NIH: Open the Doors,
by Rob Camp, for the AIDS Treatment Activists Coalition (ATAC)

On Tuesday, May 25, 2004, the National Institutes of Health (NIH) hosted a public meeting to seek comment from invited individuals, organizations, and other stakeholders on the use of the government march-in authorities under 35 U.S.C. 203 for Norvir© (ritonavir). Norvir© is a drug manufactured by Abbott Laboratories that was developed with NIH funds using inventive technologies. The "march-in authorities" refer to a clause of a piece of legislation (the Bayh-Dole Act) passed in 1980. This Act—spearheaded by Senators Birch Bayh of Indiana and Bob Dole of Kansas—aimed to stimulate research and product development of new drug agents funded by the US Government.

Point 1: <u>This meeting was not public</u>.
Speakers were by invitation only, and invitations were secured through a lobbying effort on an individual level. Of the 11 invited speakers, 4 were for the march-in, and 7 against. Three of the 7 speakers opposed to NIH "marching-in" on the Norvir patent admitted to knowing nothing or little about HIV/AIDS treatment and care, access to Norvir, or any particulars of the case at hand. They argued from a theoretical standpoint that march-in rights were not intended as a form of price control. Of course, if you substitute "access for everyone" for "price control," the great fear might disappear, and the arguments become less vehement.

Point 2: <u>It appears that at NIH, "public" does not fully include "community</u>."
People living with HIV/AIDS and their advocates were allotted 1 slot at this hearing. Bob Huff, GMHC's editor for *Treatment Issues*, was the scheduled community speaker. A second speaker, Lynda Dee (co-chair of ATAC's Drug Development Committee) was also able to speak, because Dr. Ben Young ceded 2 remaining minutes of his slot to her. Unfortunately, Lynda's speech was more than 2 minutes long, and NIH did not allow her to speak for more than 1 minute. When Lynda continued speaking over the moderator, the moderator used a musical instrument to gong her; and at one moment, it looked as though she herself would be removed from the podium by NIH officials. The next and final word of the day was reserved for Abbott laboratories. Abbott's Chief Operating officer, Jeff Leiden, was announced while Lynda Dee was speaking, and eventually ceded some of his time to her. The black Abbott limousines waiting out front attested to who had the power in this room.

Point 3: <u>There is no public record of this meeting</u>.
Written documents were submitted, but NIH has chosen not to make the docket public. The meeting was not recorded or webcast, and the 2 deliberating NIH chairs, Mark Roerbaugh and Bonnie Harbinger, sat through the whole morning without pen or pencil. If they don't remember it; it didn't happen. When questioned about this decision during the press conference, Roerbaugh explained that this was a (one-way) "listening" experience for NIH to learn for its "own benefit."

Also at the press conference, Roerbaugh mentioned that if march-in is granted, Abbott can appeal—which would take years—and another company seeking to produce ritonavir would have to go through the normal FDA channels of any generic drug. This was a surprise.

SPEAKERS & TESTIONY, in order of appearance

The Honorable Birch Bayh spoke first, roundly denouncing the idea of using his legislation as a means for "price control." He explained that the Act was designed as an economic incentive to counter the declining "innovation" seen in the late 70s. Of 28,000 patents the US government helped to develop by the late 70s, only 4% were in the market. Senator Bayh underlined the importance of the pharmaceutical industry, claiming that industry provides 90% perspiration to what may be considered the inventor/government's 10% inspiration. Senator Bayh articulated what became the crux of the day's testimony against the petition; namely, the argument that the word "reasonable" in health and safety terms as seen in the Act does not refer to pricing. If seen as such, he argued, then drug companies will move away from NIH collaboration. Senator Bayh concluded that march-in could only be used if evidence exists that the drug is not reaching people who need it.

Ted Poehler of the American Association of Universities and Johns Hopkins University resurrected the "price controls boogeyman," testifying that access issues should not be resolved through the march-in rights. He argued that companies will stop investing if NIH overrides Abbott's patent and allows for compulsory licensing of ritonavir. Though Poehler failed to provide empirical evidence, he guaranteed that commercial entities such as Abbott Laboratories are "responsible hands," and should be left alone. According to Poehler, if companies are not left alone, then technology transfer from investigative mechanisms (universities, small biotech start ups, the NIH) to production machines such as Abbott Laboratories would stop.

