Ministry of Health Malaysia

NATIONAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN HERBAL MEDICINE (NRDHM)

GUIDE TO INTELLECTUAL PROPERTY RIGHTS MANAGEMENT

GUIDE TO

INTELLECTUAL PROPERTY RIGHTS MANAGEMENT

Message by

The Honourable Dato Chua Jui Meng,
Minister of Health of Malaysia

Traditional medicine has formed the basis of health care throughout the world since the earliest days of mankind and is still widely used. It has been estimated that nearly 80% of the world's population use some form of traditional and complementary medicine (T/CM). The use of herbal medicines is growing steadily worldwide, increasing at a rate of 10-20% annually.

Of the approximately 250,000 known plant species in the world today, it is estimated that only about 5% have been examined for their medicinal properties and 25% of all prescription drugs are based on plants belonging to only 40 species. There are at least 150,000 species of flowering plants in the tropics and in South East Asia alone, there are 35,000 species of which 8,000 are found in Malaysia. In the tropics, a total of 6,000 floral species have been reported to possess medicinal values. Of these, a total of 1,230 local species have been recorded as plants used in traditional medicines. Malaysia is one of the 12 mega biodiversity countries in the world and is nestled in the oldest rainforest in the world. It is also a melting pot of 3 important T/CM systems, namely the Malays, Chinese and the Indian traditional medicine systems and It is hardly surprising therefore to note the growing interest of T/CM amongst policy makers, researchers, clinicians, entrepreneurs and the community at large in this country.

This growing popularity and appeal of T/CM the world over, have created both an opportunity and the obligation for the Government to conduct proper scientific studies and evaluation in T/CM. It has been reported that an estimated USD 500 million is spent annually on T/CM compared to USD 300 million on modern medicine in Malaysia. There is now greater demand for evidence on the safety, efficacy and quality of T/CM products and practices.

I would like to therefore congratulate the **National Committee for Research & Development in Herbal Medicine (NRDHM),** the brainchild of the Ministry of Health, for producing several guidelines pertaining to herbal medicine research to ensure that good research practices, as well as authenticity, safety, efficacy of therapies involving herbal medicinal products are assured. These guidelines are indeed very timely and will serve to enhance consumer confidence in T/CM.

Dato Chua Jui Meng,
Minister of Health of Malaysia

Message by

Y Bhg Tan Sri Datu Dr. Mohamad Taha bin Arif
Director General of Health
Ministry of Health

The Ministry of Health (MOH) is responsible for ensuring the availability of appropriate, safe, effective health care services in the country. While much of the healthcare currently provided by the MOH is driven by modern medicine which is based on scientific evidence, there is a growing interest in the use of traditional and complementary medicine (T/CM) as either an alternative or an adjunct to modern medicine. The MOH launched the policy on T/CM in 2001 in recognition and anticipation of the increasing popularity of T/CM not only in this country but also worldwide.

The WHO encourages the integration of safe and efficacious T/CM into mainstream healthcare system. Before considering the integration of T/CM into our mainstream health care system, the MOH has the responsibility of ensuring that only appropriate, safe and effective herbal medicines of consistent quality are developed and available to those in need. It is also our responsibility to ensure that the herbal medicinal products not only meet the required product quality standards (GMP), but have also in place, the necessary evidence to support its safe and appropriate use in specific disease states (evidence-based therapeutic use). The development of such medicinal products needs to be carried out in a coordinated, systematic and scientific manner, similar to that of pharmaceutical drug development.

It is therefore gratifying to note that the Ministry of Health, through the **National Committee for Research & Development in Herbal Medicine (NRDHM)**, has produced four guidelines for researchers in T/CM to use as guidance documents to strengthen research and development in herbal medicine and thus bring the practice of T/CM to a higher level of quality for greater acceptance by providers of modern medicine and the public. The stage will then be set for the integration of modern and T/CM into mainstream healthcare system.

Tan Sri Datu Dr. Mohamad Taha bin Arif
Director General of Health
Ministry of Health

Message by

Dato Dr. Hj Mohd Ismail Merican
Deputy Director General of Health
(Research & Technical Support)
Ministry of Health

There are generically three groups of traditional/herbal preparations in Malaysia: the Malay traditional preparations, the Chinese preparations, and the Indian traditional preparations. Within each of these groups are different remedies that are being compounded and sold for the same disease indication. It is very clear that there is a great deal of variation and secrecy as to the composition of these "local" remedies. Absence of standardisation is a common feature. The lack of collaboration and co-operation within the group and between groups make it difficult to develop a truly Malaysian traditional/herbal formulary for treatment of the different illnesses found in this country.

Some of the reasons delaying the development of a national formulary specific for herbal products include the lack of co-ordination between the traditional herbalists and feeble attempts to systematically evaluate locally available flora to identify active ingredients that will be viable commercially, especially in the context of the emergence of new chemical entities.

In order to facilitate the future development of traditional/herbal medicines in this country, one has to understand the processes and activities that need to be in-place to ensure that commercially viable herbal products can be systemically developed and internationally marketed. Acknowledging that herbal medicines can contribute to the economy of the country, the development of such medicinal products need to be carried out with some urgency.

The timely approval by the Malaysian Cabinet of the establishment of the **National Committee for Research & Development in Herbal Medicine (NRDHM)** in April 2002 under the auspices of the Ministry of Health and chaired by the Deputy-Director General of Health (Research and Technical Support) has given herbal medicine research the much needed catalyst to steer it in the right direction and in accordance with international standards.

The terms of reference of NRDHM include the development and coordination of the strategic master plan for R&D in herbal medicine research, the production of relevant guidelines to ensure quality, safety and integrity of data in line with local regulations, creation of harmonization, understanding and collaboration between researchers, identification of training and infrastructure needs in herbal medicine R & D, the setting of targets and facilitation of new product discovery and development and addressing issues pertaining to Intellectual Property Rights management.

Members of NRDHM include senior representatives from the various ministries, universities and appropriate stakeholder agencies such as the Science University of Malaysia, Agriculture and Research Development Institute, Drug Control Authority, Ministry of Science ,Technology and Environment, Ministry of International Trade and Industry , Ministry of Education, Malaysian Industry Government Group for High Technology, Malaysian Herbal Cooperation and the Institute for Medical Research.

The guidelines that have been prepared by NRDHM pertain to clinical research, standardization, claims and intellectual property rights management. They will serve as guidance documents to ensure rigorous quality in herbal medicine research and safety of our herbal products. It is hoped that the quality of studies conducted will be of the highest standards and generating findings and products that are accepted not only in Malaysia, but also globally.

These guidelines have been prepared in consultation with various existing guidance documents from the Federal Drug Control Authority (FDA), USA the World Health Organisation (WHO), European Union and Therapuetics Good Administration (Australia)

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Terms of Reference

- To develop, coordinate and monitor the strategic master plan for Research & Development in Herbal Medicine Research.
- To produce relevant guidelines to ensure quality, safety and integrity of data in line with local and international regulations.
- To create harmonization, understanding and collaboration between researchers.
- To conduct dialogues and other related activities for promotion of Herbal Research & Development.
- To identify training and infrastructure needs in Herbal Medicine Research & Development.
- To set targets and facilitate new product discovery and development.
- To address issues pertaining to Intellectual Property Rights Management.

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Introduction

Intellectual Property may be the most effective business tool a business will ever use. Herbal medicine business that produces innovative products, designs or ideas would require specialist advice as to whether any of these can be protected and commercialized because different Intellectual Property Rights vary in the protection they provide. Often, more than one type may be necessary to fully protect a creation. For instance to develop a position in the market a herbal medicine business may take out a patent on its product, register its design and register a mark; or it may decide that a patent protection is not worthwhile and that maintaining secrecy and using confidentiality agreements suffice; or it may just focus on a trade mark. Having one or more trade marks for the products can also substantially support the herbal medicine business. It might also be suitable to register one or more designs for the herbal medicine products to avoid an imitation of their outward appearance by a competitor. Using a range of protective measures gives a herbal medicine business layers of protection and strengthens its position in the market and increases the returns on their investment.

This Guide is concerned with the strategic aspects of managing Intellectual Property in order to exploit economies of scale. Since there are commercial advantages in having a good Intellectual Property Rights Management in place it is recommended that a herbal medicine business consults an Intellectual Property lawyer who can be entrusted with all its objectives and concerns it might have in the field of Intellectual Property protection to assist it in developing its Intellectual Property Rights Management strategies. Professional advice at an early stage will ensure that the business protects its own Intellectual Property and does not infringe the Intellectual Property of third parties.

This Guide focuses on Intellectual Property arising from research in herbal medicine and its exploitation. This Guide deals with all types of Intellectual Property including patent, trade mark, industrial design and copyrights. There are also samples of statutory forms, an extract of the current prescribed filing fees for easy reference.

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Guide to Intellectual Property Rights Management

The objective of this Guide is to highlight the importance and relevance of an effective Intellectual Property Rights Management.

