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## THAILAND'S LAWFUL COMPULSORY LICENSING AND ABBOTT'S ANTICOMPETITIVE RESPONSE

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Today, on a global day of action against Abbott Laboratories, a Thai network of people living with HIV/AIDS (TNP+), AIDS ACCESS Foundation and an alliance of supporting organizations and individuals will march to the Thai Ministry of Commerce to demand that the Thai Trade Competition Commission instigate criminal actions against Abbott. The complaint alleges that Abbott breached the Competition Act by refusing to supply drugs in Thailand in response to a legal government compulsory license. This memo explains why (1) Thailand was fully within its rights under its own law and under the WTO TRIPS agreement in issuing compulsory licenses to procure medicines, and (2) why Abbott's refusal to supply several medicines to Thailand in response, and its refusal to license generic provision of its products before the license, may violate Thailand's Competition Act.

### A.

#### Background on the Thai Licenses and Abbott's Response

Thailand recently joined the ranks of nations that have taken advantage of the flexibilities in the TRIPS Agreement authorizing compulsory licenses for pharmaceutical patents to increase access to medicines in its health system. Between November 2006 and November 2007, the Ministry of Health granted licenses for patents on two antiretroviral drugs; Efavirenz, sold by Merck as Stocrin, and Lopinavir+Ritonavir, sold by Abbott as Kaletra. A compulsory license was also issued for the clopidogrel, a heart medication sold by Bristol Myers Squibb as Plavix. The licenses were issued for government use, and include a 0.5% royalty rate.<sup>2</sup> Other countries that have issued compulsory licenses for AIDS medicines include Indonesia, Malaysia, Ghana, Eritrea, Mozambique, Zambia, and South Africa.<sup>3</sup>

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<sup>2</sup> Text of the licenses is available at [www.wcl.american.edu/pijip/thai\\_comp\\_licenses.cfm](http://www.wcl.american.edu/pijip/thai_comp_licenses.cfm)

<sup>3</sup> See [www.cptech.org/ip/health/cl/recent-examples.html](http://www.cptech.org/ip/health/cl/recent-examples.html)

The license for Kaletra arose from Thailand's need to gradually shift its treatment priorities to so-called "second-line" AIDS medications. Thailand's successful AIDS program, which treats over half a million HIV positive people, has predominantly relied on local production of older "first-line" antiretroviral drugs, which are available from many generic producers and can be purchased for under \$200 per year per patient from some generic suppliers. However, as people continue treatment, they develop resistance to first-line medications, and need to switch to newer and more expensive second-line drugs, of which Kaletra is a key example.<sup>4</sup>

On the date of the Thai compulsory license, Abbott was demanding \$2,200 for a one year's supply of Kaletra in Thailand. This is more than ten times the lowest generic price for a complete first-line cocktail, although Kaletra must still be combined with at least two other drugs to create an effective second-line treatment. Forecasting that it would not be able to maintain adequate treatment for all who need it at this price, Thailand attempted to negotiate lower prices for the Kaletra and other needed drugs and, when those negotiations failed, issued licenses to purchase generic products.<sup>5</sup>

In March 2007, Abbott responded to the compulsory license for Kaletra by announcing it would no longer register new drugs for sale in Thailand.<sup>6</sup> Drugs that will not be registered in Thailand include a new version of Kaletra that does not need refrigeration.<sup>7</sup> The refusal to sell the only heat stabilized version of a ritonavir-boosted protease inhibitor in a poor tropical country threatens many lives and, as described below, appears to violate Thailand's Competition Act.

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<sup>4</sup> Kaletra is a combination of an effective protease inhibitor, lopinavir, with a small dose of one-of-a-kind boosting agent, ritonavir, in a fixed dose (single pill) formulation. The inclusion of ritonavir allows increased effectiveness with less medication, thus leading to lower side effects for many patients. In the U.S., Abbott laboratories increased the price of ritonavir standing alone (i.e. used with competitors' protease inhibitors) by 400% in December 2005 in an apparent attempt to shift market share to Kaletra.

