

SOUTH-EAST ASIA IPR SME HELPDESK

IP Considerations in the Medical Device & Healthcare Industry in South-East Asia



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IP advice within three working days
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1. Overview: Medical Device & Healthcare Industry in South-East Asia

With the exception of Singapore, the medical device and healthcare industry in the South-East Asia countries are considered as not very developed in comparison to the markets in the United States, the EU, and Japan. For example, Vietnam, Indonesia and Thailand import more than 85% of their medical devices. Amongst many South-East Asia countries, local pharmaceuticals are not well trusted, making way for foreign players with strong brands to establish significant market share in South-East Asia.

Rapid demographic changes and health reforms within South-East Asia are expected to create enormous demands in the health care market. Growth in average annual healthcare expenditure between 2014-18 is expected to be around 11% of GDP in ASEAN - but with highly varied rates among the countries: Vietnam with the highest at 6.6% and Myanmar with the lowest at 1.8%.¹

The healthcare industry in South-East Asia also serves a rapidly growing medical tourism industry which is expanding globally at a rate of 25% and valued at over US\$55 billion (approx. EUR 46 billion) with a market of over 11 million consumers. Nearly a third of all medical tourists in the world receive medical attention in South-East Asia² and specialised web portals have sprung up over the last few years which allow medical tourists to compare and access clinics and hospitals in the region³.

¹ <https://www2.deloitte.com/content/dam/Deloitte/sg/Documents/life-sciences-health-care/sea-lshc-predictions-2020-sea-supplement-noexp.pdf>

² <http://sea-globe.com/southeast-asians-drive-medical-tourism/>

³ <https://www.digitalnewsasia.com/thailand-medical-departures-raises-us2mil-series> ; <https://techcrunch.com/2015/04/27/docdoc-whos-there/>

The heterogeneity of the South-East Asia healthcare market, coupled with its large size of about 630 million in population, offers tremendous opportunities to a broad range of medical device companies and healthcare service providers in various fields. Governments in the region share the common desire to enhance their healthcare systems and to provide better quality care to their people. Their respective healthcare institutions also have country-specific needs and operate within different financial constraints.

For medical equipment and devices, European brands with high and positive brand recognition is expected to be favoured by local governments and clinicians over their lesser-known competitors. However, the high cost of European equipment can result in the use of such assets beyond their appropriate lifecycle. European companies supplying medical equipment either through innovative financing mechanisms or redesigned manufacturing for low resource settings could be an attractive proposition to purchasers in the region. Innovative companies that develop telemedicine and remote health monitoring solutions are also expected to find success in South-East Asia given its substantial rural class and uneven distribution of healthcare as well as quick of adoption of mobile health initiatives.

Medical devices span a broad spectrum of products from simple single-use consumer products such as medical gauze to extremely complex diagnostic tools that operate at the forefront of technological advancements. The inception of the IoT (Internet of Things), data analytics and digital health has spawned a wave of smart wearable medical devices that enable patients to monitor their health condition and allow health care professionals to form better diagnosis and make fine adjustments to therapy based on the clinical health data generated. EU SMEs would benefit from understanding the different intellectual property rights (“IP”) that are relevant to the medical device & healthcare industry and determine the effective way to protect their IP rights in South-East Asia.

2. Considerations concerning Patents and Industrial Designs

Medical device companies are driven by innovation and inventions that involve significant research and development costs. Compared to the automotive, defense, and telecom industries, the medical device industry invests more of its yearly revenues into product innovation. This reflects the competitive nature of the industry, and constant innovation and improvement of existing technologies.

In order for medical device companies to protect themselves against market failures and prevent others from selling duplicate products, registration of patents rights is vital. Not surprisingly, across in Europe, the European Patent Office’s Annual Report 2016⁴ shows that medical technology continues to lead other fields in terms of patent filings, as medical technology remained the top sector for patent filing rankings last year.

Generally, for an invention to be patentable, it must meet the following three requirements: (1) novelty, (2) inventive step, and (3) industrial applicability.

By registering a patent for the innovative aspect of the product, the medical device company will be able to:

- create legal barriers to entry for competing medical devices by preventing others from copying, selling, or manufacturing the patented product
- license the patented invention to generate revenue
- enhance the value of the company by building equity in the company and creating assets that may attract other investments

Besides protecting inventions via the traditional approach of patent registration, medical device companies may also wish to explore protection of their products under a different type of IP right known as utility models or simple patents. Many South-East Asia countries, including Cambodia, Indonesia, Laos, Malaysia, Philippines, Thailand and Vietnam accept registration of “simple patents” as opposed to standard invention patents. In Malaysia and Laos, a lesser degree of innovation is required for simple patents; in others, like Indonesia, Philippines, Thailand and Vietnam, no inventive step is required at all. Thus, companies that develop medical devices, kits which have minor improvements or adaptations to existing products and are low in inventive step should consider utility models or simple patent registration.