This Guide will identify issues which need to be addressed if the potential benefits of an effective Intellectual Property Rights Management are to be realized and will provide the herbal medicine business with some of the measures and actions to be taken on how to identify, protect and market its Intellectual Property Rights, commonly in the form of patentable invention; trade mark/service mark; copyright works; design rights. However the measures and actions proposed here are not intended to be complete. Hence, it is recommended that the herbal medicine business seeks the services of a professional adviser to further explain to it the important issues, help develop the necessary standard operation procedures for its Intellectual Property Rights Management, assist it in the decision making and finally, ensure that the decided actions are reliably carried out.

What is Intellectual Property?

Intellectual Property encompasses the tangible representations of intellect and creativity and Intellectual Property Rights are the rights given to people over the creations of their minds.

World Intellectual Property Organisation (WIPO) defined the scope of Intellectual Property as being :

"the rights relating to

- literary, artistic and scientific works;
- performances of performing artists, phonograms and broadcasts;
- inventions in all fields of human endeavour;
- scientific discoveries;
- industrial designs;
- trade mark, service mark and commercial names;
- protection against unfair competition; and
- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields"

Intellectual Property takes a number of forms:

- Patent for new or improved products or processes;
- Trade mark for words, symbols, pictures, sounds, smells or a combination of these, to distinguish the goods or services of one trader from those of another;
- Industrial design for the shape or appearance of manufactured goods;
- Copyright for the original material in literary, artistic, dramatic or musical works, films, broadcasts, multimedia and computer programs;
- Confidential information/trade secrets.

Key types of Intellectual Property and Intellectual Property Rights

Forms of Intellectual Property	Subject Matter	Intellectual Property Rights
Patent	The inventive subject matter capable of industrial application	The exclusive right to prevent others from manufacturing products based on the protected idea. Intellectual Property Rights occur upon registration.
Trade mark/ Service mark	A brand which the public associates the goods or services with a business	The exclusive right to put your goods or services on the market under the brand. Intellectual Property Rights occur upon registration.
Industrial design	A functional design capable of industrial application	The exclusive right to prevent others from copying substantial parts thereof. Intellectual Property Rights occur upon registration.
Copyright	The intellectual creation either in writing or other permanent medium	The exclusive right to control certain acts eg reproduction in any material form, the communication to the public, the performance in these works. Intellectual Property Rights occur automatically upon creation.
Confidential information /trade secret	The confidential information	The exclusive right to use and disclose confidential information under obligations of confidence.

In a research based organization there are 5 common forms of Intellectual Property associated with the organization's diverse activities. Please see Fig 1 for the diverse range of activities and their associated forms of Intellectual Property.

Fig. 1 Activities and their Associated Forms of Intellectual Property

ACTIVITY	PATENT	CONFIDENTIAL INFORMATION	COPYRIGHT	DESIGN RIGHTS	TRADE MARKS
Using others' research papers, publications, etc		✓	✓		
Research information Preparing and collating research or experimental results		✓	✓		
Publishing or presenting research, academic or technical papers	✓	✓	✓	✓	
Industrial design projects	✓	✓	✓	✓	
Contract research	✓	✓	✓	✓	
Consultancy projects	✓	✓	✓	✓	✓
Starting discussions on a collaborative project or contract research	✓	✓			
Receiving important confidential information		✓			
Giving out confidential information	✓	✓			
Using computer software		✓	✓		✓
Developing computer software	✓	✓	✓		✓
Revising or providing a manual or computer assisted drawings		✓	✓	✓	
Preparing notes for lectures		✓	✓		
Responding to telephone queries of a technical nature		✓			

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Management of Intellectual Property Rights

Intellectual Property strategies begin the process of increasing an organization's wealth. Thus, to effectively commercial these Intellectual Property the organization should raise awareness of the value in all forms of Intellectual Property Rights amongst its Board and senior management and have a proactive and structured Intellectual Property Rights Management programme.

A. Benefits

Good Intellectual Property Rights Management is important because of the financial returns that it can generate. In addition, a well-managed Intellectual Property portfolio will make the herbal medicine business a more attractive partner to research sponsors and will encourage investment from post-research investors.

B. Methodologies

A proactive and structured programme should begin with an in-house Intellectual Property Rights Management Committee headed by a suitably qualified person who is well versed in Intellectual Property matters to spearhead the Intellectual Property Rights movement within an organization. The Committee should comprise experienced and knowledgeable persons who can be trusted to achieve the optimal results of the Intellectual Property work for the organization. The task of the Committee is quite comprehensive. The Committee will, for instance:

i. develop an Intellectual Property strategy for new products. Remembering always that different Intellectual Property Rights vary in the protection they provide so using more than one type will protect and strengthen the organization's position in the market. Also, in developing an Intellectual Property strategy one must not think of an Intellectual Property protection strategy solely for the home country; one must also think about one that stretches across the globe;
ii. handle all communication between the organization and the external Intellectual Property lawyer/patent agent/trade mark agent;
iii. ensure compliance by the organization of all applicable laws and regulations;
iv. ensure compliance by the organization of its contractual obligations;
v. create awareness amongst its researchers/research teams of the Intellectual Property issues, both opportunities and dangers. Policies must be in place to make clear to its staff their responsibilities in relation to Intellectual Property protection including where appropriate the maintenance of research laboratory records and the prevention of premature public disclosure of research results or other key information prior to obtaining Intellectual Property protection;
vi. ensure that security arrangements for key information are appropriate;
vii. develop Intellectual Property Rights search procedures, patent evaluation system;
viii. obtain from the Patent Office the patent information which is a patent document disclosing bibliographic and technical information for its researchers.

Intellectual Property Rights Management would involve the following elements:

(B.1) the identification of the organization's Intellectual Property. This process involves:
- an Intellectual Property Audit on the business to identify, analyse and evaluate its Intellectual Property and their associated Intellectual Property Rights; and
- the development of a Legal Risk Management to identify, assess, control and mitigate legal risk exposures.

(B.2) the protection of the organization's Intellectual Property. This process involves the registration of its registrable Intellectual Property under:
- Local Intellectual Property Protection System and/or
- International Intellectual Property Protection System.

(B.3) the exploitation of the organization's Intellectual Property. The real value of Intellectual Property is the way Intellectual Property can be integrated as part of the business strategies - marketing, capital raising, research and development or business development.

B.1 Identification of Intellectual Property

In order to design an Intellectual Property Rights Management framework the organization would have to first identify all the Intellectual Property associated with its business. Identification of the Intellectual Property means it would have to identify, analyse and evaluate its Intellectual Property and their associated Intellectual Property Rights (Intellectual Property Audit) and thereafter identify, assess, control and mitigate the legal risk associated therewith (Legal Risk Management). This process should involve a legal team.

B.1a Intellectual Property Audit

An Intellectual Property Audit should be conducted on the business as soon as possible. Briefly, an Intellectual Property Audit should:

i. identify all Intellectual Property associated with an organization;
ii. check that the organization indeed is the owner of all Intellectual Property used in its business or at least have the right/licence from the owner of those Intellectual Property to use them in its business;
iii. compile a list of all the registered, unregistered and non registrable Intellectual Property and place a RM value on those assets which is contingent upon the mode and efficacy of its commercialization. It is recommended that a Financial Adviser be consulted in determining the value of an Intellectual Property;
iv. identify the key research staff and train them on the importance of use and management of Intellectual Property. Establishing and maintaining regular awareness of Intellectual Property amongst the staff in particular the researchers/research teams are essential for early identification of key innovations. Procedures should be established to assist them to identify

Intellectual Property that can be protected and/or exploited and reduce the possibilities of accidental disclosures of information that could prejudice the organization's application for patent rights. Effective ways of increasing Intellectual Property awareness include seminars, use of printed matter and articles in the organization's newsletter.

B.1b Legal Risk Management

Once the Intellectual Property and Intellectual Property Rights have been identified the organization should conduct an assessment of the legal risk associated therewith. The legal team should develop a proactive and structured programme for legal risk management for use by the Committee.

Legal Risk Management is about balancing risks with profit maximization in a manner that will protect, enhance and preserve the legal interests of the individual and/or enterprise and its process involves legal risk identification, assessment, control and mitigation. Legal Risk Management is vital to an organization because it will help avoid or at least minimize its potential liability to:

i. the regulatory authorities, for instance, failure to meet legal compliance;
ii. the other party named in the contracts, for instance, failure to meet contractual obligations; and
iii. third parties, for instance, infringement of third party's Intellectual Property Rights.

The process of Legal Risk Management involves inter alia:

i. identification of all employment contracts, consultancy services agreements, research contracts, licensing agreements etc entered into by the organization;
ii. checking for warranties and undertakings, indemnity provisions, comprehensive terms and the enforceability issues;
iii. identification of all applicable laws and regulations.

The Legal Risk Management should include a Compliance Programme with compliant procedures pre-established to ensure contractual and statutory compliance. Such Compliance Programme should be periodically reviewed for changes in the law. Compliance Programme is further discussed under item B.3 of this Guide.

