

Thailand Pharmaceutical



Interview with Mr. Edward Kelly, Mr Edward Madden, Ms Tiziana Sucharitkul - Tilleke & Gibbins - Partners

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What is the situation of IP today here in pharmaceuticals?

(Mr Kelly) I would begin to answer that question by suggesting that the situation is very fluid and dynamic. The reason for this is that, until now, October 2006, there had been the possibility of a free trade agreement ('FTA') between the US and Thailand and one of the more controversial elements of the FTA negotiations involved intellectual property rights ('IPR') issues in general and also IPR as applied to the pharmaceutical industry in Thailand.

In January of 2006, in the 6th round of the FTA negotiations, IPR issues were formally tabled for discussion, for the first time. In Chiang Mai, during this time, there were a lot of protests by activists and NGOs who had been convinced by propaganda that there would be an impact from increased protection for IPR on the access and availability of drugs, particularly HIV/ AIDS.

In the months following that FTA negotiation session, there was quite a bit of one-sided media coverage where activists spoke out against what they had mistakenly understood the US position to be in terms of IP protection. Lost in the debate was the fact that the most important contribution that innovative pharmaceutical companies make to patients is the investment that they make in the research and development of new medicines. Without this investment, patients would not have the treatment options that are currently available. Most of the therapies now available as generics were made possible by the research and development of innovative companies.

Patient access to effective therapies obviously requires more than just the availability of medicines. Affordability is often restriction, but it is only one of many barriers to care for patients. In the case of HIV, effective treatment requires a comprehensive approach which includes the accessibility of well trained doctors and nurses and community support for patients and their families. Innovative pharmaceutical companies have made significant contributions in all of these areas to improve the access of Thai patients to effective HIV treatment:

This debate really came to a head in February 2006, and continues today to be a lively debate. However, in a certain sense, that debate has become of secondary importance because of our political turmoil where we have had a new government imposed by a military coup on September 19, 2006. Whether as a result of the coup or the frustration with dealing with Thailand's schizophrenic approach to the FTA prior to the FTA, American legislators reportedly seem to have lost interest in Thailand. Other FTA negotiations are underway with various competitors in the region, such as Korea, Malaysia, and Indonesia. Moreover, preparations are now focused on Vietnam's upcoming accession to WTO. If the Kingdom is left on the sidelines, Thailand's loss in agricultural exports, garments and textiles, seafood and electronics, will be her neighbours' collective gain.

The stakes could not be more important. From the standpoint of healthcare, for example, no country can go it alone in protecting its citizens from the effects of new evolving diseases. Recent headlines in Thailand justifiably express concern for the human spread of the H5N1 virus, Dengue fever outbreaks in Lat Phrao, and even more worrisome, threats of a new HIV subtype, stemming from the local subtype E and the foreign subtype C, reported at Siriraj Hospital. These headlines point up the fact that disease is not static, disease evolves. In order to stay ahead of the evolution of such diseases, research and innovation is needed. Unfortunately, research and innovation is not free.

Patents perform an essential role in stimulating the development of essential drugs, including HIV/AIDS drugs, by offering incentives for investing in expensive and long-term research and development of new drugs. Without patents, existing HIV/AIDS drugs would not have been produced, and new and better drugs that are needed to overcome the increasing resistance of the AIDS virus would not be developed. Merck's new vaccine Gardasil[®], produced as a result of research in Australia, would not have been available to prevent HPV and cervical cancer in females without the funds needed to support such research. The question of how to assure long-term access to new and innovative drugs is often ignored in favor of arguments addressing only short-term immediate access to affordable drugs.

At the same time, the patent system also contributes a disclosure function to society as a whole by accumulating and making available state of the art human knowledge to fight against diseases. But it is the issue of patented medicines, more than any other issue, which has largely stopped the FTA negotiations from proceeding with Thailand's number one export market, the USA.

