

Malaysia



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How do you get a patent in your jurisdiction?

Types of protection and eligibility criteria

Patents and utility innovations (UI) are available in Malaysia. The basic criteria for patentability are:

- novelty;
- inventive step; and
- industrial applicability.

Malaysian patent law has a worldwide novelty standard, qualified by a 12-month novelty grace period in respect of any public disclosures of the invention that originate from the applicant before the filing date of the Malaysian patent application. This period is calculated from the date of first disclosure and does not protect against third-party disclosures.

'Inventive step' is assessed based on obviousness to a skilled person.

An invention is considered capable of industrial application if it can be made or used in any kind of industry.

Unlike a patent application, the inventive step requirement does not apply to a UI application in Malaysia. A Malaysian UI application undergoes substantive examination much like a patent application, albeit with a lower registrability bar.

The application – process and costs

The cost, from filing to grant, for a smooth-sailing application with 10 claims or fewer and undergoing normal substantive examination can be less than \$2,000, including official fees. This is provided that only one examination report is issued and that no extensions of time become necessary.

It typically takes about four years for an application to proceed to grant. There are several options for expediting prosecution, namely:

- to request modified substantive examination;
- to request expedited examination;
- to participate in the Intellectual Property Corporation of Malaysia (MyIPO)-Japan Patent Office (JPO) Patent Prosecution Highway (PPH) pilot programme;
- to participate in the MyIPO-European Patent Office (EPO) PPH pilot programme; or
- to participate in the MyIPO-State Intellectual Property Office (SIPO) PPH pilot programme.

Modified substantive examination is a simplified examination process where the specification of the application is amended to adopt the specification of a relevant (ie, European, US, UK, Australian, Japanese or Korean) corresponding patent. It is atypical for an adverse examination report to issue following a request for modified substantive examination.

Allowance of the application can be expected within six to 12 months after the request.

A request for expedited examination can be filed once a request for normal examination has been submitted and the application has been published. The grounds on which expedited examination may be considered are:

- national or public interest;
- there is evidence of potential infringement or ongoing infringement proceedings;
- registration is a condition for obtaining grants from the government or recognised institutions;
- the invention has been or will be commercialised within two years of requesting expedition;
- the invention relates to green technologies; or
- other reasonable grounds.

Examiners prefer to base their decision to allow an application on the positive results of relevant (ie, European, US, UK, Australian, Japanese or Korean) corresponding patent applications and will seldom make a decision solely on the basis of technical or substantive arguments. Unless a suitable allowed or granted corresponding claimset is available, pursuing expedited examination will result only in the application being issued with an adverse examination report and, ultimately, returned to the normal prosecution track.

A request to participate in the MyIPO-JPO PPH pilot programme can be made on the basis of a corresponding Japanese or Patent Cooperation Treaty (PCT) application, which has received a positive patentability opinion from the JPO. Prosecution is significantly reduced to as little as four months under this programme, as opposed to between two and three years under normal examination. It is possible to obtain a grant within four to five months of filing provided that the request for normal examination and the request for participation in the PPH are filed simultaneously with the application.

A request to participate in the MyIPO-EPO PPH pilot programme can be made on the basis of a corresponding European or PCT application, which has received a positive patentability opinion from the EPO. The first office action (if any) can be expected within three months of requesting to participate in the PPH and a decision on grant is obtainable within six months of such a request.

A request to participate in the MyIPO-SIPO PPH pilot programme can be made on the basis of a corresponding Chinese or PCT application, which has received a positive patentability opinion from the SIPO. The first office action (if any) can be expected within three months of requesting to participate in the PPH and a decision on grant is obtainable within six months of such a request.



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Technology-based considerations (eg, software and pharmaceuticals)

Software inventions: There are various options for protecting software inventions in Malaysia provided that such inventions meet the statutory definition of an invention that is required to solve a technical problem. Data processing that does not involve a technical effect or advance will not constitute a patentable invention. Software inventions that are construed as a business method are not patentable as business methods are excluded from patentability.

According to MyIPO's patent examination guidelines, claims directed to computer programs *per se* or a computer program embodied on a carrier, regardless of its content, are not allowed. A computer program may be patentable if the claimed subject matter makes a technical contribution to the art (eg, program-controlled machines or program-controlled manufacturing processes).

Pharmaceuticals: Methods of treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body are excluded subject matter in Malaysia. MyIPO currently allows first and second medical use claims.

MyIPO examiners tend to adopt the approach of the EPO with regard to substantive matters concerning life-science inventions and are often guided by the relevant provisions of the European Patent Convention (EPC 2000) and the EU Biotech Directive (98/44/EC).