<sup>5</sup> See Thailand Ministry of Public Health and National Health Security Office, *Facts and Evidence on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand* (February 2007), available at [www.wcl.american.edu/pijip/thai\\_comp\\_licenses.cfm](http://www.wcl.american.edu/pijip/thai_comp_licenses.cfm)

<sup>6</sup> It also responded with global price cuts for Kaletra, likely fearing similar action by other developing countries. April 10, 2007, Abbott announced a price cut from \$2200 per patient per year to \$1000 per patient per year. This lower price will be available not only to Thailand but also to low and low-middle income countries. Abbott's price cut came shortly after the Indian generics firm Cipla announced it was offering a generic version for \$1560 per patient per year. Cipla and other generic producers are expected to offer deeper price cuts for generic versions of heat-stabilized Kaletra in the future. Thus, it appears that the dynamic downward spiral of prices in response to generic competition that made first line drug affordable (dropping from \$10,000 /year to under \$200 /year over seven 5 years) may be beginning in the second line market.

<sup>7</sup> Other drugs that Abbott is refusing to sell in Thailand include Brufen (ibuprofen), Abbotec (clarithromycin), Clivarine (heparin), Humira (adalimumab), Tarka (trandolapril/verapamil HCl ER), and Zemplar (paricalcitol).

**B.**  
**Thailand's Compulsory Licenses Are Legal Under its Own Law and the WTO  
Trips Agreement**

**1. *The TRIPS Agreement Authorizes Public Use Licenses Without  
Negotiation With the Patent Holder***

Some pharmaceutical industry representatives, including a recent article by Abbott's lawyers from the 3400 attorney Baker & McKenzie law firm, misleadingly and incorrectly argue that Thailand's compulsory licensing actions violate World Trade Organization rules. This is clearly false. Under TRIPS, a government may use a patent for a public purpose without negotiation and without prior notice, subject to the duty to provide an appellate process to determine the adequacy of the remuneration.

**a. *There is no TRIPS prior negotiation requirement for public-use  
licenses.***

One of the main arguments often used against the Thailand licenses is that they were not adequately negotiated with the patent holder before their issuance. But the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was intentionally designed to protect the common U.S. government practice of authorizing any private or public entity to use patents for government purposes without prior notice and without negotiation. Thus Article 31(b) explicitly directs that the obligation to make "efforts" to obtain authorization from the patent holder "may be waived by a Member . . . in cases of public non-commercial use." There is no obligation under TRIPS for Thailand to attempt to negotiate patent licenses with Abbott or any other pharmaceutical company because the licenses will be used solely for supply through its public health program.<sup>8</sup>

Indeed, Thailand did not even have to notify the patent holders that it was issuing a license for public use prior to the actual use. It could have simply purchased generic versions of whatever patented drugs it wished and provided notice and an opportunity to settle adequate remuneration "promptly" afterwards. This is what the U.S. government normally does in Defense and other industries where its requests for proposals for procurement contain clauses authorizing uses of other patents with the only recourse for the patent holder being a complaint against the U.S. for remuneration.

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<sup>8</sup> In fact, Thailand did enter into negotiations with the patent holders for an extended period. See Thailand Ministry of Public Health and National Health Security Office, *Facts and Evidence on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand* (February 2007), available at [www.wcl.american.edu/pijip/thai\\_comp\\_licenses.cfm](http://www.wcl.american.edu/pijip/thai_comp_licenses.cfm)

**b. Use of the medicines in the public sector health program constitutes a public use.**

Some commentators have attempted to evade this aspect of the TRIPS compromise by suggesting that Thailand's action does not constitute "public non-commercial use" because the compulsory license permits the Government Pharmaceutical Organisation (GPO), which arguably has commercial purposes and functions, to use the patents. But the commercial status of the supplier is irrelevant. Only the "use" must be public and non-commercial, which distribution through the public health sector undoubtedly is. Thus TRIPS Article 31(b) describes public non-commercial use of "the government or contractor." The United States, for example, commonly issues "public non-commercial use" licenses to permit private contractors (e.g. Boeing or Lockheed Martin) to use patents to supply the Defense Department's procurement needs. Thailand could have issued the license directly to Pfizer and it would not have affected the legality of the license under TRIPS.