Thailand could lose a significant competitive trade advantage with the US in months to come because the Kingdom may no longer qualify for the Generalized System of Preferences ('GSP') scheme provided to developing countries by the US Trade Act of 1974. Recent reports suggest that certain export sectors such as fruit and jewelry may see GSP extended, following then- Caretaker Deputy Prime Minister Somkid Jatusripitak's visit to the US, but other sectors have already been removed from GSP.

This disadvantage has provoked panic in a number of industries, most notably Thailand's textile and garment sector, because this sector is dependent upon the FTAs with the US and Japan, representing 58% of the Kingdom's garment export market, for its very survival. The 'giant sucking sound', a phrase made popular by US presidential candidate Ross Perot in the 1992 US presidential elections to describe the loss of American jobs to Mexico after the implementation of NAFTA, could apply to Thailand's garment sector as investment, jobs and tax revenues move to Malaysia, Cambodia, Vietnam and Indonesia.

This could represent one of the biggest economic reversals of fortune experienced by any country in many decades. The reason? One reason is that anti-globalization interests and NGOs have hijacked Thailand, primarily on the drug patent issue, and made it a political football, with outright fear-mongering, stirring up nationalism, anxiety, and 'loss of sovereignty' concerns with a calculated mis-information and dis-information propaganda campaign.

Fears expressed by some of the commentators border on the xenophobic and irrational: many express concerns and fears about the FTAs and the effect on foreign investment. Some academics and commentators have actually proclaimed loudly and often that pharmaceutical patents, for example, will lead to the deaths of 'hundreds of thousands' of Thais because patients will not be able to gain access to patented medicines.

It is difficult for observers to distinguish between the dry facts and the emotional [and manufactured] hype surrounding the relationship between patents and pharmaceuticals.

One fact that is often overlooked is that many essential medicines are not patented at all, such that any improvements to the patent system in Thailand can have no effect on prices of drugs that have already been introduced into the market. Only seventeen of 319 products on the World Health Organization's ('WHO') Model List of Essential Medicines are patentable (usually not actually patented).

Any improved patent system will only have prospective, and not retro-active effect. Another fact is that the Department of Internal Trade, within the ministry of Commerce, is tasked with the responsibility of setting price controls on all medicines in the Thai market. The same anti-patent academics who conjure up unfounded profiteering conspiracies by companies are strangely silent about the 10% duty generally imposed on imported medicines. If price is the issue, why not attack the 10% duty, which would have an immediate and beneficial impact on drug process for all Thais?

Objective economic data from various FTAs with other countries (e.g., Jordan, Singapore, Australia) establish that FTAs profit both countries by greatly increasing the amount of investment in the foreign economy. More free trade is better than less free trade. A rising tide lifts all the boats. The question that should be asked by the academics is : can Thailand really afford to miss this chance?

With no FTA and GSP in jeopardy, Thailand, once poised to be the regional hub for export for so many products, could be facing a hopeless disadvantage with other SE Asian countries which will have FTAs and GSP, and which trade in the same categories of goods and services. The Kingdom's aspirations to move up the value chain toward a more knowledge-based economy, for example in becoming a Centre for Excellence in Life Sciences, could be dashed.

Neither the pending US-Thailand nor Japan-Thailand FTSA's have been signed although the newly installed government of Thailand, following the September 19, 2006 coup, has indicated that the FTA's are under review and are still considered viable.

(Mr Madden) To add to that, a lot of the reform that is actually needed relates almost directly to matters of interpretation and implementation of laws which already exist. Thailand's pharmaceutical patent laws are (in substance) generally seen as being up to the standards of many of the world's developed nations but in one or two areas are clearly deficient. It is in these areas of deficiency that Thailand that the competitiveness of Thailand is undermined when compared with its neighbours. Amongst the principal areas of deficiency the mechanics for obtaining a patent (for instance unreasonable delays), and once a patent is granted, the inability to effectively enforce those patent rights. For instance, there is no possibility to obtain reasonable compensation for unfair delays in having a patent granted, yet some pharmaceutical patents are taking in excess of 7 or 8 years to be granted – a far longer time than neighbouring countries. As regards enforcement, various procedural hurdles exist which can make litigation overly burdensome with little prospects of an outcome that can be said to properly compensate a patent owner for losses sustained from infringement.