Legal Risk Management is particularly important for new research projects because Intellectual Property issues need to be identified and considered at the initial contract negotiation stage of research projects. It is advisable to define the rules of the game among all partners to avoid problems deriving from deficiencies in the definition of objectives, tasks or responsibilities within the project, to anticipate problems and devise mechanisms for conflict resolution and to complement and cover any missing point in the contract. It is therefore recommended that Legal Risk Management starts as soon as possible i.e. at project initiation stage or feasibility studies stage. If an organization is in a "reactive" mode for risk management, it will often be too late to help.

B.2 Intellectual Property Protection System

Once the Intellectual Property has been identified the organization should consider protecting them under the local Intellectual Property protection system and if it wishes to enhance its competitive edge in the global market, it should also register them through the international Intellectual Property protection system.

With the exception of copyright, trade secret and database, formal steps must be taken to register an Intellectual Property to obtain the Intellectual Property Rights in order to receive protection. The registration includes a description of what is being protected - the invention, design, brand name, logo etc - and the description is public information.

B.2a Malaysian Intellectual Property Protection System

An overview of Patent

The relevant provisions of the **Patents Act 1983** and **Patents Regulations 1986** are provided here as a practical guide for identifying and registering an invention with the Patent Office, Malaysia.

A patent granted under the **Patents Act 1983** accords protection to the patentee only within Malaysia. For exploitation of patented invention outside Malaysia, registration of the invention in the country in question is required.

Once the invention is patented the owner will have the exclusive rights to exploit the patented invention, assign or transmit the patent or to conclude the license contracts **(Section 36 (1) of the Patents Act 1983).**

There are 3 statutory criteria for an invention to fulfill before the patent right is granted in Malaysia. **Section 11 of the Patents Act 1983** provides an invention is patentable if it:

i. *is novel/new,* which means if the invention is not anticipated by prior act **(Section 14 of the Patents Act 1983).** Prior act consists of everything disclosed to the public, anywhere in the world whether by written publication, oral disclosure or use. Novelty is judged at the priority date i.e. the date of first filing at a Patent Office. To be patentable, the invention must not have had prior public disclosure which includes any published papers, conference papers, speeches and even general discussion with anyone who is not bound by a Confidentiality Agreement. Because accidental disclosure of key information could prove fatal to the patentability of the organization's future work it should consider imposing confidentiality obligations before publishing information and starting discussions on collaborative projects or contract research;

ii. *involves an inventive step,* which means the invention should not be obvious to a person skilled in the art, taking into account the state of the art existing as at the priority date **(Section 15 of the Patents Act 1983);** and

iii. *is industrially applicable*, which means if the invention can be made or used in any kind of industry **(Section 16 of the Patents Act 1983)**.

Section 12 of the Patents Act 1983 has defined an invention as an idea of an inventor which permits in practice the solution to a specific problem in the field of technology. An invention may be or may relate to a product or process.

However not all ideas which fall within the definition of "invention" are patentable. **Section 13 of the Patents Act 1983** provides that the following types of invention are specifically excluded from patent protection:

i. discoveries, scientific theories and mathematical methods;
ii. plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;
iii. schemes, rules or methods for doing business, performing purely mental acts or playing games;
iv. methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practiced on the human or animal body
Provided that this paragraph shall not apply to products used in any such methods.

Accordingly, a herbal medicine business is not permitted to patent the methods for treatment of human by therapy but its products may enjoy statutory protection if they fulfill the 3 statutory pre-requisite criteria, namely novelty, inventive step and industrial application.

Because patentability is a complex area good advice is essential.

Patent Search

A search can be performed prior to submission of a patent application to the Patent Office. It is recommended that a patent search and evaluation be conducted on the novelty of the "invention" before embarking on a research project because a search at the Patent Office can avoid costly duplication of research and development. Besides, the bibliographic and technical information derived from a patentability search can provide the organization with a fair amount of commercial information such as when a particular competitor's patent expires or where in the world a particular patent right exists and can assist its agent to draft its patent application.

A patent search may be conducted at the Patent Office located on the 32nd floor Menara Dayabumi Jalan Hishamuddin 50654 Kuala Lumpur during office hours upon payment of the prescribed fee.

Understanding Patent Registration Procedures

Any person may make an application for a patent either alone or jointly. A person who is neither domiciled nor resident in Malaysia has to file his patent through a local patent agent. It is usual to appoint a patent attorney and patent agent when applying for a patent. They can render professional advice on the patentability of the invention, the necessity of obtaining a patent, the search procedures, the preparation of the patent specification and the drafting of claims. In addition to that a patent agent is empowered to represent the applicant in proceedings before the Patent Registration Office, file documents and sign documents on its behalf.

The name of the inventor must be disclosed in the application otherwise a statement justifying the applicant's rights to the patent must be submitted.

No person resident in Malaysia shall, without written authority granted by the Registrar, file or cause to be filed outside Malaysia an application for a patent for an invention **(Section 23(A) of the Patents Act 1983)**.

Rule 5 of the Patents Regulations 1986 provides that an application shall contain

i. a request for grant of a patent. **Rule 6 of the Patents Regulations 1986** requires the name and address of the inventor. An inventor not wishing to be named shall submit a declaration to the Registrar indicating that he does not wish to be named. See **Appendix 1** for a sample of the Request For Grant of Patent form (Patent Form 1). If there are more than one applicant and the applicants have not appointed a patent agent to represent all of them then in the Request For Grant of Patent they must designate one of them as their common representative failing which the applicant first named in the request shall be considered the common representative **(Rule 11 of the Patents Regulations 1986)**;

ii. a description. **Rule 12 of the Patents Regulations 1986** provides that the description shall first state the title of the invention as appearing in the request and shall

a) specify the technical field to which the invention relates;
b) indicate the background art which, as far as is known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention and wherever possible, cite the documents reflecting such art;
c) disclose the invention in such terms that it can be understood and in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skill in the art, and state any advantageous effects of the invention with reference to the background art;
d) briefly, describe figures in the drawings, if any;
e) describe the best mode contemplated for carrying out the invention, using examples where appropriate and referring to the drawings, if any; and

f) indicate explicitly, when it is not obvious from the description of nature of the invention, the way in which the invention is industrially applicable and the way in which it can be made and used or, if it can only be used, the way in which it can be used.

The description shall not contain drawings.

iii. a claim or claims. **Rule 13 of the Patents Regulations 1986** provides that the claims shall be clear and concise and fully supported by the description; and the number of the claims shall be reasonable taking into consideration the nature of the invention. If there are several claims they shall be numbered consecutively in Arabic numerals. Claims shall not contain drawings and shall not, unless necessary, rely, in respect of the technical features of the invention, on references to the description or drawings.

Prior to grant of patent by the Patent Office, the applicant may stamp, engrave or impress on its product the phrase "patent pending no. _" and upon the patent being granted, the words "patented" or the phrase "patent no. _"

iv. a drawing or drawings, where required; and

v. an abstract.

Prosecution Cost

The Intellectual Property lawyer's/patent agent's fees associated with the preparation of a Request For Grant of Patent vary depending on the complexity of the invention. Also, their fees for filing an application in foreign countries vary depending on the complexity of the invention and whether translations are involved. For an extract of the relevant current local patent filing fees see **Appendix 2**.

Flowchart of Patent Application

For an overview of the steps forming a patent application see **Appendix 3**.

An overview of Trade Mark

A trade mark can be protected in Malaysia as an intellectual property right either by registration under the **Trade Marks Act 1976** or by common law provided the owner of such unregistered mark can show proof of goodwill and reputation in the use of the said mark in relation to his goods or services. Unlike an unregistered mark, the person registered as proprietor of a trade mark will have ease of proving ownership of the mark.

This Guide will focus on the protection of marks through registration under the **Trade Marks Act 1976** and **Trade Marks Regulations 1997**.

What is a trade mark/service mark?

It is any "sign", eg word, device, logo, label etc which serves to distinguish a trader's goods and services from those of other traders. However not all marks are capable of being registered. **Section 10 of the Trade Marks Act 1976** provides that in order for a trade mark to be registerable it shall contain or consist of at least one of the following particulars:

i. the name of an individual, company or firm or of some special or particular manner;
ii. the signature of the applicant for registration or of some predecessor in his business;
iii. an invented word or words;
iv. a word having no direct reference to the character or quality of the goods or services not being, according to its ordinary meaning, a geographical name or surname (eg DAIRY would be unregistrable for butter); or
v. any other distinctive mark.

The registration of a trade mark provides an organization with the right to exclusive use, license or sell goods and services under the mark in relation to goods and services for which it is registered. There is no maximum term for which a trade mark can be registered.

Unlike patent and registered designs, use of trade mark before filing does not prejudice an organization's rights to registration. However, early application for registration is encouraged as it is the first on the register who acquires the right.

Trade Mark Search

Remember that a business brand may be the herbal medicine business's biggest asset. The business should therefore consider registering its trade mark and even domain names. Once a mark is chosen for use in the herbal medicine business, it is strongly recommended that a search be conducted to determine whether it will conflict with any mark already registered or pending registration. This is to avoid an infringement action of the trade mark rights of others. Inspection of the Register of Trade Marks can be made at the Trade Mark Office located at the 32nd floor Menara Dayabumi Jalan Hishamuddin 50654 Kuala Lumpur during office hours upon payment of the prescribed fee.