**c. Abbott may appeal the royalty if it disputes the amount.**

Some critics have argued that the royalty rates on the licenses are too low. But TRIPS requires, and Thailand provides, an appeal mechanism to determine the adequate royalty for the patent. Trite principles of administrative law would bar the companies from challenging a royalty they have not appealed.

**d. The licenses were individually considered and granted.**

Some also contend that Thailand did not consider each license on its own merits, a requirement of Section 31(a) of TRIPS. But Thailand clearly did comply with this requirement by issuing separately justified licenses for each drug.

**e. TRIPS does not require a public health "emergency" to grant a compulsory license.**

Finally, it has been contended by some that the TRIPS authorizations of compulsory licenses are only justified by public health "emergencies," and that AIDS or heart disease in Thailand does not rise to this threshold. But the idea that only emergencies justify compulsory licenses is a common misperception.

The U.S. government does not declare an emergency every time it uses a patent for a defense or other procurement. The TRIPS agreement authorizes special flexibilities in cases of emergencies, namely doing away with the need to negotiate prior to the license. But nothing confines compulsory licensing to emergency situations. The Doha Declaration on the TRIPS Agreement and Public Health of Nov. 2001 specifically addressed this fact, explaining in paragraph 5(b) that: "Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

At bottom, it is clear that there is nothing in TRIPS that is contrary to the Thai licenses.

## **2. *Thai Law Authorizes the Government Use Licenses***

Section 51 of the Thai Patent Act makes clear that the Thailand Department of Disease Control was well within its rights in granting a license for the public purchase and use of generic versions of Kaletra and other drugs without further negotiation with the patent holder. The patent holder is given a right to appeal the terms of the license, including its royalty rate. The Department may, however, use the license to begin purchase of generic versions of patented medicines immediately, regardless of whether any dispute may exist or arise as to the reasonableness of the royalty or other terms established in the license.

Section 51 of Thailand's Patent Act defines the right of "any ministry, bureau or department of the Government," "by themselves or through others," to exercise the rights in any patent "for public consumption." Specifically, the section states:

In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis. In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis.<sup>9</sup>

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<sup>9</sup> To view the text of the Patent Act of 11 March B.E. 2522 (1979) as amended by Act (No. 3) B.E. 2542 (1999): [http://www.jpo.go.jp/shiryu\\_e/s\\_sonota\\_e/fips\\_e/pdf/thailand/patents\\_act.pdf](http://www.jpo.go.jp/shiryu_e/s_sonota_e/fips_e/pdf/thailand/patents_act.pdf)

**a. Treating AIDS and Other Health Conditions are Valid Public Interest Grounds.**

Section 51 broadly authorizes the government use of patents to “carry out any service for public consumption” or to meet a list of specific public needs, including “to prevent or relieve a severe shortage of . . . drugs or other consumption items.” The public notice contains adequate statements invoking both of these authorized grounds.

The Decree authorizing exploitation of patents on Kaletra explains that the license is “for the public use,” namely “non-commercial use” by the public health services.<sup>10</sup> Specifically, the Decree limits the use of the license to supply of medicines to no more than 50,000 patients per year who are “covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employees medical benefits scheme.”

The public use of the patents for supply of the public health service is sufficient grounds to permit the license under Section 51 and TRIPS. There is no obligation in Thai law (or U.S. law or the WTO TRIPS agreement) that the public use of patented technology be limited to emergency situations, a point discussed above. The fact that the license will be used to support a public program is sufficient grounds to justify the license under Thai law.

The public notice also demonstrates that a second independent ground for the license under Section 51 is met: namely “to prevent or relieve a severe shortage of . . . drugs or other consumption items.” The notice explains that the license is needed to respond to a shortage of Kaletra in public treatment programs for people with AIDS:

The situation of HIV spreading is the key problem of Thai public health. More than 1 million Thais have been infected with HIV, among this, more than 500,000 people are still alive. These infected individuals will eventually need long-term uses of antiretroviral drugs to maintain their productive lives.. The Thai Government has launched a policy of universal access to anti-retrovirals since 1st October 2003, and has a budget specifically allocated for them. However, it is still difficult to get accessed to some effective and safer anti-retrovirals. The high price of these patented anti-retrovirals have hindered their