It should also be noted that Thailand's modernisation of substantive pharmaceutical patent law to the TRIPs standard took place before the TRIPs Accord was concluded, problems exist with interpretation of the enacted laws. Sometimes very clear laws are interpreted incorrectly or perhaps applied too restrictively in a manner that is not in the interest of developing a scientific community. Whilst the US-Thai FTA provided the opportunity to create a viable and attractive system of IP laws which would have made Thailand more attractive to industry, it appears as though the opportunity may have been lost. Unfortunately, history has shown that IP laws have only been enacted in the Kingdom as a result of international pressure rather than any sound economic analysis and this stance is not reassuring for those involved with leading or cutting edge technologies.

In your assessment, which will be the real impact that the FTA in IP will have?

(Mr Kelly) I think that Thailand is at a crossroads at this point in time. If you view the countries in the ASEAN region, many industry commentators would agree that Singapore has the highest level of IPR protection and is seen as the most attractive destination for foreign direct investment, for research, for technology transfer, and for innovation and life sciences. In the years leading up to the FTA negotiations with Thailand and the US, Thailand and Malaysia have been essentially competing very closely for the number two designation for foreign direct investment for life sciences and high-tech and research-based industry. Malaysia is also negotiating a Free Trade agreement with the US and so, what we have here is the possibility that Thailand may lose ground to its neighbour to the south if they do not sign an FTA or, at least, reform its patent regime, because Malaysia may be seen as a more attractive destination for foreign direct investment, research initiatives, and innovation. Let me note here that the FTA was in fact requested by the former Prime Minister of Thailand, Thaksin Shinawatra. It was then approved by President Bush on Prime Minister Thaksin's request. This is an interesting point because many Thai people believe that the agreement is being forced upon them by the United States and in fact, the request was generated by Thailand. The question how does Thailand maintain or improve its competitiveness in the ASEAN region, never mind falling behind other countries, is one that the Kingdom must consider carefully. If you look at the developments that are going on right now, Vietnam is going to join the WTO probably at the end of this year. Malaysia and South Korea are negotiating FTA's with the US. Indonesia will likely be next with an FTA, and so there is a real risk that by not seizing the opportunity, the Kingdom of Thailand will fall further behind its competitors in the region.

How could the population and the government possibly be aware of and understand the benefits of protecting and having a more modern IP? And what would be the roles that of law firms like yours can play?

(Mr Madden) Education will and must play a central role in at least two aspects. At a fundamental level there is a tremendous lack of understanding of the role, function and economic nature of IP and IP rights. This lack of understanding permeates every level in Thai society, including high levels of government where IP rights are still erroneously identified as 'foreigners rights'. This attitude is not surprising as in light of Asian culture which traditionally would have abhorred the concept of a monopoly rights, preferring collective or communal ownership instead. Whilst the willingness of Thai's to embrace IP may be hampered by a cultural lack of awareness of IP, some academics have may matters worse by disseminating untruths and erroneous information as to patent laws and the patent system to the general public. This is most frequently seen with respect to the areas of pharmaceuticals, traditional knowledge and plant protection where a number of high profile law professors have adopted untenable and sometimes inflammatory positions, which ultimately do the Thai public a tremendous disservice.

The lack of economic understanding is most deeply worrying. Many Thai's do not understand that a weak IP system deters investment and technology transfer – these are two areas where Thailand cannot afford to miss out on. For instance, over the last 40 years Thailand has depended mostly upon foreign technology transfer. We do not necessarily have an indigenous technology transfer industry here which exports technology. History shows that where technology has come into this country, it has come from foreign multi-national players. If this is to continue, respect for IP and an understanding of the increasing importance of IP to modern high-tech industry is needed. This is particularly the case now as respect for IP is a core element in modern nation's competitiveness.

