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# FORCED LICENSING OF DRUG PATENTS REFLECTS “IP COUNTERFEITING” EFFORTS ON WORLD STAGE

by

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Much has been discussed in the media during the past few months about the Thai and Brazilian governments declaring compulsory licenses on legally valid drug patents held by foreign pharmaceutical companies. In fact, the Brazilian government concluded recently that Brazilian and World Trade Organization (WTO) law countenanced the issuance of a compulsory license on the HIV/AIDS drug Efavirenz.<sup>1</sup> Arguably, it was emboldened by the Thai government’s<sup>2</sup> earlier controversial issuance of a compulsory license on two patented antiretroviral drugs – Abbott’s Kaletra and Merck’s Efavirenz, and one heart disease drug – Sanofi’s Plavix.<sup>3</sup>

The justification given for what amounts to an illegal government expropriation of private property is that it was necessary to protect the Brazilian “public interest,” consistent with Brazil’s Constitution<sup>4</sup> and Industrial

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<sup>1</sup>See “Brazil Sanctions Compulsory License on Efavirenz”, TWN Info Service on Health Issues (May 9, 2007) at <http://www.twinside.org.sg/title2/health.info/twninfohealth088.htm>.

<sup>2</sup>See Marwaan Macan-Markar, “Junta Defends Cheap Generic Drugs”, Inter Press Service News Agency (Jan. 31, 2007) at <http://ipsnews.net/news.asp?idnews=36382>.

<sup>3</sup>“Bold drug-patent challenges by Thailand could lead other emerging-market governments to follow suit, putting pressure on big pharmaceutical companies that are looking to these developing countries for growth...Some experts said Thailand's move could set off similar actions in other emerging markets. “ANALYSIS-Thailand’s Drug Patent Moves Could Spread”, Reuters (May 1, 2007) at <http://www.msnbc.msn.com/id/18417406>.

<sup>4</sup>While Article 5, par. XXII of the Brazilian Constitution provides that “the right of property is guaranteed, Art. 5, par. XXIII provides that “property shall fulfill its social function,” par. XXIV provides that “the law shall establish the procedure for expropriation for public necessity or use, or for social interest...” par. XXV provides that, “- in case of imminent public danger, the competent authority may make use of private property...” and par. XXIX provides that, “the law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, viewing the social interest and the technological and economic development of the country...”

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Property Law.<sup>5</sup> The government also argued that Brazilian law and practice appropriately implement Article 31 of the WTO Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement which, when read together with the Doha Declaration, reflects expansively broad flexibilities that “allow governments to [subjectively] declare a ‘national emergency’ and [to] issue compulsory licenses *on any grounds without consulting the foreign patent owner*” (emphasis in original).<sup>6</sup>

Brazil’s justification for issuing the compulsory license is based on several dubious and disingenuous rationales. First, it claimed that the practice of issuing compulsory licenses has been employed by developed (Italy & Canada) *and* developing (Mozambique, Malaysia, Indonesia, Thailand and Zambia) countries alike.<sup>7</sup> Second, it claimed that the deeply discounted national price Merck gave to Thailand, a much poorer and less developed country than Brazil, and the deep discount pricing Merck had previously provided to UNICEF and the Pan-American Health Organization had established a deeply discounted *international* price for its HIV/AIDS drug. Brazil argues it is entitled to this price so it can meet its national pledge of providing all Brazilians with universal access to medicines.<sup>8</sup> Third, the government claimed that by charging a more expensive price than Brazil was willing to pay to ensure the viability of its universal access to healthcare (the PN DST/AIDS) program, Merck violated the “public interest.”<sup>9</sup> Fourth, it claimed that, as evidence of its intention to preserve Merck’s patent rights in the drug Elfinarez, it issued a *nonexclusive* compulsory license to three certified Indian generic manufacturers (Cipla, Ranbaxy and Aurobindo), rather than an exclusive compulsory license to a single Brazilian generic manufacturer capable of reverse engineering the drug. In addition, the government claimed that it had previously undertaken extensive negotiations with Merck to ensure that it was paid “adequate compensation” for the use of its drug. Brazil explained that it had done so even though, under North American law, governments are not required to do so.<sup>10</sup> It then arrived, bearing in mind the economic value of the patent *to Brazil*, at a “reasonable” 1.5% royalty rate. And, that rate was apparently based on the rates paid by other developing countries to the patent holders of similar drugs – namely between 0.5% and 4%.<sup>11</sup>

***Patent Expropriation Unlikely to Enhance Brazilians’ Welfare.*** The Government of Brazil’s official position, no doubt, was shaped and encouraged by well-funded, propaganda-motivated health activist groups (nongovernmental organizations – NGOs) including Knowledge Ecology International<sup>12</sup> and Oxfam,<sup>13</sup> as well as

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<sup>5</sup>Article 71 of the BIPL (1996) provides that, “In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patent holder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio, without prejudice to the rights of the relevant titleholder...” (Law No. 9,279 of May 14, 1996).

