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IP LAW REFORM IN SOUTH AFRICA

Candice Sehoma

PUBLIC HEALTH NEEDS IN SOUTH AFRICA

- 7.5 million people living with HIV
- 5.2 million on treatment for HIV
- TB is the leading cause of death in SA
- Non-communicable disease such as hypertension, cancers, diabetes are growing in SA at a high rate
- Making us very vulnerable to the Covid19 pandemic given the burden of underlying conditions and under-resourced health systems
- SA spends 8% GDP on health, which includes purchasing drugs
- 80% population relies on public sector to access health services

BACKGROUND ON THE ACCESS TO MEDICINE CAMPAIGN

- Founded on the principles of making Medicine Affordable, Available and Accessible
- Multiple barriers were preventing – and still prevent – access to lifesaving medicines
- The AC was set up to respond to this crisis by overcoming barriers, that prevent access to medicines, and stimulating research and development (R&D) in areas of public health needs

SECTION 1

BARRIERS TO ACCESS

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WHAT IS A PATENT?

A patent is a reward given to a company
for inventing something new

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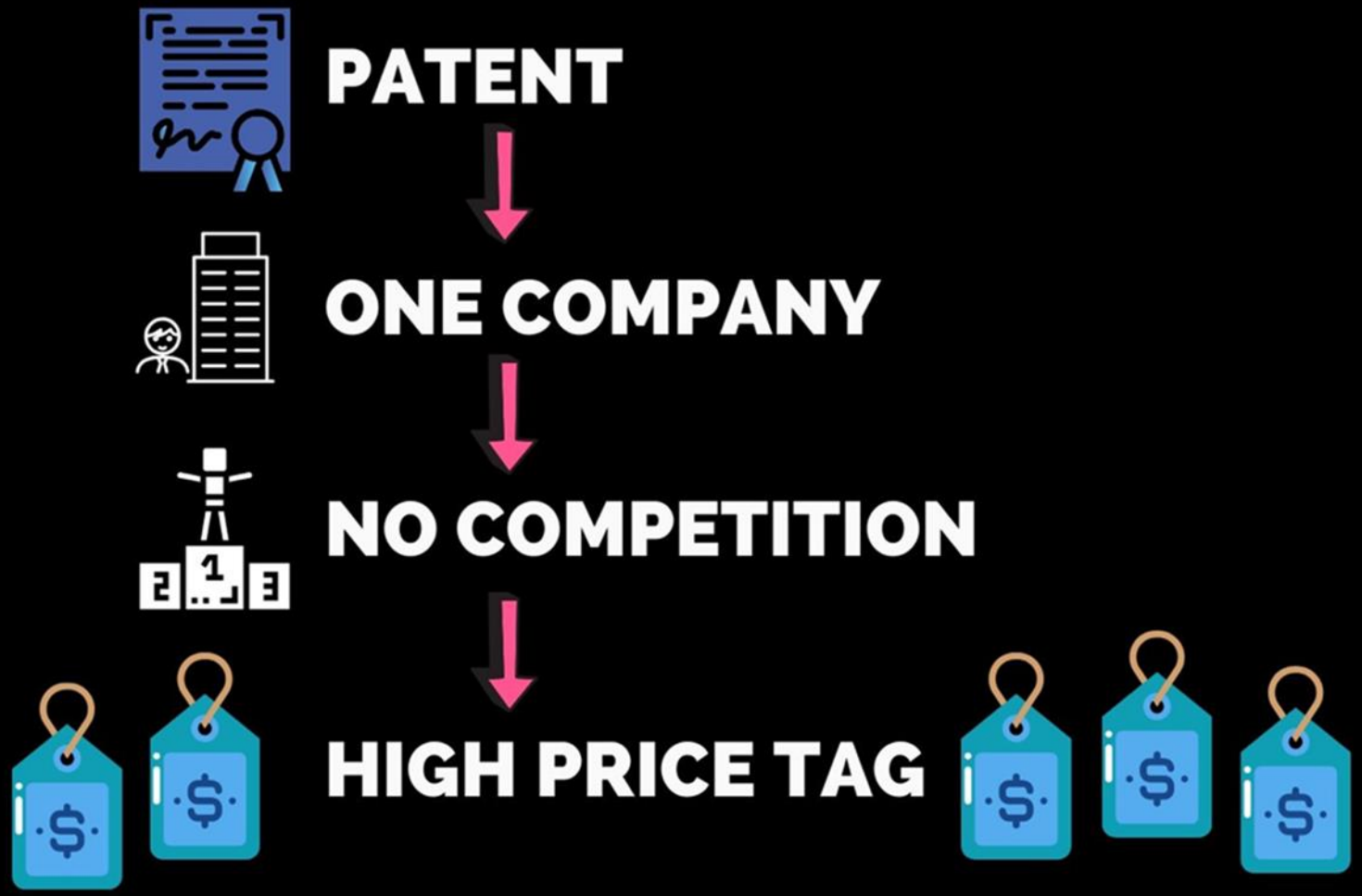
Only the patent holder can use, make, sell, produce or import that invention for 20 years