Assuming that the mark is free for use, it would then be advisable to apply immediately to register the mark.

Understanding Trade Mark Registration Procedures

There is a formal registration procedure conducted in Malaysia by the Trade Mark Registry which results in a registration which can last indefinitely provided renewal fees are paid. A person who is neither domiciled nor resident in Malaysia has to file his trade mark through a trade mark agent.

There are 45 classes of goods and services of which 38 are classes of goods, and a mark may be registered in one or more of these classes. Identical marks can sometimes be registered in different classes when there is no risk of confusion (eg PENGUIN books and PENGUIN biscuits) but using the same trade mark in relation to the same or similar goods or services will attract an infringement action.

If a business is unsure whether its mark is registrable it may make an application to the Registrar for preliminary advice. The application for a preliminary advice is by way of submission of Form TM4 together with the prescribed filing fee.

Prior to filing a trade mark registration, it is prudent to conduct a search for any similar mark whether registered or pending registration. A search is normally conducted for the class of goods or services in which it intends to apply for its trade mark.

Procedures for applying to register a trade mark:

i. Form TM1 to be signed by the applicant if it has appointed a trade mark agent;
ii. Form TM5 (See **Appendix 4** for a sample of TM5) in five copies. A representation of the mark must be affixed to the form in the space provided but if the mark exceeds the space the representation should be mounted on a durable material and annexed to Form TM5;
iii. Payment of the prescribed filing fee; and
iv. A statutory declaration signed by the organization confirming it is the owner of the mark.

Each application shall be in respect to one class of goods or services.

The mark can be applied for registration in colour or in black and white. If a mark is limited to certain colours, the choice of colours will be taken into consideration for the purpose of determining distinctiveness. Where a mark is registered in black and white, it shall be deemed to be registered for all colours. If the mark is a word, it is usually best to register it in block capitals, which covers any type of print. If a word is registered in a particular print or in a stylized form, the registration is centred on that form.

Once an application has been filed at the Trade Mark Registry it is examined, and if found acceptable it is advertised to give third parties the opportunity to oppose. Assuming there is no opposition to the application, such mark is then registered for 10 years calculated from the date of filing the application and thereafter can be kept in force indefinitely by renewal at intervals of 10 years.

Prosecution Cost

The Intellectual Property lawyer's fees/trade mark agent's initial fees associated with the preparation of a trade mark application is approximately RM1,000 and would increase with the stages of the application. Once the application is filed there are a number of other costs associated with the prosecution, see **Appendix 5** for an extract of the relevant current filing fees.

Flowchart of Trade Mark Application

For an overview of the steps forming a trade mark application see **Appendix 6.**

An overview of Industrial Design

The shape, configuration, pattern or ornamentation of a manufactured good, for instan containers, bottles may be protected under the **Industrial Designs Act 1996.** In short, anythi that is pretty and has an aesthetic value should be protected.

The application for registration of industrial design is governed by the **Industrial Designs A 1996** and **Industrial Designs Regulations 1999** which came into force on 1st September 1999.

"Industrial designs" is defined under **Section 3 of the Industrial Designs Act 1996** as features shape, configuration, pattern or ornamentation applied to an article by any industrial proc or means, being features which in the finished article appeal to and are judged by the eye, b does not include

i. a method or principle of construction;
ii. features of shape or configuration of an article which
    - are dictated solely by the function which the article has to perform; or
    - are dependent upon the appearance of another article of which the article intended by the author of the design to form an integral part.

To be registrable an industrial design has to be new **(Section 12 of the Industrial Designs A 1996).** As in the case of patent, the industrial design must not be disclosed to the pub anywhere in Malaysia prior to filing for registration.

Industrial Design Search

Searches on the Register of Industrial Designs can be conducted at the Industrial Desig Registration Office located at 32nd floor Menara Dayabumi Jalan Hishamuddin 50654 Ku Lumpur during office hours upon payment of the prescribed fee.

Understanding Industrial Design Registration Procedures

An application for registration of an industrial design shall be made by submitting t following to the Industrial Designs Registration Office

i. ID Form 1 (See **Appendix 7** for a sample of the ID Form 1);
ii. six copies of the representation of the article to which the industrial design is applie
iii. a statement of novelty; and
iv. the prescribed filing fee.

If an application is filed pursuant to any international treaty eg **PARIS CONVENTION** and contains a declaration claiming priority of an earlier application ("priority application"), the priority date, of the application, for purposes of determining novelty, shall be the date of filing of the priority application **(Section 17(2) of the Industrial Designs Act 1996).**

Prosecution Cost

The Intellectual Property lawyer's fees associated with the preparation of an industrial application vary depending on the complexity of the industrial design. The relevant current filing fees for an industrial design application is set out in **Appendix 8.**

Flowchart of Industrial Design Application

For an overview of an Industrial Design application procedure see **Appendix 9.**

An overview of Copyright

The **Copyright Act 1987** outlines the nature of works eligible for copyright, the scope of protection and the manner in which the protection is accorded. Copyright is a property right that accords protection to the expression of an idea but not the idea itself. It seeks to protect a work from being used without the consent of the owner.

The types of works protected by copyright in Malaysia **(Section 7 of the Copyright Act 1987)** are

i. literary works;
ii. musical works;
iii. artistic works;
iv. films;
v. sound recordings; and
vi. broadcasts.

However copyright protection shall not extend to any idea, procedure, method of operation or mathematical concept **(Section 7 (2A) of the Copyright Act 1987).**

Copyright protection occurs automatically upon creation i.e. when an expression is first reduced to writing or other permanent medium. Copyright requires no formal registration.

The author of a work is the first owner of any copyright in it. The author, for this purpose, is the person who actually carries out the work/supplies the knowledge or skill by which the work is copyright but if the author creates the work in the course of his employment duties then the first owner is his employer.

Where the copyright work is produced by the collaboration of two or more authors for which the contribution of each author is not distinct from that of the others, it will be a work of joint ownership.

Derivative works are protected as original works **(Section 8 of the Copyright Act 1987).** Example of derivative works are translations, adaptations, arrangements and other transformations of works eligible for copyright and collections of work eligible for copyright which, by reason of the selection and arrangement of their contents, constitute intellectual creations.

Copyright does not subsist in any design which is registered under the **Industrial Designs Act 1996.**

An overview of Confidential Information/Trade Secret

Confidential information such as a formula, pattern, compilation, program, data, device, method, techniques or process that derives independent economic value from not being generally known to other persons i.e. having commercial value, may be protected against breach of confidence or breach of fiduciary duty. Because there is no statutory protection reasonable steps must be taken to keep the information secret, for instance imposing the obligations of confidence without which the protection is lost. Thus, a business should enter into a Confidential Agreement with a third party when its disclosing confidential information of know-how to it. This is particularly important if the business plans to patent any of its technology.

Trade secret protection is most appropriate for a technology that is unlikely to be discovered or duplicated by anyone else because it is so specific to a particular process or product.

B.2b International Intellectual Property Protection System

There is the global protection system. Treaties such as the **PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, PATENT COOPERATION TREATY (PCT), COMMUNITY PATENT CONVENTION** define internationally agreed basic standards of Intellectual Property protection in each country. However Malaysia is currently only a member of the **PARIS CONVENTION.**

Malaysia joined the **PARIS CONVENTION (International Union 1883 1967)** on 1 January 1989, an act which brings Malaysia at par with international standards in relation to the protection of industrial property.

In terms of patent protection **PARIS CONVENTION** ensures that one international registration or filling will have effect in any of the relevant signatory States thereby reducing the complexity of applying for overseas patent protection. **Article 2(1)** requires signatory States to accord national treatment to nationals of other signatory States which means each member country must grant the same right to nationals of other signatory States as it grants to its own nationals. Another notable provision is the **Convention Priority (Article 4A-C),** which allows the filing date of a Malaysian patent application to be used to establish priority for corresponding patent applications made overseas within the following twelve (12) months. **PARIS CONVENTION** also provides reciprocal protection of industrial property, inter alia, industrial design to its members. Any person who has filed an application for an industrial design in one of the signatory States shall have for the purpose of filing in the other signatory States a right of priority of six (6) months.

Soon, Malaysia will become a member of the **PATENT COOPERATION TREATY (PCT)**, which will provide a simpler way of commencing patent applications in a number of countries simultaneously unlike the **PARIS CONVENTION** whose procedures involve considerable duplication and expense.

Aside from Intellectual Property Rights Protection Treaties, there are also internationally agreed trade rules for Intellectual Property Rights, for instance the **Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS)** to which Malaysia is a signatory. **TRIPS Agreement** sets out the minimum standards of protection to be incorporated and enforced by each member country for each of the main areas of Intellectual Property, such as the scope of subject matter that is to be protected, the rights to be conferred, exceptions to those rights and the minimum duration of protection of those rights.

B.3 Exploitation of Intellectual Property

Given the high cost of development and testing of herbal medicine a business would naturally expect a return on its investment. To ensure commercial returns from its Intellectual Property it should have a sound Intellectual Property protection strategy and once the Intellectual Property protection has been secured, manage its Intellectual Property Rights well.