The second area where education will and must play a central role is in the development of scientific capacity amongst Thai indigenous industry. This education is separate from IP education, but directed to facilitating Thai enterprise evolve from IP importers to IP exporters. At present Thailand's education infrastructure does not produce enough scientists and technical graduates and this is an area that needs urgent attention.

Hence, one of core means of educating the public as to the value and benefits of the IP system is to engage in the development and dissemination of educational policies which will facilitate bring basic IP courses into schools at an earlier age, and general broad information dissemination programs. At present the private sector are already actively engaged in such education efforts with the pharmaceutical firms leading by example. The message being spread is that intellectual property, innovation, technology does not grow on trees. It requires investment and it requires protection in order to safeguard investments for the future. So we need to educate the people that we need strong protection; you cannot steal. Innovation costs money and without respect we threaten our future.

As regards educational infrastructure, it will be necessary for the Government to revise existing education plans and steps have already been taken in this regard. It will be important for the Government to liaise with industry to ensure that industry and the Kingdom's needs will be met so that we have sufficient scientists and engineers who will ultimately lead Thailand's growth to a IP exporting nation.

(Ms Sucharitkul) I think what Ed Madden says is significant. The mindset here is that there is nothing wrong with infringing IP rights. The lesson that needs to be conveyed through education is that there are ownership rights in IP, that IP infringement constitutes 'theft' and that, contrary to belief, violation of IP rights is not a victimless crime. In fact, there can be severe consequences.

(Mr Kelly) There are two areas to focus on concerning education. One is to correct the record. There is a lot of fear mongering in the media by activists and by NGO's who may be well-intentioned but the argument that they are putting out there are simply wrong. Critics claim patents restrict access to medicines and raise the price of medicine. The FTA, or any meaningful reform of the patent system, will have no impact on the availability or price of medicines presently on the market in Thailand. In fact, the FTA will create an environment that actually fosters introduction of new innovative medicines to treat HIV into the Thai market.

Most HIV medicines are already made available in Thailand by companies such as Merck at no profit prices; the FTA will not affect this.

Thailand and the US seek to, and I think eventually will strike the right balance within the FTA between providing strong intellectual property rights protection so that new medicines will be developed and addressing the needs of the poorest consumers to

obtain essential medicines. The Doha Declaration on the TRIPS Agreement and Public Health provide the flexibility to ensure access to medicines to address pandemics for those countries that lack manufacturing capacity.

HIV medicines that are currently unpatented in Thailand (such as the components of the popular government produced GPOvir) will remain unpatented and will still be available to generics producers after the FTA is concluded.

The patent status of HIV medications that have patents, including second line therapies, will not change under the FTA.

Thailand's remarkably successful track record in developing the Kingdoms' response to AIDS/HIV will continue. Presently, less than 1 in 100 persons in the Kingdom are infected with HIV. According to statistics released by the Thai Ministry of Public Health, AIDS-related deaths dropped from 5,020 in 2004 to 1,640 in 2005, while the number of HIV-positive patients developing full-blown AIDS was 8,681 in 2005 compared to 13,364 in 2004. These positive trends will continue to improve over time as new innovative medicines are introduced into the Thai market. Patent reforms will not include any provisions that will increase the price of medicines presently on the market in Thailand, in fact an FTA, by eliminating the 10% tariff on imports, will even lead to a reduction of import duties. The price of medicines is controlled by the Thai Internal Trade Department - nothing in the FTA will change this.

What would be the challenges in order to enforce IP?

(Mr Kelly) I think we have two issues for enforcement. The first is enforcement against counterfeits which are endemic in SE Asia, fake medicines made out of inert materials like glue and chalk. The WHO has estimated more than 10% of medicines worldwide are counterfeit. That's a frightening statistic, like Russian Roulette. The other is enforcement against unfair competition by copy products that are granted market approval by the FDA despite being covered by a patent that would otherwise preclude such a copy drug from being in the market. In Thailand, this phenomenon occurs because we have no formal [patent linkage] system, and this is a reform that is urgently needed.

