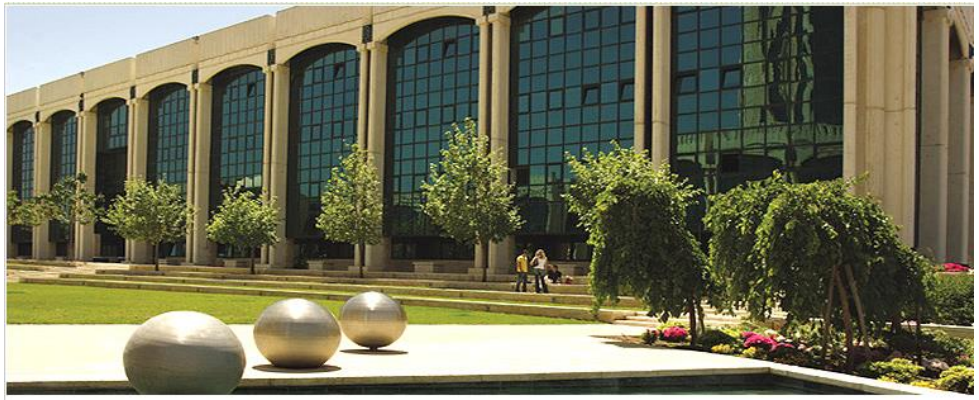
רשות הפטנטים



מדינת ישראל
משרד המשפטים

“Evergreening”

Tali Sharan Chechik – Patent examiner

Interdiction

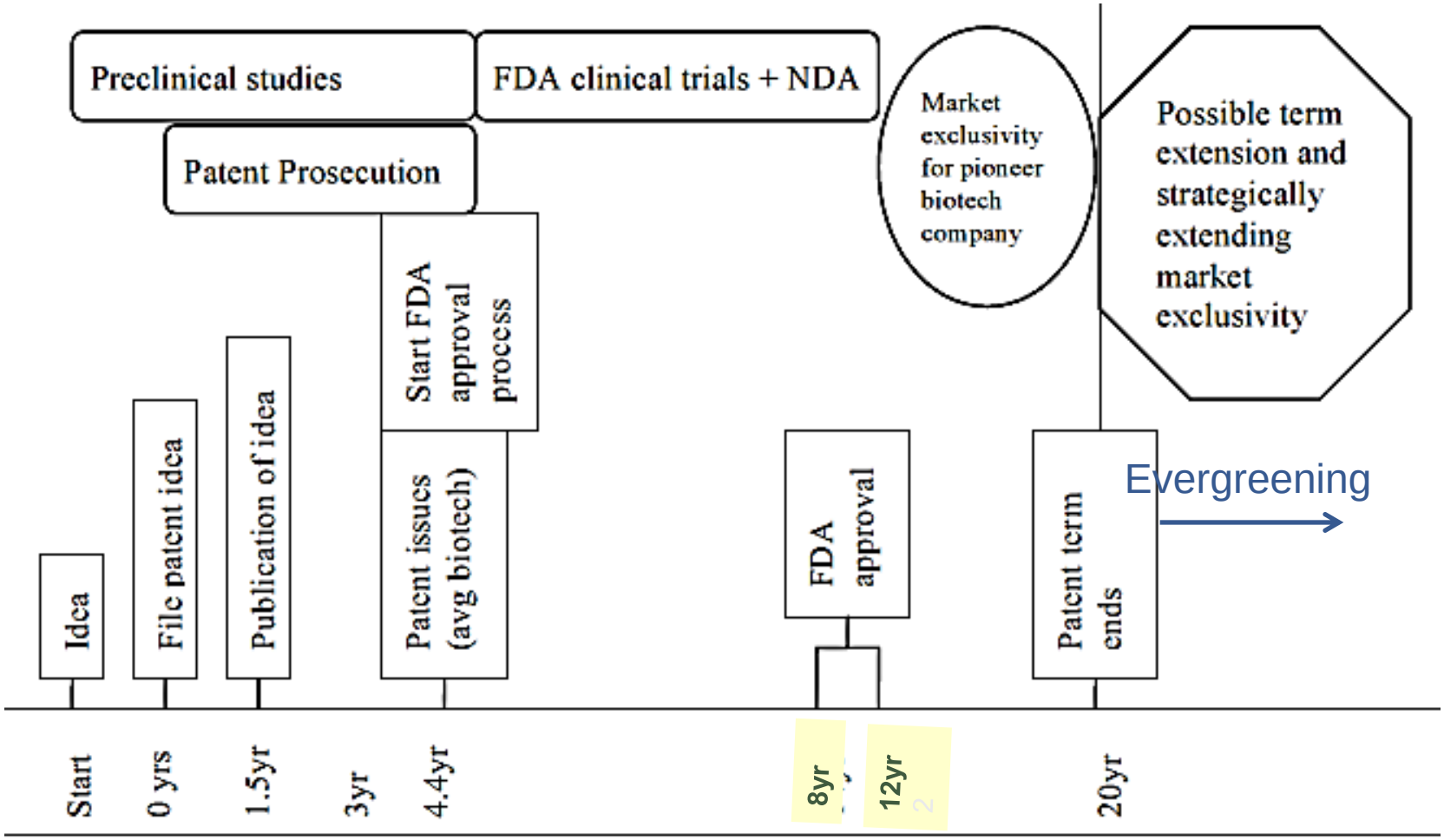
- "Evergreening"
  - legal and business patent strategies.
  - used to convey the impression that research-based pharmaceutical companies abuse the patent system
  - obtaining patents on what are characterized as "minor" improvements to existing medicines.
  - prevent competition by delaying the legitimate market entry of generic products
- most common in the pharmaceutical industry