B.3a Common Forms of Exploitation

Usually exploitation of Intellectual Property begins at home but a business may also wish to take its Intellectual Property to the global market in which case it is recommended that it seeks international protection. As it is costly to file for protection in every country the organization will have to identify the key markets to protect its Intellectual Property.

Commercialisation of Intellectual Property generates income for a business and it commonly takes the form of:

i. an assignment of the Intellectual Property, the effect of which is that all its rights interest and title in its Intellectual Property is transferred for a one-off payment. Assignments of Intellectual Property should be formalized by way of written agreement; or
ii. licensing of the Intellectual Property Rights, the effect of which is that the owner will retain ownership of its Intellectual Property but will allow the licensee to use (but not own) its Intellectual Property Rights for a license fee and royalties. In a licensing arrangement the owner may place limitations and obligations on the licensee, for instance controlling the use; geographical extent; royalty payments etc; or
iii. cross-licensing Intellectual Property Rights in research areas; or
iv. undertake a joint venture/co-operative arrangement to exploit the Intellectual Property; or
v. self manufacture.

Which exploitation route to follow will depend on the nature of the Intellectual Property, the market condition, the organization's financial position and resources. To assist it in deciding which exploitation route to follow, it is recommended that it does an assessment of both the current and potential income to be generated by each of these routes.

B.3b Compliance Programme

In order to benefit from the innovation whether old or new, a Compliance Programme should be developed to ensure that the organization's liability to the other contracting party and regulatory authorities are avoided or minimized. There are two aspects of compliance, namely contractual and statutory, relating to the registration (and renewal) of herbal medicine and Intellectual Property Rights.

B.3b (i) Contractual Compliance

It is inevitable that an organization will have to enter into more than a few contracts in the process of exploiting its Intellectual Property. Signing the contracts per se does not guarantee it of the rewards promised in the contracts. It has to device a system to ensure that the other party to the contracts complies fully with the terms and conditions therein. It is also prudent to formulate a 'remedy strategy' in advance in order to minimize the losses and damages to it in the event the other party breaches the contracts.

When legal remedy is being sought for breach of contract, generally the party suing bears the burden of establishing that it is entitled to the relevant legal protection.

B.3b (ii) Statutory Compliance

In addition to contractual compliance, statutory non-compliance will attract penalties.

Apart from the **Patent Act 1983, Trade Marks Act 1976, Industrial Designs Act 199(** **and Copyright Act 1987** there are other relevant laws relating to herbal medicine which require legal compliance. The following laws regulate the production and sale of herbal medicines:

i. **Dangerous Drugs Act 1952** which regulates the cultivation, production possession, sale and distribution of raw opium, coca leaves, poppy-straw and cannabis. A herbal medicine business must ensure that the herbal medicine manufactured or distributed by it does not contain any form of dangerous drugs as set out in the **First Schedule of the Dangerous Drugs Act 1952.**

ii. **Poison Act 1952** regulates the dealing in poisons, including but not limited to importation, manufacture and sale of poisons set out in the **First Schedule** "Poison" has been defined as any substance specified in the Poisons List and includes any natural substance containing such substance. If the herbal medicine contains any poison in its natural form or otherwise the provisions of the **Poison Act 1952** will apply.

iii. **Sale of Drugs Act 1952** regulates the sale of any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on human or any animal, whether internally or externally, for medicinal purposes and "medicinal purposes" includes, inter alia, controlling body weight and the general maintenance or promotion of health or well-being. Accordingly the **Sale of Drugs Act 1952** regulates the sale of specific herbal medicine.

iv. **Medicine (Advertisement and Sale) Act 1956** prohibits advertisements which are calculated to lead to the use of the article as a medicine for the purpose of treatment or prevention of diseases or conditions of human beings unless such advertisement has been approved by the Medicine Advertisements Board. A herbal medicine business is cautioned not to make any claims that its herbal medicine may treat or prevent diseases or conditions of human beings unless such advertisement has been approved by the Medicine Advertisements Board.

v. **Control of Drugs and Cosmetics Regulations 1984.** The Drug Control Authority (DCA) was formed under the **Control of Drugs and Cosmetics Regulations 1984.** DCA is responsible for the registration of pharmaceutical products, traditional medicines, and cosmetics. Herbal medicines are therefore registrable with DCA. The registration process carried out by DCA which is located at Jalan University 46730 Petaling Jaya is briefly discussed in the following paragraphs.

Registration with Drug Control Authority (DCA ")

Regulation 7(1)(1) of the 1984 Regulations requires that all products to be registered with the DCA prior to being manufactured, imported, sold or supplied, unless the product is exempted under the specific provisions of the **1984 Regulations.**

A 'product' as defined in the **1984 Regulations** means 'a drug in a pharmaceutical dosage form or a cosmetic, having a singular identity, composition, characteristics and origin'.

The following herbal medicines and pharmaceutical products used in herbal medicines practice are registrable with DCA:

- Pharmaceutical products containing essentially of chemical therapeutic substances but are used in herbal medicines practice (e.g. methyl salicylate).
- Herbal medicines containing combination of natural substances of plant, mineral or animal origin in the unextracted or crude extract forms with vitamins or other chemical therapeutic substances (e.g. paracetamol, acetylsalicylic acid, methyl salicylate etc.). These do not include homeopathic medicines and external herbal medicines containing combinations with one or more of the following substances camphor, menthol, and essential oils.

Further details can be found in DCA's **Guidelines for Application for Registration of Pharmaceutical Products (Containing Scheduled Poisons and Non-Scheduled Products).**

In addition,

- Pharmaceutical dosage forms containing natural substances of plant, mineral or animal origin in the unextracted or crude extract forms.
- Substances which can be accepted as excipients in oral herbal medicines.
- Homeopathic medicines.
- External herbal medicines containing combinations with one or more of the following substances camphor, menthol, and essential oils such as clove oil, nutmeg oil, eucalyptus oil, etc.
- Dietary and health products containing solely natural substances of plant or animal origin in unextracted or crude extract forms.

Further details can be found in DCA's **Guidelines for Application for Registration of Traditional Medicines.**

Effect of Registration With DCA

A registration number will be given for every herbal medicine registered with DCA. The Registration Number is specific for the herbal medicine registered with the name, identity, composition, characteristics, origin and holder of registration certificate as specified in the registration documents.

Registration with DCA only allows the herbal medicine business to manufacture, import, sell or supply the herbal medicine. It does not protect its Intellectual Property Rights related to that herbal medicine.

Patent and DCA Registration

The DCA will register products covered by patent rights in Malaysia to the patent owner. Where the patent owner is foreign, registration will be in the name of the local firm authorized by the patent owner.

It follows, if a herbal medicine business has successfully patented a particular type of herbal medicine in Malaysia or is authorized by a foreign patent owner to register their herbal medicine, no other party will be able to register that herbal medicine with DCA and accordingly, no other party is entitled to manufacture, import, sell or supply the same in Malaysia.

Patent, Trade Mark, Industrial Design Renewal

In order to continue to enjoy statutory protection for the Intellectual Property the organization's Compliance Programme should keep track of the remaining period of statutory protection and ensure that its application for renewal together with its payment of the prescribed fees are made to the relevant registry before the expiry date.

The period of protection are as follows:

i.	Patent	:	20 years subject to annual renewal.
ii.	Trade mark	:	10 years and may be extended for a period of 10 years from the date of expiration of the original registration or the last renewal of registration.
iii.	Industrial design	:	5 years and may be extended for two further consecutive terms of 5 years each.

ACTION POINTS

Intellectual Property affects a herbal medicine business. To successfully make the Intellectual Property work for it, it should have a sound Intellectual Property Rights policy aligned with its business strategy. This would mean putting its Intellectual Property Rights policy in a strategic framework aiming at optimizing the overall return from innovations. Such a policy should address the following issues:

- the development of internal procedures to support Intellectual Property creation activities;
- the development of processes to identify, analyse and evaluate your its Intellectual Property and their associated Intellectual Property Rights which is part of an Intellectual Property Audit;
- the conduct of a Legal Risk Management review;
- the review of commercialization potential, both locally and globally;
- the review of the current support system in an organization (administrative, legal support).

Remember, an earlier treatment of Intellectual Property Rights issues avoids the appearance of problems later on.

Appendix 1
- - *Request For Grant of Patent Form*

Patents Form No. 1 PATENTS ACT 1983 REQUEST FOR GRANT OF PATENT (Regulation 7(1)) To: The Registrar of Patents Patent Registration Office Kuala Lumpur Malaysia	**For Official Use** APPLICATION RECEIVED ON: ..... Fee received on: ..... Amount: ..... * Cheque / Postal Order / Money Order / Draft / Cash No: .....
Please submit this Form in duplicate together with the prescribed fee.	Applicant's or Agent's file reference: .....

THE APPLICANT(S) REQUEST(S) THE GRANT OF A PATENT IN RESPECT OF THE FOLLOWING PARTICULARS:

I. TITLE OF INVENTION : .....

.....