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<sup>10</sup> See Decree Of Department Of Disease Control, Ministry Of Public Health, Regarding Exploitation Of Patent On Drugs & Medical Supplies By The Government On Combination Drug Between Lopinavir & Ritonavir (January 29, 2007), available at [www.wcl.american.edu/pijip/thai\\_comp\\_licenses.cfm](http://www.wcl.american.edu/pijip/thai_comp_licenses.cfm)

accessibility under the universal access policy because of patent protection by law, then there's no competition. The government cannot allocate enough budget. However, budget for health services in the national health security system allocated for HIV /AIDS patients in the fiscal year 2007 (B.E. 2550) is only 3,855.6 million baht for the target group of 108,000 patients. Some of this group have resistance to the first line ARVs and have to move to the second line.

Lopinavir + Ritonavir under the tradename Kaletra is a highly effective and safe antiretroviral. It is also placed in the Thailand's National List of second line Anti-retrovirals. Because it's protected by patent, no one can produce or import to share the market. So, it's price is much higher than generic products in some other country. With this higher price, the budget allocated from the Thai Government can only cover some patients with it, whereas the rest has to face with fatal opportunistic infections. If this ARVs formula could be produced or imported, the lower price would help more accessible.

Although the license for Kaletra is limited to use in the public health system, it is notable that Section 51 does not restrict the use of licenses issued under it so narrowly where the purpose is to address "a severe shortage of . . . drugs or other consumption items." This ground is independent from the ground that the license is intended to be used "to carry out any service for public consumption." Section 51 could, therefore, be used to authorize a compulsory license for use in the private sector (e.g. for purchases through private insurance or other private suppliers) if the purpose is to address a shortage of needed medicines.

**b. The Department of Disease Control is an Authorized Licensing Authority**

Under the Thai Patent Act, the Director General of the Department of Commerce is authorized to grant most types of compulsory licenses. A public use license under Section 51, however, may be issued by "any ministry, bureau or department of the Government," "by themselves or through others." Thus, it is clear that the Department of Disease Control in the Ministry of Public Health was within its authority to issue a public use license.

**c. There is no Prior Negotiation or Notice Requirement**

Section 51 does not require prior negotiation with the patent holder. It rather requires that the licensing authority “shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis.” It thus takes advantage of the TRIPS flexibility permitting public use licenses without negotiation with the patent holder.

The exemption from the requirements of Section 46, 47 and 47 bis make clear that the government is not required to (1) wait until “the expiration of three years from the grant of a patent or four years from the date of application,”<sup>11</sup> or (2) have “made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances.”<sup>12</sup>

**d. The Department May Set an Initial Royalty**

Section 51 states that the ministry issuing the patent “shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General.” The royalty rate and terms shall either be (1) “as agreed upon by the ministry or bureau or department and the patentee or his licensee,” or (2) set in terms of Section 50, which “shall apply mutatis mutandis” (i.e. with necessary changes).

The reference to Section 50 makes clear that the authorizing ministry has the right to set a royalty absent agreement with the patent holder, subject to appeal. Section 50 discusses the right of the “Director General” to set a royalty rate. But this provision applies when the Director General (of the Department of Commerce) is the requesting authority. When another ministry is requesting the license under the terms of Section 51, then the command to apply section 51 “mutates mutandis” (i.e. with necessary changes made) indicates that the references to the Director General should be read as applying to the authorizing ministry or department, in this case the Department of Disease Control. Thus, the applicable language in section 50, with necessary changes made, states:

If no agreement has been reached by the parties within the period prescribed by the [Department of Disease Control], the [Department] shall fix the royalty and prescribe the conditions and restriction as he deems appropriate subject to the following requirements: (1) the scope and duration of the license shall not be more than necessary under the circumstances; (2) the patentee shall be entitled to further license others; (3) the licensee shall not be

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<sup>11</sup> Section 46.

<sup>12</sup> See Section 46 (failure to work); Section 47/47 bis (patent necessary for subsequent invention).



entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license; (4) the licensing shall be aimed predominantly for the supply of the domestic market; (5) the remuneration fixed shall be adequate for the circumstances of the case.

