

The articles in this newsletter are also available on our website: www.taypartners.com.my

TAY & PARTNERS

legal TAPs



Channels for Discovery

Discovery is defined by *Osborne's Concise Law Dictionary (8th Edition)* as a process whereby the parties to an action disclose to each other all documents in their possession, custody or power relating to matters in question in the action. In short, it is a process whereby opposing parties disclose their evidence to each other before trial so as to prevent the element of surprise or avoid a trial by ambush.

Who is entitled to seek discovery?

The legal annals are replete with authorities for the proposition that discovery is only available to parties to an existing suit. Thus it is apparent that a party would have to have a cause of action against the other in the first place in order to file a suit and it goes without saying that the necessary evidence to establish a prima facie case against the opposing party would have to be in existence or available beforehand.

However, such a form of discovery, commonly referred to as "post action discovery", is somewhat rigid in that it only binds parties to a suit having a cause of action against one another to disclose their evidence before a trial (Ref: *024 Rules of the High Court 1980*).

What happens to potential litigants who suspect or have general knowledge that a party has wronged them but lacks clear cut evidence to back up their claim? What if a potential litigant knows that a 3rd party is in possession of evidence of the wrong doing of another? Are they to be left out in the cold for a want of cause of action or persuaded

not to commence legal proceedings to right the wrong due to lack of evidence?

The alternative channel

In the interests of due administration of justice, equity intervened to enable a separate cause of action for discovery against a third party (a stranger), commonly referred to as pre-action discovery. The principle, famously enunciated in the celebrated case of *Norwich Pharmacal Co and others v. Commissioners of Customs and Excise (1973) 2 All ER 943*, prescribes as follows:

"Although as a general rule no independent action for discovery would lie against a person whom no reasonable cause of action could be alleged, or who was in the position of a mere witness in the strict sense, the rule did not apply where: -

- (a) *Without discovery of the information in the possession of the person against whom the discovery was sought no action could be begun against the wrongdoer, and*
- (b) *the person against whom discovery was sought had himself, albeit through no fault of his own, been involved in the wrongful acts of another so as to facilitate the wrongdoing. In such circumstances, although he might have incurred no personal liability, he was under a duty to assist the person who had been wronged by giving him full information and disclosing the identity of the wrongdoer".*

continues...

Contents

3	New Foreign Investment Committee Procedure a Boon to Foreign Investors and M&A
4	Combating Counterfeiting: A "Beginners" Guide
7	Whistle Blowing (Part 2)
9	A Second Tier of Protection?

...from cover

Pre-action discovery is the right to access certain documents in the possession of another, in order to ascertain *inter alia* the identity and/or the address of yet another party who was known or suspected to have acted unlawfully towards the party which is seeking discovery. Pre-action discovery against a stranger is merely the first step towards identifying a potential entity against which a lawsuit may be filed and it is not meant to be used for evidential purposes. Nevertheless, it is a powerful tool if utilised in appropriate circumstances. Recognising this, the Lords in *Norwich Pharmacal* set out several conditions that must be fulfilled before an order for pre-action discovery is granted:

i. Active concern/participation

The party against whom the order of disclosure is sought must have participated in a way which **facilitated** the wrongdoing of the wrongdoer. This participation or involvement must be active in nature. It follows therefore that a mere witness cannot be subjected to the order. The Lords gave two explicit examples where a third party cannot be forced to disclose the identity of a wrongdoer: -

1. the witness of a "hit-and-run" who has written down the plate numbers of the vehicle; and
2. a person in possession of a letter which has been used to slander another.


In either case, the third party did not become actively involved in the wrongdoing of the wrongdoer. S/he cannot therefore be ordered to disclose the identity of the wrongdoer under the *Norwich Pharmacal* rule.

ii. Nature of involvement

The Lords further stated that the nature of the third party's involvement is immaterial. It does not matter whether the involvement or participation was innocent and in ignorance of the wrongdoing. Nor does it matter whether the involvement was incidental, or made in performance of a statutory duty. The fact of his participation alone places him under the duty to assist the person who has been wronged by giving him full information and disclosing the identity of the wrongdoers.

Following *Norwich Pharmacal*

Ever since the *Norwich* case was decided in 1973, there has been a tendency for the Courts to limit applicability of the principle to situations where the wrongdoer had *prima facie* committed a tortious act. Almost thirty years down the road, the Court of Appeal in *Ashworth Hospital Authority v. MGN Ltd.* (2001) 1 All ER 991 had come to the fore and firmly removed the misconception by providing that the jurisdiction was one of general application, existing in equity whenever the person against whom disclosure was ordered had gotten "mixed up" in the wrongful conduct which infringed a claimant's legal right.

