

July 29, 2012

Honorable Magistrate

**Dr. EDILBERTO BERROCAL ARAUJO**

Procurador 147 Judicial II Administrativo

Supreme Administrative Court of Cundinamarca

First Section Sub section B

**SUBJECT: APPEAL COURT RULING. FILE No. 2009- 0269**

We are writing to express our support for the Colombian civil society groups' appeal to the Supreme Administrative Court in the ongoing "acción popular" for a compulsory license on the HIV treatment lopinavir/ritonavir (marketed by Abbott Laboratories as Kaletra or Aluvia). We are lawyers and academic experts specialized in the fields of intellectual property and health. We urge the Supreme Administrative Court to reconsider the interpretation of compulsory licensing in the decision of the Administrative Court 37 of Bogotá.

We applaud the Administrative Court 37 of Bogotá for ruling that the high prices charged by Abbott Laboratories for Kaletra and maintained by the Ministry of Social Protection – above the established reference price and significantly higher than in neighboring countries—threatened and violated collective rights to public health. This decision sets an important and positive precedent for health rights in Colombia and potentially throughout the world.

The decision by Administrative Court 37 however, did not order adequate and effective remedies, notably the use of compulsory licensing, to address Abbott's anticompetitive practices, introduce generic competition, reduce costs to health programs and support access to medicines in Colombia.

Administrative Court 37 incorrectly asserted that compulsory licenses are reserved for truly extraordinary cases. In fact, World Trade Organization (WTO) patent rules preserve countries' sovereign rights to issue compulsory licenses and "the freedom to determine the grounds upon which such licences are granted,"<sup>1</sup> which may include serving a variety of public interests, among improving health services and reducing healthcare costs. The WTO calls the idea of an emergency requirement "a common misunderstanding."<sup>2</sup>

Article 31 of the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) references "national emergencies or matters of extreme urgency" only in order to allow expedited procedures that do not require prior negotiations with patent holders. Indeed, Article 31 addresses other specific purposes directly, including public non-commercial use, where negotiations are also not required. It allows compulsory licenses on other public interest grounds

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<sup>1</sup> Paragraph 5 of the "Declaration on the TRIPS Agreement and Public Health," World Trade Organization, 20 November 2001. Available at: <http://www.who.int/medicines/areas/policy/tripshealth.pdf>

<sup>2</sup> "TRIPS and Health: Frequently Asked Questions, Compulsory licensing of pharmaceuticals and TRIPS", World Trade Organization, 2006. Available at: [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)

so long as there is a prior attempt to negotiate a voluntary license on reasonable commercial terms with the right holder.

All doubt about countries' sovereign rights to define the grounds upon which compulsory licenses may be issued were resolved in the 2001 Doha Declaration on the TRIPS Agreement and Public Health, a document signed by all WTO members including Colombia. There, in Paragraph 5, it was clarified that compulsory licenses could be issued on any grounds whatsoever. Compulsory licensing rights are not limited to particular diseases. Countries can choose the grounds for licenses and in addition identify those urgent matters that permit expedited licenses. Administrative Court 37 itself recognized that licenses may be granted in Andean Community countries for reasons of “public interest” (Decision 486, Article 65).

In addition, it is clearly permissible to issue competition-based compulsory licenses under Article 31 to address the kind of abusive pricing violations found by the Administrative Court. When competition violations are found, not only is there no need to engage in prior negotiations for voluntary licenses, it is also permissible to reduce the royalty. In addition, it is permissible to export unlimited quantities of medicines produced under the compulsory license to other countries. Notably, Andean Community rules also provide for compulsory licensing as a means to remedy anti-competitive practices (Decision 486, Article 66). The Administrative Court stated that Abbott abused its dominant market position, which is typically considered an anti-competitive practice.

Court 37's interpretation of compulsory licensing overlooks international practice, including but not limited to frequent government use and court-issued licenses to remedy anti-competitive practices in the United States.