An important distinction between patents and utility models/simple patents is that the term of protection for patents is typically twice as long as that for utility models/simple patents. On the other hand, the application process for standard patents in South-East Asian countries can be lengthy and require dedicated resources to support the patent applications through to grant. To hasten the lengthy application process of standard patents, patent applicants may wish to take advantage of the ASEAN Patent Examination Cooperation (ASPEC) Programme as well as any other relevant Patent Prosecution Highway Programmes between the national patent offices.

The extent of patent protection of software that enables smart diagnostic equipment is not yet well established in the South-East Asia region. In the Philippines and Thailand, it is explicitly provided in IP laws that computer software or programs are not patentable. On the other hand, in some countries, like Singapore and Cambodia, software may be protected by patents if they fulfil specific conditions. Another issue with patenting diagnostic equipment is that medical diagnostic methods carried out by the equipment on a living human or animal body are generally not patentable in South-East Asia.

EU SMEs should consult with local IP experts able to advise them on how to achieve their goals and better address their need for patent protection. Due to limitations in patenting software and medical diagnostic methods described above, there may be instances where it is more beneficial to keep the inventive concept as a trade secret than to submit a patent application.

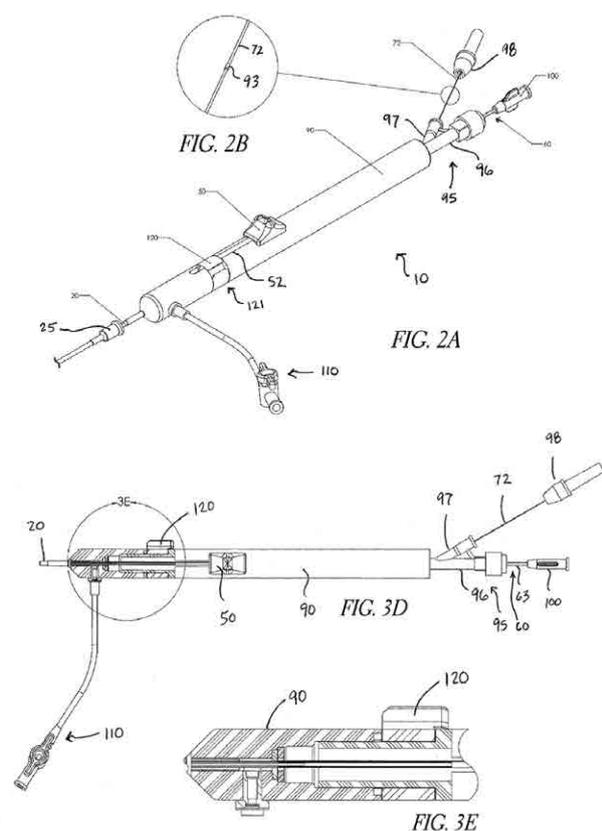
⁴ <https://www.epo.org/about-us/annual-reports-statistics/annual-report/2016/statistics.html>

Do not forget Industrial Designs

Apart from patents, medical device companies should also include industrial design registration as part of their overall IP strategy. Medical devices that deliver medicinal products can be, and are very often, protected by registered designs. Registering the design of a device is a relatively fast and inexpensive way of protecting the entire three-dimensional feature of the medical device or parts of its design. Such registration can be used to stop competitors making or selling a similar looking product. The relatively quick registration rate of industrial designs allows the rights owner to prevent sale of imitations by counterfeiters when the corresponding patent application is still pending and cannot be enforced. Industrial designs have been registered for medical devices in South-East Asia include blood sampling devices, diagnostic devices, implant delivery tools and respiratory masks.