Daniel Raucher of the Public Patent Foundation explained that ritonavir is comprised of six orange book patents, 4 of which can be legally marched-in.

Next was **John Erickson** of Sequoia Pharmaceuticals, who "empathized" but ultimately came down against the petition. Erickson worked in Abbott's Drug Discovery division from 1985 through 1991, and currently presides over an agency involved with health programs in the developing world. He described a research grant awarded to Abbott by the National Institute of Allergy and Infectious Diseases (NIAID), which was part of a search for synergy between government and academic labs. The funding was used to recruit a new protease team at Abbott, without which ritonavir would not have "come up" through the pipeline. Importantly, Erickson noted that not long after ritonavir discovery, Abbott stopped accepting funding from the government to avoid any march-in problems. Erickson went on to say that the new price only affects competitor agents (not Kaletra), and that any "money vs. health/well-being" issue needs to be a national dialogue. In other words, if health a human right, industry must be helped, and if people want lower prices, more money has to be given to research.

Robert (Bob) Huff of Gay Men's Health Crisis spoke next. He took us on a journey into the "chilling effects" of Abbott's price hike on the future of drug development. Bob detailed prices before and after ($2.14 to $10.71 a day), and explained the concept of protease-boosting. Bob argued that "we may have come to the end of protease boosting" due to Abbott's irresponsible behavior. As an example, the 4 new protease inhibitors (PIs) coming through the pipeline are in jeopardy. The prices of these PIs will all be adjusted, and many of them may now be well out of an affordable or reasonable price range (and potentially inaccessible).

A side argument to Bob's testimony was an emphasis on Abbott's "off-label use" of ritonavir as a boosting agent. Abbott does not have approval for the indication on which they are basing their justification of the increase – but they have no problem selling it like that. Is the FDA listening? Kaletra is in fact a fixed-dose combination that seems to fall outside the rules of the rest of the drugs in its class, because it is also made by Abbott. When coformulated, the price has not gone up. Further, Abbott does not allow "co-formulation" of ritonavir and non-Abbott produced PIs in the same pill. Abbott has also gone out of its way to stop the use of less than 100mg of ritonavir, despite the fact that 50mg or 25mg may be useful for a patient.

In closing, Bob argued that Abbott has failed to behave as a responsible corporate partner; so much so that working with Abbott (to coformulate new PIs with ritonavir, for instance) has proven an unsupportable risk for companies who may have previously been interested in boosted drugs.

Norman Latker, former patent counsel of the US Department of Health, Education, and Welfare (HEW) suggested that because the impact of the price increase is unknown, the Bayh–Dole Act cannot be used. The flip side of this argument places the burden of proof on NIH; we could argue instead that NIH has a responsibility to investigate claims of access shortage and make a finding before dismissing the petition. Latker speculated that the Act was not meant to be an arbiter of public health issues, despite its own language suggesting otherwise [investigation must be made "readily available to society" and must be "no threat to public health."] Latker argued that the reasonable terms set out in the Act do not include a concept of reasonable prices. Legally, Abbott is the contractor, not the licensee. Latker speculated that poor healthcare resources distribution—not price—is the problem. Drug pricing controls must be legislative.

James Love of Essential Inventions, who filed this petition, asked a series of questions:

- Is a 400% increase 8 years after marketing a government invention responsible, especially when it only applies to the US?;
- Are there any limits to Abbott's anti-competitive behavior?;
- Why do march-in rights exist at all if not for this issue? (We'll never have a more egregious case.)
- What are the odds of a "successful" investment funded by the NIH?

Love argued that march-in is a safeguard to help us avoid parallel trade, the other available option. Love also claimed that the "recoupment" provision needs to be taken out of the Act. He ceded two minutes of his time to **David Halperin**, a patent attorney who told us that "reasonable terms" must include "reasonable prices" and that the "egregious pricing" practices of Abbott must trigger the march-in.