II. APPLICANT(S) (the data concerning each applicant must appear in this box or, if the space is insufficient, in the space below)

Name: .....

I.C./Passport No.: .....

Address: .....

.....

Address for service in Malaysia: .....

.....

Nationality: .....

* Permanent residence or principal place of business: .....

.....

Telephone Number (if any)	Fax Number (if any)
.....	.....

Additional Information (if any)

* Delete whichever does not apply.

III. INVENTOR

Applicant is the inventor ☐ Yes ☐ No

If the applicant is not the inventor:

Name of inventor : .....

Address of inventor : .....

.....

A statement justifying the applicant's right to the patent accompanies this Form:

☐ Yes ☐ No

Additional Information (if any)

IV. AGENT OR REPRESENTATIVE

Applicant has appointed a patent agent in accompanying Form No. 17 ☐ Yes ☐ No

Agent's Registration Number: .....

Applicants have appointed .....

to be their common representative.

V. DIVISIONAL APPLICATION

This application is a divisional application ☐

The benefit of the filing date ☐ ☐ priority date

of the initial application is claimed inasmuch as the subject matter of the present application is contained in the initial application identified below:

Initial Application No. : .....

Date of filing of initial application : .....

VI. DISCLOSURES TO BE DISREGARDED FOR PRIOR ART PURPOSES

Additional information is contained in supplemental box

(a) Disclosure was due to acts of applicant or his predecessor in title ☐

Date of disclosure: .....

(b) Disclosure was due to abuse of rights of applicant or his predecessor in title ☐

Date of disclosure: .....

A statement specifying in more detail the facts concerning the disclosure accompanies this Form ☐ Yes ☐ No

Additional Information (if any)

VII. PRIORITY CLAIM (if any)

The priority of an earlier application is claimed as follows:

Country (if the earlier application is a regional or international application, indicate the office with which it is filed) :

.....

Filing Date : .....

Application No. : .....

Symbol of the International Patent Classification:

If not yet allocated, please tick ☐

The priority of more than one earlier application is claimed:

☐ Yes ☐ No

The certified copy of the earlier application(s) accompanies this Form:

☐ Yes ☐ No

If No, it will be furnished by ..... (date)

Additional Information (if any)

VIII. CHECK LIST

A. This application contains the following:

1.	request	
2.	description	..... sheets
3.	claim	..... sheets
4.	abstract	..... sheets
5.	drawings	..... sheets
	Total	..... sheets

B. This Form, as filed, is accompanied by the items checked below:

(a)	signed Form No. 17	☐
(b)	declaration that inventor does not wish to be named in the patent	☐
(c)	statement justifying applicant's right to the patent	☐
(d)	statement that certain disclosures be disregarded	☐
(e)	priority document (certified copy of earlier application)	☐
(f)	cash, cheque, money order, banker's draft or postal order for the payment of application fee	☐
(g)	other documents (specify)	☐

IX. SIGNATURE ....

*(Applicant / Agent) (Date)

If Agent, indicate Agent's Registration No. : .....

For Official Use

1. Date application received: .....

2. Date of receipt of correction, later filed papers or drawings completing the application :

.....

* Type name under signature and delete whichever does not apply.

Appendix 2

- - An Extract of the Filing Fees In Respect of A Request For Grant of Patent

All application or requests lodged shall be accompanied by the relevant forms and the prescribed fees as listed below:

MATTER/PROCEEDING	CORRESPONDING FORMS	FEE (RM)
(a) Request for grant of patent (b) Claims: (i) for first ten claims (ii) for every additional claim	1	200.00 Nil 10.00 (per claim)
Request for substantive examination	5	700.00
Request for modified substantive examination	5A	450.00
Request to amend Register	5D	50.00
Request for reinstatement of lapsed patent	5E	100.00
Application for recording of assignment or transmission	6	100.00
Application for entry in Register that any person may obtain a licence	7	50.00
Application for cancellation of entry in Register that any person may obtain a licence	8	50.00
Application for recording of particulars of licence contract in Register	9	100.00
Application for recording expiry or termination of licence contract in Register	10	75.00
Request to amend application for grant of patent	16	50.00
Request to amend patent	16A	50.00
Furnishment of address for service	20	100.00
Request for extension of time	21	200.00

Other Fees

MATTER/PROCEEDING	FEE (RM)
Copy of patent	30.00
Copy of search report	20.00
Examination of Register	10.00 hour
Certified extract from Register	10.00 per page
Photocopy of extract from Register	2.00 per page
Inspection of file relating to patent or patent application	10.00 hour
Certified extracts from file relating to patent or patent application (a) for first five pages (b) for every additional page	10.00 per page 2.00 per page

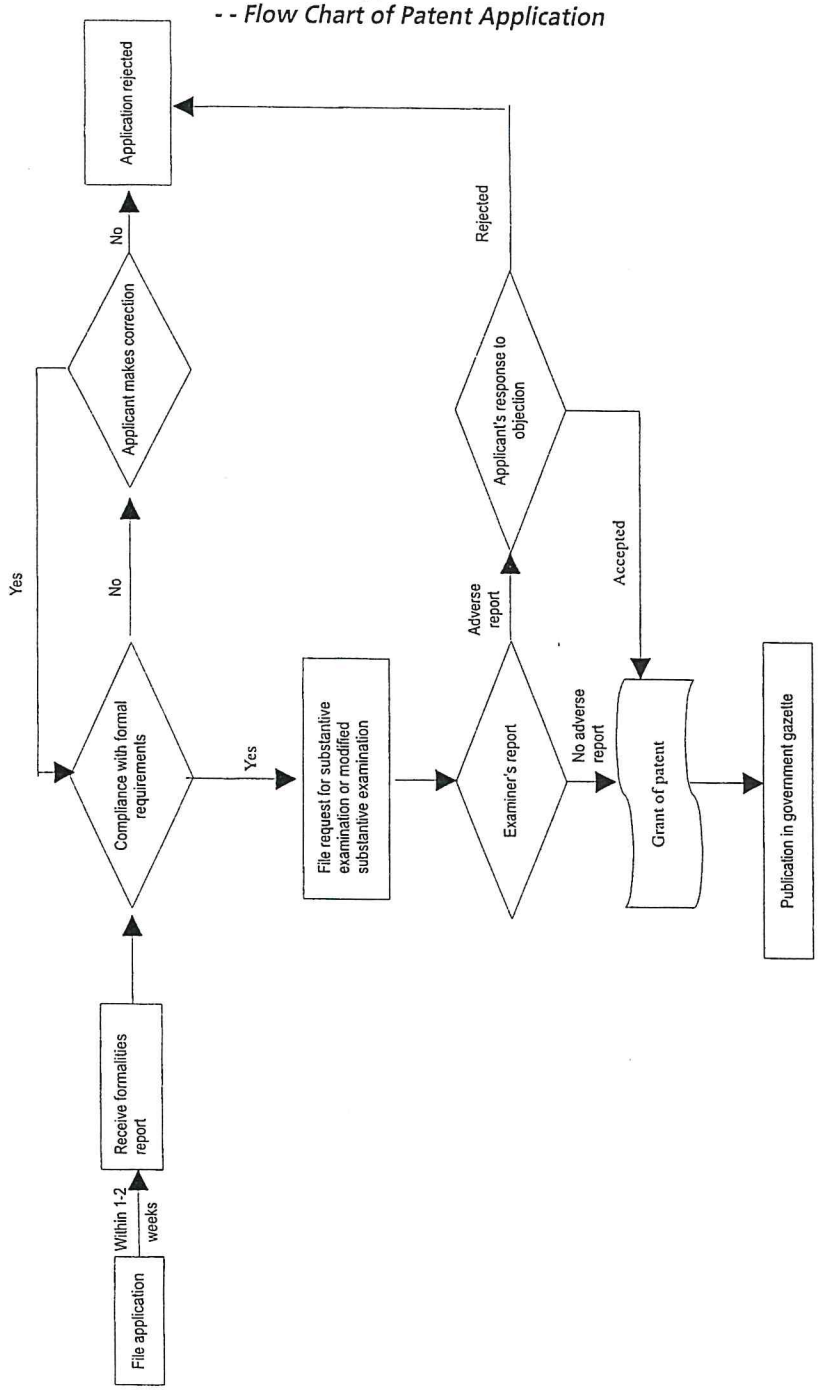
Annual fee for patent:

(a) for second year after grant of patent	200.00
(b) for third year after grant of patent	250.00
(c) for fourth year after grant of patent	300.00
(d) for fifth year after grant of patent	350.00
(e) for sixth year after grant of patent	400.00
(f) for seventh year after grant of patent	450.00
(g) for eight year after grant of patent	500.00
(h) for ninth year after grant of patent	550.00
(i) for tenth year after grant of patent	600.00
(j) for eleventh year after grant of patent	650.00
(k) for twelfth year after grant of patent	700.00
(l) for thirteenth year after grant of patent	800.00
(m) for fourteenth year after grant of patent	900.00
(n) for fifteenth year after grant of patent	1000.00
(o) for sixteenth year after grant of patent	1200.00
(p) for seventeenth year after grant of patent	1400.00
(q) for eighteenth year after grant of patent	1600.00
(r) for nineteenth year after grant of patent	1800.00
(s) for twentieth year after grant of patent	2000.00

Provide that the duration of a patent shall not exceed twenty years from the filing date of application.