The background features a blue and white pattern of binary code (0s and 1s) and several hands reaching out towards the center. A vertical yellow bar is on the left side of the page.

The obligation to disclose the identity of wrongdoers is not dependant upon whether or not the stranger has or has not incurred liability but on the fact that he had facilitated the wrongdoer and consequently is under a moral obligation to make disclosure. The decision of the Court of Appeal has since been upheld by the House of Lords in *Ashworth Hospital Authority v MGN Ltd.* [2002] 4 All ER 193.

Conclusion

The combination of the judgments referred above has to a large extent alleviated the rigidity of post-action discovery and amounts to a potent weapon enabling a person to source for information in order to determine whether or not one has substantive claim against the wrongdoer.

Although Malaysian cases such as *First Malaysia Finance Bhd v. Dato' Mohd Fathi Bin Haji Ahmad* (1993) 2 MLJ 497, *Interfood Sdn. Bhd. v. Arthur Andersen & Co. & Anor* (2000) 1 CLJ 511, and *Teoh Peng Phe v. Wan & Co.* (2001) 5 CLJ 222 (pp. 66 PBOA), to name a few have applied the principle of pre-action discovery in Malaysia, they tended to confine them to tortuous cases. It thus remains to be seen whether judicial activism would result in the Malaysian Courts adopting the House of Lords case and expanding the principle of discovery any further.

By Brian E. Cumming (brian.cumming@taypartners.com.my) (assisted by Nurul Tajuddin). Brian specialises in commercial litigation and practises in Litigation and Dispute Resolution Practice Group,

For information and advice on Litigation and Dispute Resolution, please contact:

Asmet Nasruddin (asmet@taypartners.com.my)

Leonard Yeoh (leonard.yeoh@taypartners.com.my)

A new investor-friendly guideline unveiled by Malaysian Prime Minister in May 2003 came into effect from 1 August 2004. The Foreign Investment Committee (FIC) will now respond to completed applications within 10 working days of receipt. In the past, the process took between 2 to 3 months, and not infrequently, held up investments and other M&A work in the country.

Foreign investors, lawyers, merchant bankers, chambers of commerce and the private sector are generally relieved by this improvement citing the past processing time as unnecessarily long for the scope of scrutiny that FIC is concerned with.

The new procedure requires the applicant (who is usually the acquirer or investor) to submit a declaration of compliance or an undertaking to comply with a clear set of conditions. Generally, all foreign investors are allowed to own 70% of the equity interest of their investments in Malaysia, with the balance 30% to be owned by Bumiputra. For projects with no bumiputra partners, the undertaking referred to requires them to have such a partner within two years of the FIC approval.

FIC was established by the government in 1974 to implement the New Economic Policy of affirmative action to help the lot of bumiputra or indigenous people of Malaysia and to correct the imbalance of foreign and local ownership of business and assets at that time. Three decades later, the original policy has been substantially modified along the way by policy exemptions and dramatically too in certain aspects. For example, FIC's foreign ownership content has shifted from 30% in favour of foreigners when the policy started to 70% today.

The FIC name is a misnomer given that it affects investments by Malaysians as well as foreigners. As a national investment policy, it also does not actually cover several important areas like manufacturing, the information technology sector under Malaysia's Multimedia Super Corridor project and the financial sector. However, the FIC is still very relevant in corporate Malaysia given that the widely-drafted guideline captures many aspects of M&A work, projects in the service sector and real property acquisitions.

The new processing time frame is in line with the Malaysian government's move to improve the delivery system of government services. This improvement in


FIC procedures will be welcomed by all in corporate Malaysia.

New Foreign Investment Committee Procedure a Boon to Foreign Investors and M&A

Tay Beng Chai

(bengchai.tay@taypartners.com.my)

Beng Chai is the Managing Partner of the firm & practises in the Corporate, M&A and Banking Practice Group



Combating Counterfeiting: A "Beginners" Guide

Counterfeiting, in layman language, refers to the unauthorized use and application of a mark that is identical with or confusingly similar to a registered trade mark.

