Adams & Adams

SA PHARMACEUTICAL REGULATORY AFFAIRS ASSOCIATION

PATENT LAW - WHAT A REGULATORY PHARMACIST SHOULD KNOW

Danie Dohmen
Partner

"The law of capital punishment is far more complicated than I portrayed it … A Supreme Court Judge once remarked that the only thicket of similar legal obscurity is patent law"

Richard North Patterson

BACKGROUND

- What is a Patent?
  - Statutory granted, temporary monopoly for a fixed period (20 years)
  - For an invention
  - To encourage improvement and disclosure of improvements
  - Encourages the putting into practice of the invention
  - After expiry of the patent the new knowledge created by the invention is available for general utilisation

- Patent laws are governed by international treaties and national legislation
  - The Paris Convention for the Protection of Industrial Property (Administered by WIPO)
  - The Agreement on Trade-Related aspects of Intellectual Property Rights ("TRIPS") (administered by WTO)
  - Patents Act no. 57 of 1978 and the Patent Regulations
    - Give effect to and are substantially compliant with the Paris Convention and TRIPS

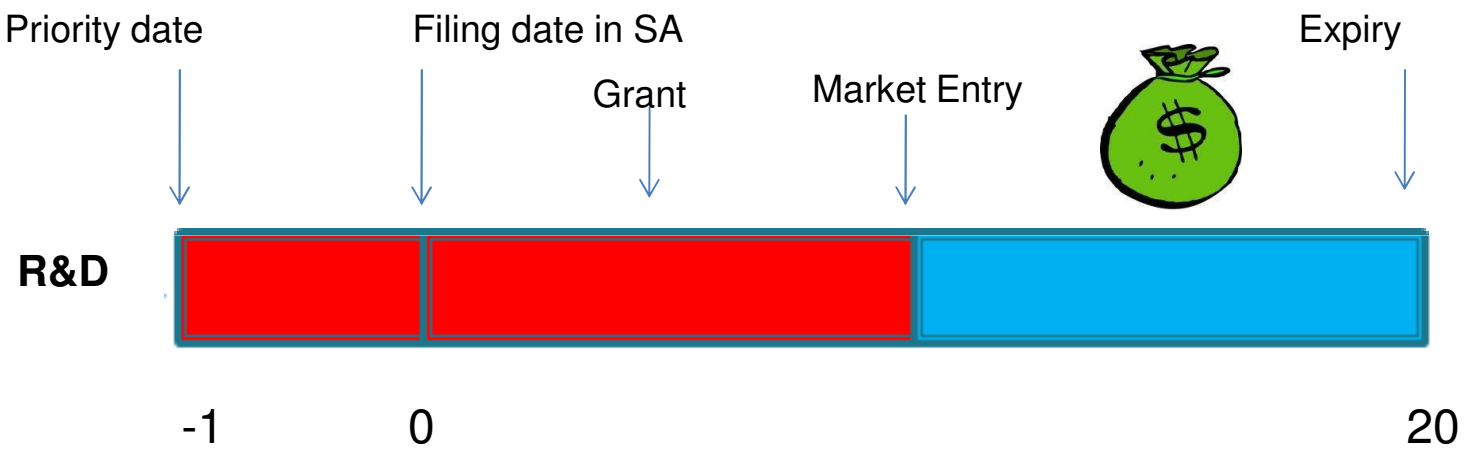
PATENTABLE SUBJECT MATTER

Main requirements for patentability

- Novelty - the invention must be new - take into consideration all matter (whether a product, process, information about either, or any thing else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description by use or in any other way

- Inventive step - the invention must not be obvious to a person of ordinary skill in the art

