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# *Patent Strategies Towards Generics*

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# The "Toolkit"

- **Strategic patenting (patent clusters)**
- **Life-cycle strategies (evergreening)**
- **Patent disputes and litigation**
- **Interventions before national regulatory authorities**

# Patent Clusters

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# The Issue

- **1300 patents and applications for one medicine**
- **On the one hand**
  - 500 of 1300 are applications
  - each actual patent held in 27 Member States
  - so only 30 patent families
- **On the other**
  - still potentially over 800 litigations

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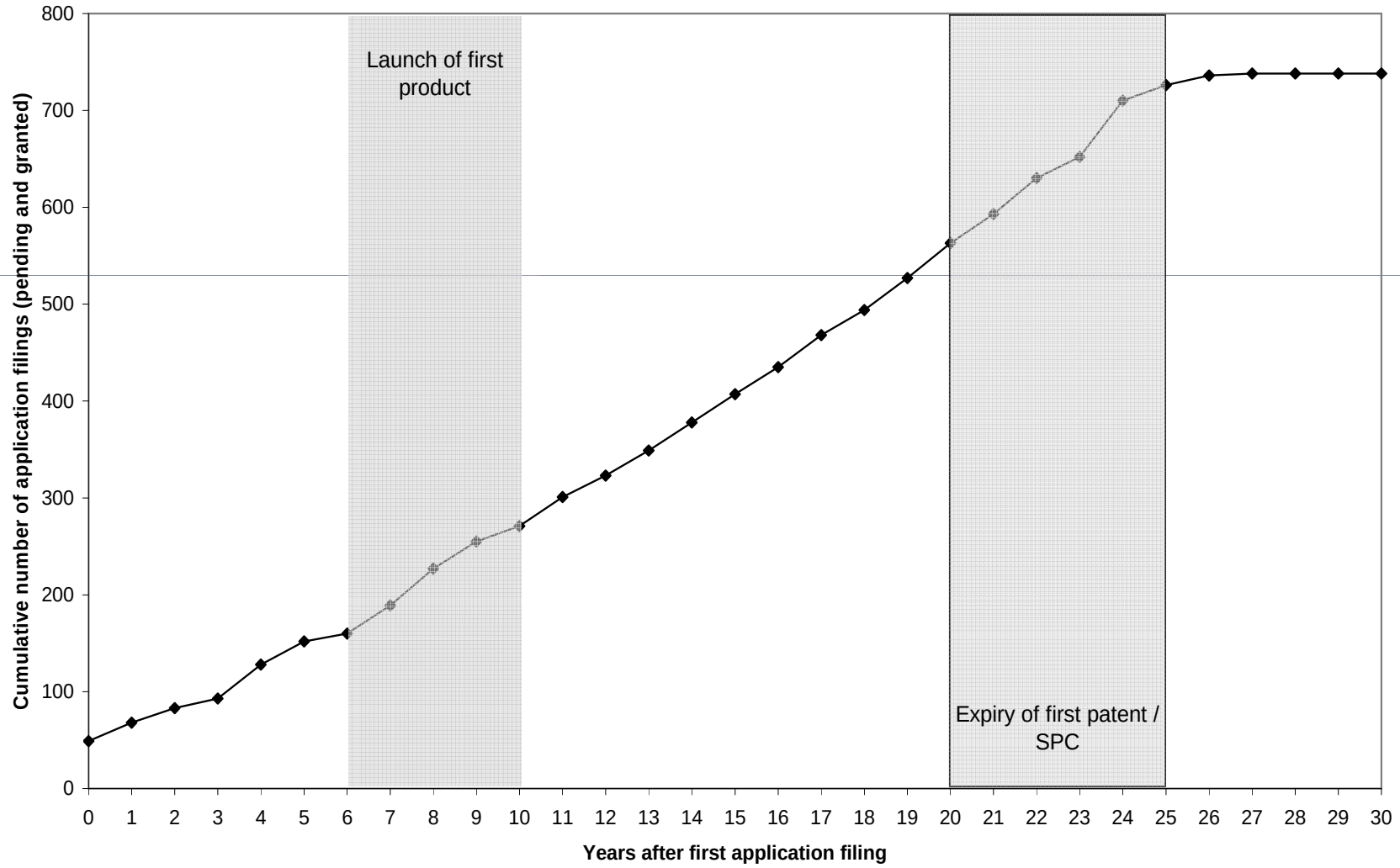
# The Issue (II)



