

NAVIGATING COMPETITION LAW ISSUES IN IP SETTLEMENTS

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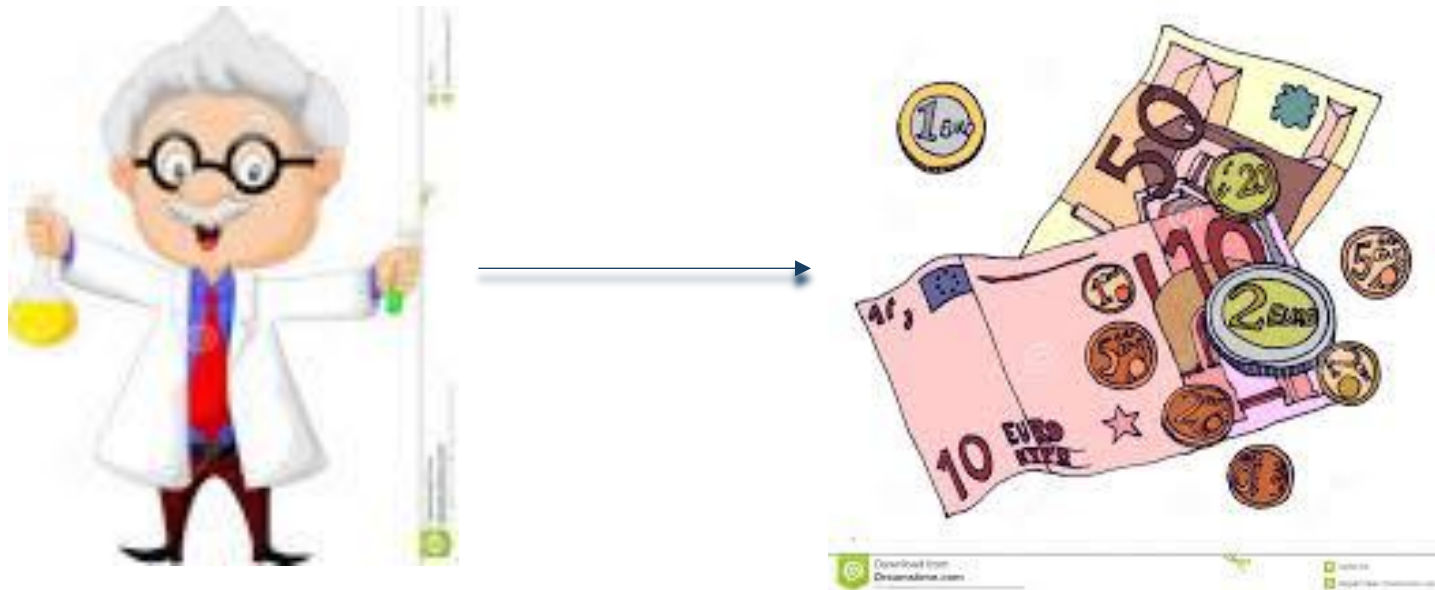
NAVIGATING COMPETITION LAW ISSUES IN IP SETTLEMENTS

OVERVIEW

- THE CONUNDRUM
- THE LAW
- THE PRACTICAL IMPLICATIONS

HOW DO THESE CASES ARISE?

COMPANY B INVENTS A GENERIC VERSION OF A DRUG



HOW DO THESE CASES ARISE?

