

20 years of TRIPS: failed promises

Carlos M. Correa

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TRIPS Agreement

‘The current GATT victory, which established provisions for intellectual property, resulted in part from the hard-fought efforts of the US government and US businesses, including Pfizer, over the *past three decades*. We’ve been in it from the beginning, taking a leadership role’.

Ed Pratt Jr, CEO Pfizer (1972-91):

What the TRIPS Agreement would achieve...

- Foreign direct investment
- Transfer of technology
- Innovation

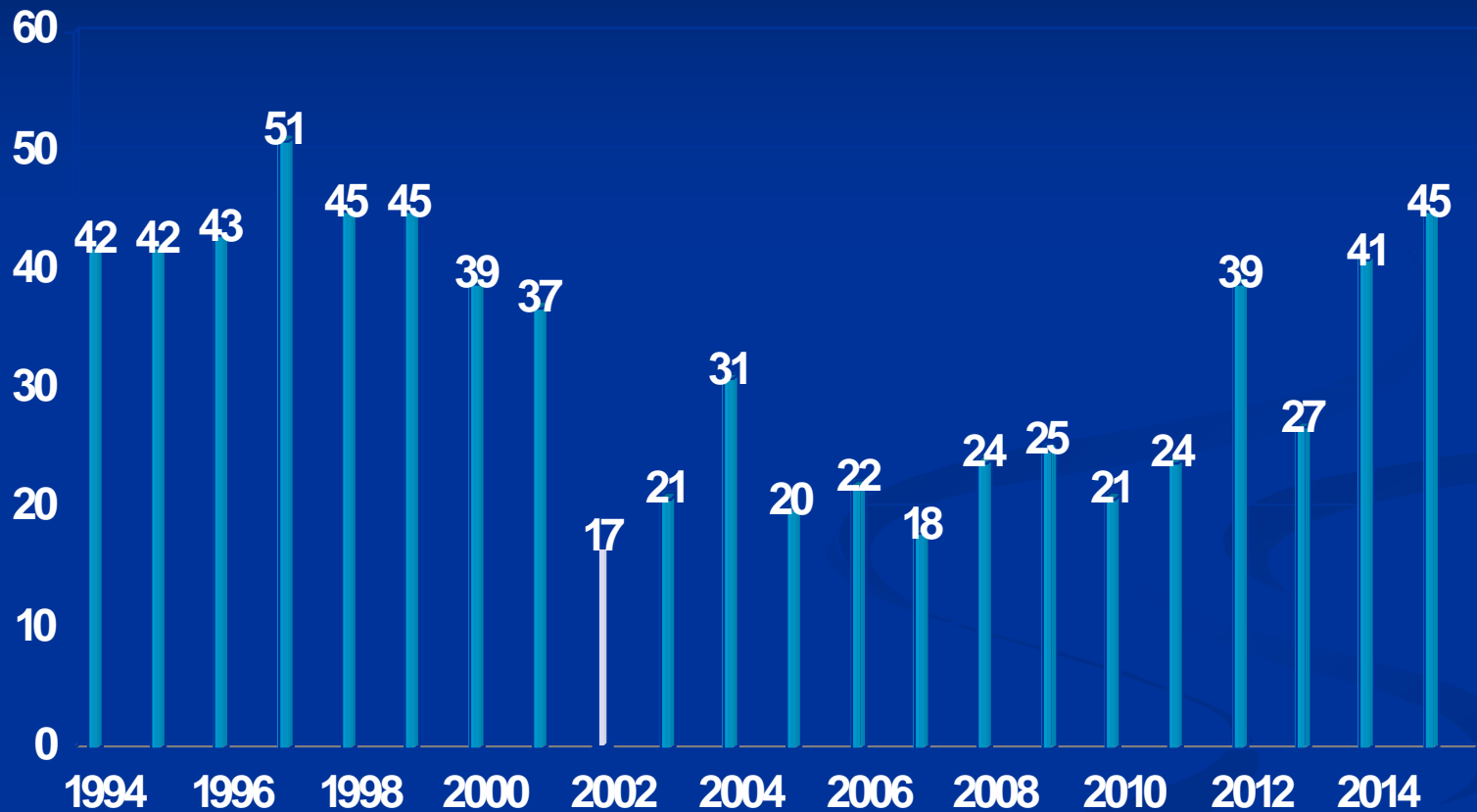
Was the worldwide patent protection of drugs the solution?

