The importance of innovation and the patent system in South Africa

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Ramez Naam in his book entitled "The Infinite Resource – The Power Of Ideas On A Finite Planet" says that the most critical human faculty that exists and the most important source of our prosperity is innovation.

Mr Naam says that the most valuable resource we have isn't energy or minerals or land. It is our ever increasing store of ways to put things together in new and more inventive forms that give us greater and greater value.

He goes so far as to postulate that almost all of the economic growth of the last two centuries has been dependent on new innovations and discoveries. He says that tapping into innovation and further augmenting it, is our best strategy for overcoming any potential limits to growth. In order to flourish he says we need to invest in innovation. Thus he says that innovation is the ultimate source of human progress, and that wealth is created through innovation.

So if innovation is so important how can it be encouraged?

Mr Naam believes the answer lies in leveraging the power of self-interest. He says that civilizations that have tapped into the power of self-interest to drive people to act in the common good – rewarding them for and incentivising them towards behaviours that meet the needs and desires of others – have seen themselves grow more prosperous over time. They have seen themselves innovate. He says if we want to solve our problems today, then we must make sure that the power of self-interest is fully engaged. If we want to save the world, we have to make sure people can get rich – or at least make a good living – by doing so.

It is important to note this self-interest is self-interest to act in the common good, not self-interest which results in action not in the common good. Mr Naam makes it clear that self-interest is not the only motivator of human behaviour. He says far from it - men and women perform altruistic, courageous, noble deeds without any thought of personal gain quite frequently. We act out of love, out of concern for our children and family members, out of a sense of duty, out of friendship, out of a sense of justice, out of a sense of charity.

However he says that self-interest on a global scale is the most consistent driver of human behaviour. He says that while many drivers besides self-interest have helped make the world a better place, virtually no society that has failed to leverage self-interest has thrived.

His concluding paragraph is most interesting. He says that:

"*The human mind is the ultimate source of all wealth. We stand poised on the brink of the largest-ever explosion of human mental power, a second Renaissance, more*

transformative, more far-reaching, and more inclusive than the first. If we make the right choices to empower human minds and encourage innovation, to steer innovation toward the solutions for our planet's problems, and to embrace the fruits that it offers, then the future will be one of almost unimaginable wealth, health and well-being."

This is indeed a delightful prospect.

So how do we leverage the power of self-interest? In my view the most important way of doing this is to ensure that we have an efficient and effective intellectual property system, and in particular an efficient and effective patent system.

The theory underlying the patent system is that inventors are rewarded with a monopoly for a limited period of time, in return for making their inventions available to the public. The prospect of obtaining a monopoly encourages innovation. Without a monopoly competitors of an innovator will be educated for free, at the innovator's expense. In addition, because the innovator will generally not be able to charge a premium for an innovation without a monopoly, the innovator may not even be able to recoup the cost of the research and development which went into making the innovation. This is likely to deter further research and development.

The intellectual property system, and the patent system in particular, can be an extremely powerful tool for leveraging the power of self-interest which, as mentioned, leads to innovation and consequent growth and prosperity.

Companies are more likely to invest in a country that has an efficient and effective intellectual property system than in a country which does not have such a system.

In the South African context the question is whether or not South Africa has an efficient and effective patent system.

In my view there are two aspects of the South African patent system which require consideration in order to answer this question. The first relates to the prosecution system, and the second to the litigation system.

The prosecution system relates to the filing of patent applications at the Patent Office and their prosecution to grant before the Patent Office.

The South African prosecution system is a deposit based system in which patent applications are only examined as to their formalities. In other words if a patent application complies with the required formalities, the application can proceed to grant.

Some countries however examine patent applications not only as to their formalities, but also as to their merits. An examination on the merits requires inter alia an investigation into whether or not the invention claimed in the patent application is novel and inventive, before the patent application can proceed to grant.

Examination on the merits is an extremely costly business, if it is to be done efficiently and effectively. One of the reasons for this is that independent examiners, skilled in all the different technical fields, need to be employed to examine the patent applications. In addition, examination on the merits can lead to significant delays in the grant of patents, and to a decrease in the competitiveness of a country in certain instances.

At first blush a merit based examination system appears to be attractive because it could lead to "stronger" patents. However even the United States, with its vast resources and thousands of skilled patent examiners, struggles somewhat to maintain an efficient and effective merit based examination system.

In my view, the South African system has the best of both worlds from an examination perspective. I say this because patent applications in South Africa are generally also effectively examined as to their merits. There are various reasons for this which I set out below.