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# The Issue (III)

- **“The strategy today is to try and provide a solid protection for the substance … and a portfolio protecting different aspects of product providing extended protection both in brea(d)th and time but inevitably less solid and robust” (504)**

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# Tetra Pak II

- **"Tetra Pak has pursued a particularly extensive patents policy. The group has not merely patented all the basic technology which it has developed in relation to machines, cartons and processes, but has also patented all modifications, however minor, made subsequently … As a result, although the basic technology … was developed in the 1960s and has remained basically the same ever since, the latest patent relating to these cartons expire in the early years of the next century … Tetra Pak claims over 100 patents for cartons and a further 100 or more patents for machines" (Cmsn, 22)**

- **"all the infringements found, which were set in the context of a totally autonomous production and distribution organization and a very active patents policy, lawful in themselves …" (CFI, 242)**

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# Tetra Pak I

- **Acquisition of exclusive IP rights may constitute an abuse where competition is excluded as a result**
  - **“acquisition of the exclusivity of the licence not only strengthened Tetra' s very considerable dominance but also had the effect of preventing, or at the very least considerably delaying, the entry of a new competitor into a market where very little if any competition is found” (23)**

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# *AstraZeneca* (1st Abuse)

- **AZ dominant in PPIs via patented drug Losec**
- **Submits misleading SPC applications**
  - incorrect/incomplete information re date of 1st MA
- **As a result of which**
  - AZ wrongly granted patent right extensions
  - market entry of generic PPIs delayed
  - AZ's dominance in PPIs prolonged

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# Basic Principle

- **"submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled … constitutes a practice falling outside the scope of competition on the merits … Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position" (355)**

- **Intention to mislead/bad faith not necessary (356)**
  - "misleading nature of representations … must be assessed on the basis of objective factors" (356)
  - AZ "could not reasonably be unaware" that submissions misleading (493)
  - "intention nonetheless constitutes a relevant factor" (359)
  - AZ acted intentionally and not in good faith (495, 573)

# Duty to clarify?

- **AZ argued**
  - underlying legislation ambiguous
  - submissions consistent with its interpretation
  - had obtained two supporting legal opinions

- **General Court found AZ had "refrained from disclosing" its interpretation of the legislation (496) and the facts relevant if its interpretation was wrong (591)**

- **Failure to disclose interpretation of the law was a "manifest lack of transparency" (493)**

# Duty to seek to correct errors

- **“in so far as an undertaking in a dominant position is granted an unlawful exclusive right as a result of an error by it in a communication with public authorities, its special responsibility … requires it at the very least, to inform the public authorities of this so as to enable them to rectify those errors” (358)**

# All IP applications?

- **“the limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to raise regulatory obstacles to competition” (357)**

- **AZ’s “misleading” representations to courts in Germany and Norway formed part of the first abuse (597)**

# Impact on Competition

- **Abuse started when the misleading application made (370 and 373)**

- **No requirement that SPCs were granted or entered into force**
  - since AZ's behavior "cannot, in any way, be regarded as being covered by normal competition between products on the basis of an undertaking's performance" it was sufficient that it was "capable of restricting competition" (376)

# Patent litigation

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# The Issue

- **Generics win 62% of cases litigated to final judgment (621)**
  - av duration of litigation 2.8 years (636)
- **On the one hand**
  - what is the “right” success rate?
  - 40% chance of success seems respectable
- **On the other**
  - generics win 74% of secondary patent cases litigated to final judgment (628)

# ITT Promedia

- **Access to justice is a fundamental right**
  - "it is only in wholly exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an abuse" (60)

- **Action must be**
  - "manifestly unfounded" in that it "cannot reasonably be considered an attempt to establish the rights of the undertaking" and
  - "conceived in the framework of a plan whose goal is to eliminate competition" (55 and 56)

