COMPULSORY LICENSES – COLOMBIA'S EXPERIENCE.
THE KALETRA CASE

Kaletra.
Kaletra is an anti-retroviral medicine containing RITONAVIR and LOPINAVIR that is used in the treatment of HIV/AIDS

Mechanisms employed as a part of the case:
Price control
Direct request to the Ministry of Social Protection
Direct request to the Supervisory Authority for Industry and Trade (SIC)
Acción popular (similar to a private attorney general action)

Legal framework.
Law 81 of 1998

Control directo	(medicine pricing regime covering medicines already covered by *Libertad regulada* regime and whose unit price is higher than the reference price)
Libertad regulada	(medicine pricing regime covering medicines essential to the protection of public health)
Libertad vigilada	(medicine pricing regime covering all medicines sold on the domestic market, except for those covered by the *Control directo* and *Libertad regulada* regimes)

Case

- Circular 02 of 2008: placing Kaletra under the *libertad regulada* regime but not setting a reference price. The ruling referred to the setting of the reference price in accordance with Article 9(3) of Circular 4 of 2006 (average price for the preceding three-month period, reported by the laboratory).
- Circular 002 of April 28, 2009, fixing the reference price for Kaletra.
- On October 30, 2009, the Ministry of Trade, Industry and Tourism (MCIT) requested the Supervisory Authority for Industry and Trade (SIC) to open an inquiry into pricing regime violation -Circulars Nos. 004 of 2006 and 002 of 2009- concerning ABBOTT Laboratories de Colombia S.A.
- Circular No. 006 of November 11, 2009. The National Commission for the Pricing of Medicines turned down the request for the (partial) withdrawal of Circular 02 of 2008 and rejected the request for the withdrawal of Circular 002 of 2009, made by ABBOTT LABORATORIES.
- On December 1, 2009, the SIC launched an administrative inquiry into the activities of Abbott, culminating in Ruling 9160 of February 19, 2010, shelving the proceedings.
- Direct request to the Ministry of Social Protection
  - Request made by the Working Group of HIV/AIDS Organizations, the Colombian Network of Persons Living with HIV (RECOLVIH), the IFARMA Foundation, - Health Action International (HAI) and the Social Mission Foundation for access to the medicine Kaletra, produced by Abbott, to be declared in the public interest; July 16, 2008.
  - Request made by Abbott to participate as an interested third party. September 2, 2008.

- Response issued by Abbott to the request for access to Kaletra to be declared in the public interest. October 6, 2008.
- The General Directorate for Public Health of the Ministry of Social Protection submitted all the documentation to the SIC. October 22, 2008.
- The SIC sent back the case file owing to lack of competence, citing as grounds for its decision Decree 4302 of 2008, which establishes the procedure for the declaration of the existence of grounds for public interest. November 14, 2008.
- *Derecho de petición* (Request for information/action) submitted by Abbott requesting: (a) the rejection *in limine* of the request for the declaration of public interest; (b) that it be named as an interested third party to the case should the request set out in (a) be rejected; (c) that it be informed whether remedies were available through government channels. January 23, 2009.
- Through an administrative act dated February 3, 2009, the Technical Committee on the declaration of grounds of public interest of the Ministry of Social Protection initiated an administrative action to establish whether grounds existed for a declaration of public interest concerning access to Kaletra under competitive conditions and naming Abbott as an interested third party.
- Abbott requested the ordering of taking of evidence. March 25, 2009
- The Ministry of Social Protection responded by stating that it was the Technical Committee which had the power to determine which documents it required, the party submitting the *derecho de petición* not being empowered to incorporate documents as a part of what was a special administrative proceeding.

- *Acción de tutela* (action for protection) lodged by Abbott
  - The Administrative Tribunal of Cundinamarca refused to grant protection of due process concerning the indication of the remedies admissible against the act declaring the existence of grounds of public interest and upheld the right to due process and defense with regard to the request for the taking of evidence. May 7, 2009
  - The Technical Committee issued a recommendation to the Ministry of Social Protection to the effect that access to Kaletra should not be declared in the public interest.
  - Through Ruling 1444, of May 8, 2009, the Ministry of Social Protection closed the action, stating that no grounds existed for declaring access to Kaletra to be in the public interest.
  - The Council of State upheld the ruling of the Administrative Tribunal of Cundinamarca. July 9, 2009.
- Direct request to the SIC
  - June 21, 2008. Jorge Pacheco, coordinator of the Working Group of HIV/AIDS Organizations, submitted a *derecho de petición* to the Supervisory Authority for Industry and Trade and the President of the Republic, requesting an open compulsory license for Kaletra on public interest grounds. Further *derechos de petición* were received supporting the request made by Mr. Pacheco.
  - July 25, 2008. The SIC responded to the *derecho de petición*, stating that the proceedings were admissible provided that the conditions and requirements concerning such requests were met.
  - March 2, 2010. IFARMA, Health Mission Foundation and the Working Group of HIV/AIDS Organizations submitted a *derecho de petición* concerning the initiation of an administrative action for the issuance of an open license for Kaletra on public health emergency grounds

- March 24, 2010. The Supervisory Authority declared that it lacked competence to suspend the patents issued and the applications being processed, as well as any future applications, concerning the products covered by the public health emergency declaration issued; consequently, the Supervisory Authority stated that the request concerning said applications was not admissible.