In South Africa a patentee is not entitled to any relief for infringement (such as an interdict and damages) under a patent if any of the claims in the patent are invalid. This means for example that, even if only one claim of a patent is invalid, the patentee will not be entitled to any relief. This has led to a practice of amending patent applications and patents to limit the scope of their claims in the light of known prior art. (Prior art consists of anything made available to the public prior to the priority date of a patent.) If a patentee delays unduly in applying to amend a patent, the application to amend may be refused. This has the effect of encouraging patentees to apply to amend sooner rather than later.
In particular patents are often amended prior to commencing infringement proceedings, with a view to limiting the scope of the claims in the light of known prior art. Furthermore, once infringement proceedings have commenced, it is possible to stay the infringement proceedings, pending an application to amend the relevant patent, if it becomes apparent from an attack on the patent that one or more of the claims are invalid.

Thus those patents which are likely to be the subject of litigation, or which are the subject of litigation, generally undergo significant "examination". These patents are often the commercially valuable patents. Thus resources are generally not wasted on "examining" patents which have no or limited commercial value.

In addition most patent applications originating from abroad are filed through an international patent system. Such patent applications include a search report

which contains details of potentially relevant prior art, and a report on the patentability of the invention claimed in the application. These reports are generally prepared by skilled examiners, who may be based in Europe or the United States of America. Thus many patent applications filed in South Africa are already examined as to their merits.

In summary there are therefore three factors which, in my view, contribute to South Africa having a prosecution system which has the best of a deposit based examination system and a merit based examination system. As mentioned these three factors are the legal requirement that a patentee is not entitled to any relief on an invalid or partially invalid patent, the practice of amending patents, and the examination of international patent applications.

If it is correct that South Africa has the best of both worlds when it comes to its patent prosecution system, then there is no need to introduce a merit based examination system in South Africa. This is relevant because a draft national policy document on intellectual property (IP), published for comment on 4 September 2013, recommends inter alia a merit based patent examination system.

It would seem that one of the main aims of the proposed merit based patent examination system is to prevent so-called "evergreening" of pharmaceutical patents. In this regard the policy document states*: "A patent in the area of medicine is important since drugs are approved after clinical trials have been concluded. Drugs, therefore are based on a valid patent. It is contended that if "weak" patents are granted, it stifles the possibility of having access to public health. This means that if a patent is granted, even if there is no innovation on the original or dependent patent, access to public health may be difficult to attain. This also means that South Africa may need to create a Substantive Search and Examination since it is using a depository system that inherently grants weak patents."*

The policy document also states that "*Government departments should integrate their databases so as not to grant patents on medicines that may be expiring as this may undermine access to public health."* and that *"Weak patents frustrate the accessibility and affordability of medicines and technologies.".* The policy document also states that new uses of known products should not be patentable.

I have dealt above with why South African patents are effectively examined, and therefore why "weak" patents should not be an issue of concern. I return below to the topic of "evergreening".

Insofar as not granting patents on medicines that may be expiring is concerned, I believe that this is a reference to not granting "evergreening" patents. Here I would caution against failing to leverage the power of self-interest as some of the "evergreening" patents may be warranted and in the public interest. The

same applies to a possible prohibition on the patentability of new uses of known products, especially in the pharmaceutical field. As mentioned above, leveraging the power of self-interest leads to innovation, growth and prosperity.

The policy document also recommends pre- and post-grant opposition "*to effectively foster the spirit of granting stronger patents*". The previous Patents Act provided for pre-grant opposition. I understand that this was done away with in the current Patents Act at least partly because of the delays that were encountered in the granting of patents.

It is said in the policy document that "*Legal systems must have the capacity to reject IP rights that are invalid and* (it is)*, therefore, difficult to attain that if the depository/registration system is used, not the search and examination.*" I have explained above how I believe that the South African patent prosecution system effectively "rejects" patents that are invalid via a process of amendment and examination of international patent applications. Patents which are invalid, and which are not "rejected" by the prosecution system, should be rejected by the litigation system, a topic to which I now turn.

It is important to bear in mind that if patents cannot be efficiently and effectively enforced, there is not much incentive to file them, or for that matter, to innovate in the first place.

Unlike a number of other countries in the world, South Africa does not have a specialist patent court.

In my view, if the South African patent system is to be improved, the focus should be on improving the patent litigation system.

I believe that what we require in South Africa is a specialist patent court in which the judges have experience in patent law, which for good reason has been referred to as the metaphysics of law. The judges should, where necessary, be assisted by persons with the requisite technical background. Ideally the judges should also have a technical background because the inventions claimed in the patents litigated on, require an understanding of the technology or science involved. In other words, not only should the judges be qualified lawyers with experience in patent law, they should also be qualified engineers or scientists.

A specialist patent court could be structured to provide relatively quick and inexpensive decisions on patent matters. Such a specialist patent court would, in my view, be vastly cheaper and more effective than a merit based examination system. In addition from a businessman's perspective, the ability to obtain relatively quick and inexpensive decisions on patent matters would, in my view, enhance confidence in the country. I believe that this would also lead to increased investment in the country and result in job creation.