Whilst counterfeiting is unlawful, it is unfortunate that many people still think of counterfeiting as a “victimless crime”. Although some purchasers are aware they are buying counterfeit products, they continue to do so without any remorse. This reflects the total disregard for intellectual property laws.

The surge in counterfeiting reflects an increasing demand from the brand-conscious society (albeit without wanting to pay for the intellectual property that has been incorporated into the products), the ability of counterfeiters to adapt quickly to satisfy public consumption of supposedly branded goods and the enormous profits that can be made from the sale of counterfeit products.

Therefore, apart from the conventional legal remedies available to fight counterfeiting, trademark owners should also look at the more practical ways in which they could help themselves to combat counterfeiting.

Prevention is better than cure

Trademark owners should always bear in mind that “prevention is better than cure” when coming out with a product. They should endeavour to make their products as difficult to copy as possible.

Creating overt and covert measures on the appearance of their products would be the first line of defense against counterfeiting. Examples of overt measures include the application of highly distinctive patterns on the packaging, deliberate print errors, holograms, security labels, etc. Covert measures, on the other hand, require high technology and this would be a much more expensive precautionary measure. Such measures include the creation of infra-red marking, thermal chromic threads, biological tags, microscopic prints, etc.

The creation of overt and covert measures is aimed at deterring and preventing counterfeiters from copying, especially the covert features since it requires a substantial amount of research and technology. Such measures would also enable trademark owners or their agents to quickly identify that a certain product is original or counterfeit.

...from page 4

Enforcement action

Trademark owners could also seek the assistance of the Enforcement Division, Ministry of Domestic Trade and Consumer Affairs (MDTCA¹) to conduct raid actions under the power granted by the Trade Descriptions Act 1972 (“TDA”).

To initiate a TDA raid action, a complaint has to be lodged with the MDTCA. The MDTCA will carry out the raid if it is satisfied that a case has been made out. The MDTCA has wide powers under the TDA to enter (with or without a search warrant) and search and seize all counterfeit products as well as any relevant documents or contrivance used to copy, manufacture or in any way deal in counterfeit products. The raid and seizure proceeds in the name of the MDTCA and this, prima facie, shields the complainant from potential liability arising from the raid action. All materials seized in the raid under the TDA will become evidence. Based on the evidence, the MDTCA will either offer a compound or prosecute the counterfeiter for the relevant criminal offences under the TDA. After the case has been concluded, the counterfeit products would be destroyed.

Speedy action

Speed is of the essence in the combat against counterfeiting. The activities of infringers have become increasingly sophisticated. Counterfeiting is no longer a home-based industry done in dwelling houses or three-shift sweatshops. The lure of substantial tax-free profits, the relatively low risk of being caught, and the minimal penalties, if convicted, has made counterfeiting an attractive business for organized-crime syndicates. It is believed that organised-crime and syndicates with deep pockets are now financing high-tech manufacturing networks in fully computerized factories. Law enforcement officials lack the time, equipment and expertise to track down these counterfeiting operations effectively particularly as, the counterfeiters are all very mobile and always on the move to avoid detection. Therefore, as soon as counterfeits are encountered in a certain market, speed of action is essential for the trademark owner.

Within the shortest period of time available, a trademark owner must decide the following:

- (i) the origin of the counterfeit products.
- (ii) assuming that the trademark owner is able to confirm the origin of the counterfeit product, the location of the premises producing such counterfeits.
- (iii) surveillance must be conducted as soon as possible. After such surveillance has been conducted, the trademark owner would then have to ascertain:
 - (a) the problems faced by the counterfeiter in this operation.
 - (b) the problems faced by the trademark owner in this operation.
 - (c) the counterfeiter’s weakest link in his chain of manufacture/ storage/distribution/ retail.
 - (d) whether the counterfeiter belongs to a bigger syndicate running the business.
 - (e) the risk level involved if a raid action is initiated, during and post-raid.
 - (f) whether to be more lenient on this counterfeiter in return for him disclosing the identity of the actual “Kingpin”

Commitment and sustainability

Most of the time, it may not be possible to identify the real syndicate or persons behind the counterfeiting operations. Some identified syndicates may be so big and most of the time so organized and well-connected that they really could not be flushed out in a raid or two. In such cases, trademark owners must understand that anti-counterfeiting is not just a one-day operation or a “touch and go” thing. It must be a comprehensive and long-term programme as opposed to an isolated battle.