COMPANY A IS FACED WITH IMMINENT GENERIC ENTRY

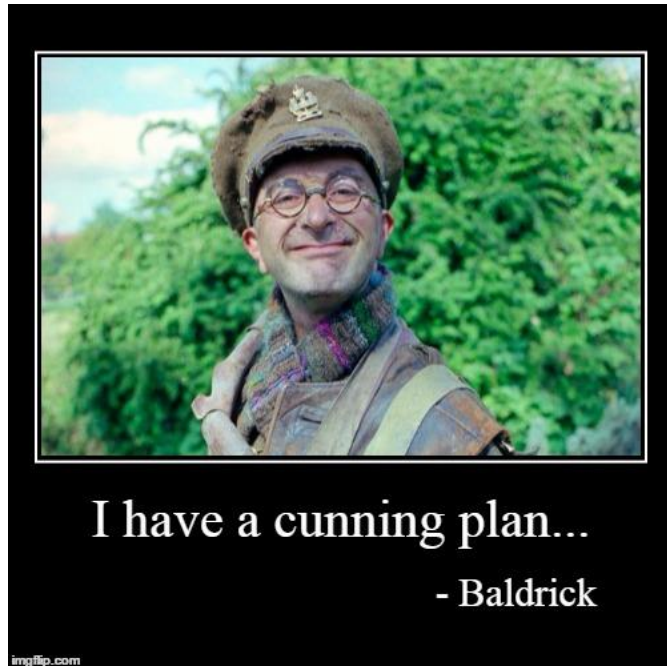


Numerous generic companies join company B in the race to be the first to enter



Company A, the incumbent, is worried about the threat of generic entry

HOW DO THESE CASES ARISE?



Company A devises a plan to respond to the threat of generic entry; it might:

- 1) sue generic companies for patent infringement
- 2) apply for more patents of better production processes
- 3) intervene in the applications by generics for MAs
- 4) enter into settlement agreements with generics

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THE CONUNDRUM (1)

- IMAGINE COMPANY A SUES COMPANY B FOR PATENT INFRINGEMENT
- B HAS SEVERAL OPTIONS. IT CAN EITHER:
 - ❖ CONTINUE TO LITIGATE
 - ❖ CAPITULATE COMPLETELY
 - ❖ SETTLE WITHOUT A VALUE TRANSFER
 - ❖ SETTLE WITH A VALUE TRANSFER

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THE CONUNDRUM (2)

- A & B SETTLE THEIR PATENT DISPUTE ON THE FOLLOWING TERMS:
 - ❖ B MUST NOT ENTER THE MARKET DURING AGREEMENT
 - ❖ B MUST NOT CHALLENGE THE VALIDITY OF THE PATENT
 - ❖ A WILL PAY B £10 MILLION IN CASH
 - ❖ A WILL SUPPLY B WITH A FIXED VOLUME OF A'S PRODUCT

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THE CONUNDRUM (3)

- DOES THE AB SETTLEMENT AGREEMENT HAVE AS ITS *OBJECT* THE RESTRICTION OF COMPETITION?
- DOES THE AB SETTLEMENT AGREEMENT HAVE AS ITS *EFFECT* THE RESTRICTION OF COMPETITION?

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THE LAW (1)

- FOUR RECENT JUDGMENTS:
 - CASE T-691/14 *SERVIER* EU:T:2018:992
 - CASE C-307/18 *GENERICS* EU:C:2020:52
 - CASE C-591/16 P *LUNDBECK* EU:C:2021:243
 - CASE 1251/1/12/16 *GENERICS* [2021] CAT 9

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THE LAW (2)

- THREE KEY QUESTIONS:
 - ❖ **FIRST**, WERE A & B (AT LEAST) POTENTIAL COMPETITORS AT THE TIME OF THE SETTLEMENT?
 - ❖ **SECOND**, DID B ACCEPT RESTRICTIONS ON ITS OWN EFFORTS TO ENTER THE MARKET?
 - ❖ **THIRD**, DID A TRANSFER SUFFICIENT VALUE TO B TO INCENTIVISE B NOT TO COMPETE ON THE MERITS?

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POTENTIAL COMPETITION

- A & B ARE **POTENTIAL COMPETITORS** IF THERE ARE REAL & CONCRETE POSSIBILITIES OF B ENTERING THE MARKET; EG:
 - ❖ B HAS TAKEN SUFFICIENT PREPARATORY STEPS TO ENABLE IT TO ENTER
 - ❖ THERE ARE NO INSURMOUNTABLE BARRIERS TO ENTRY

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RESTRICTON OF COMPETITION

- B ACCEPTS ENTRY RESTRICTIONS – FOR EXAMPLE:
 - B PROMISES NOT TO LAUNCH ITS OWN PRODUCT ANYWHERE IN THE WORLD
 - B AGREES NOT TO LAUNCH ITS OWN PRODUCT IN CERTAIN COUNTRIES
 - B AGREES TO SHELVE ITS R&D EFFORTS
 - B AGREES TO DESTROY ITS OWN STOCK

