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IP CASE STUDY



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Background

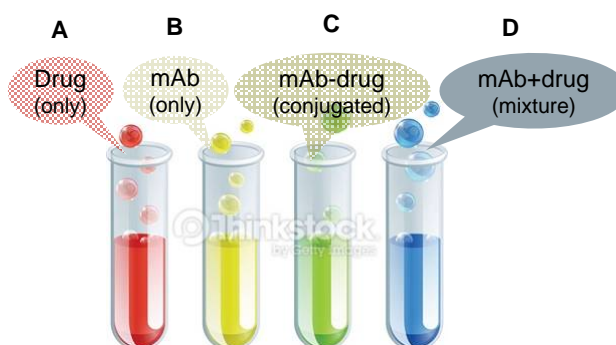
- § Scientists at the Weizmann Institute conduct research on using antibodies as carriers to target treatment for specific cancers.
- § A former colleague provides materials for use in experiments.
- § Promising results are obtained.
- § A patent application is filed.
- § The patent is licensed to a biopharma company.
- § Ownership of the patent is disputed.
- § Litigation proves costly.

The research programme

- § Objective: to target cancer cells with a chemotherapeutic drug.
- § Sela's research group at the Weizmann Institute received two monoclonal antibodies (mAb) from former colleague Professor Schlessinger.
- § mAb binds to specific site on cancer cells (selective targeting).
- § One mAb selected for experiments.
- § Drug chemically linked to mAb (conjugated).
- § Effects targeted delivery of chemotherapeutic drug.

The experiments

Treatment of tumour with mAb and chemotherapeutic drug



A = some effect **B = some effect** **C = some effect** **D = significant inhibition**

The results

§ Expectation that **experiment C** would show best results

- mAb should carry drug directly to tumour and destroy cancer cells.

§ **Experiment D** shows a surprising effect

- Free mixture of chemotherapeutic drug and mAb creates synergistic effect on inhibiting growth of cancer cells.
- Unpredicted result demonstrates "inventive step".

The publication

§ **Sela** did not consider filing a patent application

- mAb owned by Schlessinger's employer, Rorer Biotechnology.
- Might give rise to complex negotiations.
- Happy to disseminate results in *Journal of the National Cancer Institute*.

§ **Sela's** group prepares publication

- Draft of paper shown to Schlessinger on next visit.
- Schlessinger also named as author for contribution of mAb.
- Paper published in December 1988.

The patent application

Schlessinger discusses results with colleagues at Rorer:

§ Clinical studies initiated.

§ Patent application prepared.

§ Claimed "antibodies" + "antibody/drug mixtures" in cancer treatment.

§ Inventors named are all Rorer employees.

§ US patent application filed September 1988 (unknown to Weizmann).

The licence

§ 1994: Rorer grants exclusive licence to ImClone.

§ ImClone invests USD 190m in developing cancer therapy.

§ 1999: Aventis acquires Rorer and patent after series of mergers.

§ "Erbix" receives FDA approval:

- 2004: colorectal cancer
- 2006: head and neck cancer

§ 2007: sales of "Erbix" in the order of USD 400m per year.

The patent dispute

§ 2001: Patent granted and published (US6217866):

- US patent limited to claims for mAb/drug mixture.
- Other territories grant claims to mAb only and to mixture.

§ 2002: Sela becomes aware of patent and raises concerns.

§ Yeda (technology transfer company for Weizmann Institute) enters discussions with Aventis and ImClone • no resolution.

§ 2003: Yeda starts court proceedings against Aventis and ImClone.

Litigation

§ Yeda's case

- Experiments and inventive concept originated solely from Sela's group.
- Data and figures for patent specification drawn from draft publication.

§ Defendants' case

- Provided mAb for the experiments.
- Schlessinger advised Weizmann scientists on the project.
- Had already contemplated mixture of mAb and drug.

The court decision

- § Weizmann scientists are sole inventors of US patent.
- § Inventorship of patent corrected at USPTO.
- § Yeda becomes owner of patent.
- § Out-of-court settlement reached 2007:
 - Yeda owns US patent.
 - Yeda and Aventis jointly own patents in other territories.
 - Aventis and ImClone pay USD 60m each to Yeda.
 - ImClone pays Yeda royalty on sales in US.
 - ImClone pays Yeda and Aventis royalty on sales outside US.

Note on inventorship

Judge Buchwald: *"Conception is the touchstone of inventorship, the completion of the mental part of invention."*

- § The inventors are those who conceived of the idea of using the mAb in an unconjugated mixture in order to treat human tumour cells.
- § The provision of mAb alone does not give entitlement to inventorship.
- § There was no evidence of collaboration or contribution to conception or reduction to practice of the invention by Schlessinger's group.

Discussion

- § What procedural steps might have been introduced in the two organisations involved that could have prevented the situation of incorrect inventorship arising?

Lessons learnt

- § Exercise caution in disclosing research results • use an **NDA**.
- § Clarify terms for exchange of materials • use an **MTA**.
- § Complete an invention disclosure form (**IDF**) to help inventors focus.
- § Keep **notebooks** to provide convincing documentary evidence.

Thank you for your attention!