The Department of Disease Control fixed a royalty and prescribed conditions of the license in its public notice and states the intent to “notify the patent owner and the Department of Intellectual Property, Ministry of Commerce immediately.” Negotiation over the terms and royalty of the license may follow this notice.

**e. The Initial Royalty Term May be Appealed.**

Should the patent holder and the government not reach agreement on the terms and royalty of the license, the patent holder may file an appeal of such terms without affecting the right of the Department to begin using the license immediately (i.e. through the purchase of generic medications for its treatment program).

Section 50 states in relevant part:

The decision of the [Department] made under the first paragraph of the Section is appealable to the Board within sixty days from the date on which such decision is received.

The decision made “under the first paragraph of the section” deals with the setting of the terms of the license, including the applicable royalty. It is not the ultimate decision to grant a license, which appears unreviewable under Thai law. Thus, as under U.S. law, the patent holder has no right to appeal the grounds for the decision to grant a government use license but rather is limited to contesting the compensation due for the expropriation. This also suggests that, as under U.S. law, a patent holder may not receive an injunction prohibiting the government from using the patented invention pending the outcome of an appeal of the royalty rate.

In sum, Thailand’s law appears to incorporate the most important TRIPS flexibilities for issuing public use licenses, and Thailand’s action in licensing several medicines recently appears to have been carefully tailored to comply with both its own law and the TRIPS agreement. Arguments to the contrary, which have not been brought in any competent tribunal, should be dismissed as political posturing.

### C. Abbott's Anticompetitive Conduct

#### 1. *Abbott's Response to the Thai License of Refusing to Supply Other Essential Medicines Is Anticompetitive and Subject to Legal Sanction Under Thai Law*

In response to Thailand's local and international law justified decision to issue a public health compulsory license for Kaletra and other medicines, Abbott announced that it would refuse to market a new heat-stabilized version of Kaletra, along with several other drugs, from Thailand's market. This decision may violate Thailand's Competition Act.

Many competition laws, including Thailand's, prohibit dominant companies doing commerce in the country from withholding provision of products without adequate pro-competitive justification. Section 25(3) of Thailand's competition law prohibits a dominant firm from "suspending, reducing or restricting services, production, purchase, distribution, deliveries, or importation without justifiable reasons."<sup>13</sup> Penalties under the Act can include 3 years imprisonment and a fine of 6 million bhat, with the possibility of double penalties.<sup>14</sup>

The plain text of the Thailand statute supports the Thai treatment activists complaint against Abbott for its actions, setting up the question of whether the exercise of legally valid regulatory authority by the state is a "legitimate reason" for refusing to sell an essential good by a dominant firm (that still does business in the country). Few may question the authority of Abbott to completely refuse to engage in the Thai market. But it has not gone so far. Instead, it continues to sell drugs in Thailand, therefore continuing to subject itself to the jurisdiction of Thai law, but seeks to punish Thai consumers for its government's legal efforts to promote access to

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<sup>13</sup> Thailand Competition Act 1999, Section 25, states:

A business operator having market domination shall not act in any of the following manners:

1. unreasonably fixing or maintaining purchasing or selling prices of goods or fees for services;
2. unreasonably fixing compulsory conditions, directly or indirectly requiring other business operators who are his or her customers to restrict services, production, purchase or distribution of goods, or restrict opportunities in purchasing or selling goods, receiving or providing services or obtaining credits from other business operators;
3. suspending, reducing or restricting services, production, purchase, distribution, deliveries, or importation without justifiable reasons, or destroying or causing damage to goods in order to be lower than market demand;
4. intervening in operation of business of other persons without justifiable reasons.

<sup>14</sup> Section 51 of the Act states:

Any person who violates section 25, section 26, section 27, or section 29 or fails to comply with section 39 shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding six million Baht or to both, and, in the case of the repeated commission of the offence, shall be liable to the double penalty.

medicines by withholding certain drugs from the market that had already been introduced for registration.

It is important to note that at least one of the products that Abbott is withholding from the Thai market is an improvement of the existing product, Kaletra, that Abbott already markets in the country. In a tropical weather country such as Thailand, this heat-stabilized form is also the version of the product most needed by majority of poor people who may lack refrigeration.