<sup>6</sup>J. Reichman, and C. Hasenzahl, “Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America”, UNCTAD/ICTSD (2002).

<sup>7</sup>See “Brazil Decrees Obligatory Licensing of Efavirenz”, Press Release, Brazilian Ministry of Health (Brasil Ministerio da Saude) (May 4, 2007) at [http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias\\_detalhe.cfm?co\\_seq\\_noticia=29717](http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717).

<sup>8</sup>*Id.*; see EFAVIRENZ: QUESTIONS ON THE OBLIGATORY LICENSING, Brazilian Health Department, Secretariat of Monitoring in Health Strategic Secretariat of Sciences, Tecnologia and Insumos (English Translation) (Apr. 25, 2007), at Question 4, at [http://portal.saude.gov.br/portal/arquivos/pdf/anti\\_retroviral\\_efavirenz.pdf](http://portal.saude.gov.br/portal/arquivos/pdf/anti_retroviral_efavirenz.pdf)

<sup>9</sup>EFAVIRENZ: QUESTIONS ON THE OBLIGATORY LICENSING, *supra*.

<sup>10</sup>“It fits to stand out that the North American law of patents and clauses of the Agreement of free commerce of the North American countries does not stipulate the necessity of previous negotiations with the detainers of the patent in the case of the obligatory licensing for public interest.” EFAVIRENZ: QUESTIONS ON THE OBLIGATORY LICENSING, *supra*, at Question 6.

<sup>11</sup>“[T]he Federal [Brazilian] Government arrived at the value of 1,5% for payment of royalties to the bearer of the patents, thus guaranteeing, its rights the remuneration due.” *Id.*, at Question 9.

<sup>12</sup>“Brazil’s decision to issue a compulsory license on the patents for the AIDS drug [E]favirenz is an important first step to implement the Doha Declaration’s requirement that the WTO TRIPS agreement ‘should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.’ We wish Brazil had done this in 2001, when it was first proposed.” See Jamie Love, “KEI Statement on Brazil Compulsory License on Efavirenz” (May 4, 2007) at [http://www.keionline.org/index.php?option=com\\_content&task=view&id=46&Itemid=1](http://www.keionline.org/index.php?option=com_content&task=view&id=46&Itemid=1).

<sup>13</sup>Oxfam President Raymond Offenheiser wrote in a *Wall Street Journal* op-ed that “more stringent intellectual property rules ‘do not drive drug research for diseases that particularly affect poor people in developing countries’... The system established to ‘protect intellectual property rights exists for the sake of society, not for the enrichment of a few...After all, expensive medicine in poor countries doesn’t mean higher profit for drug companies, it just mean poor people don’t get medicines’” (emphasis added). “‘Biggest Winners’ In Thailand’s Decision To Issue Compulsory Licenses Are ‘Poor, Sick,’ Letter To Editor Says”, MEDICAL NEWS TODAY (May 11, 2007) at <http://www.medicalnewstoday.com/medicalnews.php?newsid=70426&nfid=crss>.

by Brazilian academics.<sup>14</sup> These groups and individuals who wish to weaken the grasp of private property-based capitalism on Brazilian society at large are now working to eliminate private property as the foundation for the current international IP legal order.

Indeed the Government of Brazil enlisted these groups to help promote a new global anti-IP paradigm of open source/universal access to healthcare and information technology that eschews strong private property rights, particularly, those held by American patent, copyright and trade secret owners.<sup>15</sup> The government of President Luiz Inacio Lula da Silva has artfully incorporated this global agenda into its national innovation plan.<sup>16</sup>

Underprivileged Brazilians are not any better off, in real economic and social terms, as the result of having received monthly government aid payments (Brazil's Bolsa Familia Program). The capital markets are also no better off in the longer term for having supported President Lula da Silva's re-election, even if they did benefit in the short term from the relative market calm surrounding the primary and run-off.<sup>17</sup> In each case, these groups are no *less* welfare-dependent on his government's bureaucracy than they were before his re-election, and their personal welfare and ability to sustain themselves, have certainly not been *more* enhanced since.