PRODUCT AND PATENT LIFECYCLE

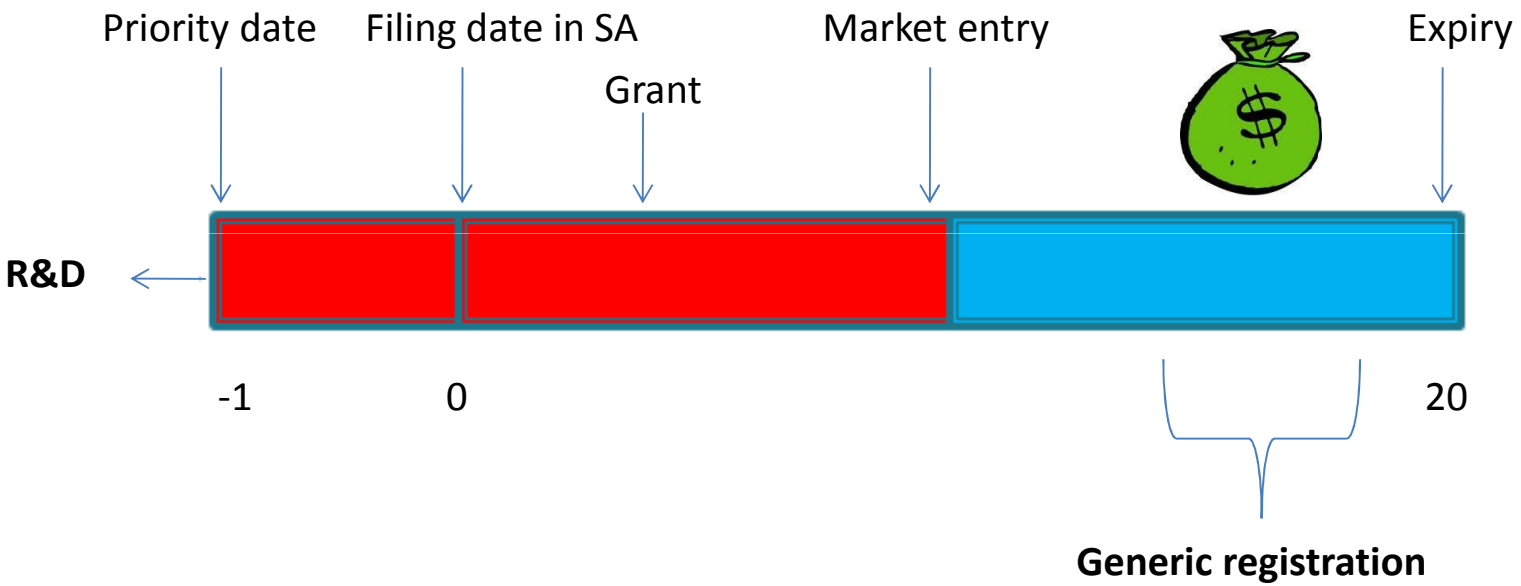


PRODUCT AND PATENT LIFECYCLE

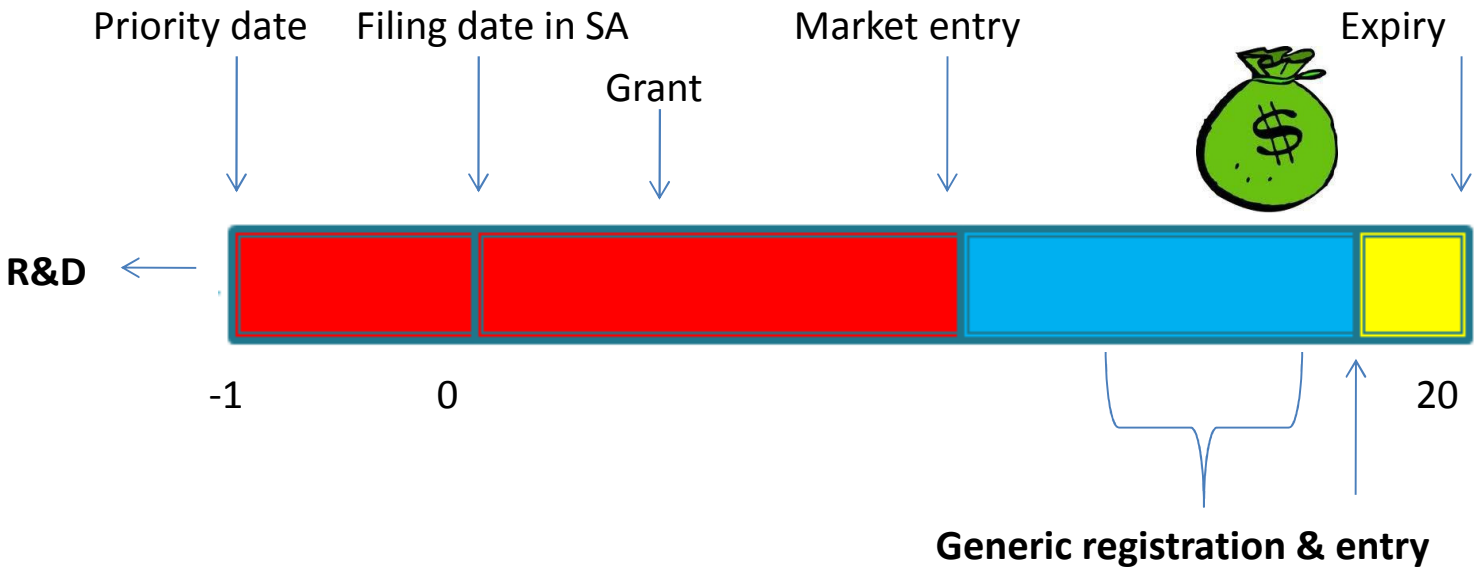
- It shall not be an act of infringement to exploit a patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product