There is a supportive case decided by Thailand's Competition Commission. In early 2000, the Thai Competition Commission received complaints that the newly registered cable television company, UBC, was refusing to offer basic cable service desired by the majority of moderate income cable subscribers. The Commission ultimately found that the refusal to supply the basic product desired by the majority of poorer households was a potentially illegal refusal to supply without justifiable reasons under Section 25(3).<sup>15</sup> Similarly, here Abbott is refusing to offer the version of its Kaletra product that is needed by most poorer consumers.<sup>16</sup> The willingness of the Thai Commission to challenge anti-poor market segmentation strategies as anti-competitive under the refusal to supply doctrine may suggest that a receptive audience will be found in that institution.

## ***2. Abbott's Previous Refusal to License Essential Medical Patents Are Valid Grounds for a Compulsory License for Anticompetitive Conduct***

Thailand may also consider a second ground for a competition-based complaint against Abbott – its refusal to license generic versions of Kaletra to supply Thailand's market prior to the public use license. This ground could be added to the existing public health ground for the compulsory license, which, under the TRIPS agreement, would permit penalizing Abbott through lower (including zero) royalties as well as authorization of unlimited exports of compulsory licensed products.<sup>17</sup>

There is strong precedent for using competition law as a basis for compulsory licenses for needed medicines. In 2001, the South Africa Treatment Action Campaign filed a complaint with the South Africa Competition Commission against GSK and BI for excessive pricing of first-line AIDS drugs. In 2003, the Commission ruled that the companies were dominant in their respective markets and

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<sup>15</sup> Ultimately the case was decided on other grounds. See *Review of Recent Experiences in the Formulation and Implementation of Competition Law and Policy in Selected Developing Countries, Thailand, Lao, Kenya, Zambia, Zimbabwe*, UNCTAD 22-23 (2005).

<sup>16</sup> Consider another potentially analogous situation: Envision an energy firm responding to a public utility rate making decision it does not like by pulling applications for building new, improved, transmission lines and generating plants and capping all output at existing levels, thereby restricting access to energy to a growing population. These kind of decisions by dominant suppliers of essential goods appear to "suspend[,], reduce[e] or restrict[ ]services, production, purchase, distribution, deliveries, or importation without justifiable reasons."

<sup>17</sup> See TRIPS Article 31.

that that the companies abused their dominance by excessive pricing and refusing to license generics. Menzi Simelane, then Commissioner at the Competition Commission, explained:

Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licenses would provide for competition between firms and their generic competitors.<sup>18</sup>

South Africa now produces and imports low cost versions of the medicines at issue, and exports them to many countries in sub-Saharan Africa.<sup>19</sup>

Abbott has refused to license generic versions of Kaletra in Thailand and in other countries. This refusal similarly restricts competition despite the fact that licenses would be economically feasible for Abbott with reasonable commercial royalties and would likely have the effect of lowering prices for Thailand consumers through competitive supply. Accordingly, Abbott's refusal to license generic products may violate section 25(1) of Thailand's Competition Act, which prohibits "unreasonably fixing or maintaining purchasing or selling prices of goods or fees for services." It may also violate section 29, which prohibits "any act which . . . has the effect of . . . impeding or restricting business operation of other business operators or preventing other persons from carrying out business."

### **3. *Abbott Is Dominant in Kaletra's Market***

There are a large number of U.S. cases finding that a single drug can be viewed as a market for U.S. competition law purposes, and this logic is particularly compelling with AIDS drugs where for at least some patients only one drug can be used in their cocktail most efficaciously. In the market for fixed-dose ritonavir-boosted protease inhibitors, Abbott is dominant -- there being only one drug (Kaletra) in that market.

In the U.S., a product market is one for which there are no effective substitutes, where "[a]n 'effective substitute' is one close enough to the examined good that it becomes a substitute when the price of the examined good rises" 5-10 percent above the competitive level.<sup>20</sup> Using the test, U.S. courts narrowly define the relevant

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<sup>18</sup> The full text of the Commission's findings is available at [www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm](http://www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm)

<sup>19</sup> More information on the case can be found at [www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm](http://www.wcl.american.edu/pijip/CompetitionPolicyProject.cfm)

<sup>20</sup> HERBERT HOVENKAMP, MARK JANIS AND MARK LEMLEY, *IP AND ANTITRUST* 4-41 (2002); *see also SmithKline Corp. v. Ely Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978) (stating that the relevant

market for antitrust analysis, often limiting the market to a single branded product.<sup>21</sup> Whether a patent holder has market power is determined by application of the same test, which normally turns on whether there are sufficient substitutes in the relevant market to control pricing behaviour.