It is noteworthy that the South African Patents Act provides for the designation of a Commissioner of Patents. The Patents Act goes so far as to say that no tribunal other than the Commissioner shall have jurisdiction in the first instance to hear and decide any proceedings, other than criminal proceedings, relating to any matter under the Patents Act. This is to my mind a clear indication that the patent court should be a specialised court.

The policy document is most encouraging on the topic of IP enforcement. It states that "*South Africa should also foster the enforcement of IP in its entirety.*" and "*The current structures in the resolution of IP need some revamping and strengthening*" and that "(The) *Patents Commissioner (Judge of the High Court) deals with disputes related to patents disputes. In this regard, a tribunal may have to be established as proposed in 2) above. This should be dealt with without compromising the high standards that apply to resolving sophisticated cases.*" The reference to "2) *above*" is a reference to an existing Trade Mark Tribunal "*which resolves disputes related to trademarks during pre-granting of marks.*"

Reverting now to the topic of "evergreening" of pharmaceutical patents, I believe that the single biggest threat to a generic company wishing to sell a generic pharmaceutical product which may fall within the scope of the claims of a patent, is that of an interim interdict being granted under the patent by a court against the sale of the product.

I believe that the second biggest threat to a generic company wishing to sell a generic pharmaceutical product which may fall within the scope of the claims of a patent, is the threat of protracted patent litigation, the cost thereof, a possible award of damages against it, and the uncertainty created by the litigation amongst its customers, if it manages to avoid an interim interdict under the patent in the first place.

In an application for an interim interdict for patent infringement, it is necessary for a judge to consider the validity and infringement of the patent when deciding whether or not to grant an interim interdict under the patent. A judge with the requisite experience in patent law and ideally with the requisite technical background, or assisted by a person with the requisite technical background, should more easily be able to make such a decision. In so doing unwarranted "evergreening" should not result in the grant of an interim interdict against the sale of a generic pharmaceutical product. In addition, unwarranted "evergreening" should not result in a final interdict being granted at trial against the sale of the generic pharmaceutical product.

In my experience a generic pharmaceutical company does not launch a generic product at risk, unless it has good reason to believe that the relevant patent is invalid, and/or that its product will not infringe the patent. Infringement is however generally not in dispute because the product is a generic product. Validity and infringement are however only two of a number of issues which are considered by a judge when deciding whether or not to grant an interim

interdict. The other issues which are considered are irreparable harm, the balance of convenience and no other satisfactory remedy. The issues of irreparable harm and no other satisfactory remedy generally tend to favour the patentee.

The issue of balance of convenience resolves itself into a consideration of the prospects of success in the trial and the balance of convenience. The stronger the prospects of success, the less the need for the balance of convenience to favour the patentee, the weaker the prospects of success, the greater the need for the balance of convenience to favour the patentee. A determination of the prospects of success requires a consideration of validity and infringement. As mentioned, infringement is generally not in dispute because the product is a generic product.

Thus generally the only issue which may tend to favour the generic pharmaceutical company, other than possibly the balance of convenience, is the validity, or rather the lack of validity, of the relevant patent. Therefore this issue should play a very important role in an application for an interim interdict. However the science involved in warranted and unwarranted "evergreening" patents can be complicated. As such there is a risk of the issues, other than the issues of validity and infringement, dominating a decision to grant an interim interdict. This is why it is important for a judge to have the requisite experience in patent law, and ideally to have the requisite technical background, or to be assisted by a person with the requisite technical background. This is especially so since in an application for an interim interdict the issue of validity is only dealt with for the first time in the answering evidence of the generic pharmaceutical company, because it bears the onus of proving invalidity of the patent. The generic pharmaceutical company cannot as of right, file further evidence dealing with what is said in the replying evidence of the patentee on the issue of validity.
It is noteworthy that the claims of many of the pharmaceutical patents which have been litigated upon in South Africa, and which are alleged to constitute "evergreening", have substantially the same scope as the claims of certain of the corresponding foreign patents. These corresponding foreign patents have undergone examination as to their merits in sophisticated examination systems in their respective foreign countries. In other words, even if South Africa was to institute a merit based examination system, "evergreening" would not be eliminated.

I believe that a specialist patent court would go a long way to alleviating the abovementioned threats to the sale of generic pharmaceuticals in South Africa, if there has been unwarranted "evergreening".

If there is to be a specialist patent court, it would make sense to broaden its ambit to deal with all intellectual property cases including design, copyright and trade mark cases. It would also make sense for such an intellectual property court to be staffed with judges who have experience in these matters.

In summary, I believe that a merit based patent examination system would be very costly and would be likely to lead to significant delays in the grant of patents. In addition resources would be wasted examining patent applications which have no commercial value. On the other hand, a properly functioning specialist patent court would provide a very focused and effective approach to the issue of patent validity.

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