

South Africa

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Selection, clearance and registration

South African trademark law is governed by the Trademarks Act (194/1993). Section 10 sets out the criteria for registering trademarks, including both absolute and relative grounds for refusal.

In addition, applicants for pharmaceutical trademarks should be aware of the regulatory environment for medicines in South Africa.

The Medicines Control Council (MCC) regulates medicines under the Medicines and Related Substances Control Act (101/1965) and regulations. All medicines in South Africa must be registered with the MCC and must include a proprietary name. Pursuant to this, the MCC publishes guidelines from time to time setting out criteria for registration.

One of the fundamental guidelines is that a proprietary name should not convey a misleading therapeutic or pharmaceutical

connotation. Any registration for a proprietary name which contains, for instance, the term 'Cardio' should be restricted to treatments for heart disease. In terms of Section 10(12) of the Trademarks Act, any trademark which is inherently deceptive or whose use would be likely to deceive, cause confusion or be *contra bonos mores* (contrary to good morals) shall be refused. It follows, therefore, that a trademark for pharmaceuticals which includes 'Cardio' should be refused if its specification is not appropriately restricted.

In this context, the MCC's guidelines on stems of international non-proprietary names (INNs) are also relevant. Section 3 (2) (5) of the guidelines requires that, "as a general principle, proprietary names should not be derived from an INN by deletion or alteration of any component part of the INN". There are exceptions to this general principle, but the salient point is that any trademark application for a proprietary name which contravenes this is potentially open to refusal under Section 10(12) as a mark which is *contra bonos mores*, on the

premise that the prevailing *mores* in respect of pharmaceuticals are dictated by the MCC.

Colour, shape and non-traditional marks are also problematic in the context of pharmaceuticals.

Section 1 of the Trademarks Act defines a 'mark' as any sign that is capable of being represented graphically, including a device, name, signature, word, letter, numeral, shape, configuration, pattern, ornamentation, colour or container for goods, or any combination of the aforementioned.

The pharmaceutical industry has recourse to a useful source of prescription medicines, the *MIMS Desk Reference*. In it can be found tablet and capsule identification charts with both colour and black and white photographs of numerous pills and capsules. Over the years, attempts have been made by pharmaceutical organisations to seek protection for a colour (or combination of colours) or the shape of a particular tablet or capsule.

Apart from the general principle that a trademark must be capable of

distinguishing the product it represents, which is difficult in the case of a single colour, any applicant for a single colour trademark is faced with the 'colour-depletion doctrine', which holds that there are only a limited number of colours available in certain spheres of industry. Section 10(11) of the act states that a mark which consists of a container for goods or the shape, configuration, colour or pattern of goods, where the registration of such mark will or is likely to limit the development of any art or industry, shall be refused. This section recognises the possibility that manufacturers of pharmaceutical capsules may be limited in the number of colours available that can be applied to the gelatin used in soft capsules. In this case the attempted monopolisation of a single colour, or even a combination of colours, could "limit the development of any art or industry".

Those seeking trademark protection for the shape of a tablet have encountered many difficulties, best illustrated in the landmark case *Beecham Group plc v Triomed (Pty) Limited* (2002 4 All SA 193 (SCA)). In this matter, a trademark registration for the shape of a tablet was attacked on numerous counts, including that the registration:

- did not constitute a trademark in terms of Section 10(1);
- consisted exclusively of a shape necessary to obtain a specific technical result in terms of Section 10(5); and
- consisted of a shape that was likely to limit the development of any art or industry in terms of Section 10(11).

The Supreme Court of Appeal found that the tablet's shape was necessary to obtain a specific technical result (ease of swallowing), but also canvassed the other two grounds with approval.

The question of technical necessity is a matter to be determined on the facts in each case, as is the issue in Section 10(11). However, Section 10(1) seems to pose a major obstacle to the registration of a tablet as a shape/colour trademark. Pharmaceuticals are selected primarily by name, particularly in the case of scheduled drugs which are selected by medical doctors or pharmacists, who are – the argument goes – unlikely to prescribe medication by reference to its shape or colour. It was countered in the *Beecham* case (*supra*) that patients distinguish their various medications by reference to shape or colour. However, the court dismissed this argument on the basis that the shape/colour in that context performed an identification role and was

not a badge of origin. The fact that pharmaceutical producers do not, as a rule, market their products with reference to shape and colour makes the registration thereof more difficult.