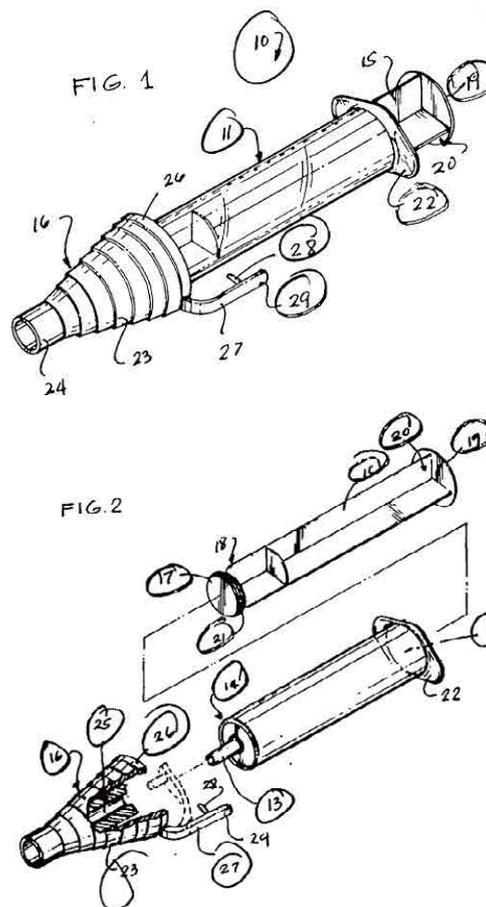
Singapore patent no. 2013053103

STENT DELIVERY SYSTEM WITH PUSHER ASSEMBLY



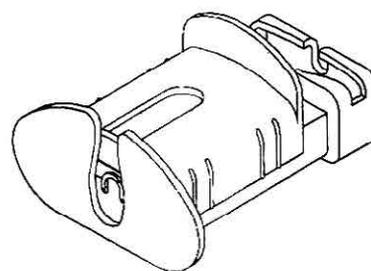
Philippines Utility Model PH/2/2004/377

AN IMPROVED SYRINGE FOR ORAL MEDICATION



Malaysia Design No. 08-01413-0101-0001

AIDING TOOL FOR SELF-INJECTION



For more information about Patents in South-East Asia, please refer to our Guide on Protecting Your Patents in South-East Asia at http://www.southeastasia-iprhelpdesk.eu/sites/default/files/publications/EN_patent.pdf

For more information about Industrial Designs in South-East Asia, please refer to our Guide on Protecting Industrial Designs in South-East Asia at http://www.southeastasia-iprhelpdesk.eu/sites/default/files/page_pdf/Industrial%20Designs%20Protection%20in%20South-East%20Asia.pdf

3. Considerations concerning Trade marks

The medical device and healthcare industry is still perceived as lagging far behind other industries in areas related to marketing and branding. A major reason why this industry is so conservative and low-profiled can be explained by the complex healthcare industry's customer profile where the decision power is split between three groups, the prescribers (primary care physicians, specialists and hospitals), the payers (hospitals, pharmacies, health insurers and governments) and end consumers (patients). However, miniaturization, wireless interconnectivity and other advancements in technology have made medical devices more accessible to consumers so that companies used to selling their products to hospitals and physicians are increasingly finding that patients are their new customers. Moreover, it is often the case that the marks chosen by companies in this field are quite 'descriptive' of the product itself, making it difficult to obtain registration due to lack of distinctiveness that is a requirement for trade mark registration worldwide.

Trade marks is a business asset that businesses can rely on to provide long term competitive differentiation amongst their competitors. Historically, brands have promised quality and reliability, features that are especially valued in the medical device & healthcare industry where products and services directly affect the well-being of the user.

EU SMEs entering the South-East Asia market should not overlook the importance of developing a branding strategy that can be effectively replicated across the region. A good branding strategy ideally should leverage on the reputation and goodwill that the EU SMEs have developed in other markets. Hence securing ownership of the trade marks that will be used in the region is a crucial first step in ensuring the smooth implementation of the branding strategy.

If trade mark clearance searches had not been conducted for the South-East Asia region during conceptualization of the trade mark, it should be done before the trade mark is filed. EU SMEs are highly recommended to use tools available such as databases of the respective trade mark offices or ASEAN TMview, to perform a preliminary search to see whether their trade mark is still available for registration. This will also ensure that the use of the trade mark does not violate the trade mark rights of others or conflict with other rights protected in the country.

Many local businesses in South-East Asia still operate without registration of their trade marks hence trade mark clearance searches preferably should include common law searches to identify unregistered marks, this is specifically relevant in South-East Asia for Vietnam, Thailand, Philippines, Malaysia and Singapore where protection of non-registered trade marks is also available under the tort of 'passing-off').

Due to the differences in customs, religion and history of various language used in the South-East Asian region, an important consideration in an EU SME's branding strategy would be the foreign translations of their trade marks.