Anti-counterfeiting programmes may be designed in a cost-effective manner. Costs typically involved may comprise investigators' fees, incentives and rewards to informers and legal fees. Depending on the industry, monetary return from anti-counterfeiting programmes may be procured from settlement with infringers.

Education and public awareness

Today, there is a great need to increase awareness and educating the public concerning counterfeit products. No anti-counterfeiting campaign would be complete without public awareness and education. A trademark owner may:

(i) Educate the public on the dangers and negative effects of counterfeiting and on how to reduce the risk of purchasing counterfeit products. Helpful messages could include:

- (a) what is a counterfeit product and why the public should be vigilant,
- (b) the dangers of buying cheap products over the Internet or from other unknown entities,
- (c) good purchasing practices and cultivating them, and
- (d) identifying lawful sources of purchasing genuine products.

(ii) Educate consumers on how to identify counterfeit products (including how to recognize anti-counterfeiting technologies on packages, labeling, and the products themselves) and instructions on what to do when they have identified a counterfeit product;

(iii) Provide individual strategy for educating and increasing awareness tailored to different categories of consumers. These creative strategies could take the form of public service announcements, educational fliers and communication tools that can reach wide distribution, toll-free numbers on labels or packaging; posting messages on appropriate industry and private group websites.

Counterfeiters thrive on the ignorance of consumers. Well-informed and educated consumers will help conquer back a portion of the market for original goods.

Conclusion

With every successful raid and seizure action, the risk and danger of each subsequent raid action heightens. Depending on the industry, there is a real threat of physical violence by counterfeiters to the personal safety of representatives, licensees, distributors, law firms, investigative personnel and the law enforcers. Every party involved in an anti-counterfeiting programme is in for the long haul and the battle against counterfeiters will only be won with the close cooperation between the trademark owners, experts and professionals in the field and last but not least, the consumers.

By Anderson Leong (anderson.leong@taypartners.com.my). Anderson Leong practises in Intellectual Property and Technology Practice Group and specialise in IP enforcement.

For further information and advice on IP, Technology and Consumer laws, please contact:

Linda Wang (linda.wang@taypartners.com.my)

Su Siew Ling (siewling.su@taypartners.com.my)

Whistle Blowing [Part 2]

Previously, Part 1 of our article talks about the duties of auditors being in a position to “blow the whistle” on listed companies audited by them if they uncover any corporate misdeeds or breaches which in their professional opinion amounts to a breach or non-performance of the securities laws and the rules of the Malaysian stock exchange to the relevant authorities for example the Commission. This duty also extends to the chief executive officers of the company or those responsible for preparing and approving financial statements or financial information. However, such actions by these people would not go unnoticed as they are given legal protection against removal, dismissal, discrimination or suspension from their lawful employment.

Who are lawyers?

A lawyer or attorney refers to any person who is admitted, licensed, or otherwise qualified to practise law in any jurisdiction, domestic or foreign, or who holds himself or herself out as admitted, licensed, or otherwise qualified to practise law.

Lawyers as whistle blowers versus legal professional privilege

In the course of discharging their professional duties, a lawyer may uncover certain corporate misfeasance. What then should they do? Should they “blow the whistle”? Or are they prevented from disclosing such information?

Communications between a lawyer and his client made in the course and for the purpose of employment as a lawyer are safeguarded by the “lawyer and client privilege”. Subject to certain exceptions, the lawyer is not permitted (and not compellable) to disclose these communications. As far as the client is concerned, he is also not obliged to disclose any communication made between himself and the lawyer or the legal professional adviser unless he waives or gives up his right to the privilege either by express consent, by voluntarily giving evidence on the very matter to which those communications pertain or questioning the advocate and solicitor (as a witness) on such matters. Even though the client waives or gives up his right to the privilege, it should not mean that the first thing the lawyer should be doing is to blow the whistle on his client or to expose or reveal whatever transpired between the client and the lawyer. The lawyer is still bound by legal professional privilege which has been the statutory law entrenched in our Malaysian Evidence Act 1950.

Section 126 – Professional communications

(1) No [advocate]⁴ shall at any time be permitted, unless with his client’s express consent, to disclose any communication made by him in the course and for the purpose of his employment as such [advocate] by or on behalf of his client, or to state the contents or conditions of any document with which he has become acquainted in the course and for the purpose of his professional employment, or to disclose any advice given by him to his client in the course and for the purpose of such employment:

Provided that nothing in this section shall protect from disclosure –

(a) any such communication made in furtherance of any illegal purpose;
(b) any fact observed by any [advocate] in the course of his employment as such showing that any crime or fraud has been committed since the commencement of his employment.