Government rights to authorize use of a patented invention are embedded and expressly reserved in the grant of a patent. Exercising these rights by issuing a license does not modify or expropriate the patent right. Further, a license does not prevent the patent holder from continuing to sell its product, prohibit non-licensed uses of the invention or prohibit non-licensed parties from using the invention.

Additionally, if indemnification in the court's decision means compensation, compulsory licensees pay compensation via royalties to patent holders.<sup>3</sup> If indemnification means making the patent holder whole for all market loss, then the court's reasoning would vitiate one of the primary purposes of compulsory licensing – cost savings. Under an indemnification rule, savings from licenses would be wiped out, passing instead back to the patent holder. This would depart radically from international practice and render aspects of Colombian law and Andean Community licensing rules all but meaningless.<sup>4</sup>

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<sup>3</sup> For more information on royalties, see: Love, J., *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, UNDP and World Health Organization, 2005. In the United States, the trade association for the pharmaceutical industry, the Pharmaceutical Research and Manufacturers Association (PhRMA), claimed that 5 percent was the average US royalty rate for licenses on pharmaceutical drugs. (Love, J. *Compulsory Licensing: Models for State Practice in Developing Countries, Access to Medicines and Compliance with the WTO*, Third World Network, 2004.)

<sup>4</sup> Andean Community Decision 486 (Common Intellectual Property Regime) is law in member countries. Article 65 provides for licensing on public interest grounds. A separate article (Art. 61) provides for licenses to remedy patent

We express our strong support for this acción popular and urge the Supreme Administrative Court to consider the remedy of compulsory licensing to initiate generic competition. Such a decision could generate enormous savings for the health system, enabling it to expand access to the medicine and reduce mortality due to HIV/AIDS.

Sincerely,

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holder failures to exploit or work a patent. Public interest grounds must therefore mean something other or more than working failure. Common international practice and many sources of legal analysis worldwide suggest cost control is a, if not the, leading purpose for such rules.

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## Colombian Court: Abbott Labs' AIDS Drug Pricing Abuse Violated Health Rights

*Both sides appeal in ongoing civil society lawsuit for compulsory license*

*-- Background --*

A Colombian administrative judge has ruled that Abbott Laboratories and the Ministry of Health threatened and violated collective rights to public health by maintaining the price of an HIV medicine above the reference price, flouting a government order. The court's decision is a groundbreaking condemnation of Big Pharma pricing abuses and a precedent for health rights in Colombia.

The decision arises from a lawsuit filed by health groups seeking a compulsory license on lopinavir + ritonavir (LPV/r), marketed by Abbott as Kaletra and Aluvia. A compulsory license would introduce cost-cutting generic competition with Abbott's patent-based monopoly.

The decision, technical documents and brief histories of Colombia's ongoing access campaign are now *available at*: <http://www.citizen.org/actions-colombia>.

### **The Decision and Case**

The February 29, 2012 decision by Administrative Court 37 of Bogotá finds that Abbott violated a 2009 government pricing order and directs the Ministry of Health to initiate procedures for sanctions against Abbott (potentially including financial penalties). The court states that Abbott abused its dominant market position by pricing its essential medicine 350% higher in Colombia than in neighboring countries (about \$3500 compared to about \$1000). This harmed the sustainability of Colombia's health system and violated "public administrative morality." According to the court, "mercantile utility and patent ownership" does not justify "disobeying the national policy of price control for HIV/AIDS medicines." The decision calls for maintaining Kaletra on a parallel importation list to ensure availability of the international reference price.

The lawsuit, filed by Colombian health organizations in September 2009, is an “Acción Popular,” a mechanism under Article 88 of the Colombian Political Constitution to protect collective rights, public services and administrative morality. It is analogous in some regards to a private attorney general action in the United States.