Favorable association with the product or consumer specially incorporated in the original trade mark are likely not easily reproduced in the literal translation or its phonetic similarity in the foreign language. In other cases, phonetic equivalents of the intended mark may have surprising negative connotations in a particular South-East Asian language.

Registering a version of the trade mark in the local script used in the South-East Asian countries of interest is useful in getting rid of the above-mentioned problems. By doing so, an applicant can exercise greater control over the local version of the mark by choosing local words with the right connotations and preventing local traders from using or registering adaptations of the mark in local script.

This gives a brand owner the ability to introduce both their "localized" mark and the original mark to the local consumers. A brand owner can apply both marks in packaging and advertising to educate consumers of the original mark which would be used in other countries. For optimal brand recognition, the visual presentation of the "localized" version should be as close to the original mark as possible.



For more information about Trade marks in South-East Asia, please refer to our Guide on Protecting Your Trade marks in South-East Asia at http://www.southeastasia-iphelpdesk.eu/sites/default/files/publications/EN_TM.pdf

For more information about Trade marks searches in South-East Asia, please refer to our How to Guide on ASEAN TMview at http://www.southeastasia-iphelpdesk.eu/sites/default/files/publications/How_to_TMview.pdf

4. Considerations concerning Copyrights

Copyright is a type of IP that EU SMEs in the healthcare and medical industry might not be very familiar with and, as result, its relevance might be neglected in their IP strategy. Original artwork and text on packaging, instructions leaflets of use of medical equipment and advertising if applied in a manner consistent with the branding strategy is likely protectable by copyright and can be used to enhance brand value and brand recall.

These works have to be original in the sense that they result of at least some creative effort on the part of its authors. Copyright arises automatically and usually vests in the employer if the work has been created in the course of employment. If a third party, such as a graphics designer or advertising agency, is commissioned to produce promotional materials, it is crucial to obtain a written assignment of the copyright of the promotional material.

Copyright also exists in source code of computer programs and copyright protection is granted from the sole fact of the creation of the computer program. However it should be noted that neither the functionality of a computer program, nor the programming language constitute a form of expression of that program, and thus are not protected by copyright.

Since copyright arises automatically without need for registration, EU SMEs may wish to mark their works and documents with the © symbol to put others on notice of the copyright in these materials.

It is also worth noting that in the majority of countries in South-East Asia, except for Brunei, Myanmar and Singapore, it is also possible to voluntarily record the copyright with local authorities. Although registration is not required, copyright registration is helpful in proving ownership in case the need to take enforcement actions arise later. Authorities prefer to rely on copyright registrations as evidence of ownership before accepting a case from the complainant who claims to be the copyright owner.

For more information about Copyright in South-East Asia, please refer to our Guide on Protecting Your Copyright in South-East Asia at http://www.southeastasia-iprhelpdesk.eu/sites/default/files/publications/Copyright_english.pdf

⁵ <https://www.edb.gov.sg/content/edb/en/industries/industries/medtech.html>

⁶ <https://www.edb.gov.sg/content/edb/en/industries/industries/medtech.html>

5. R&D and joint product development: How to protect your IP

The South-East Asian region almost doubled its share of the world's scientific literature, and increased its patenting activity, a common industry measure of innovation, by more than 40 percent in the last three years (2014-2016), suggesting that the region is becoming a hub of research and innovation activity.

In the field of medical devices and healthcare, few local governments, for instance as in the case of the Singapore government, have launched a series of incentive schemes, including tax-relief and training grants towards attracting foreign medical device manufacturers, which has resulted in 30 global medical technology companies including Biosensors, Becton Dickinson, Alcon and Hill-Rom as well as local start-ups like HealthSTATS and Veredus Laboratories setting up R&D facilities Singapore. Singapore's medtech sector contributed about S\$10 billion in output and about 16,000 jobs across manufacturing, R&D and HQ functions.⁵

As part of the Research, Innovation and Enterprise (RIE) 2015 plan, the Singapore government established Sector Specific Accelerators (SSA) to identify, invest and grow start-ups in strategic but newly growing sectors, such as medical and clean technology. A total of S\$70 million has been committed under the SSA Programme to encourage the formation and growth of start-ups in medical technology. In 2015, it was announced that S\$4 billion would be invested in biomedical sciences research for the period 2015 to 2020⁶.

As examples in other South-East Asian countries, the Thai government is promoting medical technology and innovation with incentives such as 8-year corporate income tax exemption plus merit-based incentives under which specific activities like research, technology and innovation development will be eligible for additional expenditure deduction for qualified activities.