- Data package exclusivity not applicable in South Africa

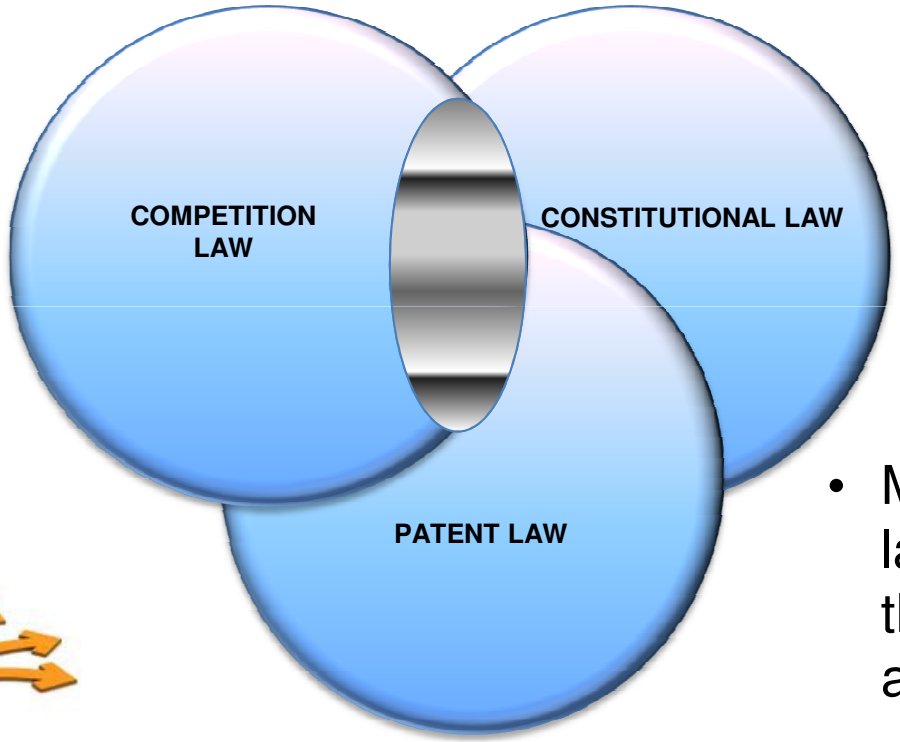
PRODUCT AND PATENT LIFECYCLE



PRODUCT AND PATENT LIFECYCLE



LITIGATION LANDSCAPE



- Multiple areas of law now feed into the enforcement of a patent right.

ENFORCEMENT

The interim interdict

a) A right which is at least prima facie established ("prospects of success at trial");
b) a well grounded apprehension of irreparable harm if the interim interdict is not granted and the ultimate relief is eventually granted;
c) that the balance of convenience favours the granting of interim relief; and
d) that the applicant has no other satisfactory remedy

ENFORCEMENT

Generic arguments

- Prospects of success at trial weak (usually amounts to an attack on the validity – obviousness)
- Do not need to respect invalid patents
- The generic is a company of substance that can pay damages and will keep accurate sales records
- Spent money gearing up to launch (or have already launched) – generic will suffer greater prejudice if launched prevented or if removed from market
- Trial imminent
- More affordable medicines will become available more quickly