Surcharge for reinstatement	100% fee for year concerned
Surrender of patent	60.00
Holding of hearing	100.00
Certificate of grant of a patent	150.00
Appeal against examination results	200.00 per subject
Extension of time (for every month or part of a month)	50.00 per month
Surcharge for late payment of annual fee	100% of fee for year concerned
Public search through computer	20.00 per hour
Computer print-out (bibliography data)	5.00 per page
Permitted information (upon request).	100.00 for less than 10 pages and; 5.00 for the subsequent pages

Appendix 3
- - Flow Chart of Patent Application



Appendix 4
- - *Application For Registration of Trade Mark*

INTELLECTUAL PROPERTY DIVISION – TRADE MARK

TRADE MARK REGISTRY

TM 5

TRADE MARKS ACT 1976

TRADE MARKS REGULATIONS 1997

APPLICATION FOR REGISTRATION OF A MARK
(Subregulations 18(1))

Application is hereby made for the registration of a:

Trade mark ☐ defensive trade mark ☐

Certification trade mark ☐

Note: Please tick the box appropriate to the kind of mark for which registration is desired.
In the case of a trade mark, a copy of oath, sworn statement or statutory declaration by the applicant are true must be attached.
In the case of a certification trade mark a copy of the rules governing its use must be attached.
In the case of defensive trade mark a copy of the statement of case by a statutory declaration, must be attached.

In part [A] of the Register

(Five (5) copies of this Form must be enclose with the application)

2. Representation of mark:

Note: If the space provided is sufficient, the representation may be made on a separate sheet which must be firmly annexed to this Form.
If the application is for series of trade mark under Section 24 a representation of each mark in the series must be given.
Representation must be clear and durable and comply with regulation 34.
If the mark is coloured and to be limited accordingly, please tick this box: ☐

3. List of goods or services: 4. Class: ☐

Goods or services falling within more than one international class must be subject of separate applications. Continue on a separate sheet if necessary.

5. Limitations, etc:

Insert below any condition, disclaimers or other limitations to which the registration will be subjected to. If the mark contains or consists of a word in non-Roman characters or in language other the English language or the national language a certified transliteration and translation as appropriate must be provided.

6. Full name and address of applicant:

If the applicant resident abroad, an address for services in Malaysia must be provided.

7. Full name and address of agent (if any):

If this is the address for services and is not already on record, Form TM1 must be filed with this Form.

8. Agent's registration no. (if known):

9. Agent's own reference:

10. International Convention priority Claim:

If priority date is claimed under International Convention or bilateral arrangement, please give details below and attach the document.

Convention country: _____ Priority date claimed: _____

11. Date of first use of the mark in Malaysia (if any):

12. Declaration: I/We claim to be the bona fide proprietor of the mark whose registration is applied for and, where the mark has not been used in Malaysia, that the application is made in good faith and that I/We/are entitled to be registered as the proprietor.

An agent signing this Form on behalf of the applicant must satisfy himself as to the truth of the declaration.

Signature: _____

Name of signatory (in block letter): _____

Date: _____

If the applicant is a partnership, the full names of all the partners must be stated.

Appendix 5

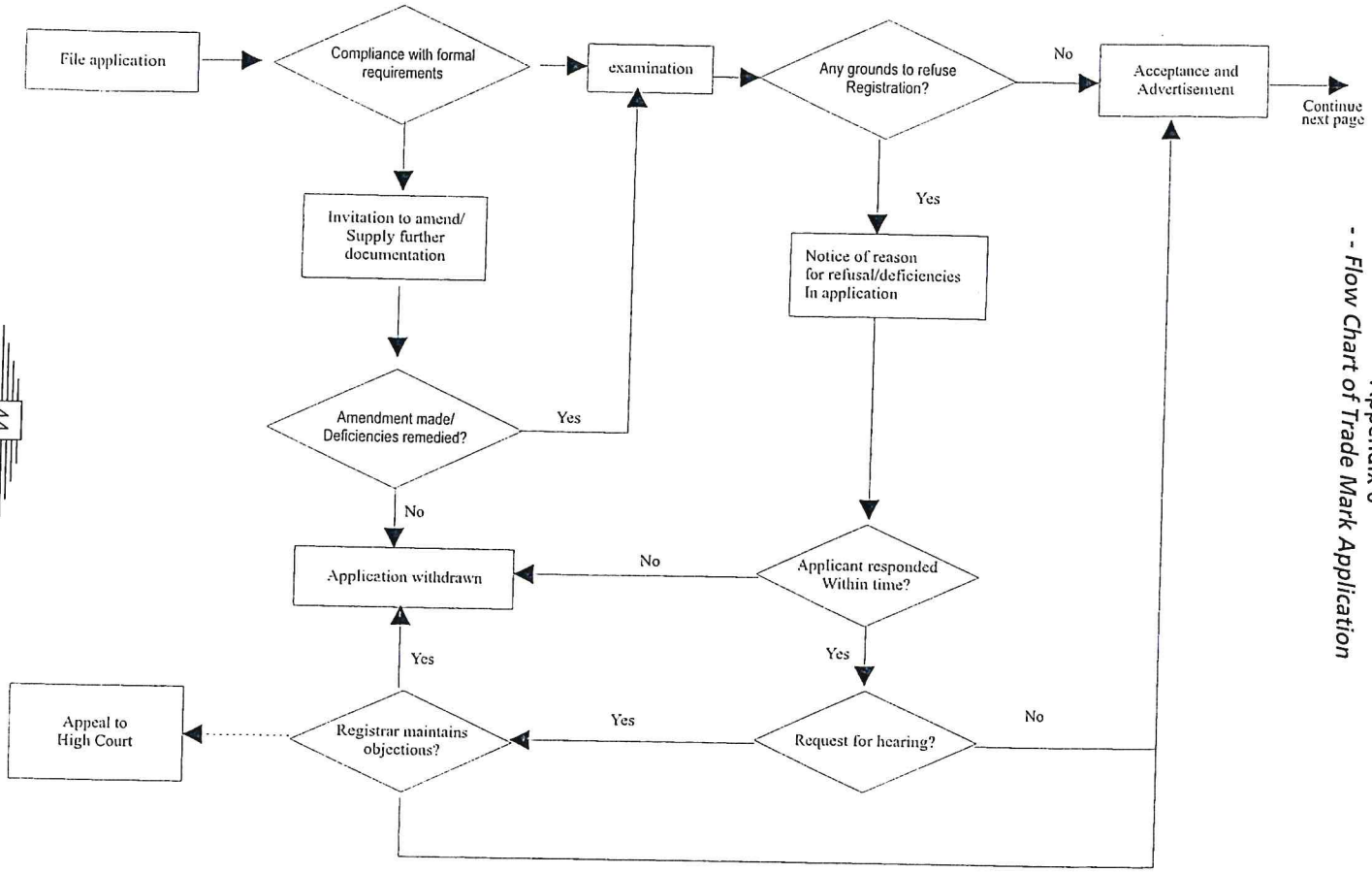
-- An Extract of Filing Fees In Respect of Registration of Trade Mark