Parallel imports and repackaging

Unlike Europe, South Africa does not have a rich source of case law devoted to the repackaging of parallel imports. Instead, the courts are guided by specific guidelines issued by the MCC, as well as general principles flowing from the Trademarks and the Merchandise Marks Acts.

Parallel imports (or the doctrine of exhaustion of rights) in South Africa are exempt from trademark infringement by virtue of Section 34(2)(d) of the Trademarks Act, which holds that a trademark is not infringed by the import into or distribution, sale or offering for sale of goods to which the trademark has been applied by or with the consent of the proprietor thereof. Section 34(2)(d) confirms the common law first articulated in the Supreme Court of Appeal case *Protective Mining & Industrial Equipment Systems (Pty) Ltd v Audiolenz (Cape)* ((Pty) Ltd 1987 2 SA 961 (A)), where the proprietor of the PENTAX trademark sought to restrain an unauthorised licensee from importing genuine PENTAX cameras into South Africa. The attempted injunction failed on the grounds that the proprietor of the PENTAX trademark had implicitly authorised the use of the mark and could not unilaterally withdraw the right to do so.

The term 'genuine' implies 'unaltered' and the later case of *Television Radio Centre (Pty) Ltd v Sony Kabushiki Kaisha t/a Sony Corporation* (1987 2 SA 994 (A)) confirmed that parallel imported products adapted for South African use fell outside the exemption, since they were no longer genuine.

The Merchandise Marks Act (17/1941, as amended) prohibits both the application of a false trade description to any goods and the alteration of a trademark.

In line with all of the above, repackaging medicines is allowed within the following parameters:

- Any medicine may be imported if it is already registered in South Africa, provided that the importer obtains a permit. If the medicine is not registered in South Africa, the importer must do so and inform the owner of the proprietary medicine within 30 days of registration. Either way, the importer must inform the owner of its intention to parallel import four weeks before importation.
- The parallel importer may use the proprietary name approved in South

Africa as well as any trademarks applicable to the medicine, in order to ensure "public health interests".

- The words 'parallel imported medicine' or the abbreviation PIM must be included on the label of each distribution pack.
- The batch numbers of repackaged medicines must be identical to those of the original medicines and all original packaging material must be destroyed.
- Relabelling by way of over-sticking the original label is not specifically prohibited under the Medicines Act, regulations or guidelines, but may contravene the Merchandise Marks Act if it amounts to an alteration of the trademark.
- Since partitioning is not a consideration in South Africa, rebranding would constitute trademark infringement.
- Co-branding by the importer would constitute trademark infringement; the importer is entitled only to place descriptive material on the packs (eg, imported by XYZ Ltd).
- The product cannot be tampered with or altered in any way, and must remain the 'genuine product' – whether tearing blister packs into smaller units constitutes tampering or altering remains to be seen. The *Sony* case suggests that the alteration must be to such an extent that the product's nature is altered before any trademark infringement occurs.
- No descriptions that are materially false can be applied to the new packaging.

Anti-counterfeiting and enforcement

'Counterfeiting' is defined by the Counterfeit Goods Act as manufacturing, producing or making, or applying the subject matter of an IP right to protected goods without the rights holder's authority in order to create confusion with the protected goods of the rights holder or its licensee. 'IP rights' are limited to registered trademarks, works of copyright and prohibited marks.

The act is extremely effective in combating counterfeits by allowing inspectors to seize suspected goods without the need for a court order. Rights holders therefore list their brands with Customs, various commercial units of the national police and private investigators. These will then seize suspected goods in terms of the act and/or notify the rights holder thereof. The matter can then proceed as a civil or criminal case; after successful finalisation thereof, the goods are destroyed.

Aside from counterfeits, which appear to be the real headache for the pharmaceutical industry, there remain classic trademark opposition and infringement. South African trademark law protects well-known marks under Section 6bis of the Paris Convention and has also incorporated anti-dilution measures into its act.

Neither of these areas is controversial when it comes to pharmaceuticals. The only real issue is the South African courts' insistence that scheduled drugs be treated differently from over-the-counter products, despite cogent evidence from abroad that healthcare experts can and do make errors. Without similar evidence in South Africa, the courts are reluctant to move away from the conventional approach.