- Extension of patents to developing countries will have only a marginal impact on pharmaceutical R&D
- ‘...global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations’
- Scherer, ‘A Note on Global Welfare in Pharmaceutical Patenting’, *The World Economy*, Vol. 27, No. 7, July 2004

Plummeting efficiency

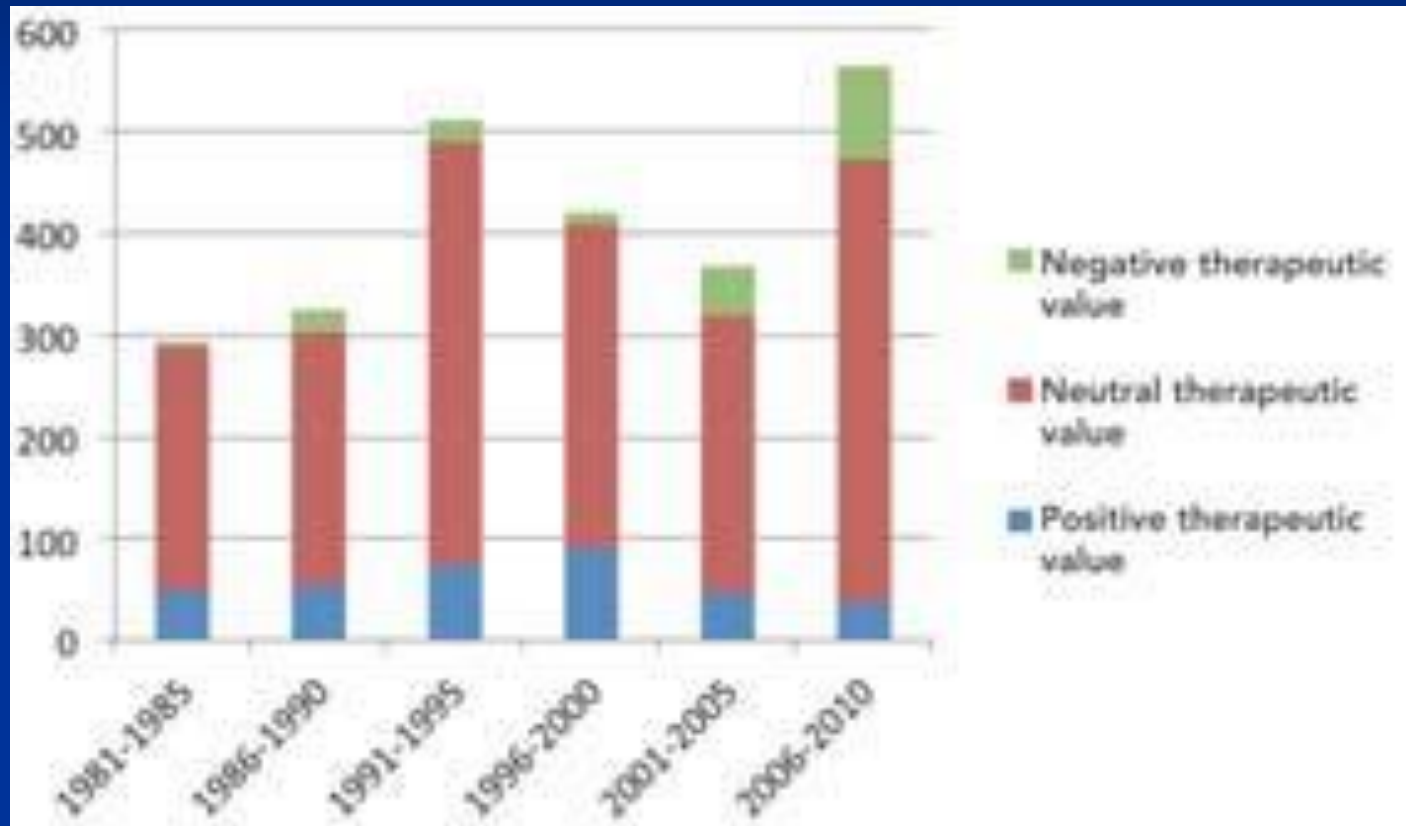
- ‘The number of new drugs approved per billion US dollars spent on R&D has halved roughly every 9 years since 1950, falling around 80-fold in inflation-adjusted terms’
- Scannell JW¹, Blanckley A, Boldon H, Warrington B., Diagnosing the decline in pharmaceutical R&D efficiency, *Nat Rev Drug Discov.* 2012 Mar 1;11(3)