ENFORCEMENT

Innovator arguments

- Patent prima facie infringed and valid
- Sales records of generic cold comfort because damages difficult to prove at trial
- Have to drop price to compete and cannot increase price later if successful at trial
- Rapid market penetration that will destroy market created and maintained by innovator (unrecoverable costs)
- Redundancies, redeployment
- The generic will suffer less prejudice by waiting until expiry – should have cleared the way with a revocation application

ENFORCEMENT

- 5 products @ R100m per annum
- 1 year left on patent /30% market share
- R2-3 million per case
- R 10-15 million costs to litigate them all
- One success R30 million

DEPOSITORY SYSTEM AND ENFORCEMENT

- No substantive examination, formalities only
- An invalid or partially valid patent is not enforceable
- Onus on patentee to keep patent in a valid form otherwise at risk of patent being unenforceable or a loss of all rights
- Revocation of a patent on various grounds available at any time by any person

PUBLIC INTEREST

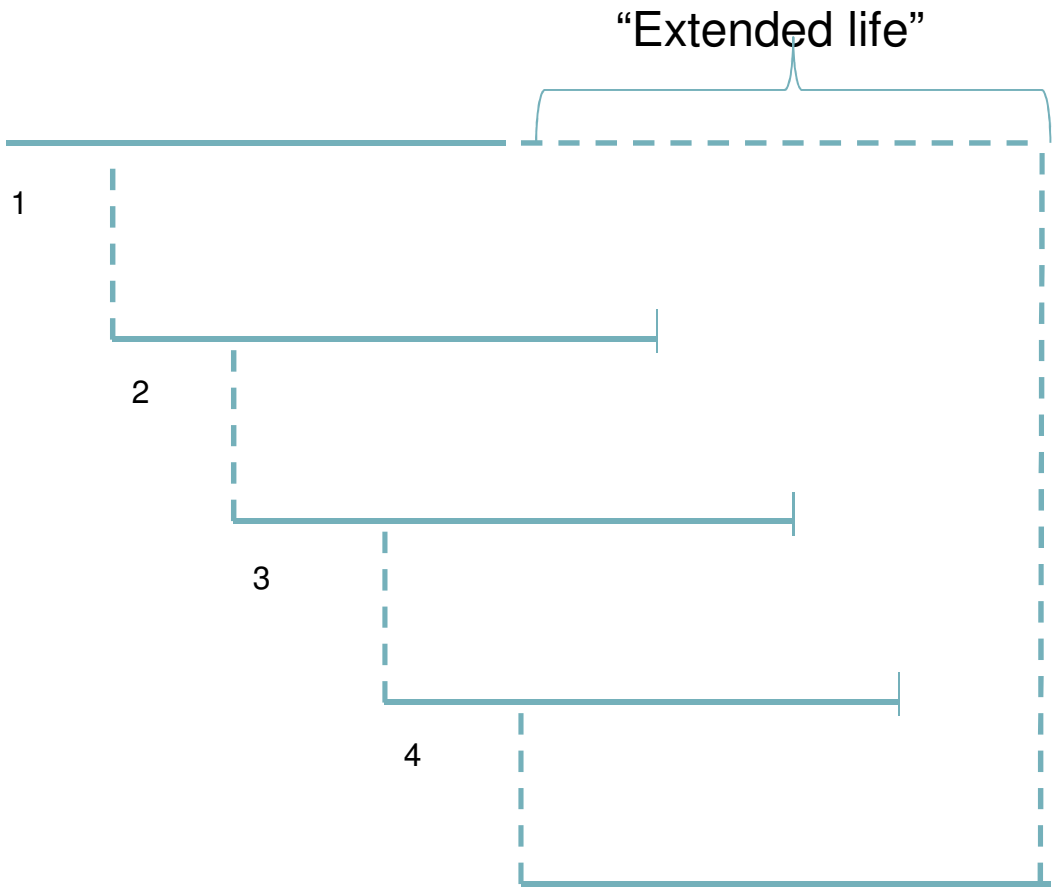
- Patents limit access to medicines! New patents on old drugs! Patent rights needs to be balanced with patient rights and human rights! Non examination! Reduce the number of patents granted! Allow pre and post grant oppositions!
- Prima facie right vs. balance of convenience
- Balance of convenience
  - Public interest requires enforcement of patent rights
  - The patentee satisfies demand
  - Pricing: Public and private sectors
  - Products are therapeutically equivalent
  - No disruption to patients
- SCA in *Aventis v Cipla:* Where the public was denied access to a generic during the lifetime of a patent, that was the ordinary consequence of patent protection. To refuse an interdict only to frustrate the patentee's "lawful monopoly", would be an abuse of the court's discretionary powers