### **Colombia’s Access Campaign**

In April 2008, with prices for Abbott’s monopolized HIV treatment Kaletra in the several thousands of dollars per person per year, Fundación IFARMA, the Colombian Network of People Living with HIV (RECOLVIH), Misión Salud and the Group of NGOs working on HIV/AIDS (la Mesa) requested a license from Abbott to facilitate generic competition. When Abbott did not respond, the groups petitioned the Colombian government and launched a public access to medicines campaign. In April 2009, the government issued an order establishing a price ceiling for Kaletra, which Abbott ignored. In September 2009, the health groups filed their lawsuit, seeking a compulsory license to inaugurate competition. In January 2010, Colombia announced a financial emergency in its health system and strengthened the powers of the medicines pricing commission. Abbott finally complied with the price order. The price reductions, initially around 54-68%, were projected to save Colombia’s HIV programs approximately US\$12 million in the first year alone.

Despite these savings, thus far Abbott’s monopoly over LPV/r remains intact in Colombia. A compulsory license and generic competition could reduce prices much further.

### **Court Declines to Issue Compulsory License**

In its recent decision on the Acción Popular, Administrative Court 37 declined to issue a compulsory license, stating that Colombian law does not permit “expropriation without indemnification.” This reflects a misunderstanding of compulsory licensing.

Government rights to authorize use of a patented invention are embedded and expressly reserved in the grant of a patent. Exercising these rights by issuing a license does not modify or expropriate the patent right. Further, a license does not prevent the patent holder from continuing to sell its product, prohibit non-licensed uses of the invention or prohibit non-licensed parties from using the invention.

Additionally, if indemnification in the court’s decision means compensation, compulsory licensees pay compensation via royalties to patent holders. If indemnification means making the patent holder whole for all market loss, then the court’s reasoning would vitiate one of the primary purposes of compulsory licensing – cost savings. Under an indemnification rule, savings from licenses would be wiped out, passing instead back to the patent holder. This would depart

radically from international practice and render aspects of Colombian law and Andean Community licensing rules all but meaningless.<sup>5</sup>

The court mistakenly asserts that compulsory licenses are reserved for “truly extraordinary cases.” This too overlooks international practice, including but not limited to government use and court-issued licenses to remedy anti-competitive practices in the United States. The World Trade Organization clearly states that countries are free to grant compulsory licenses on “grounds of their choosing.” The Colombian court itself recognizes that licenses may be granted in Andean Community countries for reasons of “public interest.”

Notably, Andean Community rules also provide for compulsory licensing as a means to remedy anti-competitive practices. The court states that Abbott abused its dominant market position, which is typically considered an anti-competitive practice.

### **Both Sides Appeal; Access Campaign Expands**

Parties on both sides of the case – the health groups and Abbott – have appealed Administrative Court 37’s judgment to the Supreme Administrative Court.

Since 2008, Colombia’s access campaign has led to major price reductions, intensified and high-level public scrutiny of medicine price abuses, a government regulation on compulsory licensing in the public interest, and has helped reinstate parallel importation -- a means to reduce medicine prices by shopping on the world market. Colombian groups have consistently expanded their campaign across the country and found new mechanisms to challenge pharmaceutical monopoly power.

More on the case, including the court’s decision (in Spanish), source documents, and a history of the campaign is *available at*: <http://www.citizen.org/actions-colombia>.

Read about the global Kaletra campaign *at*: <http://citizen.org/Kaletra-campaign>.

Public Citizen’s Global Access to Medicines Program (formerly Essential Action) has worked with and provided technical assistance to the Colombian health organizations since 2008.

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<sup>5</sup> Andean Community Decision 486 (Common Intellectual Property Regime) is law in member countries. Article 65 provides for licensing on public interest grounds. A separate article (Art. 61) provides for licenses to remedy patent holder failures to exploit or work a patent. Public interest grounds must therefore mean something other or more than working failure. Common international practice and many sources of legal analysis worldwide suggest cost control is a, if not the, leading purpose for such rules.



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