Malaysia aims to grow its healthcare sector by encouraging more private investments in areas such as medical devices, clinical research and supporting collaborative efforts between the public and private healthcare providers. The medical devices industry has been identified as one of the growth areas and has been included under its healthcare initiative.

EU SMEs that intend to establish R&D operations in the South-East Asia region will need to have an IP Strategy that anticipates and manages IP issues arising from the research. Ideally, the IP strategy addresses issues relating to ownership of and right to use the IP, procedures for identification, evaluation, protection and management of IP, procedures for cooperation with third parties, guidelines on the sharing of profits from successful exploitation; and mechanisms to ensure respect for third-party IP rights.



An effective IP strategy would include measures to:

- Ensure that all externally sourced research or software is properly licensed, and that the ownership and direction of all IP is clearly laid out from the start.
- Establish clear ownership of copyright material, such as test results, and the creation of data. Test results can significantly steer research direction and affect the commercial life of products. It is also important to keep such information confidential so that it doesn't fall into competitors' hands.
- For R&D conducted in collaboration with local research institutions and universities, or together with other companies in the private sector, ensure that the ownership of intellectual property arising from the research is clearly defined between all parties before research takes place. This can be regulated by written contracts among the parties. It is also very important to regulate the ownership of IP that can derive from improvements of applied research (for instance a common example is improvements to existing inventions that could be patented or utility models/simple patents deriving from the first original patent).

As a practical tip to avoid issues of joint ownership of IP, when possible, EU SMEs may wish to arrange for the IP to be owned by the company paying for the research.

- Ensure that all parties involved in the research collaboration are notified before allowing the research institute/university to publish academic papers relating to the research. The publications must also be reviewed to ensure that they do not compromise the patentability of the technology.

For more information about R&D in South-East Asia, please refer to our Guide to R&D in South-East Asia which will be available shortly at <http://www.southeastasia-iprhelpdesk.eu/en/content/helpdesk-guides>.



6. Distribution, product sourcing and licensing

A major challenge for EU SMEs operating in the medical device or healthcare sectors when setting up their South-East Asia business division is developing an effective setup to access and serve the regional market. Having dedicated operations in each ASEAN country might not be ideal as the domestic markets are usually not sufficiently large enough to warrant an "in-country" operation. Moreover, various countries in South-East Asia have a very different economic, legislative and political stage and the internal situation may affect the Healthcare sector more than other sectors as it is one of specific public interest. For some countries like Myanmar, where the public health system is underdeveloped and basic infrastructure challenges are ubiquitous, medical device companies can choose to rely totally on distributors for their operations in these countries. Many companies will also outsource the creation, manufacturing or design of their medical products in foreign countries.

Exporters often realize about the importance of protecting their IP once they are faced with imitators or counterfeiters or when they are being accused of infringing the rights of others. It is therefore just as important to understand the IP environment of the South-East Asian market as much as it is to understand all other facets of the business environment in that market.

What to avoid

Some of the most common IP pitfalls made by foreign exporters include the following:

(a) Believing that their local IP registration is enforceable in other countries. Many exporters believe that the trade mark, patent or industrial design registered in their own country can be recognized and used against infringers in other territories. Intellectual property rights are territorial rights, and IP offices only grant protection for the relevant national jurisdiction.

(b) Assuming that laws and procedures for the protection of IP rights are the same worldwide. While there has been significant harmonization of laws and procedures for the protection of IP rights worldwide, there remain many areas in which there are significant differences amongst the South-East Asian countries. One example is the absence of utility model protection in Singapore and lack of trade mark, patent and industrial design laws in Myanmar.

(c) Not conducting IP clearance searches before entering a new market. If the intended trade mark for the medical device is already used by a different company, sale of the product could be considered an infringement on the other firm's trade mark rights. The other firm could obtain an injunction to the use of the intended trademark and be awarded damages for infringement, which would be a huge setback to the entire marketing and export strategy of the foreign firm.

Most common issues related to the relationship with local distributors

It is good practice to include IP relevant clauses in the agreement regulating the relationship with local distributors to avoid issues especially with regards to ownership, authorized use, and in case of termination. IP issues may additionally arise when a distributorship relationship is terminated. The distributor may continue to distribute medical devices marked with the exporter's trade mark or offer for sale competing medical devices that are very similar

in physical appearance. In some instances, distributors had been discovered to have registered the trade mark in their own name. EU SMEs can minimize those risks by making proper use of written contracts to regulate these issues in advance.