EVER GREEN
RECYCLE IT
COMPOST IT

INCREMENTAL INNOVATION

- Molecule → Patent 1
- Crystalline form → Patent 2
- New indication → Patent 3
- Salt form → Patent 4
- Process of manufacture → Patent 5
- Formulation → Patent 6
- Dosing regimen → Patent 7

INCREMENTAL INNOVATION



INCREMENTAL INNOVATION

Sector inquiry-European Competition commission

- *"....strategy documents of originator companies confirm that some of them aimed at developing strategies to extend the breadth and duration of their patent protection"*
- *"Filing numerous patent applications for the same medicine (forming so called "patent clusters" or "patent thickets") is a common practice"*
- *"Documents gathered in the course of the inquiry confirm that an important objective of this approach is to delay or block the market entry of generic medicines"*
- *"When the number of patents and in particular of pending patent applications is high (patent clusters), this can lead to uncertainty for generic competitors – affecting their ability to enter the market"*

INCREMENTAL INNOVATION

- "*The upshot of all this is that were the patent valid, X's monopoly in practice would last until 2020. But, as the Judge held and we confirm, it is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name. I am not sure that much could have been done about this at the examination stage. There are other sorts of case where the Patent Office examination is seen to be too lenient. ... The only solution to this type of undesirable patent is a rapid and efficient method for obtaining its revocation. Then it can be got rid of before it does too much harm to the public interest*"

- "*It is right to observe that nothing X did was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) may, under the English litigation system, lie in an award of costs on the higher (indemnity) scale if the patent is defended unreasonably... "*

INCREMENTAL INNOVATION

- "*The judge had not erred in his approach to inventive step. He had taken into account that there were a number of avenues of research open to the skilled man seeking a solution to the problem and that he would not, therefore, have taken the diol route unless satisfied that there was a real prospect that the necessary reaction would work. The judge had rejected the respondents' evidence that there was a high expectation that the experiment would be a very easy ring closure which would work. Once he had done this, his conclusion that the diol route was not obvious was unassailable*"

INCREMENTAL INNOVATION

- "*The essence of the respondents' case was that the skilled man could have come by the invention by doing a short and simple experiment. But that could be said, with hindsight, of many an invention. It was not enough for an experiment revealing an invention to be short and simple. There also had to be a reason why the skilled man would have carried it out. Normally that would require at least an expectation that something might come out of it. Otherwise, short and simple though it would have been, doing the experiment would have been pointless. The judge had rejected the evidence of the respondents' expert who had suggested there was a point, saying "the reaction looked promising". There was clearly material upon which the judge could do so. The appeal on obviousness failed.*"

PATENTS AND ACCESS

- Innovation cannot take place in isolation from concerns about access, and access has to be seen in the broader context of the need for innovation and effective regulation (*Promoting Access to Medical Technologies and Innovation, Intersections between public health, intellectual property and trade*, WTO, WIPO, WHO 2013 ("PAMTI"), p30)

- While patents may increase costs to society in the short term by restricting competition, they should generate greater and more dynamic benefits as a result of encouraging more innovation in the long term (PAMTI, p56)

- Access and IP concepts are intrinsically intertwined. Merely to leverage enhanced access to the stock of existing, proven medicines is insufficient (PAMTI, p32)