IP Evergreening
or
Next Generation Pharmaceutical Technology

The market…

- **Consensus sales forecasts for world's top 10 drugs in 2014 ***
  1. **Avastin (cancer) Roche $8.9 Bil.**
  2. **Humira (arthritis) Abbott $8.5 Bil.**
  3. **Enbrel (arthritis) Pfizer/Amgen $8.0 Bil.**
  4. **Crestor (cholesterol) AstraZeneca $7.7 Bil.**
  5. **Remicade (arthritis) Merck/J&J $7.6 Bil.**
  6. **Rituxan (cancer) Roche $7.4 Bil.**
  7. **Lantus (diabetes) Sanofi-Aventis $7.1 Bil.**
  8. **Advair (asthma/COPD) GSK $6.8 Bil.**
  9. **Herceptin (cancer) Roche $6.4 Bil.**
  10. **NovoLog (diabetes) Novo Nordisk $5.7 Bil.**
- ***Source : Thompson-Reuters**

FDA Approval / Patent Exclusivity Timeline



http://www.iploft.com/PTO-FDA.pdf **www.iploft.com, 2011**

The equilibrium of the patent interest

Reward inventor for useful new inventions

public good

Conflicting interest in the Pharmaceutical Sector

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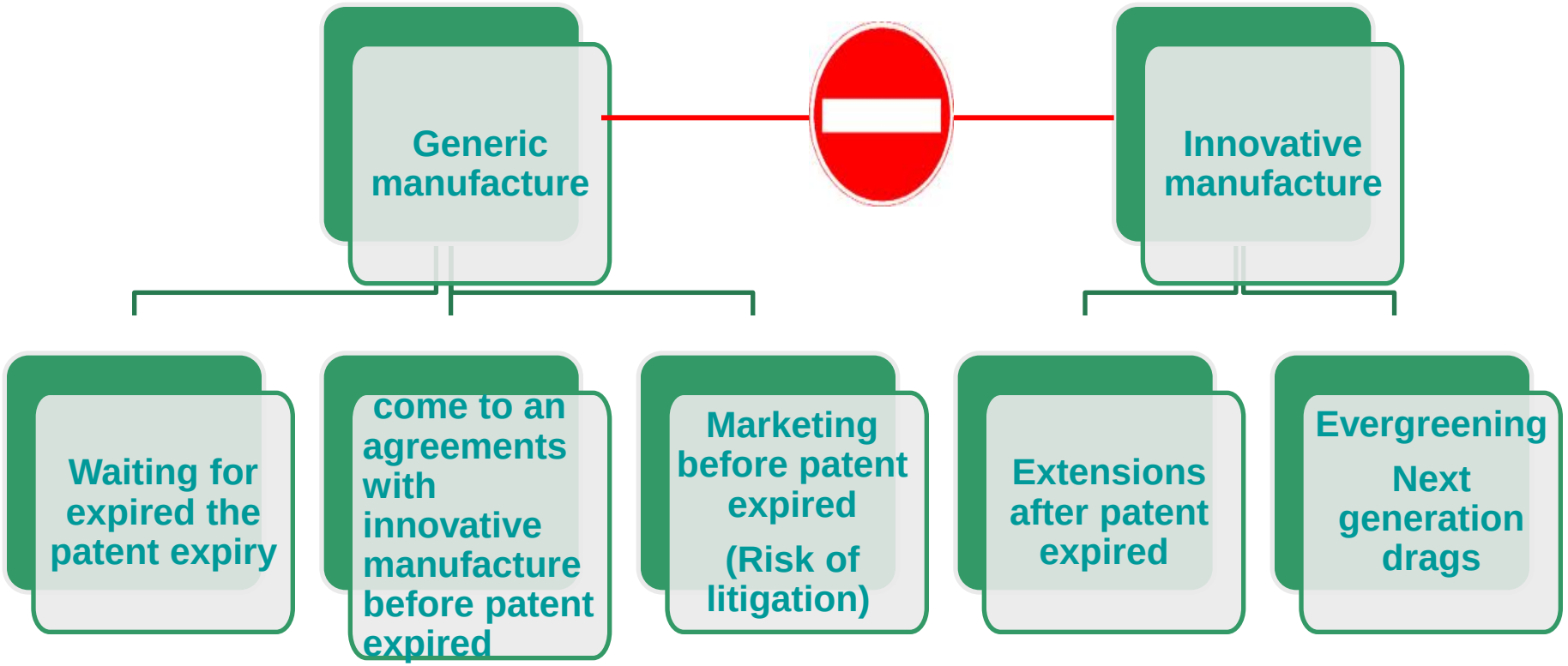