Andrew Neighbor from the Intellectual Property Committee spoke, also representing UCLA and 150 research centers, hospitals, and universities. Neighbor rehearsed the argument that discovery, preservation, and transference of inventions is important, and that this is an unusual and unprecedented case. But, march-in would shift the balance to hurt progress, and we must recognize that the "public good" is market driven (a throwback to catch phrases used when

"Reaganomics" was the economic strategy du jour). The march-in provisions of the Act have never been invoked, because the "free market" provides needed checks and balances. An intensive dialogue by all stakeholders is needed to work this out. Neighbor concluded that the situation needs to be examined in the larger context of tomorrow's inventions and products.

Jerome Reichmann, a law professor at Duke, argued for the petition. He stated the "reasonable terms and conditions" of compulsory licensing need to be put into today's context, translated to today's world and accompanying political, economic, and social realities. He detailed the 5 situations when compulsory licensing is permissible. Reichman argued convincingly that the march-in clause 1) protects the public interest by controlling the patentee's abuse of making "windfall profits" through unreasonable prices, and 2) prevents anti-competitive abuse and market undersupplying (high prices naturally undersupply the market). Monopoly leveraging in order to raise prices is abuse, which harms competition in both the PI market and the unlicensed but profitable PI booster market. Far from demanding price controls, this petition reasonably asks a question NIH must attend to: "Can the purchasers afford it?"

Benjamin Young of the group Organized HIV Healthcare Providers (OHHP) gave us an activist provider perspective. In a room unfamiliar with HIV treatment, Dr. Young provided a background of today's reality, including a population of privately insured patients with significant drug resistance. Abbott has a monopoly on these peoples' lives; people who generally do not have a choice to use something else. Their costs have risen from approximately $6 a day to $48 a day. AIDS Drug Assistance Programs (ADAPs) have also been affected. By not allowing co-formulation of ritonavir with drugs from other companies, Abbott may be negatively impacting the life expectancies of people who are forced to take more pills.

In a compelling argument, Dr. Young observed that Abbott receives free research and marketing support from other companies that perform studies using ritonavir. This is occurring during a time of skyrocketing healthcare costs and mounting public outrage at pharmaceutical greed. Close to 2,000 doctors sent a letter to Abbott to roll back the price; the FTC is looking into this; and the Senate Commerce Committee may be investigating as well. Even conservative politicians recognize that this price increase threatens access. Like Huff before him, Young recognized the importance of a profit-making─but not profiteering─pharmaceutical industry. If industry is to remain unregulated (as it wishes), it must adhere to idea code of *corporate citizenship*, which does not mean donations to developing nations instead of responsibilities toward consumers. Young reminded the NIH of the precedent set by Abbott's unethical behavior: today it's an HIV medication, tomorrow a breast cancer drug, next week the price of gas goes from $2 to 10.

Young ceded his remaining time to **Lynda Dee,** who demanded more time from the Chairs. The Chairs did not respond. Dee tried to explain that ADAPs are affected through co-pays and premiums (Leiden asked his neighbor "there are 50 ADAPs?"). If Abbott is offering to pay for people who can't pay, why did they raise the price to begin with? Because they are making money on this! Private insurance providers say they will pay approximately $58 million more this year because of the price hike. There will be less HIV research, and Abbott itself has an empty HIV pipeline. Abbott stands to make up to $2 billion dollars over the next ten years with ritonavir at the old price. Dee was then disrupted and forced off the podium.

Jeff Leiden is the President and Chief Operating Officer of Abbott Products. He began by saying that Abbott is "all about patient care" and that the company did not intend to provoke anger or frustration (the money yes, the anger no). Much of Leiden's testimony was disingenuous and misleading. For example, he stated that Abbott will not charge more for Medicaid (framing this as an act of corporate largesse), but failed to explain that federal law prohibits companies from raising the price beyond the annual inflationary increase. Leiden also described the marvels of HIV drugs, and repeatedly used the word "remission" to describe patients with undetectable viral loads. Remission? I wonder how much he knows about HIV disease. He gave the phone number of the Patient Assistance program for people who cannot afford ritonavir: 800-222-6885. Leiden also said that 54% of the market will never see an increase in the price because they are ADAPs or Medicaid, while the 42% with private insurance should just look for the best deal, and if they can't find one, give Abbott a call.