The Guide to Life Sciences: Key issues for senior life sciences executives

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The fourth edition of the Guide to Life Sciences delivers key analysis designed to help senior life sciences executives better understand the strategic and legal IP challenges that they face around the world. This specialist intelligence will help them to protect, enforce and monetise the IP rights that are so crucial to businesses in the space.

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South Africa: Winning strategies to keep pace with evolving pharma sector

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Summary

LEGAL FRAMEWORK

The South African pharmaceutical industry has evolved into a robust sector, witnessing notable growth in recent years. While the industry has traditionally been focussed on formulation and packaging products for the domestic market, in the wake of the covid-19 pandemic, there has been increased interest in active pharmaceutical ingredient production and export, particularly to other African countries.

In the healthcare landscape, the public sector plays a pivotal role in pharmaceutical distribution, while the private sector dominates revenue generation, supported to a large extent by private medical aid schemes. The government's primary focus in the sector is to expand healthcare access, particularly in rural areas, and promote the use of generic medications and safe traditional medicines.

Noteworthy was South Africa's joint proposal with India presented to the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council on 16 October 2020, advocating for a patent waiver to facilitate equitable access to covid-19 products. The proposal shone a spotlight on the gap between developing and developed countries regarding access to medicines.

South African patent legislation, with its origins in British law, has undergone significant divergence as legal principles have developed and evolved. The current legal framework is embodied in the Patents Act 57 of 1978 (the Patents Act) and the regulations thereto. Judicial decisions, extensively documented in the South African Law Reports, contribute significantly to shaping patent law in the country.

PATENTABILITY ISSUES

One of the most important features of the South African patent system is that there is no substantive examination of patent applications on their merits. The South African Patent Office merely examines patent applications for conformity with formal requirements and, once these are met, a patent is granted.

The other side of this equation is that the Patents Act provides that if, in infringement proceedings, a single claim is held to be invalid, even where other claims are found to be valid and infringed, then no relief can be obtained on the valid and infringed claims until the invalid claim has been amended or deleted. Thus, the patent is unenforceable until such time as the invalidity is cured by amendment. Any application for amendment after grant to amend or delete the invalid claims may only be narrowing in scope and can be opposed, which can obviously further delay the obtaining of relief for infringement. Thus, the onus is on the patentee to ensure that its patent is granted in a valid form to have the best chance of succeeding in an infringement action.

The Patents Act grants exclusive rights to patent holders to control the use, sale or disposal of their inventions within South Africa. However, a common challenge faced by pharmaceutical and medical device products is determining their eligibility for patent protection. In accordance with international standards, novelty and inventiveness of an invention are crucial considerations for patentability, with an absolute novelty requirement and well-established principles for determining non-obviousness.

Section 25(2) of the Patents Act outlines exclusions from patentability, such as methods of treatment and diagnostic methods. However, the Patents Act also provides that second and

subsequent medical uses of a known product may be regarded as patentable subject matter, provided the requirements of novelty and inventiveness are met.

In terms of decided South African case law, a claim directed to a first medical use should be drafted in the 'for use-type' claim format, similar to the EPC 2000 claim format, and a claim directed to a second medical use should be drafted in the 'Swiss-type' claim format.

New dosage regimes and inventions targeting selected patient populations may also qualify as patentable subject matter, provided they satisfy the requisite patentability criteria.

There is no decided case law on acceptable formats for claiming biologics and antibodies. However, given the commonality between South African law and British law, the South African courts tend to follow the guidance of the European courts and particularly the British courts. Thus, it is likely that South African courts will require antibody claims to include at least the six complementarity-determining regions (CDRs) or the variable fragment heavy chain (VH) and variable fragment light chain (VL) domains.