Generic industries POV

- **Evergreening has a negative effect upon public health.**
  - **Delaying the entry of generic products to the legitimate market**
  - **Prevent generic competition**
  - **drug costs stay up**
  - **less available to the public.**
  - **Evergreening leads to patents that relate to trivial advances or simple variation of known technologies.**

Innovative companies POV

- Use IP rights to recoup their R&D investment and compensate for the risks they have assumed.
  - "Patents are pivotal to the research-based pharmaceutical industry, given the enormous investment and risk required to develop innovative medicines. It can cost €1 billion or more to develop a new medicine in the period between discovery and marketing, normally a duration of 12 to 13 years. Only around 20% of new products ever recover the cost of development."
- Medicines patent usually enjoy shorter term of effective protection.
  - patent protection extension (IL maximum 5 year, EP maximum 15 years).

Innovative companies POV

- The Patent law does not distinguish between inventions consisting of “brand new products” (for example, a new compound) and inventions relating to improvements
- Patent for a new product will give exclusive rights which are **broader** than a patent for an improvement of that same product.
- Patent applications relating to developments or modifications are filed not just by those who originally developed the product but also by other companies, including generic companies.

Innovator Product vs. Generic - Extended Patents

GlaxoSmithKline's: The accusation of Evergreening is based on a number of fallacies:

Generic companies accusation	Innovative companies response
improvement patents are not justified within patent law.	Patents are only exists if they meet the requirements of patentability (new, useful, inventive steps)
that improvements subject to later patents are not medically important and should not be encouraged	patent system is intended to provide incentives to improve products and support innovation
that later improvements delay generic competition.	allow for generic versions of the basic product to compete with the improved product.

GlaxoSmithKline's Position

Examples of aspects in “Evergreening”

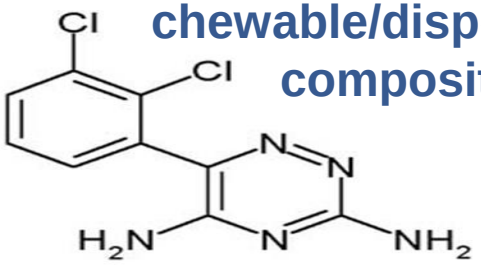
- Polymorph forms
- Isomeric forms
- Delivery profiles
- Dosing regimen
- Combination
- Field of use
- Pharmaceutical compositions
- New Process
- salts

“Evergreening” usage example: Lamictal

- GlaxoSmithKline: Lamictal™ (Lamotrigine) for treating epilepsy in children and adults
- 1980 – patent on active ingredient
  expired: 2000
- 1992 – patent on chewable tablets
  expiration: 2012