Innovation in pharmaceuticals: new drugs 1994-2014



Source: US FDA

‘Corporate influence over clinical research: considering the alternatives: Rev Prescire April 2012; 32 (342): 311-314,



R&D on neglected diseases

- Of the 336 new chemical entities approved around the world from 2000 to 2011, only 1% were for neglected diseases.
- Of the 150,000 clinical trials for new therapeutic products registered as of 2011, only 1% were aimed at diseases of the developing world.
- [Belen Pedrique, Nathalie Strub-Wourgaft, Claudette Some, Piero Olliaro, Patrice Trouiller, Nathan Ford, Bernard Pécoul, Jean-Hervé Bradol](#), The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment, *The Lancet*, **[Volume 1, No. 6](#)**, e371–e379, December 2013

Newer drugs cost more and do less...

- By the 1980s drugs were less than four times better than placebo; by the 1990s, twice as good, and by the 2000s just 36 percent better than a placebo.
- Mark Olfson (Columbia University) and Steven Marcus (University of Pennsylvania), Decline In Placebo-Controlled Trial Results Suggests New Directions For Comparative Effectiveness Research, [10.1377/hlthaff.2012.1353](https://doi.org/10.1377/hlthaff.2012.1353), *Health Affairs*, June 2013 vol. 32 no. 6 1116-1125

Evergreening

- Formulations/dosage forms
- Salts
- Analogue processes
- Combinations
- Markush claims/selection patents
- Polymorphs
- Optical isomers
- New indications (therapeutic methods)