INTELLECTUAL PROPERTY



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PATENTS AND MEDICINE PRICES

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DOHA DECLARATION

Countries have the right to take legal steps to limit IP to protect public health—"TRIPS flexibilities"

Every single Article of the TRIPS Agreement can be read to make sure only the minimum requirement is fulfilled.

Whilst other countries like India, Argentina, Thailand, Brazil etc. have implemented TRIPS flexibilities—South Africa has not.

TRIPS FLEXIBILITIES

BEFORE GRANT OF PATENT

- Patent examination
- Strict patentability criteria
- Pre-grant oppositions

AFTER GRANT OF PATENT

- Post-grant oppositions
- Patent revocations
- Parallel importation
- Compulsory licenses

DRUG PATENTS = UNAFFORDABLE MEDICINES

IN 2008 ALONE,
SOUTH AFRICA GRANTED

242

VS.

FROM 2003-2008,
BRAZIL ONLY GRANTED

273

PATENTS ON MEDICINES

SOUTH AFRICANS PAY THE PRICE

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MEDICINE EXAMPLES

Table 2: Unit Prices of 24 Case Study Medicines (ZAR)

	Medicine Name	SA Private Sector Price	SA Public Sector Price	Indian Price
1	Thalidomide	130	Not available	8
2	Lenalidomide	3308	Not available	30
3	Bortezomib	10994	Not available	2540
4	Bendamustine	4182	Not available	1304
5	Daunorubicin	515	93	81
6	Dacarbazine	204	Not available	63
7	Dasatinib	728	Not available	Not available
8	Nilotinib	243	17	Not available
9	Rituximab	3365	1590	1016
10	Asparaginase	1327	Not available	188
11	Pegaspargase	NA	Not available	Not available
12	Erlotinib	736	Not available	64
13	Crizotinib	NA	Not available	Not available
14	Trastuzumab	23562	10596	11687
15	Trastuzumab emtansine	NA	Not available	Not available
16	Lapatinib	161	Not available	Not available
17	Abiraterone acetate	319	Not available	30
18	Enzalutamide	266	Not available	Not available
19	Ipilimumab	4805	Not available	Not available
20	Sorafenib	229	Not available	12
21	Bevacizumab	4440	2784	5030
22	Octreotide	218	93	40
23	Filgrastim	1493	464	456
24	Pegfilgrastim	8544	Not available	1728

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TESTING KITS – COVID-19

- The majority of COVID-19 laboratories in the Netherlands work with equipment made by pharmaceutical corporation Roche and depend on the company for supplies of the testing reagents, which are the liquid buffer needed to run the tests.
- A shortage of this buffer is one of the reasons why the Netherlands was not able to carry out mass testing for COVID-19 during the early stages of the pandemic in late March.
- Despite the shortage, Roche initially refused to provide the recipe for the buffer, blocking laboratories from quickly making their own solution and ramping up their testing capability
- This experience highlights how developing countries like South Africa would continue to have their Covid-19 medical tool response scale-up hamstrung due to IP barriers, despite having the required capacity.