The MCC warns against confusion with regard to pharmaceutical trademarks in its guidelines, which prompts the question – when does the cloak of infallibility fall away? The guideline in question states: “The proposed proprietary name should not be liable to cause confusion in print, handwriting or speech with the proprietary name of another product. For example, the names ‘AMYTAL’ (barbiturate) and ‘AMITOL’ (multivitamin) could have serious safety implications if a barbiturate is supplied to a patient instead of a vitamin.” Clearly, the MCC anticipates that a scheduled drug is confusable with a vitamin.

Advertising

The regulations published under the Medicines Act prohibit the direct advertising to the public of most prescription medicines. More specifically, medicines which contain a substance appearing in Schedule 2 and upwards may be advertised “only for the information of medical practitioners, dentists, veterinarians, pharmacists and other persons authorised to prescribe or in a publication which is normally or only made available to such persons”.

Apart from the absolute ban on advertising scheduled medicines, the Advertising Standards Authority also publishes specific regulations for the voluntary regulation of the advertising of medicines. For example, “no advertisement should offer any product for a condition which needs the attention of a medical practitioner” and “no advertisement should cause the public unwarranted anxiety lest they are suffering from any disease or condition of ill health; or falsely suggest that any product is necessary for the maintenance of health or the retention of physical or mental capacities”. Particular emphasis is devoted to children:

“advertisements for pharmaceutical product should not encourage unsafe practices by children, or other inexperienced persons, or to create perceptions that such practices are desirable.”

Although membership of, and submission to, the Advertising Standards Authority and its decisions is voluntary, it remains a powerful body. Any organisation that ignores a directive by the authority can be blacklisted – an effective excommunication which can result in a marketing blackout.

Generic substitution

Generic substitution is encouraged, at least in terms of the Medicines Act, by Section 22F thereof, which states that a:

“pharmacist or a person licensed in terms of section 22C(1)(a) shall-

(a) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution; and
(b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.”

The only exemption to this peremptory provision is if the healthcare professional in question writes “no substitution” on the prescription.

However, generic substitution does not nullify the provisions of the Trademarks Act and confusingly similar marks for generics are still subject to opposition or infringement.

Online issues

The sale of prescribed medicines through legitimate e-pharmacies is restricted in terms of the Medicines Act, since scheduled medicines can be prescribed only by pharmacists or doctors, and only to members of the public who are over 14 years of age. Further, Schedule 2 medicines (and above) cannot be advertised directly to the public.

Legitimate e-pharmacies are therefore restricted to Schedule 0 products.

Naturally, this does not prevent

illegitimate sale, by either South African pharmacies or foreign e-pharmacies, if those parties cannot be traced or are located outside the jurisdiction of South African law.

The registration of domain names in the country-code top-level domain ‘.za’ is regulated by the South African domain dispute resolution regulations, published in the Electronic Communications and Transactions Act (68/2002), which prohibits both abusive and offensive registrations.

Abusive registrations are those which are registered or otherwise acquired in a manner which, at the time when the registration or acquisition took place, took unfair advantage of or were unfairly detrimental to the complainant’s rights; or have been used in a manner that takes unfair advantage of or is unfairly detrimental to the complainant’s rights. An ‘offensive registration’ means a domain name in which the complainant cannot necessarily establish rights, but whose registration is contrary to law, *contra bonos mores* or likely to give offence to any class of persons.

All other top-level domains are dealt with under the Internet Corporation for Assigned Names and Numbers’ Uniform Domain Name Dispute Resolution Policy. [WTR](#)

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Brian Wimpey is the head of the trademarks department at DM Kisch Inc, the oldest IP law firm in South Africa. He qualified as a trademark attorney in 1989 and has been a partner at the firm since March 1 1992. Mr Wimpey is immediate past president of the South African Institute of Intellectual Property Law and is also an examiner for its trademark exams. His practice covers a broad range of trademark and related work, including trademark availability searches and filings, and litigation before the High Court and the registrar in respect of trademarks and related matters. He was instrumental in obtaining the Supreme Court of Appeal's stamp of approval for the existence of copyright in package inserts which accompany pharmaceutical products. Mr Wimpey specialises in the pharmaceutical, alcoholic beverage and financial sectors, acting for top international and national corporations in those industries.