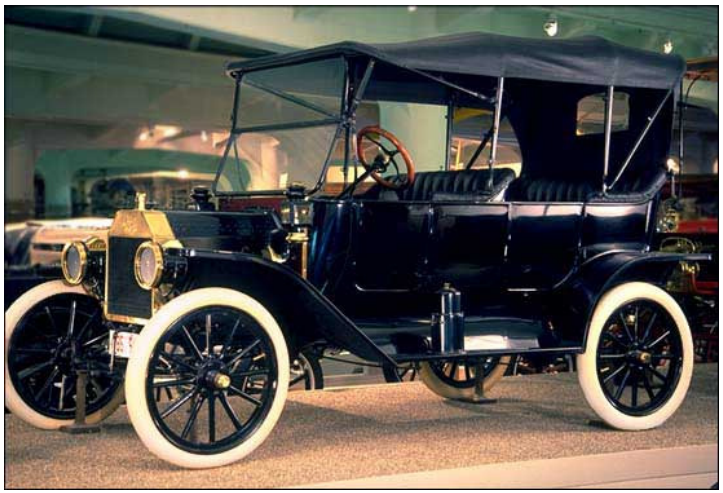
PATENTS AND ACCESS

- There is a continuing need for new, adapted and more effective medicines. Access is not a static equation – an integral feature of appropriate access strategies must be a recognition of the value of targeted and appropriate innovation, both for major new breakthroughs and for adaptations to, and improvements in, existing technologies (PAMTI, p35)

- The mere existence of IP rights on a product is not a barrier to, nor its absence a guarantee of, access to that product (PAMTI, p171)

- WHO list of essential medicines: +95% were once patented, now world wide less than 1.4% remains under patent (probably no patents on these in Africa and Southern Africa)

PATENTS AND ACCESS



Karl Benz received a patent for a gas-fuelled car on 29 January 1886.

The first production Model T Ford was assembled at the Piquette Avenue Plant in Detroit on October 1, 1908

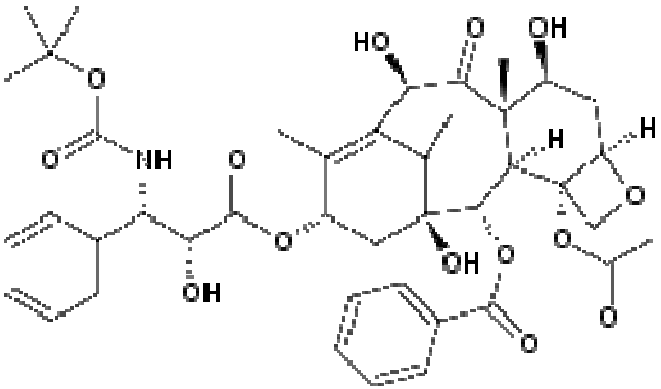
Solid front and rear axels; top speed 72 kph; 2.9L 4 cylinder; 15kw at 1600 rpm; 2 speed gearbox.

In developing the A6, Audi filed 9,621 patents.

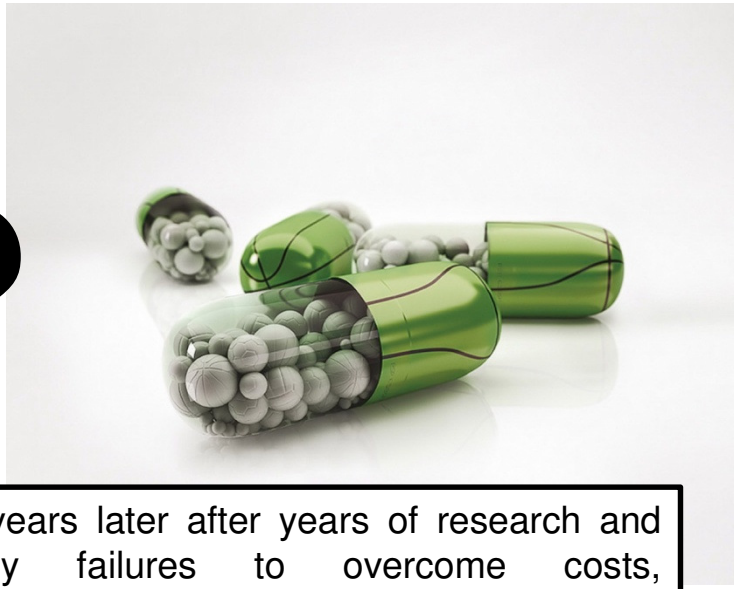
There would have been an number of additional inventions for the 2014 Audi RS 7 which is considered by many as the epitome of aesthetic design, innovation technology and track-tested performance.

0 – 100 kph 4.1s; 309kw @ 5500 rpm; 550 Nm @ 1400 rpm; 4L V8 BiTurbo, 32 valves, DOHC, TFSI; 7 Speed S tronic gearbox, all wheel drive

PATENTS AND ACCESS



?