STRATEGIES FOR ENFORCEMENT (INCLUDING WHETHER INJUNCTIONS ARE NECESSARY OR EASILY AVAILABLE)

As mentioned above, if in any litigation a claim is found to be valid and infringed but another claim is found to be invalid, then no relief can be obtained on the valid and infringed claim until the invalid claim has been amended or deleted. For this reason, most applicants for pharmaceutical patents in South Africa adopt a strategy whereby they keep their patent application pending, by filing one or more requests for an extension of the acceptance deadline, until prosecution of corresponding patent applications in examining jurisdictions has progressed sufficiently for them to determine a valid claim scope. At that time, they amend the claims of their South African patent application to conform them to a valid scope and allow it to proceed to grant. In this way, the patentee has a reasonable assurance that the patent claims are valid, so that they can enforce their rights.

Unauthorised infringement of a pharmaceutical patent encompasses the actions of making, using, exercising, disposing (eg, selling), offering to dispose (eg, advertising) or importing the patented product.

Patent infringement proceedings may be brought by the patentee or, in some instances, by a licensee operating under a licence of right, where the patentee has refused to institute proceedings after being called upon by the licensee to do so.

A successful plaintiff in infringement proceedings may obtain an interdict (injunction), delivery up of patented goods, damages or a reasonable royalty instead of damages and they may recover legal costs.

Patent infringement proceedings are usually instituted by way of an action procedure, which is commenced by issuing a combined summons, together with a particulars of claim setting out the cause of action. The defendant has an opportunity to defend the action by delivering a plea to the particulars of claim, and a counterclaim, if any. The plaintiff is then provided with an opportunity to reply to the defendant's plea and to plea to the counterclaim. Thereafter, the defendant may offer a final reply to the plea. This is followed by discovery and expert summary evidence, and any other interlocutory proceedings, whereafter a trial date is requested and allocated.

Invalidity of the patent is available as a defence in an infringement action and is instituted by way of counterclaim for revocation.

Applying for marketing authorisation does not constitute patent infringement per se. However, in specific cases, when coupled with other factors, such application may raise concerns about potential infringement upon product launch following authorisation. In such cases, an interim interdict (injunction) may be sought, pending final resolution by the court. For the applicant for an interdict to be successful, it must be demonstrated that there is urgency and a well-founded apprehension of irreparable harm if interim relief is not granted pending final resolution.

STRATEGIES FOR EXTENDING PROTECTION

South African law lacks provisions or mechanisms for extending the term of a patent. Indeed, there is no linkage between the South African patent and regulatory laws. In fact, section 69A of the Patents Act, provides for a Bolar provision, which specifically exempts non-commercial scale activities reasonably related to obtaining and submitting regulatory information required under law from patent infringement. However, this section also stipulates that it is not permissible to stockpile products for sale in anticipation of patent expiration.

NON-PATENT EXCLUSIVITIES (EG, BIOLOGICS EXCLUSIVITY OR REGULATORY DATA EXCLUSIVITY)

South African legislation does not incorporate data exclusivity measures for pharmaceuticals or medical devices as is the case in Europe, the United States and elsewhere. Instead, the regulatory framework emphasises early market access and includes provisions aimed at facilitating the affordability of medicines. Beyond the above-mentioned section 69A of the Patents Act, the Medicines and Related Substances Act No. 101 of 1965 outlines a mechanism allowing for potential parallel importation of medicines registered in South Africa by entities other than the registration certificate holder under specific conditions. Such importation is exempt from patent infringement.

Further, parallel importation has been the subject of a South African-decided case, where it was held that 'where a patentee himself sells or disposes of the patented article, that article is freed from all restraints which the patentee's monopoly had imposed on it and where the patented article is disposed of by the patentee's assignee or his agent, acting within the scope of his authority, it is similarly freed from such restraints.'

LAUNCH-TO-MARKET STRATEGIES – HOW TO ENSURE A CLEAR PATH TO MARKET

Launching a product in the South African market requires a keen understanding of the intellectual property framework and regulatory framework. Ensuring a successful product launch may involve the key strategies outlined below.