If this is true, why, then, didn't the Brazilian government "reorganize its public spending and curb corruption *before* violating the patents of foreign drug companies?"<sup>18</sup> And, what caused President Lula to believe that the entrepreneurial class comprising the core of Brazilian society will be persuaded that *they* will be better off as concerns their individual private property rights, following his precedent-setting executive order?

After he signed the order authorizing the compulsory license Efavirenz, "Lula warned that Brazil could break other patents, if prices weren't affordable. 'People shouldn't be able to get rich through the misfortune of others,' he said."<sup>19</sup> And, notwithstanding foreign investor warnings that his act would likely discourage foreign direct investment in Brazil,<sup>20</sup> the president admonished foreign investors that Brazil would break other drug patents not only for the benefit of Brazilians, but also for the benefit of third country citizens. "The compulsory licensing... might occur every time prices are 'far from the Brazilian reality.... If the prices are not fair; not only for us, but for every human being infected on this planet we will have to make this decision.'"<sup>21</sup>

### ***Brazilians Should Now Worry that Their Government Will Ignore Their Private Property Rights.***

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<sup>14</sup>According to Brazilian intellectual property scholar Denis Borges Barbosa, the principle of "public interest" itself "derives from the clause of the due legal process included in the Brazilian Constitution, in the balance between two constitutional requirements – protection of property and social interest – induce us to apply the principle of proportionality. In other words, the public interest must only prevail until the exact proportion, and not beyond, which is needed to satisfy such interest. It means that the compulsory license, according to the constitutional models, cannot exceed the extension, the time limit and the indispensable form to supply the relevant public interest, or to repress the abuse of patent or economic power." See e.g., Denis Borges Barbosa, *Uma Introdução à Propriedade Intelectual*, 2a. Edição, Ed. Lumen Juris, 2003, at 501.

<sup>15</sup>See Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, 38 UNIV. OF MIAMI L. REV. 1 (Fall 2006) 7-11, 30-98 at [http://www.itssd.org/Publications/IAL105-II\(frompublisher\)21.pdf](http://www.itssd.org/Publications/IAL105-II(frompublisher)21.pdf).

<sup>16</sup>*Id.*

<sup>17</sup>"With the backing of big finance capital, which never enjoyed such profits as it has attained under his government, Lula was able to maintain relative stability on the markets. The economy had almost no growth, but also avoided major oscillations." Mário Ybarra de Almeida, "Behind Lula's Reelection: Brazil's Crisis Deepens", World Socialist Website (Nov. 8, 2006) at <http://www.wsws.org/articles/2006/nov2006/braz-n08.shtml>.

<sup>18</sup>Katia Cortes, "Brazil to Break Merck AIDS Drug Patent to Lower Price", Bloomberg News (May 4, 2007) at <http://www.bloomberg.com/apps/news?pid=20601086&sid=aO6ROT9Mys1I&refer=news>.

<sup>19</sup>Alastair Stewart, "Brazil to Break Patent on Merck AIDS Drug", WALL ST. J. (May 5, 2007) at <http://www.a2kbrasil.org.br/ENG/Wall-Street-Journal-Brazil-to>.

<sup>20</sup>According to the U.S.-Brazil Business Council, "the decision was a 'major step backward' in intellectual property law and [it] warned [that] it could harm development. 'Brazil is working to attract investment in innovative industries ... and this move will likely cause investments to go elsewhere,' the council said..." See *Brazil Bypasses Patent on AIDS Drug*, Associated Press (May 4, 2007) at [http://rss.cnn.com/~r/rss/edition\\_americas/~3/114157892/index.html](http://rss.cnn.com/~r/rss/edition_americas/~3/114157892/index.html); see also Slavi Pachovski and Lawrence Kogan, "The Wolf and the Stork", Institute for Trade, Standards and Sustainable Development (June 2005) at 3-4, 7, at [http://www.itssd.org/White%20Papers/TheWolf\\_and\\_theStork-Brazil\\_snon-patentabilitylaw.pdf](http://www.itssd.org/White%20Papers/TheWolf_and_theStork-Brazil_snon-patentabilitylaw.pdf).