- same active ingredient
  patent term: 32 years

Example: Lamictal



1992
Patent application for chewable/dispersible pharmaceutical composition of Laotrigine

2012
Expired patent

20 years

1980
Patent application for the active ingredient Lamotrigine

20 years

2000
Expired patent

Patent protection term for the same active ingredient: 32 years

“Evergreening” usage example: Omeprazole

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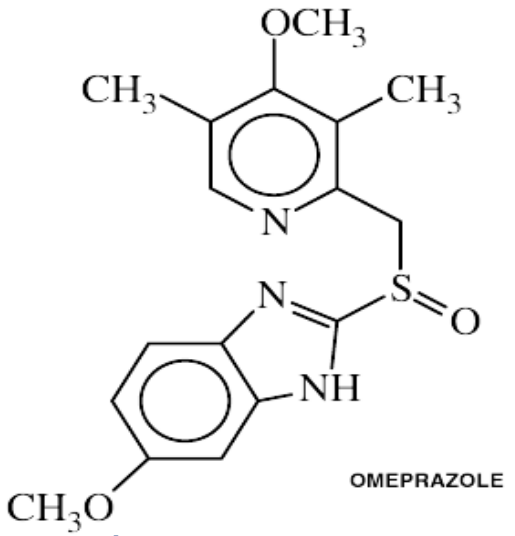
- **25 family patent**
  - **Crystal: 4**
  - **Salt: 3**
  - **Pharmaceutical composition:14**
  - **Other:4**