In both cases, the major challenge is to develop political will to such a level that law enforcement will act on its own initiative to police the market and stop the proliferation into the market of these unauthorized fake or generic copy product. Right now, that political will does not exist. Most, if not all the enforcement is generated by the companies incurring huge legal and investigative fees to commence criminal or civil litigation, or to commence police raid actions or seek FDA intervention. The second challenge is training the law enforcement officials and the FDA to a standard where they first understand how to detect the genuine product from the fake and then become willing to take action against a product that may be fake or covered by a patent. Unfortunately, we do not yet have that level of scientific training where an official or police officer or customs official feels comfortable to take action because they don't understand the science to determine whether or not a product is counterfeit or not.

(Mrs Sucharitkul) It is also true that at the moment the government doesn't have the resources to conduct the required training of officials and therefore, often, if companies want to see improvement in this area, it is up to them to lend a hand....

(Mr Madden) You're going into a third area which overlaps a second i.e. the technical limitations that presently exist with enforcement officials and before the courts.

Historically, when you look at intellectual property enforcement in Thailand, it is first and foremost based on criminal remedies, which to a certain extent is apt as the people who are behind the infringing activities are often criminals. In this respect, criminal remedies for all types of IP infringement would be regarded as a modern approach as many countries are only now trying to enact criminal remedies for IP infringements. These international developments take place amid the growing recognition that IP infringement is now attracting criminal syndicates. On the other hand, in Thailand, the legal system has always dealt with infringement of laws in the criminal courts with the civil courts playing a secondary role. Criminal remedies enable fast access to the courts and frequently the infringement can be curtailed quickly. Nevertheless, authorities charged with enforcement of IP laws are frequently deterred by the technical nature of patents meaning that patent owners need to rely on the civil system. Thailand's patent system is just over 25 years old and patent owners have rarely attempted to enforce their rights (due to perceived inability to obtain a satisfactory and cost-effective remedy). Hence, enforcement officials are uncomfortable in assisting patent owners.

In light of this, patent owners are left with the need to rely on the civil IP court. Unfortunately the civil system for enforcing patents is not ideal as time delays and inadequate compensation render the entire system impractical. Members of the

judiciary also have not had the opportunity to hear a significant amount of cases, which can mean that taking a patent civil case can at times become a real challenge. Having said that, in light of the escalating number of cases, more and more judges are becoming more familiar with patent litigation which should lead to more progressive development of the mechanics for enforcement.

(Mr Kelly) One of the criticisms of many commentators, one that I don't necessarily agree with, is that Thailand is not really a 'rule of law' jurisdiction. That is, while we have laws, the laws are selectively enforced or selectively applied and that certain industries or certain 'influential people' are untouchable according to the law because of their influence in the government or in the military in the political system. To a certain extent, that is absolutely true. Some laws here are simply more important than others. To demonstrate, let us assume that a criminal organization was caught with a kilogram of heroin at the airport. It would be assured that the perpetrators will spend the rest of their lives in very gritty prison environment, that is, if they do not get the death penalty. Now, let us assume that same group is caught with a kilogram of fake artesunate, an anti-malarial drug, which, if not taken properly, can have life-threatening consequences. The result will be totally different. It is virtually certain that this group with the fake artesunate is going to pay a small fine and spend no time in jail. It is interesting to me that the government does not take a harder position against these counterfeit drugs or these uncontrolled drugs that are being trans-shipped through Thailand because the effects on Thai patients and people who consume these drugs is, I would argue, just as harmful as heroin.

Earlier we were talking about this pharmaceutical practice group that you are building here in your office. Can you elaborate a little bit on the objective and the goals that this practice will have?

(Mr Kelly) Well I think how this has evolved is that our partners and associates have all recognized that we have some interest and background in the pharmaceutical industry. I came to the practice from being a products liability trial lawyer, where I defended pharmaceutical companies from products liability cases in the United States. I became familiar with the technology and the science and the business principles upon which pharmaceutical companies operate. Then through working on the IP side, my focus had been essentially devising strategies to suppress the counterfeiting of medicine which is an enormous problem globally, not just in Thailand. The World Health Organization estimates that 10 percent of the medicines sold worldwide are counterfeit.