What are the major administrative procedures in your jurisdiction?

Appealing patent office decisions

The Patents Act provides that MyIPO cannot refuse a patent application without giving the applicant an opportunity to be heard. If written and/or oral submissions before and/or during a hearing are insufficient to overturn a decision, the applicant has the right to appeal an adverse decision to the High Court of Malaya.

“Many cases are now filed at the Kuala Lumpur High Court, which has a dedicated IP Court”

Third-party challenges – oppositions and invalidations

There are no formal provisions in Malaysian patent law for third-party intervention and examiners are under no obligation to consider prior art submitted by a third party. However, MyIPO examiners do take into consideration such documents if the application in question is still pending under examination.

Malaysian patent law does not provide for either pre-grant or post-grant opposition. The only avenue for recourse for an aggrieved party is instituting an invalidation proceeding before the High Court of Malaya.

Administrative enforcement options

Malaysian patent law does not provide for administrative enforcement options. A patent owner may enforce its rights only upon grant of the patent and by way of civil litigation. There are no criminal actions available for patent infringement.

How are patents enforced through the courts?

Key forums and their composition

There is no scope for forum selection. All IP suits must be initiated at the geographical location of the high court where the defendant resides or where the cause of action occurs – although many cases are now filed at the Kuala Lumpur High Court, which has a dedicated IP Court.

There is no jury panel in a civil litigation suit. A single judge sits in the court of first instance (high court). At appellate levels, there is a panel of judges comprising three judges in the court of appeal and usually five judges in the Federal Court. Although nine is the maximum number, it is rare for a patent appeal to require more than five judges in the Federal Court.

Trial flow – discovery, trial, witnesses, timing and cost

Patent litigation is begun by way of writ of summons where the applicable rules are the Rules of the Court 2012. The suit is commenced by way of a writ summons, sealed by the high court, enclosing a statement of claim. All applications for interim relief (eg, injunctions, Anton Piller orders and discovery orders in aid of the interim reliefs) can be applied for by way of notice of application supported by affidavits. These interim reliefs can be applied for *ex parte* and/or *inter partes*.

Upon service of the writ, the defendant may file its defence (and counter-claim if any). The plaintiff is entitled to file its reply (and defence to the counter-claim, if any). A defendant may raise invalidation proceedings as a defence against an infringement claim.

Once the pleadings are closed, the court fixes a date for case management whereby it will issue directions as to how the trial is to be conducted. The case-management practice and directions are generally uniform – although each judge has their own peculiar directions.

Once case-management directions are complied with, the court will fix full trial dates. The current practice is that the court will direct that evidence-in-chief be submitted via witness statements in the form of questions and answers. Thereafter, opposing counsel may cross-examine the witnesses; the party calling the witness then has the opportunity to re-examine. Examination-in-chief, cross-examination and re-examination is by way of oral testimony given under oath. Nonetheless, the court may direct that all evidence be submitted orally.

The stages and estimated timeframe for a patent litigation action are provided in Table 1.

Legal doctrines, available remedies and the appeals process

Doctrine of equivalents: Malaysian courts have adopted purposive construction to determine the

TABLE 1. Stages and estimated timeframe for a patent litigation action	
Stages of litigation	Estimated timeframe
<p>Stage one</p> <ul style="list-style-type: none"> • Commencement of suit. • Writ summons. • Statement of claim. • Service of cause papers. <p>Application for interim reliefs Injunction, Anton Piller and discovery.</p> <p>Ex parte order If the matter is urgent, clients may apply for an <i>ex parte</i> order (valid for 21 days).</p> <p>Inter partes order This order must be applied for whether or not an <i>ex parte</i> order has been applied for. The term is the same as the <i>ex parte</i> order (valid from the date of grant to disposal or completion of trial).</p> <p>Anton Piller order</p>	<p>Between one and two weeks, depending on the speed at which evidence is marshalled and the court issues the writ. Service of cause papers may take up to one month, depending on the availability of the defendant(s).</p> <p>Between one and three weeks, depending on available court dates.</p> <p>Between one and three weeks, depending on available court dates and directions.</p> <p>As above.</p>
<p>Stage two</p> <ul style="list-style-type: none"> • Subsequent pleadings. • Reply. • Defence to counter-claim (if any). 	<p>Within two weeks.</p>
<p>Stage three Pre-trial matters, applications and proceedings</p>	<p>Between three and nine months.</p>
<p>Stage four</p> <ul style="list-style-type: none"> • Preparation for trial. • Case management. • Brief. • Getting up. 	<p>Between three and 12 months (depending on the court's directions).</p>
<p>Stage five</p> <ul style="list-style-type: none"> • Trial (proper). • Refresher. 	<p>Depending on the court's free dates and directions.</p>
<p>Stage six</p> <ul style="list-style-type: none"> • Execution of judgment. • Assessment of damages. • Taxation of cost. 	<p>Depending on the court's free dates.</p>

scope and infringement of patent claims. To date, there has been no application of any doctrine of equivalents, though this may change if the UK Supreme Court's decision in *Actavis UK Limited v Eli Lilly and Company* is accepted as a persuasive precedent.