Compound identified in the 1960's but is prohibitively expensive and only available in small quantities (too little for research)

30 years later after years of research and many failures to overcome costs, production, formulation, stability, safety and other issues (which resulted in a number of new and inventive inventions), extensive clinical trials, expenditure of billions of $ on R&D, trials, regulatory approvals and education of medical personnel and in the face of considerable risks, a medicine is eventually brought to market which turns a previously killer disease into a treatable condition

COMPETITION LAW

- Competition Act No 89 of 1998 – applies to all economic activity including IP
- Relates to both:
  - Horizontal relationships: agreements (broadly defined) between competitors (actual or potential). (e.g. IP License Agreements; Joint R&D Agreements; Joint Ventures; Co-marketing/branding agreements.)
  - Vertical relationships: a firm, its suppliers, customers or both (e.g. franchising agreements, IP license agreements, distribution/supply agreements.) No guidelines in South Africa but EU Technology Transfer Block Exemption Regulations and guidelines instructive
- Establishment of dominance in IP can be difficult (market analysis required)
  - A patent for the API etc. does not mean dominance. SA Competition Tribunal (merger cases): ATC3 level. However, HIV health activists complaints against GSK / BI HIV treatments: ATC4
  - Substitutability on demand and supply side?
  - Competitive constraints?
- IP abuse arguably dependent upon the validity of IP and exclusive jurisdiction provisions in IP legislation

COMPETITION LAW

- Abuse of dominance?:
  - Excessive pricing: Difficult to show and Competition Authority reticent to be a price regulator
  - Authorised generics: From a patent law perspective, patentee can launch as many of its patented products under different brands as it wants and a case by case analysis is required (does the third mover have the ability to compete on price, access to the market through its own distribution / retail levels, plan to be in a market segment from a strategic point of view and is there potential for market shares to grow?)

- When is a limitation of the rights in and to a patent problematic?:
  - Denying a patentee (by the licensee) from launching one or more authorised generics while the active/formulation etc. is under patent
  - Requiring a patentee not to provide a license under a patent in the event that it is an essential facility
  - A restriction on the terms and conditions of a contractual relationship (minimum resale price maintenance, market and customer allocation etc.)

COMPETITION LAW

- Certain agreements may out rightly be anti-competitive even if the effect is pro-competitive
  - e.g. division of markets (pharmaceuticals: public vs. private market; general: use of new developments in one market vs. other markets) and co marketing of products, between competitors, cross licensing of IP wherein trading conditions are fixed (price, quality, quantity) – results in a chilling effect

- Certain agreements may be anti-competitive if they result in a substantial lessening and prevention of competition and for which there are no pro-competitive aspects outweighing the negative effects
  - e.g. exclusivity vs. non exclusivity, rebate structures and discounts

IPRP ACT AND EXCHANGE CONTROL

- Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008 (IPRP Act)
  - Applicable to:
    - IP (including know-how, confidential information, clinical trial information etc.) emanating from publicly financed (including partly funded) R&D at “recipients” of the funding
    - “Recipients” include universities and research councils
  - Ownership of IP resides with “recipient” but co-ownership possible under conditions

- Exchange control
  - Any agreement for or export of capital including IP out of SA is subject to the prior approval of the South African Reserve Bank
  - Includes transfer of IP (SA and arguably foreign) from a SA resident to a non-resident
  - Applies to payment of foreign royalties and clinical trial data and information

DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013

STAATSKOERANT, 4 SEPTEMBER 2013
GENERAL NOTICE
NOTICE 918 OF 2013
DEPARTMENT OF TRADE AND INDUSTRY
DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013
No.36816 3

INVITATION FOR THE PUBLIC TO COMMENT ON THE NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013

I, Dr Rob Davies, Minister of Trade and Industry, having obtained Cabinet approval, hereby publish the National Policy on Intellectual Property for broader public comments.

Interested persons may submit written comments on the proposed policy not later than thirty (30) days from the date of publication of this notice to:

Director-General, Department of Trade and Industry

Private Bag X84, Pretoria, 0001

Or hand deliver to:

77 Meintjies Street, Block B, 1st Floor, Sunnyside, Pretoria

Tel: 0123943569

Email: MPadayachy@thedtLgov.za

For Attention: Ms. Meshendri Padayachy

Dr Rob Davies (MP)

Minister of Trade and Industry

Thank you

-

Discussion/Questions