While it might be possible to file for cancellation of a trade mark filed by the distributor to reclaim ownership of the mark and commence legal action against the distributor for trade mark infringement, such remedies would not be necessary if the rightful trade mark owner had registered all of its relevant registrable IP rights in the first place and included comprehensive IP clauses in the distributorship agreement. Such clauses would define the ownership of the IP subsisting in the products or services, the distributor's right to use such IP in the course of business, and the limitations of such rights during the term and after the expiration of the distributorship agreement.

Most common issues for OEM production

When approaching potential new suppliers for OEM production, it would be prudent to first conduct a background check to determine if there are any IP risks to work with a particular supplier, for example whether the supplier has received any complaints relating to managing of their client's IP. Companies should always require new suppliers to sign a Non-Disclosure Agreement (NDA) if sensitive product or business information is disclosed during negotiations.

When an appropriate supplier is identified, it is important to have well-drawn contractual agreements in place that clearly identify the IP that is owned and supplied by the medical device company, the extent of use of such rights by the supplier to manufacture the devices and clarify the ownership of IP rights to product improvements arising during the term of contract. There should also be clauses where the supplier undertakes not to apply to register these rights in the local country and that the supplier is prohibited from manufacturing excess quantities of the medical device for their own sale. For goods that contains highly sensitive IP such as trade secrets and patents, companies may choose to source only semi-finished goods from a foreign company and complete the final processing steps involving critical IP in their home country as an added assurance that such IP will not be compromised by the foreign supplier.

IP licensing

IP licensing arises when an IP rights owner (licensor) forms a business relationship with a company that desires to use such rights (licensee) in exchange for an agreed payment (fee or royalty). Various types of licensing agreements are available, and may be broadly categorized as follows:

- Technology License Agreement
- Trade mark Licensing and Franchising Agreement
- Copyright License Agreement

In practice, all or some of these agreements are combined into one single contract that encompasses transfers of all IP rights relevant to the nature of the business partnership.

As an IP owner and a licensor, licensing can be a good business strategy for overseas expansion that additionally contributes a steady stream of additional income in the form of the licence fee and rolling royalties depending on the performance of the licensee.

EU SMEs shall be aware that IP license agreement might need to be recorded with local authorities in order to have legal effect, or they would be void. Recordal further allows use of the mark by the licensee to constitute relevant use of the mark by the trade mark owner.

Generally speaking, this is a requirement that is becoming more popular in various jurisdictions in the region. For instance, since 2016, it is mandatory to record IP licences in Indonesia for the IP licence agreement to have legal effect and to be enforceable against third parties. Requirement for such recordal are also present in Vietnam (for franchising agreements) or in Thailand (for trade mark licensing). Recordal of IP licences in the rest of the South-East Asian countries is currently not mandatory but is recommended to establish notice to the public.

For more information about Technology Transfer to South-East Asia, please refer to our Guide on Technology Transfer to South-East Asia at <http://www.southeastasia-iphelpdesk.eu/sites/default/files/publications/Technology-Transfer-English.pdf>



7. SME Case Studies

Case study 1: Counterfeit Contact Lenses in Singapore

Background

A European pharmaceutical company was first alerted to the counterfeit contact lenses being sold in optical shops in Singapore when it received stocks of contact lenses bearing their trade mark for exchange from several optical shops. Laboratory examination of the suspicious products found that their packaging and chemical ingredients differed from those of the authentic products. The lenses were discovered to be counterfeit as the pharmaceutical company confirmed that they did not manufacture these seized products. The lenses were discovered to be unsafe and of poor quality, with the solution the lenses were in contaminated with dangerous bacteria and the lenses thicker and having a lower water content, both which reduces oxygen supply to the eye.

Actions taken

The discovery was reported to Health Science Authorities (HSA) and a raid was conducted on optical shops, five of which were found to be in possession of counterfeit contact lenses, laboratory tests conducted by both the company and HSA provided strong support to the

investigations. 122 boxes of the lenses falsely labelled under the brand of the European company. Eight boxes had been sold to the public. A total of seven people, including optometrists were charged.

Outcome

One of the accused, a freelance salesman, pleaded guilty in court to two charges on supplying counterfeit health products which he was fined SGD 6,000 (equal to EUR 3,750). He was fined an additional SGD 6,000 (equal to EUR 3,750) for another charge of contravening the Trade Marks Act for selling items falsely labelled under a registered trade mark.

