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## Ritonavir (Protease Inhibitor for Treatment of HIV)

### Drug Information

- Ritonavir is used with other medications to treat human immunodeficiency virus (HIV) infection. Ritonavir is in a class of antiviral medications called protease inhibitors. It works by slowing the spread of HIV infection in the body.<sup>1</sup>
- Ritonavir was approved by the FDA on March 1, 1996, for use with other antiretroviral agents in the treatment of HIV infection in adults and children 2 years of age or older. Ritonavir is now approved with other anti-HIV drugs in the treatment of HIV-1 infection in individuals over 1 month in age. Studies have shown that ritonavir works as a booster for some other protease inhibitors. Taking ritonavir makes it possible to take a lower dose of the other protease inhibitors.<sup>2</sup>
- Norvir is Abbott Laboratories' brand name for ritonavir. Kaletra is Abbott's brand name for the HIV treatment that combines lopinavir and ritonavir.<sup>3</sup>
- Ritonavir is a key component of HIV/AIDS treatment regimens worldwide.

### Drug Development

- The taxpayer-funded National Institutes of Health (NIH) provided Abbott Laboratories \$3.5 million in early-stage research grants solely for the invention and development of ritonavir. The NIH also contributed its own research on ritonavir to Abbott's efforts.<sup>4</sup>
- A 2010 search of the [NIH RePORT database](#) using the search term "ritonavir" identified 1,230 NIH grants. The RePORT database identifies 58 patents that have cited support from these grants.<sup>5</sup>
- A search for "ritonavir" on the NIH's ClinicalTrials.gov website, which tracks how many and which clinical trials are funded by the NIH, yielded 592 results.<sup>6</sup> According to KEI, at least 130 of those were funded exclusively by the NIH or other federal agencies.<sup>7</sup>

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<sup>1</sup> Quoted from U.S. National Library of Medicine, available at: <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000986/>.

<sup>2</sup> Quoted from AIDSinfo, National Institutes of Health, available at: [http://www.aidsinfo.nih.gov/drugsnew/DrugDetailNT.aspx?int\\_id=244&ClassID=1&TypeID=1](http://www.aidsinfo.nih.gov/drugsnew/DrugDetailNT.aspx?int_id=244&ClassID=1&TypeID=1).

<sup>3</sup> "Kaletra." *Abbott Laboratories*. 2010. [http://www.kaletra.com/consumer\\_kaletra\\_difference.cfm?s\\_mcid=google](http://www.kaletra.com/consumer_kaletra_difference.cfm?s_mcid=google). 6 July 2011.

<sup>4</sup> Love, James. "Statement of James Love: President, Essential Inventions." *NIH Meeting on Norvir/Ritonavir March-In Request*. 25 May 2005.

<sup>5</sup> "Prices for Abbott's Norvir (generic name Ritonavir) as a Standalone Product in 2010," Knowledge Ecology International Research Note 2010:4, August 12, 2010, Anne Mira Guha, available at: <http://keionline.org/prices/ritonavir>.

<sup>6</sup> "Ritonavir." *ClinicalTrials.gov: A Service of the US National Institutes of Health*. <http://www.clinicaltrials.gov/ct2/results?term=ritonavir>. 12 July 2011.

<sup>7</sup> "Prices for Abbott's Norvir," *supra*.



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### Exclusive commercialization and abuse

- In spite of the publicly-funded research that directly contributed to the development of ritonavir, Abbott still maintains the exclusive rights to commercialize ritonavir and lopinavir+ritonavir (LPV/r) in the United States and many low- and middle-income countries.<sup>8</sup>
- Abbott raised the price of Norvir (ritonavir) as a standalone product in the U.S. by 400% in 2003.<sup>9</sup> This meant much greater costs for competitors that sought to rely on ritonavir as a boosting agent for their own protease inhibitors. But Abbott did not similarly raise the price of its combination product Kaletra.
- This anti-competitive tying arrangement reduced incentives for other pharmaceutical companies to develop new HIV treatments that would also rely on ritonavir as a boosting agent.<sup>10</sup> In other words, ritonavir, a publicly-funded drug for treating HIV, was subsequently exclusively commercialized in a price-abusive manner that stifled, rather than encouraged, R&D.

### Generics

- There are multiple generic versions of ritonavir available, including versions prequalified by the World Health Organization – but only where patent barriers can be overcome.
- Prices for generic LPV/r, including but not limited to heat-stable tablets, are significantly lower than Kaletra prices – up to 90% lower.
- Peru has perhaps the global low price for LPV/r. By facilitating consistent competitive bidding between firms, Peru has obtained a price of \$396 per person per year from Eske Group, a Cipla affiliate. Kaletra prices in middle income countries still often approach \$4,000.<sup>11</sup>

### Benefits of licensing ritonavir

- More robust global competition for ritonavir – including through licensing facilitated by NIH – would offer major cost reductions to HIV treatment programs, public agencies and donors the world over. This in turn would enable mass scale-up of treatment and prevention services, and significantly greater access to lifesaving medicines.
- Licensing would facilitate the development of new combination therapies for HIV.

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<sup>8</sup> See e.g., Medicines Patent Pool Patent Status Database for Selected HIV Medicines, available at: <http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs>.

<sup>9</sup> Statement of James Love, *supra*.

<sup>10</sup> Testimony of Robert Weissman before the U.S. Senate Committee on the Judiciary, “The Role of Federally-Funded University Research in the Patent System,” October 24, 2007.

<sup>11</sup> Maybarduk, Peter. “Colombia Sets Price Ceiling on Important HIV/AIDS Drug.” *Essential Action*. 11 May 2009. <http://www.essentialaction.org/access/index.php?/archives/182-Colombia-Sets-Price-Ceiling-on-Important-HIVAIDS-drug.html#extended> 25 July 2011. Abbott offers an “access price” of \$1000 to public agencies in select countries; this too is far above average generics prices. In sub-Saharan Africa, Abbott prices Kaletra at \$500.