receive their campaign contributions from Big Pharma.

- [April 2, 2013 at 8:30 a.m.](#)



15.

- James
- Washington, DC

India, China, Russia and other "successful" socialist paradises (not to mention nations based on financial fraud, like Argentina) depend for their survival on the Americans providing them with knowledge and, in this case, drugs. Meanwhile working Americans (not those on welfare, who are in the same class as the Indians, et al.) pay high prices for drugs – subsidizing those who do not pay.

- [April 2, 2013 at 8:30 a.m.](#)



16.

- N Bhashyam
- Ottawa , Canada

Commendable ..medical care must be made affordable for all ...it is as important as human rights . In fact UN should take initiative to see medical needs of all on the globe is made readily available and affordable too.After all right to life and good health need not be limited to rich only...

- [April 2, 2013 at 8:30 a.m.](#)

17.



- Gunjan Sharma
- Gurgaon India

-Innovation which does not benefit 90% of the population isn't innovation.

- If Einstein copyrights theory or relativity no scientific innovation would have happened.. it is as simple as that the pharma companies are thriving on greed.

- What if India patents 0, after all it was invented in India? where do all mathematical calculations go?

- This wont really hurt any innovation, pharma companies need India and china as thats where the business is, fact of the matter is the innovation costs of these drugs is HUGELY inflated.

My humble 2 cents

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