Lessons Learned

Apart from expeditious registration of IP rights, EU SMEs should have a plan in place for monitoring, identifying and taking action against infringers of your IP. Owning IP rights for your product does not automatically stop others from infringing it. Sale of sub-standard counterfeit medical devices poses a risk to the health of the consumer and can adversely damage the reputation of the company.

Case study 2: Disclosure of confidential information and passing off in Malaysia and Singapore

Background

A manufacturer of popular over-the-counter medical devices (Company A) granted licenses to two companies formed as a result of a joint venture agreement (joint companies) to use Company A's trade marks and to manufacture, market and distribute the over the counter health products in the ASEAN countries as well as in Hong Kong, Macau, Japan, Korea, the Pacific islands and in the Middle East. The joint venture agreement (JVA) was specified to last 20 years.

Before the end of the JVA, Company A learnt from market sources that the managing director and chief executive of the joint companies would be launching a similar competing product in Singapore and Malaysia through companies that he controlled.

Actions taken

Company A filed a suit against the managing director (the defendant) claiming injunctions and damages. Company A alleged that the defendant had breached his fiduciary duties as regards to certain confidential information, had breached his contractual obligations and had engaged in passing-off.

Outcome

On an ex parte application, the High Court granted interim injunctions against the defendant. These injunctions restrained the defendant from further activities in connection with the competing product, passing off the

competing product as products originating from Company A, and making unlawful use of confidential information relating to the business and production of Company A's products acquired by the defendant as managing director of the joint companies.

Lessons Learned

It is crucial to clearly specify the type of intellectual property and the extent of use of the intellectual property in a licensing agreement. In this case, the terms of the licensing agreement had clearly specified information connected to the manufacture of the medical device as confidential information and limited the use of such confidential information solely to the production of Company A's product. Use of such confidential information in the manufacture of the competing product was a breach of the licensing agreement and thus Company A was successful in obtaining an injunction against such activity.

The judge also noted similarities between the get-up (packaging) of the competing product and Company A's product and ruled that passing off has taken place. Passing off is a common law right available to traders in to prevent using the trader's marks or other aspects of the trade get-up to represent that their goods or business are those of the trader's and should be used in conjunction with registered trade mark rights to prevent competition from unauthorized adoption of their trade mark and packaging.



8. Take-Away Messages

- EU SMEs should be aware of the different types of IP protection offered by the different South-East Asian countries and establish their IP strategy before entering new markets with the support of local experts.
- Adopting an IP strategy that makes use of a combination of IP to protect your medical devices products. A single product can be protected using patent, industrial design and trade mark registration.
- IP clearance searches should be performed prior to entering new markets to ensure that prior rights belonging to third parties are not infringed by the EU SMEs business activities in the market.
- EU SMEs should register their IP in South-East Asian countries where the option of registration is available, particularly before entering the market.
- Due diligence to identify potential IP issues should be performed before forming strategic partnerships with local entities such as research institutes and distributors. It is crucial to work only with trustworthy partners that respect your IP rights as well as the IP rights of others.
- EU SMEs should establish a surveillance protocol to identify possible infringement monitoring of market activities such as visiting of relevant trade fairs, internet searches and maintaining close communication with local distributors and licensees can help with early detection of infringing activities.