(2) It is immaterial whether the attention of the [advocate] was or was not directed to the fact by or on behalf of his client.

Section 128 – Privilege not waived by volunteering evidence

(1) If any party to a suit gives evidence therein at his own instance or otherwise, he shall not be deemed to have consented thereby to such disclosure as is mentioned in section 126; and if any party to a suit or proceeding calls any such [advocate] as a witness, he shall be deemed to have consented to the disclosure, only if he questions the [advocate] on matters which but for such question he would not be at liberty to disclose.

Nature of “lawyer and client” privilege

The reason or the rationale of the privilege is to have an effective legal representation which depends on the candid disclosure of information to the lawyer by the client. This is the basis on which the lawyer can effectively advise the client as to his rights, duties, liabilities and immunities as well as how to proceed with the matter. The doctrine of legal professional privilege is rooted in the public interest, which requires that hopeless and exaggerated claims and unsound and spurious defences be so far as possible be settled without resort to judicial decision.



...from page 7

To this end, it is necessary that actual and potential litigants, be they claimants or respondents, should be free to unburden themselves without reserve to their legal advisers, and their legal advisers be free to give honest and candid advice on a sound factual basis, without fear that these communications may be relied on by an opposing party if the dispute comes before the court for decision. It is the protection of confidential communications between client and legal adviser which lies at the heart of legal professional privilege.

Without the consent of the client, and in the absence of iniquity or dispute between client and solicitor, no inquiry may be made into or disclosure made of any instructions which the client gave the solicitor or any advice the solicitor gave the client, whether in writing or orally.

The principle for this privilege is that a man must be able to consult his lawyer in confidence, since otherwise he might hold back half the truth or even hold back everything. The client must be sure that what he tells his lawyer in confidence will never be revealed without his consent. Hence, if a lawyer were to blow the whistle on his client, then the very basic rule of a client trusting his lawyer would be shaken, forgone and even seemed meaningless.

Applicability of the principle in Malaysia

This principle can be found in many Malaysian cases. According to Suriyadi Halim Omar J in *Tan Tian Wah v Tan Tian Tiok & Ors Tan Tian Wah v Tan Tian Tiok & Ors* [1998] 2 CLJ Supp, “unless there is permission from the client to the advocate to disclose any communication for the purpose of his professional employment, no disclosures will be allowed. Any paper including any correspondence, communication or matters relating to the client solicitor relationship would be privileged from discovery and thus disentitling strangers from inspecting them. Communication once privilege “is always privileged”. This is the same for documents, once privileged, a document is always privileged. The privilege remains even after the client or the testator as in the case above is dead or long gone.

Communications with third parties popularly termed as “litigation” privilege

As its name suggests, litigation privilege has its foundation in litigation be it pending or anticipated. The principle that surrounds it is that confidential communications between an advocate and solicitor or his client and another third party made for the sole or dominant purpose of litigation are protected from disclosure. The rationale is connected to the adversarial nature of proceedings. The non-disclosure is justified on the basis that as such communications are closely connected to, and bear upon, the party’s or his advocate’s approach, which includes the strategy, planning and preparation to litigation, their revelation to the other litigants may compromise the efficacy of the adversarial system in discovering the truth through the clash of independent views.

In *Robert Hitchens v International Computers Ltd*, Simon Brown LJ said of the policy underlying litigation privilege that it “must surely be to enable parties or prospective parties to prepare properly for litigation in the confidence that others thereafter will not be entitled to examine and perhaps profit from their preparatory documentation”.

Such privilege is also to encourage third parties to be candid in the information they provide for the purpose of litigation and in turn the client can then be properly advised. With truthful information given or provided by third parties, this ensures proper adjudication of the matter.

Conclusion

It is oftentimes very difficult to weigh the balance. On the one hand, lawyers are governed by the legal professional privilege which arises from a lawyer, client relationship to enable sound administration of justice in carrying out a case or matter. Whilst at the other end of the scale, do we give way to other public interest considerations?