- <u>*Acción popular*</u>
  - *Acción popular* declared admissible. October 15, 2009.
  - Issuance of the *auto admisorio* of the *acción popular* (document in which the authorities state that the *acción popular* fulfills the relevant legal requirements). October 26, 2009.
  - In light of Law 1395 of 2010 on speeding up legal proceedings which involved the reassignment of competences, the *acción popular* was transferred to the Administrative Tribunal of Cundinamarca, the body responsible for initiating new proceedings.
  - In a ruling of February 29, 2012, Bogotá Circuit Administrative Court 37 ordered the Ministry of Health and Social Protection to initiate the punitive action relating to the case concerning threats to and the undermining of public health collective rights and interests, as a result of the maintenance of domestic prices for the medicine that were higher than the international reference price. The Court also ordered that the medicine be included on a list of "parallel imports" , in order to ensure its availability on the domestic market at the international reference price and for the purposes of any potential Solidarity and Guarantee Fund – FOSYGA (Colombia's central public health funding mechanism) reimbursements.

    As a part of the ruling, the National Government, and in particular the Supervisory Authority, was also urged to submit a bill amending the compulsory licensing regime, in terms that must be analyzed in light of the legal provisions currently in force.
  - In a ruling dated September 27, 2012, the Administrative Tribunal of Cundinamarca ordered the Ministry of Health and Social Protection to regulate the prices of the medicine and the SIC to launch the necessary inquiries to determine whether Abbott complied with the reference prices set.
  - In light of the inquiries carried out, **the SIC fined ABBOTT LABORATORIES DE COLOMBIA S.A. for selling HIV/AIDS drugs at a price higher than the maximum permitted price. The following is a summary of the notice published by the body in that regard:**

- *The Supervisory Authority fined ABBOTT LABORATORIES DE COLOMBIA S.A. 3 billion 80 million Colombian pesos for having sold the medicine KALETRA® at a price 53 to 66 per cent higher than that set by the National Government.*

- *By issuing said fine, the Supervisory Authority complied with a court ruling issued by the Administrative Tribunal of Cundinamarca as a part of an* acción popular *brought by the Colombian Network of Persons Living with HIV/AIDS (RECOLVIH).*

- *The fine was issued in order to protect both Colombians living with HIV/AIDS and the General Health and Social Security System.*

Through Ruling No. 11990 of February 26, 2014, in the first instance the Directorate of Inquiries for the Monitoring and Checking of Technical Regulations and Legal Metrology of the Supervisory Authority for Industry and Trade (SIC) fined the company ABBOTT LABORATORIES DE COLOMBIA S.A. three billion eighty million Colombian pesos ($3,080,000,000), equivalent to five thousand (5,000) minimum legal monthly wages, for having sold the medicine KALETRA®200 MG tablet/CAPSULE X 120 for the treatment of HIV/AIDS at a price higher than that set by the National Commission for the Pricing of Medicines and Medical Devices.

Pursuant to a court ruling issued by the Administrative Tribunal of Cundinamarca as a part of an acción popular *brought by the Colombian Network of Persons Living with HIV/AIDS (RECOLVIH) against Abbott Laboratories de Colombia and the Ministry of Health and Social Protection (MINSALUD), an administrative inquiry was launched to check compliance with the provisions of Article 88 of Law 1438 of 2011, prohibiting the bodies of the General Health and Social Security System from purchasing medicines at prices higher than the reference prices, and prohibiting laboratories and wholesalers from selling medicines at prices higher than the reference prices.*

The checks, which were carried out concerning sales made by ABBOTT LABORATORIES DE COLOMBIA S.A. between February 2011 and June 2012, revealed that the medicine KALETRA® had been sold at a price 53 to 66 per cent higher than that set by the National Government.

The medicine KALETRA®

KALETRA® is an anti-retroviral medicine made up of Lopinavir and Ritonavir molecules. Lopinavir and Ritonavir belong to a class of anti-HIV medicines known as protease inhibitors (PIs). PIs are designed to keep the viral load below the level of detection and to increase the number of CD4 T lymphocytes, with the aim of re-establishing immunity and reducing the risk of infections developing.

The medicine KALETRA® is produced by the multinational company ABBOTT Laboratories, headquartered in Chicago (Illinois), and was imported into Colombia by ABBOTT LABORATORIES DE COLOMBIA S.A. on the dates covered by the inquiry, with sales of over 24 billion Colombian pesos between January 2011 and June 2012. The product is currently being imported by the company ABBVIE S.A.S.

HIV/AIDS statistics in Colombia.

Since 1983, the year in which the first case of HIV/AIDS infection was reported in Colombia, more than 105,000 cases of persons living with this illness have been reported, according to studies covering the period up to but not including 2013 carried out by the Ministry of Health and Social Protection (71.1 per cent men and 28.9 per cent women).

Requests for reconsideration and appeal are currently before the same Supervisory Authority concerning the penalty imposed in the first instance.

Information obtained from the web site of the Ministry of Health and Social Protection www.minsalud.gov.co. Epidemiological Bulletin, situation concerning HIV/AIDS in Colombia, 2013. The report states that there were 86,990 cases between 1983 and 2011, a figure which, when updated to take into account the period up to but not including 2013, rises to around 105,000.