9. Glossary of Terms

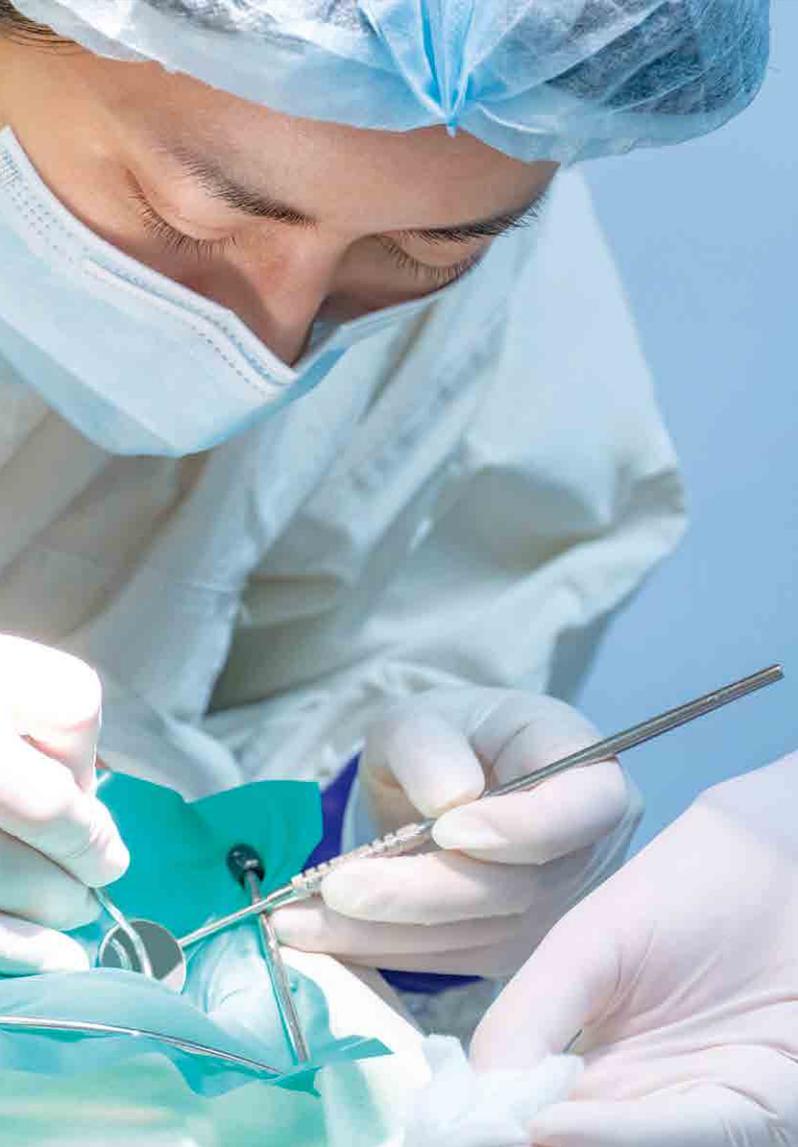
- **ASEAN Patent Examination Cooperation (ASPEC):** A regional patent work-sharing programme among nine participating ASEAN Member States.
- **Brand recall:** Also known as unaided recall or spontaneous recall and refers to the ability of the consumers to correctly elicit a brand name from memory when prompted by a product category. Brand recall indicates a relatively strong link between a category and a brand.
- **Internet of things (IOT):** The interconnection via the Internet of computing devices embedded in everyday objects, enabling them to send and receive data.
- **Medical tourism:** Medical tourism is where people who live in one country travel to another country to receive medical, dental and surgical care while at the same time receiving equal to or greater care than they would have in their own country, and are traveling for medical care because of affordability, better access to care or a higher level of quality of care.
- **Mobile health:** The use mobile technologies as tools and platforms for health research and healthcare delivery.
- **Passing-off:** In common law countries 'passing off' can be used to enforce unregistered trade mark rights. The tort of passing off protects the goodwill of a trader from misrepresentation. It prevents one trader from misrepresenting goods or services as being the goods and services of another, and also prevents a trader from holding out its goods or services as having some association or connection with another when this is not true.
- **Patent Prosecution Highway:** A framework in which a patent application whose claims have been determined to be patentable in the Office of First Filing is eligible to go through an accelerated examination in the Office of Second Filing with a simple procedure upon an applicant's request.
- **Telemedicine:** The use of telecommunication and information technology to provide clinical health care from a distance.



10. Related links and additional information

- Visit our Guide on Patent Protection in South-East Asia - http://www.southeastasia-iprhelpdesk.eu/sites/default/files/publications/EN_patent.pdf
- Visit our Guide on Copyright Protection in South-East Asia - http://www.southeastasia-iprhelpdesk.eu/sites/default/files/publications/Copyright_english.pdf
- Visit our Guide on Trade marks Protection in South-East Asia - http://www.southeastasia-iprhelpdesk.eu/sites/default/files/publications/EN_TM.pdf
- Visit our Guide on R&D in South-East Asia - <http://www.southeastasia-iprhelpdesk.eu/en/content/helpdesk-guides> (available shortly)
- Visit our Guide on Transfer of Technology to South-East Asia - <http://www.southeastasia-iprhelpdesk.eu/sites/default/files/publications/Technology-Transfer-English.pdf>
- Visit the country factsheets of each South-East Asian countries - <http://www.southeastasia-iprhelpdesk.eu/en/country-factsheets>
- Visit other publications at South-East Asia IPR SME Helpdesk website – www.ipr-hub.eu
- Visit the Helpdesk blog <http://yourIPinsider.eu> for related articles on IP in South-East Asia and China





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