(Mr Madden) I come from a IP financing background in Ireland where I advised biotechnology companies and venture capital funds on investing in intellectual property and high-tech spin-outs. After a few years I took this expertise to Singapore where I was involved in university and pharmaceutical biotech collaborations. Eventually I eventually brought these professional (and academic) interests here to Thailand. Early we recognised that we our core competencies in different supplementary areas we could analyse some of the issues faced by the pharmaceutical industry from different perspectives and combine forces to provide a uniquely one-stop facility for our clients. Over time our services morphed from the core-counterfeiting area to other areas which became equally important for the pharma industry in Thailand, such as regulatory and market access issues and collaboration between the industry and third parties (such as Universities and CROs) So collectively, we have been able to practice in all these main areas.

(Mrs Sucharitkul) I think that the cross collaboration within our departments is basically a result of us anticipating and understanding our clients needs. For this reason, our firm is making a concerted effort in addressing our clients needs by evolving our practice. You will probably find that we are quite unique in terms of what law firms offer.

(Mr Kelly) You have a whole range of issues that are concerns of the pharmaceutical industry here. Not just IP, we have certainly market access, FDA regulations covering advertising and promotion, emerging law on product liability. There are also issues involving anti-corruption laws, import tariffs, patent linkage; there is just a whole range of issues and what the clients are now insisting on is that the firm of choice have the talent and capacity to deliver all of these services in all of these areas as a 'one stop shop' and that's what we are reacting to.

How has the response of the industry been?

(Mr Kelly) I think it has been very positive. We are privileged to serve as external

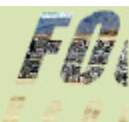
legal council for the pharmaceutical research and manufacturers association. In Thailand, there are 43 members of that association and through working with PREMA, which is the organization, we have been able to meet and have a dialogue with a lot of the leaders of these 43 member companies. As a result of that, those relationships have now evolved in to attorney-client relationships. We are privileged to act for many leading members like Pfizer, Novartis, Sanofi Aventis, Merck, Schering plough, Eli Lilly, Gilead Sciences; a lot of the major players. It is a symbiotic relationship of mutual benefit because we are able to provide lessons learned to clients because we may learn a lesson while working on a problem with Pfizer which we can then apply to working with another company confronting the same problem. At the same time, having access to all of these brilliant executives in each company gives us a lot of food for thought because we learn from them just as much as they learn from us. We learn from them about strategy, about positioning, how they train their people, and how they compete amongst each other.

(Mr Madden) I think for some country managers whom we have spoken with, they are more comfortable knowing that they have local legal support. In the past, legal counsel in head-office who may not have been in-the-know may have written off Thailand, much to the dismay of the country managers who still had to turn-in substantial growth. For such companies: a lot of times a country manager facing problems may have been told by their head office that they cant do anything to fix the situation and basically wrote off the Thai market. Fortunately we were able to come along and say look we have experience from doing x with such and such client and we can perhaps apply this to you and collectively, there is a greater chance of succeeding. A lot of clients we have won in the last year have come on board because of this and because we are able to devise solutions that fix with the client's needs. We, alone, are not pioneering where pharmaceutical law is going in this country, we are doing it together with the pharmaceutical companies and the country managers who are willing to make a stand about particular issues and drive the market in certain directions.

(Mrs Sucharitkul) I think we are willing to bring innovative ideas to the table and the clients see that so when they have a particular issue that no one else has been able to resolve for them , they are at least willing to approach us and say, 'We have this problem. What can you do?'

(Mr Kelly) It's a commercial-legal approach and although we have access to international lawyers and international talent, we are primarily a Thai firm and we have the local relationships that are necessary to understand this market. We practice realpolitik and we are in the best position to understand the real practical challenges confronting the executives in the industry, so I think that the ability to have a hybrid pool of international talent but local expertise really positions us well to serve our clients needs.

What advice would you give to the next Pharmaceutical Executives that are coming to Thailand to approach this market?

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