French J, who gave the judgment of the English Court of Appeal in *R v Ataou*, stated that the issue had to be determined by balancing the two competing public interests in protecting lawyer and client communications and the disclosure of relevant evidence:

“When a communication was originally privileged and in criminal proceedings privilege is claimed against the defendant by the client concerned or his solicitor, it should be for the defendant to show on the balance of probabilities that the claim cannot be sustained. That might be done by demonstrating that there is no ground on which the client could any longer reasonably be regarded as having a recognizable interest in asserting the privilege. The judge must then balance whether the legitimate interest of the defendant in seeking to breach the privilege outweighs that of the client in seeking to maintain it.”

The balancing process advocated by the above case appears the fairest method for resolving the conflict according to the circumstances of each case.

However, it is therefore said that “legal professional privilege is thus much more than an ordinary rule of evidence, limited in its application to the facts of a particular case. It is a fundamental condition on which the administration of justice as a whole rests.”

By Toh Mi Mi (mimi.toh@taypartners.com.my). Mi Mi practises in the Corporate M&A and Banking group with experience in unit trust work and interest in corporate laws.

For information and advice on Corporate, M&A and Banking, please contact:

Tay Beng Chai (bengchai.tay@taypartners.com.my)

Chang Hong Yun (hongyun.chang@taypartners.com.my)

A Second Tier of Protection?

A Second Tier of Protection?

Commercialization of a new pharmaceutical compound requires regulatory approval. The proprietor must demonstrate to the local regulatory authorities of the safety, quality and efficacy of the drug.

Patents are naturally the first form of protection for a new drug to be protected from being worked on or copied by other manufacturers. A patent is an exclusive right granted to an invention, which is a product and/or a process that provides a new way of doing something, or offers a new technical solution to a problem. In Malaysia, an innovator company obtains this form of protection upon application to the Patent Office and fulfilling the conditions set therein.

To sell the pharmaceutical preparation, the innovator companies are required to register the product with the Drug Control Authority. To seek such approval, the companies must submit the necessary test and clinical trial data to establish the safety and efficacy of a new drug. The crucial question with regards to the role of the Malaysian Drug Control Authority (DCA) is: does the DCA provide a second tier of protection to innovator companies in Malaysia such as by rejecting applications for drugs which are patented?

The Malaysian Drug Control Authority

Regulation 7(1) of the Control of Drugs and Cosmetics Regulations 1984 ("the Regulation") which was enacted in accordance with the Minister's powers under the Sale of Drugs Act 1952 prescribes that no person shall manufacture, sell, supply or import any product unless the product is a registered product and the person holds the appropriate licence required and issued by the DCA. In Malaysia, the DCA is the executive body established under Regulation 3 of the Regulation. The main task of DCA is to ensure the safety, quality and efficacy of pharmaceuticals, health and personal care products that are marketed in Malaysia. This objective is being achieved through the registration of pharmaceutical products and cosmetics, licensing of premises for importer, manufacturer and wholesaler and monitoring the quality of registered products in the market.

A Second Tier of Protection?

1. Registration

This form of protection sees the DCA acting as a guardian to the market availability of drugs. Can the DCA prohibit the registration of a generic drug (based on the existence of a patent in Malaysia for that particular drug thereby making any manufacture, sale, supply or import of such drugs illegal by virtue of the Patents Act 1983)?

At first glance, the Regulation does not seem to compel the DCA to refuse registration to generic manufacturers who try to register their pharmaceutical products nor is there any provision which expressly prescribes that registration may be refused on grounds that a patent has been registered for that particular compound embodied in the product.

However, Regulation 8 gives the DCA the authority to register any product subject to such conditions as it may impose in the applications. This is reflected in its standard application forms for registration of new chemical entities. In the prescribed format, the applicant has to declare that it is aware and in compliance of the provisions of the Patents Act 1983. As such, if the applicant seeks to registers the generic drug which falls within the scope of a subsisting patent by declaring that it is in compliance with the Patents Act, the applicant would have supplied false or misleading information to the Authority in connection with his application for the registration of a product. This would be in contravention of Regulation 8(9) and constitutes an offence under the Regulations.

2. Data Protection

Can a patent owner prevent a generic drug manufacturer from using its test data and clinical trials that have been submitted to the DCA earlier which form the basis of its product registration? Such data could have taken years to develop and is probably worth millions.

continues...



Data Protection has been given recognition in Article 39.3 of the Trade Related Aspects of Intellectual Property (TRIPS) Agreement. It obliges all WTO member countries, of which Malaysia is one, to protect against unfair commercial use of confidential data on new chemical entities submitted by companies to obtain approval for marketing new drugs from a regulatory agency. Many developed countries and the pharmaceutical industry have taken a step further by claiming that Article 39.3 imposes data exclusivity on third parties, in which even use by government agencies or regulatory authorities of the data submitted by the companies to assess applications by generic manufacturers should be strictly prohibited. In effect it amounts to a monopoly period for innovator companies over the test data it developed.