RITONAVIR

- More than 800 patents

India-R&D in pharmaceuticals

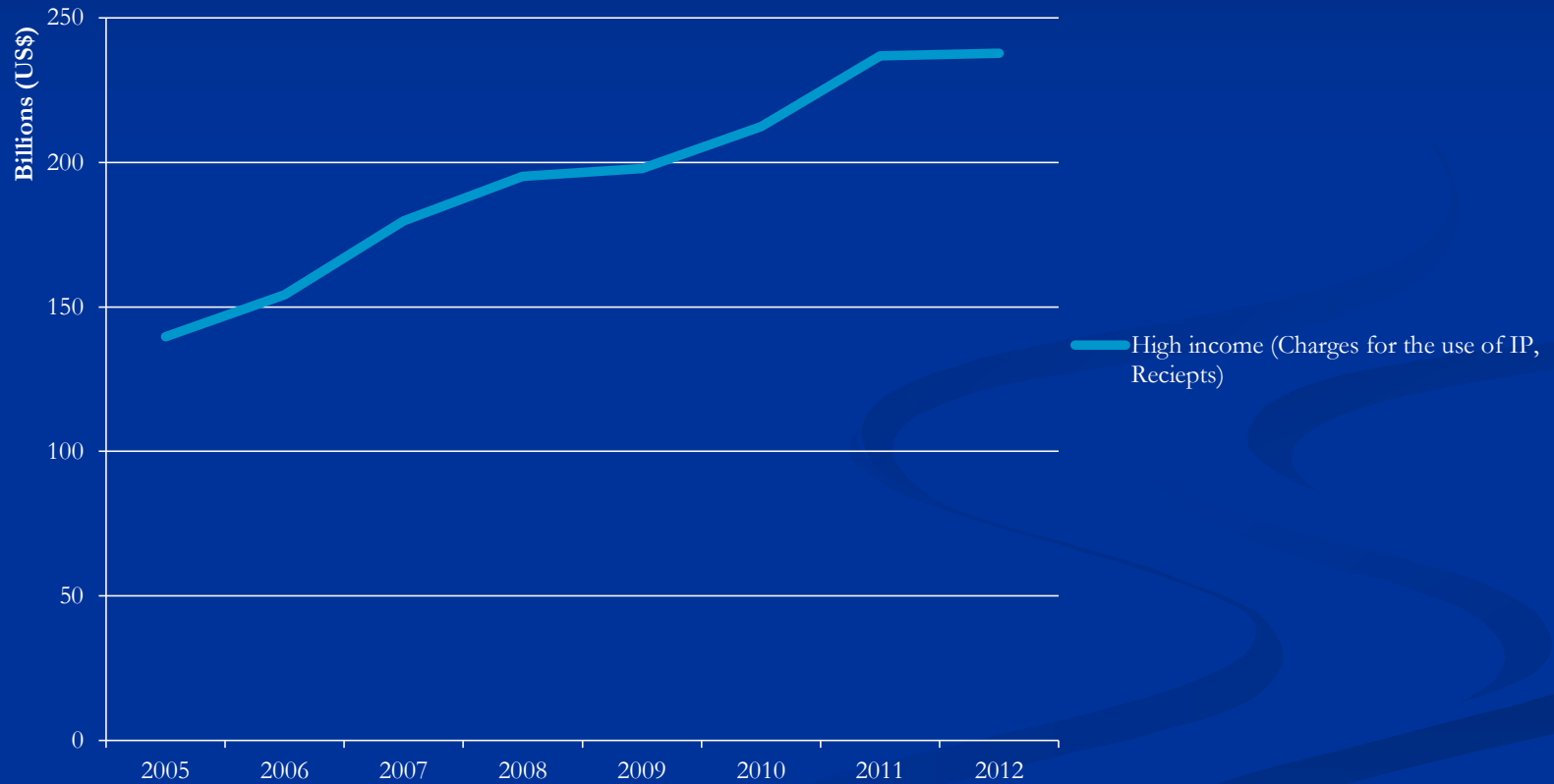
- TRIPS has not promoted more R&D to develop new drugs
- TRIPS may have accelerated R&D related to improvement of medicines, but ‘in the absence of TRIPS, such activities would still have been undertaken. With larger domestic operations, Indian companies...would have had access to larger resources and would have been better placed to undertake such research (p. 108)
- S Mani & R Nelson, TRIPS compliance national patent regimes and innovation. Evidence and experience from developing countries, Edward Elgar, 2013.

High prices

- Fifteen cancer drugs introduced in the past five years cost more than \$10,000 a month
- A cholesterol-lowering treatment for those with certain rare genetic disorders costs \$311,000 a year
- a cystic fibrosis medicine developed partly with funding from a Charity costs \$300,000 annually.

- <http://www.businessweek.com/articles/2014-05-08/why-prescription-drug-prices-keep-rising-higher>, Big Pharma's Favorite Prescription: Higher Prices. Robert Langreth May 08, 2014

Developed Economies: Receipts for the use of Intellectual Property



Developing countries' royalty payments

Developing Economies: Payments for the use of Intellectual Property

