

PhAMA Position Paper

Protection and Enforcement of Pharmaceutical Patent Rights

Objective

To incorporate provisions for protection and enforcement of pharmaceutical patent rights into the current product registration process

Background

Based on the current legal system, registration of generic products is allowed while the innovator product is still under valid patent protection. However, the marketing of generic products way before the expiry of the patent term is subject to conditions stated in the Malaysian Patent Act 1983. Marketing of generic products is only legal upon patent expiry of innovative products. A patent is valid and enforceable until it expires or is invalidated by a court of law.

As seen in recent years, generic companies have started marketing their products in Malaysia, while the innovator product is still under valid patent protection. Citing cheaper costs and product approved by DCA (Drug Control Authority), customers turn to these generics; their actions are shielded due to the absence of any written guidance or procedure in purchasing generic drugs where innovator product is still patented. To the customer, patent issues are simply matters to be resolved between the patent holder and the generic company.

In such instances, this action seriously undermines the rights and confidence of research-based innovator companies, and will in the long term, compromise the ability of Malaysia to attract further investments by companies engaged in leading-edge research and innovation.

Legal recourse is available, whereby our member companies could institute legal proceedings against the generic company, but these often bring little or no comfort as the proceedings are often costly and time consuming. In addition, this presents a further drain on the already scarce judicial resources on such lengthy and technically complex disputes, with judgments coming close to, or even past, expiry of patent.

Recommendation

A balanced mechanism to ensure effective protection & practical enforcement of patent rights

Propose a balancing mechanism in product registration system to ensure adequate and effective protection of patent rights for the innovator holders, while allowing generic products to be marketed in Malaysia as soon as the innovator patent expires.

Benefits of protect and enforce pharmaceutical patent rights will:

- Avoid confusion caused by having infringing products marketed and then subsequently withdrawn from the market following an infringement ruling, which can adversely affect patients.
- Support rule of law principle, because it gives innovators security in knowing that their efforts in creating a new drug will be respected for the duration of the patent period.
- Uphold the Government's commitment towards providing intellectual property protection, as stipulated in the 9th Malaysian Plan and the Malaysia National Medicines Policy .
- Avoid complex litigation that may further drain resources at both the Government and industry end.

Proposed measures for implementation

Propose the following measures in product registration that can be implemented without burdening DCA or NPCB in patent interpretation. These are:

a) Self Declaration

A written declaration/certification to NPCB by the applicant seeking registration for a medicine that application for approval would not involve marketing of the product until the granted patent has expired or is invalidated before expiration.

To incorporate this requirement in the Malaysia Act (legal counsel to advise).

b) Notification from registration applicant to patent holder

Notice is given by the applicant directly to the patent holder/marketing company of the existence of an application that desires registration approval during the patent period.

If NPCB is informed by the innovator that there is a potential patent infringement/dispute of innovator's patent, registration application will be put on hold.

c) Clarification in Registration Approval Certificate

Propose a disclaimer be included in the registration approval certificate by NPCB, to indicate that registration approval does not mean a marketing authorization if the innovator product patent is still in force.

Conclusion

Under the Malaysia Intellectual Property Policy, Malaysia has given its commitment to the international community that intellectual property will be protected. This move is to support Malaysia's aspiration to position itself as the life sciences and research hub in the region.

Both innovator and generic industries contribute synergistically to the healthcare system in Malaysia. The innovator products provide breakthrough treatment options to the patients, whereas the generic products can be available to provide alternative treatment options once patent expires. The life blood of innovator product lies in the protection of intellectual property, given tremendous monetary and time investment for the innovation,

PhAMA acknowledges NPCB's recognition of the importance of intellectual properties in contributing to the national objective on promoting investment in innovation, cutting-edge research and development. As such, PhAMA would like to respectfully recommend the above mechanism to ensure adequate and effective protection of patent rights for the innovator pharmaceutical products, while allowing the generic products to be marketed in Malaysia as soon as the innovator patent expires.