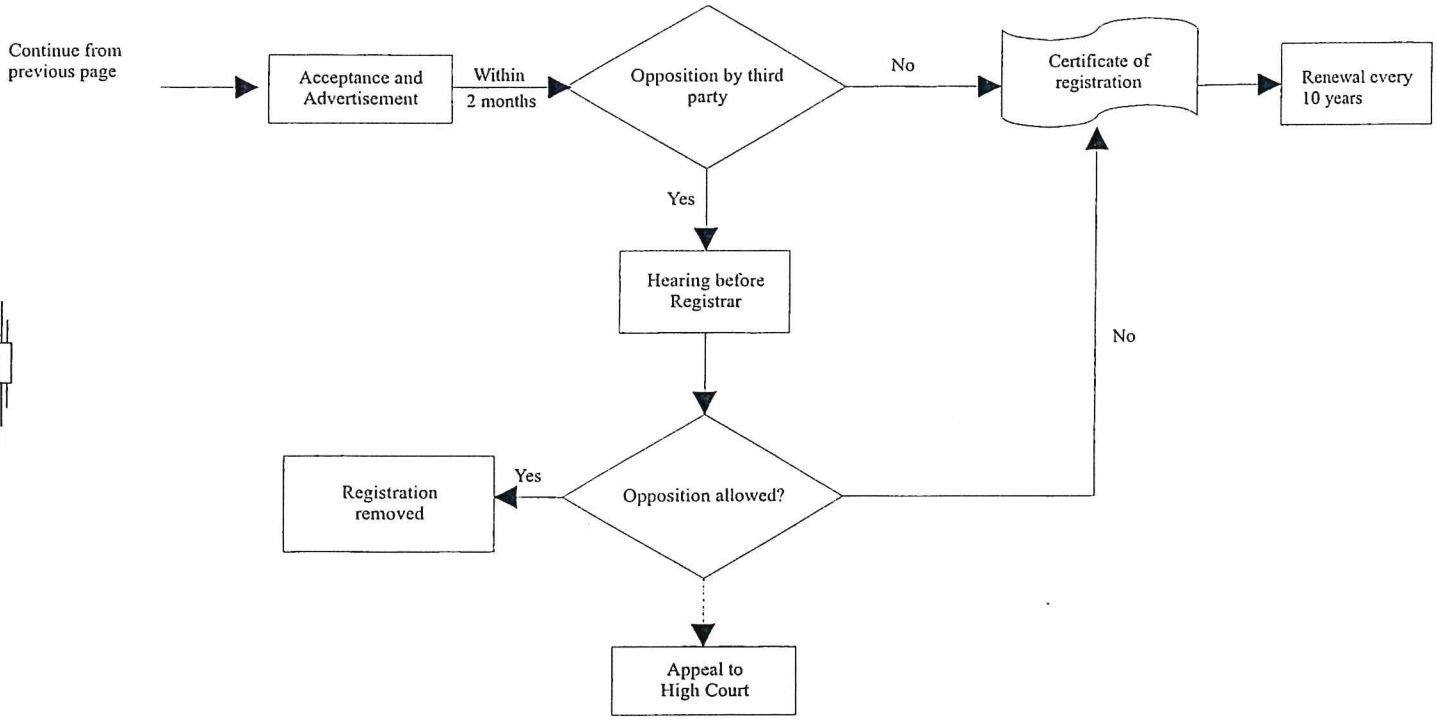
INTELLECTUAL PROPERTY DIVISION
RELATED FORMS AND RELEVANT FEES PAYABLE

FORM	MATTERS OR PROCEEDINGS	FEE (RM)
TM 4	Request for Registrar's preliminary advice as to registrability of a mark	100.00
TM 4A	Request for search	250.00
TM 5	Application for registration of a mark	250.00
TM 6	Request for statement of grounds of decision	500.00
TM 7	Notice of opposition	450.00
TM 8	Counter statement to a notice of apposition	300.00
TM 9	Notice to the Registrar of attendance at hearing	480.00
TM 11	Application to dissolve the association between a registered trade mark and other registered trade mark(s)	120.00
TM 12	Application for renewal of registration of a trade mark	420.00
TM 13	Application for late renewal of registration of a trade mark	630.00
TM 14	Application for restoration and renewal of registration	670.00
TM 15	Application and declaration of an assignment/a transmission for registration as proprietor of trade mark	180.00
TM 17	Request by registered proprietor of a registered trade mark for making, canceling or varying of an entry in the Register	100.00
TM18	Request by registered proprietor of a registered trade mark to strike out goods or services	100.00
TM21	Application of opposition to an application for an addition to or alteration of the registered trade mark	120.00
TM22	Notice of opposition to an application for addition to or alteration of registered trade mark	480.00

TM24	Application for variation of cancellation of the registration of a registered user	150.00
TM25	Request for Registrar's certificate other than certificate of registration	100.00
TM26	Request for correction of a clerical error in an application or for permission to otherwise amend an application for registration	100.00
TM29	Advertisement for registration	450.00
	OTHER FEES REQUIRED UNDER THE ACT	
1.	Request for copy of office document and manuscript: Certified extract from Registrar Non-certified extract from Registrar Computer print out	10.00 per page 5.00 per page 5.00 per page
2.	Request to conduct public search	10.00 per hour

Appendix 6 - - Flow Chart of Trade Mark Application





Appendix 7

- - Application for Registration of An Industrial Design

ID FORM 1
MINISTRY OF DOMESTIC TRADE
AND CONSUMER AFFAIRS, MALAYSIA

Industrial Design Act 1996
Industrial Designs Regulations 1999
(section 14 and Regulation 5)

INTELLECTUAL PROPERTY DIVISION,
Industrial designs Registration
Office

Application for registration of an Industrial Design
(see the notes on the back of this Form)

Application number: (For official use only)

1. Full name and address of/each applicant:
(Names of individuals including all partners in a firm shall be given in full. Underline the surname or family name. For a corporate body, give its company name)

If the applicant is a corporate body, give country/state of incorporation.

2. Full name and address of the author:

3. Name of agent (if applicable):

Address for service in Malaysia to which correspondence should be sent

4. Name the particular article or set of articles to which the design applies:

5. Classification:

Enter the class/subclass number in accordance with the International Classification for Industrial Designs.

6. Multiple application:

Enter the number of industrial design applied for registration (if any):

7. Association:

Enter the application number or registration number of the earlier design with which the applicant seeks association under section 23 and regulation 14.

8. Declaration of priority (if any): Give the convention country and filing date of any previous application made abroad from which priority is claimed under section 17	Country	Date of filing (day/month/year)

9. If the details in column 8 applies, and the previous application was not made in the name(s) given in column 1, give details of the instrument (for example, deed of assignment) which gives the applicant the right to apply for registration. Include appropriate name(s) and date(s).

(If this information is not given at the time this Form is filed, you must submit it before this industrial designs is registered

10.Divisional application: Give the number and filing date of any relevant earlier applicant whose filing date is claimed under section 20	Number	Date of filing (day/month/year)

11. Declaration: I/We apply to register the industrial design shown in the accompanying representation. I/We declare that I/We the applicant(s) who claim(s) to be the owner(s) of the design in relation to the article or set of articles specified in column 4 and to be the owner of any design right that exists in this industrial design, I/We also declare in respect of ant entry in column 8 that the application main in the convention country upon which the applicant relies is the first application made for registration of the design in a convention country.

(Delete whichever not applicable)

.....
Signature (s) Date

12. Name and telephone number of person to contact in Malaysia:

13. Checklist:

Make sure you have enclosed:
Representations of the industrial design (see note (c))
Any separate sheet of paper (See note (f))
The relevant fee (see note (g))

Notes:

(a) If you need help to fill in this Form or you have any questions, please contact the Industrial Designs registration Office at 03-22742100
(b) State your details in the column provided in capital letters using black ink or you may type them
(c) This Form should be accompanied by six identical representations (seven if application is for a set o articles) of the industrial design. Except in the case of an application for an industrial designs which applied to lace, textile article or wallpaper (or similar wall covering), a statement of the features of the industrial design for which novelty is claimed (a statement of novelty) should appear on each representation. In the case of representations which consists more than one sheet, the statement of novelty should only appear on the fist sheet. If it is impracticable for the statement of novelty to appear on a representations it may be given on a separate sheet of paper.
(d) If words, letters or numerals appear in the design, the Registrar will normally require a disclaimer of any right to their exclusive use to appear on each representation.
(e) If the column provided is insufficient, please continue on a separate sheet of paper and write "see overleaf". Any separate sheet of paper used should be attached to this Form.
(f) Different fees shall be payable according to whether the application relates to a single or multiple applications. For details of the fee(s) and ways to pay please contact the Industrial Designs registration Office, intellectual Property Division, Ministry of Domestic Trade and Consumer Affairs.

Appendix 8
- - *Filing Fees In Respect of Registration of Industrial Design*

RELEVANT PRESCRIBED FEES FOR INDUSTRIAL DESIGNS

Matters or proceedings	Fee(RM)	Form
1. Application to register an industrial design a) each design b) every additional design Rule 5	 400.00 200.00	1
2. Application for the extension of period of registration for 2nd period: a) each industrial design b) for additional industrial design for 3rd period: c) each industrial design d) for additional industrial design for each period of one month (not exceeding six months in total) (Regulation 23)	 600.00 300.00 800.00 400.00 100.00	2
3. Request to restore a registered industrial design (Regulation 24) Surcharge payable under subregulation 24(4): For each period of one month (not exceeding six months in total)	600.00 50.00	3
4. Notice of opposition to the restoration of an industrial design (Regulation 25)	50.00	4
5. Application to record the assignment, transmission or other operation of law to a registered industrial design or application for registration of an industrial design (Regulation 26)	200.00	5
6. Application for rectification of the Register or request for revocation of registration (Regulation 27)	100.00	6
7. Submission of a copy of an application to Court (Regulation 28)	Free	7
8. Notice of order of Court for rectification of the Register (Regulation 29)	100.00	8
9. Request for amendment of an application for registration of an industrial design or a registered industrial design (Regulation 30)	100.00	9
10. Appointment or change of address for service (Regulation 32 & 40)	30.00	10
11. Application for registration as an Industrial designs Agent (Subregulation 33(2))	1,000.00	11
12. Application for extension of registration as an Industrial Designs Agent (Subregulation 33(7))	400.00	12
13. Request for extension of time: a) for each period of one month (not exceeding three months in total) (Regulation 43)	200.00 50.00	13
14. Request for certified or uncertified copies of or extract from entries documents, etc a) for certified copy or extract b) for uncertified copy or extract (Regulation 45)	 10.00/page 5.00/page	14

Appendix 9
-- Flow Chart of Industrial Design Application