Remedies: The remedies must be pleaded in the statement of claim. The typical remedies that will be requested and granted are:

- permanent injunction;
- full discovery;
- delivery up;
- declarations;
- general and punitive damages (if any); and
- costs.

Permanent injunctions: It is common for courts to grant a permanent injunction but this must be

pleaded in the statement of claim. The injunction will be awarded if on the balance of probabilities the court finds that there has been infringement of the patent.

Damages: The principle of damages is to make good or replace the loss caused by the wrongful act. The following factors are used to assess damages:

- direct causation – the damages suffered arose as a direct consequence of infringement;
- evidence surrounding causation;
- market demand for the patented product;
- lack of comparable products; and
- plaintiff's or its licensees' ability to manufacture and market the product must be demonstrated.

Elements for calculating lost profits include:

- loss or diverted sales and increased expenditure caused by infringement;



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- potential or actual loss of profits attributable to past and present infringement; and
- profits likely to be lost in the future.

Punitive damages are known as exemplary damages in Malaysia. They must be specifically pleaded, with the facts being relied upon set out. The amount awarded is usually arbitrary. The factors taken into account for a plea in exemplary damages include:

- whether the defendant had deliberately infringed;
- whether the infringer knew of the plaintiff's registered rights;
- the extent of the defendant's business activities and financial position;
- the duration of the defendant's infringing activities; and
- the extent to which the defendant's infringing conduct offends the public sense of justice and propriety.

Expert witness: Expert witnesses are appointed to support the respective parties' contention (ie, either in the assertion of infringement or in the defence that there is no infringement). They usually comprise patent agents and persons skilled in the relevant art. Industry experts are encouraged and experts may come from foreign jurisdictions or within the country. The expert witnesses from each side will be subject to cross examination when giving testimony.

“There is no provision in Malaysian patent law that compels the patent owner to use or work their invention”

Appeals: The losing party has an automatic right to appeal; any appeal must be filed within 30 days of judgment. The grounds of appeal must be based on questions of law and not questions of fact. The appeal will normally take between 12 and 15 months to be heard. If an appeal goes all the way to Federal Court, it can take between two and three years for disposal.

How are patents commercialised in your jurisdiction?

Patent working requirements and pharma-specific rules

Working requirements: There is no provision in Malaysian patent law that compels the patent owner to use or work their invention. However, it does provide for the issuance of compulsory licences if:

- there is no production or application of the patented product or process in Malaysia without legitimate reason;
- there is no patented product produced in Malaysia for sale in the domestic market or there are some but they are sold at unreasonably high prices or do not meet public demand without legitimate reason; or

- the invention claimed in a patent cannot be worked in Malaysia without infringing a granted patent having an earlier priority date and if the invention of the later patent constitutes an important technical advance of considerable economic significance.

Additionally, Section 84 of the Patents Act provides for the government to allow the exploitation of a patented invention by a government agency or a third party in the following circumstances, predominantly for domestic market supply, without the consent of the patent owner but with adequate remuneration to it:

- a national emergency or where there is public interest, in particular, related to national security, nutrition, health or the development of vital sectors of the national economy; and
- a judicial or relevant authority has determined that the manner of exploitation by the patent owner or its licensee is anti-competitive.

Before the issuance of a decision under Section 84, the patent owner has the right to be heard together with any other interested party – if it so wishes. In addition, the patent owner may appeal any such decision issued by the government to the court.

Limitation of rights: On 1 August 2001 a limitation on patent rights – similar to Section 271(e)(1) of the US Hatch-Waxman Act – was introduced into the Malaysian Patents Act: “The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs.”

Inventor remuneration issues

Section 20 of the Patents Act provides that inventors are entitled to equitable remuneration if the invention acquires an economic value much greater than the parties concerned could reasonably have foreseen at the time of concluding the employment contract. There are no official guidelines for calculating equitable remuneration. If the terms of the employment contract do not dictate the compensation amount, the amount will be fixed by the courts.

It is possible for employers to have rights in an invention patent for free by virtue of the terms of an employment contract. However, the employee (inventor) can still seek compensation through the courts as Section 20 is not restricted by contract. **iam**

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