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What might be your drug of choice, sir?

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Small Thai firms are taking on the giants over the production of generic versions of potential lifesaving drugs. And this time they have government backing

The business of drug production, for years the domain of a few big players protected by swathes of patent protecting legislation, has been put in turmoil this year. In January, it was revealed that Thailand had issued licences for production of cheaper generic versions of globally used drugs for AIDS and anti-clotting, thus undermining the trade practices of the larger patent-holding firms. Such moves have been justified by trade laws for public health needs, which is something that experts feel could set a global precedent.

Generic versions of Abbott Laboratories' Kaletra, for HIV and Sanofi-Aventis's and Bristol-Myers Squibb's Plavix anti-clotting medicine, were those drugs in question, and the moves have seen others look to the rulebook for further opportunities. The breakthrough ruling is backed under laws drafted by the World Trade Organisation adopted by WTO members in November 2001 under the Doha declaration, which in special circumstances, give a degree of flexibility in international trade laws. Developing nations can issue compulsory licences in cases of 'national emergency' to ensure their populations have access to life-saving medicines. In such cases, countries can license production or sale without the permission of the patent holder.

And according to the Washington College of Law at American University, who issued a recent report concluding Thailand's actions complied with patent law: "Arguments to the contrary…should be dismissed as political posturing," claims Sean Flynn of the law school's Justice and Intellectual Property program. And indeed, it is difficult to dispute the existence of a national AIDS or heart disease 'crisis' in Thailand. Despite that, certain stakeholders have argued that there was not a sudden change in health conditions and as such, the move was without justification.

The US has also criticised the Thai Government for a lack of transparency throughout the decision process. Thailand has been added to the so-called priority watch list, which could be interpreted as a first step toward sanctions. The list pertains to the US Trade Representatives report on the effectiveness of other countries' protection of US intellectual property rights. Free-market advocates had lobbied the USTR to put Thailand on the list, which includes China, but stopped short of threatening action at the World Trade Organisation. The elevation of Thailand to this 'priority watch list' stems from what the USTR sees as an "overall deterioration in the protection and enforcement" of intellectual property rights there.

According to the report: "In late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products." The USTR acknowledged the presence of WTO rules, yet made it clear that the lack of transparency and due process exhibited in Thailand was a serious cause for concern. The country represented just one in which it was felt that copyright enforcement and trademark rules needed to be enforced.

Perhaps of greater concern to the US government is the fact that many commentators feel that the ruling could spread to other nations. Rohit Malpani, Trade Policy Adviser for Oxfam International asserts that anywhere, "where there is political ownership of the issue," including Kenya, South Africa or even India could look to emulate what the Thai government has done. Indeed, at the time of writing, Brazil were considering a similar measure with Merck & Co's Efavirenz AIDS drug. "If one country makes a decision, it can embolden others," said Lawrence Kogan, Chief Executive of the Institute for Trade, Standard and Sustainable Development, a free market group. Encouraged by the World Health Organisation and other aid groups, developing countries have seen the link between disease and poverty, and are spending more of their income on health care, he said. "They are increasingly trying to expand access to more people," Malpani said.

There is also a risk of a backlash from the large pharmaceutical companies. In response to the Thai government's decision, the producer of Kaletra – Abbott – initially said it would stop launching new drugs in Thailand in protest. This standpoint has since been rescinded, most likely with corporate reputation in mind. As Chad Bown, Economics Professor at Brandeis University asserts: "you don't want to be seen out there in the world picking on poor countries whose populations may be sick or dying."

The ruling has seen celebration amongst some of the world's poorest communities. Pharmaceutical firms have long been criticised for maintaining high prices of drugs in developing countries. Some say that allowing generics in Thailand could open a can of worms, and as soon as one firm begins production, there can be a leakage effect," which can lead to cheaper versions becoming available outside that country, he said.

The license that Thailand issued for Plavix is especially groundbreaking because these disputes have centred in the past on drugs for AIDS, a more publicised but less prevalent killer than heart disease. Heart disease kills about 17.5 million people a year, according to the World Heart Federation. In 2005, AIDS killed 2.8 million people, according to the United Nations. As the leading cause of death in the world, heart disease affects both developed and developing countries in equal measures. The decision to produce cheaper versions of drugs to combat this has been welcomed by patient rights groups.

And a slight change in attitude has resulted from the ruling. Abbott recently offered to sell a new heat-stable form of an AIDS drug in Thailand for $1,000 per patient per year, matching an offer it made earlier in the month to about 40 low- and middle-income countries. Emerging markets generate no more than eight percent of sales by major pharmaceutical companies, but are growing more rapidly than the United States and Europe, according to Gustav Ando, Health-care Analyst at Global Insight. Research firm IMS Health said it expected pharmaceutical sales in emerging markets to rise to 17.4 percent of a total $687bn market this year, up from 13 percent in 2000. Thailand accounts for less than one percent of drug makers' annual sales, Ando said, but emerging markets are where the growth is as business in Europe and the US slows dramatically. And that is where the fear for the large companies stems from as these challenges emerge to threaten their profit margins.

So, this potential milestone in the production and distribution of pharmaceuticals is of great significance to humankind and great worry to multinational pharmaceutical directors. Whether an epidemic of similar rulings breaks out remains to be seen, but the increased availability of life-saving drugs at lower prices will bring benefits far more valuable than any boardroom bonus.