Whilst countries such as China, US, Japan, New Zealand and many others have introduced data exclusivity into their system with a protection period ranging from 5 to 6 years, unfortunately in Malaysia, Article 39.3 has not been given any effect under existing laws.

Conclusion

Technically, a generic manufacturer who attempts to register its generic drug of which there is in existence a patent in Malaysia may be caught by Regulation 8 through the applicant's

declaration in the prescribed registration form that he has complied with the Patents Act. In practice, routine check on granted patents may not be made by the authorities and unless the patent owner keeps a vigilant watch over the products that are registered, a generic drug may secure registration. The onus thus lies on the patent owner to enforce its patent through legal proceedings.

However, with regards to test data, the role of DCA in providing protection of intellectual property rights is clearly inadequate. To continue enjoying benefits as a WTO member, Malaysia should incorporate a certain standard of Data Protection to protect test or trial data. The DCA could and should play a vital and more active role in ensuring that patent rights and the intellectual property of a patent owner are protected.

By Choy Sook Yee (sookyee.choy@taypartners.com.my). She is attached to the Intellectual Property and Technology practice group.

For further information and advice on IP, Technology and Consumer laws, please contact:

Linda Wang (linda.wang@taypartners.com.my)

Su Siew Ling (siewling.su@taypartners.com.my)