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TRANSFER OF VALUE

- A TRANSFERS VALUE TO B – FOR EXAMPLE:
 - A MAKES CASH PAYMENTS TO B
 - A TRANSFERS A (RESTRICTED) VOLUME OF ITS OWN PRODUCT TO B
 - A AGREES TO BUY STOCK FROM B
 - A GRANTS A PATENT LICENCE TO B SO THAT THE LATTER CAN MANUFACTURE AND SELL A'S PRODUCT

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TEST – OBJECT CASES

- THE TEST FOR CHARACTERISING THE **OBJECT** OF THE AB SETTLEMENT AGREEMENT IS:

“WHETHER THAT NET GAIN IS SUFFICIENTLY LARGE ACTUALLY TO ACT AS AN INCENTIVE TO THE MANUFACTURER CONCERNED OF GENERIC MEDICINES TO REFRAIN FROM ENTERING THE MARKET CONCERNED”

- SEE CASE C-307/18 **GENERICS**, PARA 93 AND CASE C-591/16 P **LUNDBECK**, PARA 115

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TEST – EFFECT CASES

- THE TEST FOR DETERMINING THE **EFFECT** OF THE AB SETTLEMENT AGREEMENT IS:

“WHETHER THERE WAS A REAL POSSIBILITY THAT THE GENERIC COMPANIES WOULD HAVE SUCCEEDED AGAINST GSK IN THE PATENT LITIGATION”

- SEE THE CAT IN **PAROXETINE** (2018), PARA 348 AND THE CAT AGAIN IN **PAROXETINE** (2021), PARA 75

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SOME PRACTICAL IMPLICATIONS

- **#1:** WHEN MIGHT A & B NOT BE POTENTIAL COMPETITORS?
- **#2:** WHEN CAN A & B SETTLE ON THE BASIS OF A VALUE TRANSFER?
- **#3:** CAN A & B SETTLE A PATENT DISPUTE ON DIFFERENT TERMS IN DIFFERENT COUNTRIES?
- **#4:** WHEN MIGHT A REVERSE PAYMENT SETTLEMENT AGREEMENT NOT HAVE ANTI-COMPETITIVE EFFECTS?

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PRACTICAL IMPLICATION (1)

- **WHEN MIGHT A & B NOT BE POTENTIAL COMPETITORS?**
 - B TOOK STEPS TO ENTER, BUT HAD TO GIVE UP DUE TO THE LACK OF A VIABLE PRODUCTION METHOD
 - B FACED AN INSURMOUNTABLE BARRIER TO ENTRY:
E.G. REFUSED A MARKETING AUTHORISATION

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PRACTICAL IMPLICATION (2)

- **WHEN COULD A & B SETTLE *WITH* A VALUE TRANSFER?**
 - VALUE TRANSFER WITHOUT ANY ENTRY RESTRICTION: *LUNDBECK* DECISION, PARA 164
 - VALUE TRANSFER COVERS ONLY AVOIDED LITIGATION COSTS: *GENERICS*, PARA 86
 - VALUE TRANSFER IS REMUNERATION FOR SUPPLY OF GOODS OR SERVICES TO THE ORIGINATOR: *GENERICS*, PARA 86

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PRACTICAL IMPLICATION (3)

- **CAN A & B SETTLE A PATENT DISPUTE ON DIFFERENT TERMS IN DIFFERENT COUNTRIES?**
- CASE T-684/14 *KRKA v COMMISSION* (2018) – ON APPEAL TO THE COURT OF JUSTICE IN CASE C-151/19 P
- **IN RE: HUMIRA [ADALIMUMAB] ANTITRUST LITIGATION** (2020) – ON APPEAL TO THE 7TH CIRCUIT COURT OF APPEALS

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PRACTICAL IMPLICATION (4)

- **WHEN MIGHT A REVERSE PAYMENT SETTLEMENT AGREEMENT NOT HAVE ANTI-COMPETITIVE EFFECTS?**
 - AGAIN, SEE CASE T-684/14 *KRKA v COMMISSION* (2018)
 - SEE THE CAT IN *PAROXETINE* (2021), PARA 76
 - IF THERE WERE NO REAL POSSIBILITY THAT THE GENERIC COMPANY WOULD HAVE SUCCEEDED

THANK YOU FOR YOUR ATTENTION!