For most AIDS drugs, and for Kaletra in particular, other drugs in the same class are not effective substitutes and therefore cannot restrain market power. This is true first because AIDS mutates over time and because many patients have other conditions or profiles that make them ill-suited to other drugs in a class. For example, a patient on second-line treatment or later “salvage therapy” may have developed resistance to so many of the antiretrovirals in a possible cocktail, and have poor side effect profiles for others, that only one set of currently existing drugs will contribute any treatment effectiveness.<sup>22</sup> In warm weather climates in developing countries with low literacy and other access barriers, the effective choices for a large group of patients may be further limited.

Kaletra, particularly in its heat-stable form, has added properties make substitution more difficult. Kaletra is the only brand name protease inhibitor that includes the essential booster ritonavir in a fixed dose combination (i.e. single pill). The fixed dose application is often the best option for developing countries and people with low pill tolerance. It thus likely has over 50% market share among protease

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antitrust market should include only those products that “have the ability -- actual or potential -- to take significant amounts of business away from each other.”; *H.J. Inc. v. International Tel. & Tel. Corp.*, 867 F.2d 1531, 1537 (8th Cir. 1989) (A relevant product market is one where “sellers, if unified by a hypothetical cartel or merger, could raise prices significantly above the competitive level”); *accord United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988).

<sup>21</sup> See *Times-Picayune Publishing Co. v. United States*, 345 U.S. 594, 612 n.31 (1953) (explaining that the relevant product market “must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn”); *Community Publishers v. Donrey Corp.*, 892 F.Supp. 1146, 1161 (W.D. Ark. 1995) (“the approaches to market definition endorsed by the Merger Guidelines and the case law are essentially consistent”). See, e.g., *Coca-Cola Bottling*, 118 F.T.C. at 538-39, 542, 574 (1994) (excluding generic carbonated soft drinks and all non-carbonated soft drinks from a brand carbonated soft drink market); *Olin Corp.*, 113 F.T.C. 400, 604 (1990) (excluding liquid pool sanitisers from a dry pool sanitiser market); *United States v. Gillette Co.*, 828 F. Supp. 78, 83-84 (D.D.C. 1993) (separating premium writing instruments from other lower-priced writing instruments); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997) (separating office superstores from other sellers of office supplies; “the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes.”). Cf. HOVENKAMP at 4-41 (explaining that pencils and pens would not be deemed effective substitutes if pen sellers are able to raise prices more than 10 percent above marginal cost without consumers switching to pencils. “In that case, we might still say that pencils are substitutes for pens, but they are not effective substitutes because substitution is not sufficient to hold the price of pens to their cost.”).

<sup>22</sup> See *12th Expert Committee on the Selection and Use of Essential Medicines Meeting, 15-19 April 2002* (“While accepting that there were many circumstances in medicine where one essential drug may substitute easily for other members of a class, . . . this was not possible with HIV treatment. Effective therapy requires commencement of three drugs simultaneously, and alternative regimens are necessary to meet specific requirements at start-up, to substitute for first-line regimens in the case of toxicity, or to replace failing regimens.”).

inhibitors sold in Thailand. In addition it is the only branded ritonavir boosted protease inhibitor that, in its new form, does not require refrigeration – a key advantage in a resource poor tropical country. These properties give Kaletra added market power and justify treating it as a single market for the purposes of determining dominance.

### **Conclusion**

For the foregoing reasons, this analysis concludes that (1) Thailand was fully within its rights under its own law and under the WTO TRIPS agreement in issuing compulsory licenses to procure medicines, and (2) Abbott's refusal to supply several medicines to Thailand in response, and its refusal to license generic provision of its products before the license, appears to violate Thailand's Competition Act.