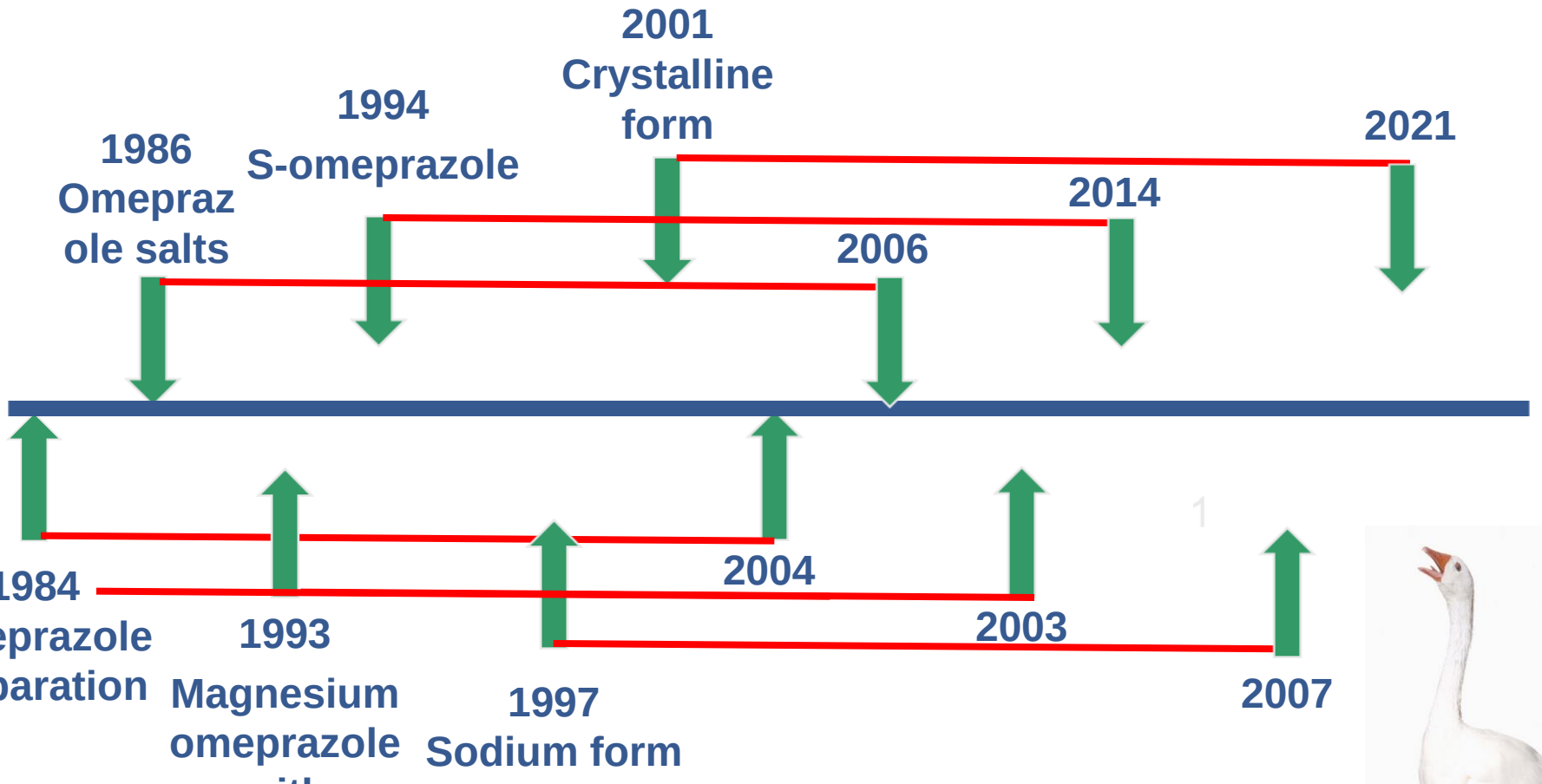


OMEPRAZOLE

proton pump inhibitor used in the treatment of dyspepsia, peptic ulcer disease (PUD), gastroesophageal reflux disease (GORD/GERD), laryngopharyngeal reflux (LPR) and Zollinger–Ellison syndrome

- First patent application- 1984 AstraZeneca
- Received FDA approval of market- 1989
- The basic patent for Prilosec expired in Apr... 2001
- Sales of 6.1 billion $ by 1999.

Example: Omeprazole



Patent protection term for the same active ingredient: 35 years

Agreement/Trading between Innovator and Generic Companies

- **Innovator companies conspicuously come to an agreement with the generic manufactures to delay or eliminate specific generic drugs from entering the market.**
  - **Tamoxifen sold by Zeneca 442 million $ in 2001. Zenca and Barr reached an agreement:**
    - **Zeneca paid 66.4 million $ to Barr**
    - **Zeneca allowed Barr to sold Tamoxifen under Barr's label**
    - **Barr agreed to enter with its own ANDA after the expiration of zeneca US pat No 4,536,516.**

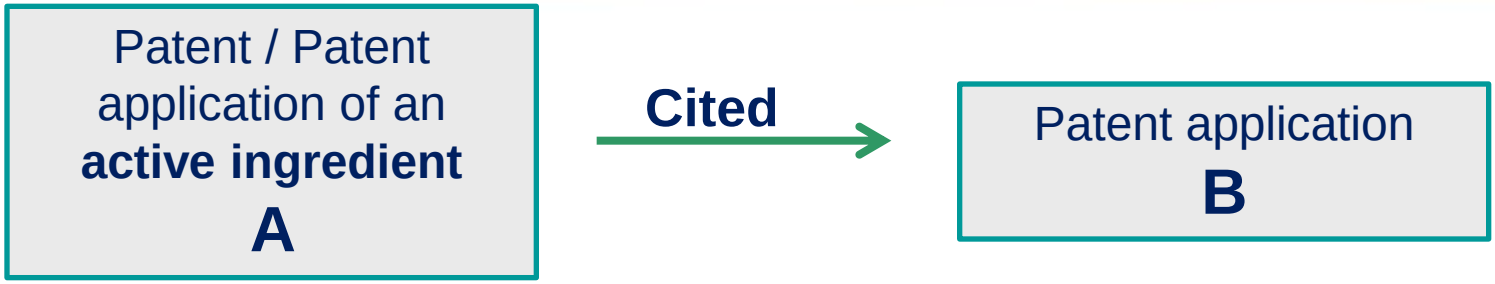
Agreement/Trading between Innovator and Generic Companies

Acquisition of	Acquisition By	Worth (Billion $)
Wheth	Pfizer	68
Ranbaxy	Daiichi Sankyo	4.8
Piramal Healthcare. Ltd	Abbott	3.7
Ratiopharm, Ivax, Barr Pharmaceuticals	Teva Pharmaceuticals	19.8
Genentech	Roche	46.8

Innovative step requirements

- **section 5** Israeli patent law:
  - "An inventive step is a step which does not, to an **average skilled person**, appear **obvious** in the light of information published before the application date in ways said in section 4"

Innovative step



- **The active ingredient of prior art A is part of the subject claiming in application B.**
  - **The examiner will cite document A combined with another prior art X or common knowledge and argue for obviousness**
    - **Unless the applicant provide reasonable evidences to ensure an inventive step.**
  - **The burden of proof Inventive step is on the applicant.**

- Israeli patent office tend to even the inventive step requirements in order to deal with the increasing flowed of “EVERGRENING” patent application, applied by the same applicant, in order to balance between the public interest and inventor interest.

Thank you ☺