<sup>21</sup>See "Brazil Threatens to Break More Drug Patents If Prices Don't Go Down", BRAZIL MAGAZINE (May 6, 2007) at <http://www.brazilmag.com/content/view/8231/54>.

Despite its rhetoric, the government simply cannot assure Brazilian companies, investors and/or inventors that research and development-orientated foreign direct investment, related science and technology spillovers and innovation-based national economic growth will continue apace, let alone increase.<sup>22</sup> President Lula and his government also cannot assure Brazilian small- and medium-sized private businesses that this act will provide them with sufficient technical and managerial skills to compete internationally.<sup>23</sup> After all, experts know full well that this is not possible as long as the Government of Brazil refuses to recognize and protect privately-owned intellectual property rights,<sup>24</sup> and to facilitate commercialization of government-funded basic research and development through recognition and protection of privately developed derivative patents.<sup>25</sup> And, the government is also hard pressed to show Brazilian entrepreneurs that the strategically important and multifaceted bilateral relationship that has evolved with the United States, Brazil's single largest trading partner, from which many Brazilians have long benefited will not suffer any longstanding damage, as the result of the illegal "taking" of American drug patents without payment of "just compensation."<sup>26</sup>

Given the volatile political debate surrounding intellectual property rights, public health, and technology transfer, it is easy to see why some pragmatic Brazilian lawyers have endeavored to interpret Brazilian constitutional and intellectual property law as reflecting a necessary "balance" between three competing interests: public interests, private economic interests and the need for national technological development.<sup>27</sup> Perhaps, their goal is nothing more than to place a politically positive "spin" on a legally and economically unsustainable interpretation of the Brazilian Constitution, its Industrial Property Law, and the WTO TRIPS Agreement. Or, perhaps it is a prudent and creative way to shield local corporate clients from a potentially dangerous public relations and asset risk situation. Whatever the case, it raises a number of probing questions.

Is this balance more apparent than real? Are private property rights in Brazil the general rule or the exception? Do the Brazilian Constitution, the WTO TRIPS Agreement and the Doha Declaration, collectively provide the Brazilian government, or for that matter, *any* national government, with the broad unilateral flexibility that has been heretofore claimed? Were President Lula da Silva's executive act,<sup>28</sup> and the Brazilian judiciary's *nontransparent* and *non-reviewable* ruling upholding it, constitutionally permissible? Will Brazilians be any better off if Brazil's executive and judiciary are able to expropriate with impunity the private assets of key *Brazilian* and foreign companies and investors whenever the executive subjectively decides that a "public interest" is at stake? These are important questions to which Brazilian citizens, especially businesses, deserve honest, well thought-out answers. Given the paucity of credible information underlying Brazil's precedent-setting first issuance of a compulsory license on foreign assets, Brazilian biotech, pharmaceutical, chemical, software, automotive and aeronautical companies and their investors should seriously be concerned that *their* privately held patents, trade secrets and copyrights will be targeted next.

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<sup>22</sup>See Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, INT'L L.J. OF ECON. DEV., Vol. 8, Nos. 1-2 (Sept. 2006) at 157-174, 224-248 at <http://www.itssd.org/White%20Papers/ijed-8-1-2-kogan.pdf>.

<sup>23</sup>*Id.*

<sup>24</sup>*Id.* at 209-224.

<sup>25</sup>*Id.* at 174-209.

<sup>26</sup>See Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, *supra* at 125-136.

<sup>27</sup>See Milton Lucídio, "Licença Compulsória: Balanceamento de Interesses, Motivação E Controle Dos Atos Administrativos," *Revista da Associação Brasileira da Propriedade Intelectual - ABPI* n.º 79, ed. (nov/dez 2005) at p. 60 (English Translation) at: [www.abpi.org.br](http://www.abpi.org.br) ("We conclude that the compulsory license is not a Brazilian or a developing country solution, but it is an instrument to keep the balance between the rights of property of patents and the other public interests involved").

<sup>28</sup>"...[T]he competence to grant the compulsory license, after being declared the public interest by an Act of the Federal Executive Power, would be to the Federal Executive Power and not to the Brazilian Patent and Trademark Office – BPTO, since it is an exceptional situation, in which there is the possibility of granting *ex officio*, different from the other cases prescribed in the BIPL, where it is stated that is needed a specific administrative process which will happen along the Federal Bureau." *Id.*, *citing* BIPL 9.279/96 – Arts. 71 and 73.