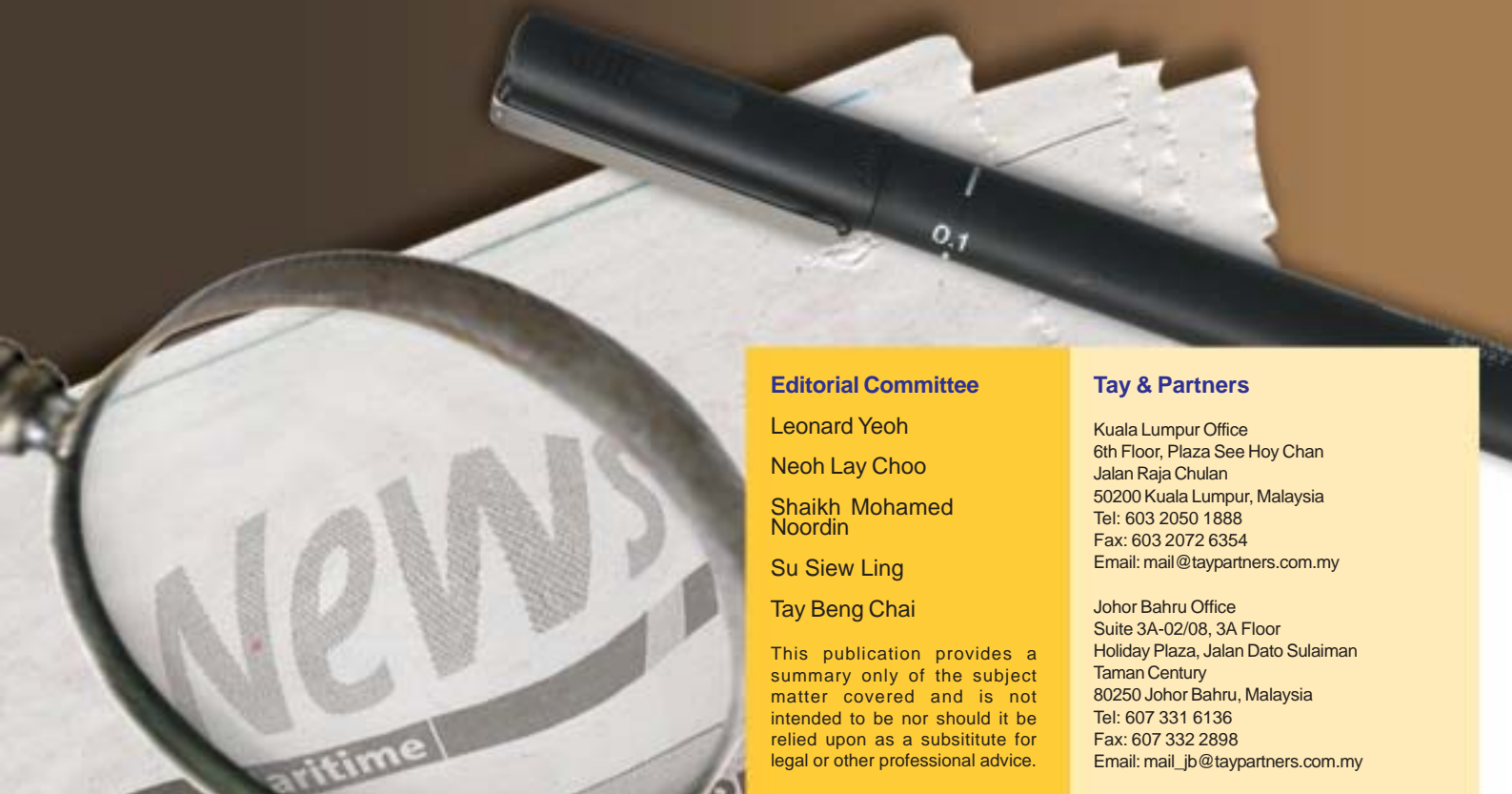
Footnotes

1. Amended Section 99E (1)-(5) of the Securities Industry (Amendment) Act 2003
2. Amended Section 99F (1)-(3) of the Securities Industry (Amendment) Act 2003
3. Section 129 of the Evidence Act 1950
4. The word 'advocate' within square brackets was amended by the Evidence Ordinance (Extension) Order 1971 (PU (A) 261/71) Schedule
5. per Bingham LJ in *Ventouris v Mountain (The Italia Express)* [1991] 1 WLR 607, at 611
7. per Cockburn CJ in *Bullock v Carry & Co* [1848] 3 QBD 356
8. see for example, *Wagh v British Railways Board* [1980] AC 521
9. Unreported, December 10, 1996
10. [1988] 2 All ER 321
11. per Taylor CJ in *R v Derby Magistrates Court* [1996] AC at 507



Legal TAPs is a collective effort of the firm to bring relevant legal updates and information to you.

TAY & PARTNERS legal TAPs



Editorial Committee

Leonard Yeoh

Neoh Lay Choo

Shaikh Mohamed Noordin

Su Siew Ling

Tay Beng Chai

This publication provides a summary only of the subject matter covered and is not intended to be nor should it be relied upon as a substitute for legal or other professional advice.

Tay & Partners

Kuala Lumpur Office
6th Floor, Plaza See Hoy Chan
Jalan Raja Chulan
50200 Kuala Lumpur, Malaysia
Tel: 603 2050 1888
Fax: 603 2072 6354
Email: mail@taypartners.com.my

Johor Bahru Office
Suite 3A-02/08, 3A Floor
Holiday Plaza, Jalan Dato Sulaiman
Taman Century
80250 Johor Bahru, Malaysia
Tel: 607 331 6136
Fax: 607 332 2898
Email: mail_jb@taypartners.com.my

T&P News

Accolades

Linda Wang, who leads the Intellectual Property and Technology practice group has been voted by clients and the industry as one of Asia's leading lawyers in intellectual property by *Asialaw Leading Lawyers (2004)*. She is also featured in the *2004 Guide to the World's Leading Trademark Practitioners* and the *International Who Who's of Trademark Lawyers 2004*.

Leonard Yeoh, our partner in the Litigation and Dispute Resolution practice group has also been voted by clients and the industry as one of Asia's leading lawyers in dispute resolution by *Asialaw Leading Lawyers (2004)*.

Legal Talks...

Chang Hong Yun, our partner in the Corporate, M&A and Banking practice group on "Corporate Legal Counsel's Role in Managing a Successful M & A Deal in Corporate Legal Counsel" Conference on May 10 and 11.

Leonard Yeoh, our partner in the Litigation and Dispute Resolution practice group presented a paper at the "Legal & Tax Aspects of Joint Ventures and Mergers & Acquisitions Conference" by *The Asia Business Forum* in June 2004. He also chaired the "9th Annual Conference on Islamic Finance Asia - Latest Developments and Innovations in the Islamic Market" in July 2004.

Siew Ling, our partner in the Intellectual Property practice group, recently provided a training session on trade mark law for the officers and Assistant Registrars of the Registry of Trade Marks, Intellectual Property Corporation of Malaysia, at a weekend retreat and seminar entitled, "Law and Issues on Trade Marks: Practice and Procedure".