Where patent protection is concerned, obtaining enforceable rights in South Africa, while relatively cheap and fast, requires an understanding of the complexities of the patent lifecycle all the way from filing to infringement proceedings, due to the non-examining nature of South African law. An understanding of appropriate claim format for a valid patent is important, especially where the onus is on the patentee to ensure that the patent is in a valid form.

As mentioned, delaying acceptance of a South African patent application until such time as there is an indication of valid rights in an examining jurisdiction is one such strategy for ensuring that the patent will pass muster.

Another strategy may include the filing of one or more divisional applications. It is possible to obtain a granted patent with a claim set that is known to be valid but is narrow in scope and to pursue a divisional application with a claim set of wider scope in the hope that this claim set will also be found to be valid.

If the patentee desires early grant of a patent, possibly with a view to instituting infringement proceedings or to deter competitors, it is also possible to request expedited acceptance of a patent application. If the request for expedited acceptance is made within the first 12 months (for PCT National Phase) or 18 months (for any other application, including a divisional application) of filing, the request must be accompanied by a search report or opinion of the international searching authority or an examining patent office, showing that the office has considered the subject matter of at least one claim of an equivalent application to be both novel and inventive, or an affidavit by the applicant, providing the reasons that expedited acceptance is required for the specific patent application.

Conducting a freedom-to-operate (FTO) analysis is important to understand whether there is potential risk of infringing existing patents. Conducting an FTO in South Africa can be a challenge, as the online records of the South African patent office only include patent numbers and titles. Thus, conducting equivalent searches for known relevant patents is one strategy for ensuring freedom to operate in South Africa. The South African patent system provides for revocation proceedings for invalidating a patent.

Finally, regulatory compliance is a cornerstone of bringing a pharmaceutical product to market. Necessary approvals may be obtained from the regulatory authority, the South African Health Products Regulatory Authority (SAHPRA). The period of marketing authorisation for approved pharmaceuticals varies depending on the product and its characteristics. The initial period of validity is ordinarily five years, but this can be shorter or longer depending on the specific product and its intended use.

Marketing authorisation can be renewed for a further period of five years if the product continues to meet the necessary requirements for safety, efficacy and quality. On the other hand, the SAHPRA can revoke a marketing authorisation on the grounds that the product is unsafe, ineffective or of poor quality, that the holder of the authorisation failed to comply with the conditions of the authorisation or that the holder failed to place the product on the market within a certain time frame.

For biologic medicinal products, there are specific obligations that must be fulfilled in South Africa for granting a marketing authorisation. Specific guidelines and requirements have been put in place to ensure that biologic medicinal products are safe, effective and of high quality. It is also worth noting that authorisation for biologic medicinal products may be more complex and take longer than for other pharmaceutical products due to their nature and the need for extensive data on their safety and efficacy.

GENERICS TO MARKET

As previously mentioned, section 69A of the Patents Act provides an exemption from patent infringement for non-commercial scale activities reasonably related to obtaining and submitting regulatory information required under law. This exemption applies equally to

generic products and it is permissible for a generic manufacturer to obtain registration of generic equivalents of patented products in South Africa, prior to the expiration of the relevant patent provided such generics are not allowed to be stockpiled for commercial sale prior to the expiration of the South African patent.

South African patent law also makes provision for a declaration as to non-infringement should an applicant wish the courts to adjudicate on the question of whether or not there is or will be patent infringement. However, this is not a requirement for generic market entry or for obtaining marketing authorisation. In fact, the medicines registration authority (SAHPRA) does not take patent protection into account at all. Furthermore, the applicant for the registration of a generic equivalent product can rely on data that is of public record in support of the application.

The SAHPRA has previously announced its intention to harmonise some of its policies and procedures with those of the European Medicines Agency and has endorsed and adopted the European Medicines Agency guidelines for quality and bioequivalence requirements. In accordance with these guidelines, the SAHPRA has adopted reliance-based evaluation procedures and evaluation may follow one of the following pathways: full review, abridged review, verified review or recognition. Thus, approval of a generic version of a previously approved drug would likely be subject to an abridged review or a verified review.

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