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REMDESIVIR

- The case of Remdesivir best sums up the how patents can block access to therapeutics. The primary patent on the base compound of Remdesivir has been granted to Gilead in more than 70 low-and middle-income countries, hence potentially blocking access to generic alternatives until 2031.
- Gilead signed secretive voluntary licenses with a few generic manufacturers of its choosing to supply countries as determined by Gilead. As a result, other manufacturers in countries with patents were excluded from manufacturing and nearly half of the world's population were prevented from being supplied by the licensee and hence denied from accessing more affordable generics

- Cipla – R5000 for 5 day course
- Gilead – R50 000 for 5 day course

- This is a result of the current monopoly-based biomedical innovation system that allows exorbitant prices to be charged for medicines, without any checks or balances.

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TRIPS WAIVER

- Several months into this pandemic there are no meaningful global policy solutions to ensure access
- **important!** All governments are facing challenges ensuring timely, sufficient and affordable access to effective medicines, vaccines, diagnostics and other essential medical tools – nationalism, shortages, 'business-as usual' approaches
- South Africa and India took a bold stance with a joint waiver request to the World Trade Organisation (WTO) to prevent countries from granting or enforcing patents and other intellectual property (IP) on COVID-19 vaccines, drugs, diagnostics and other medical tools until most of the world's population has received effective vaccines and developed herd immunity.
- The proposal by South Africa and India is in direct response to this greed and the structural challenges governments in low- and middle-income countries (LMICs) are facing to scale up their manufacturing and better their response. It is in effort to break the barriers to accessing Covid19 medical products, realizing that the "case by case" or "product by product" approach required when using flexibilities to address IP barriers at the national level could be limiting during the pandemic
- Several High-income countries have not come in support of the waiver, making statements like this below

MYTHS AND REALITIES

MYTHS

- IP is not a barrier
- IP enabled R&D in Covid19
- Voluntary license is sufficient
- Existing TRIPS flexibilities are sufficient
- Global initaitives – COVAX ACT-A can deliver equitable access
- Even if IP is removed, developing countries cannot produce covid19 technologies
- IP holders are the best to produce safe and quality products

REALITY

- Past precedents and emerging evidence
- Public funding and global collective efforts enabled R&D in Covid19
- Voluntary licenses are limited
- TRIPS flexibilities are important but can be limited
- Wealthier countries bilateral initiatives undermine local initaitives
- Presumption has been proven to be wrong
- Developing countries can produce products with robust quality and safety

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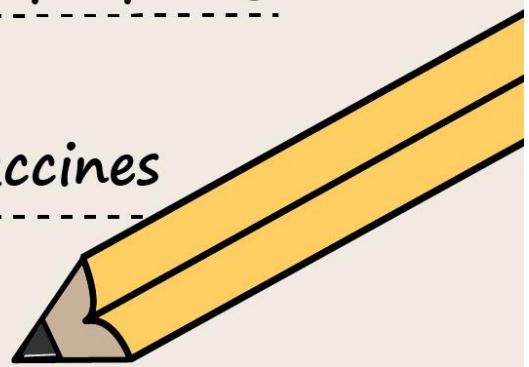
EQUITABLE ACCESS TO A VACCINE

Johnson & Johnson

New Year's COVID-19 Vaccine Checklist:

- ☐ full transparency
- ☐ openly share and don't enforce intellectual property
- ☐ help others to make more doses of new vaccines
- ☐ share doses with developing countries



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WHICH SIDE OF HISTORY WILL YOU BE ON?

... when the books on this pandemic are written?

NO PATENTS MONOPOLIES IN A PANDEMIC