# *AstraZeneca* (1st Abuse)

- **The conduct constituting the first abuse included "misleading representations before the German, Finnish and Norwegian courts"(597, 598)**
- **AZ pursued arguments on which "it could not reasonably rely" (587)**
  - **"even though it possessed consistent information" showing that those representations were not correct and**
  - **"were not relevant … upon its own interpretation of Regulation No 1768/92 " (para 582)**
- **Representations made in course of defending validity of relevant SPCs (590)**

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# *Servier v Apotex*

- **Covisil (prindopril) treatment for high blood pressure and heart failure**
- **Original perindopril patent expired 2003**
- **Follow-on patent obtained 2000 but**
- **UK Court of Appeal**
  - dismissed case without hearing counsel for Servier
  - crystalline form covered by 2nd patent indirectly disclosed in 1st
  - innovation obvious on evidence of Servier's own expert
  - patent a "try-on", not only invalid but "very plainly so" and "the sort of patent which can give the patent system a bad name"

# Evergreening

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# The Issue

- **Strategies for extending monopoly beyond the expiry of the original patent**

- **“Originator companies often launch second generation or follow-on products shortly before loss of exclusivity of the first generation product, which is sometime combined with the withdrawal of the initial product from the market. This is accompanied by intensive marketing efforts [to switch prescriptions and patients]” (989)**

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# The evidence

- **Follow-on products in 40% of cases (1003)**
  - profile “late” applications for follow-on patents
  - intensive use of marketing and promotion
- **On the one hand**
  - innovation is valuable whenever it happens
- **On the other**
  - some follow-on products may offer little or no added value

# *AstraZeneca* (2nd Abuse)

- **AZ launches new formulation of Losec**
  - tablet rather than capsule
- **Deregisters capsule MAs in certain selected countries only**
- **Entry by generics and parallel imports hampered as a result**

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# Basic Principle

- **AZ argued it was legally entitled to withdraw MAs and had no obligation to assist competitors by maintaining MAs**

- **General Court found**
  - "whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests … it cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification" (672)

# Basic Principle (II)

- **General Court found (cont.)**
  - "an undertaking in a dominant position cannot use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market" (817)
  - "AZ intended, by means of these deregistrations, to obstruct the introduction of generic products" (814)

# No objective justification

- **AZ argued withdrawal of MAs objectively justified to avoid pharmacovigilance reporting obligations**

- **General Court found**
  - AZ was barred from raising this argument as it had not raised it before the Commission (687)
  - the absence of any mention of such obligations in AZ internal documents made it "scarcely credible" that this was the reason for withdrawal of the MAs (688)
  - "Furthermore, the obligation to submit, at five-yearly intervals, reports on other suspected adverse reactions does not … constitute a serious objective ground of justification" (692)

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# Reckitt Benckiser – Gaviscon

- **RB's heartburn medicine Gaviscon Original Liquid comes off patent in 1999**
- **RB challenges attempts to adopt a generic designation for Gaviscon OL in period 2000 to 2006**
- **In 2005**
  - reformulated patented product Gaviscon Advance Liquid launched and marketed
  - packs of Gaviscon OL withdrawn from NHS channel and product delisted
  - RB condemned by regulator for aggressive marketing
- **RB agrees GBP 10.2 million penalty with OFT (Oct 2010)**

# Internal Documents

- **RB marketing manager email**
  - "If we were to change the formulation … with the rationale that we are doing it for health and safety reasons … we could withdraw Gaviscon liquid from sale within the NHS and replace it with the new formulation … We could potentially apply for a new patent on this formulation and effectively protect all our Gaviscon liquid business within the NHS for another 20 years"

# Intervention before national authorities

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# The Issue

- **"Widespread practice" of originators contacting MA bodies expressing concerns that generics**
  - infringe patent rights
  - pose health risks
  - are not equivalent to originator products (863)
- **Claims often irrelevant/pursued inconsistently**
  - patent status not relevant (Art 81, Reg 726/2004) (872)
  - safety risks typically not raised in all jurisdictions (877)
- **98% of cases litigated on patent or safety grounds lost or withdrawn by originator (885)**
- **Interventions result in average delay of 9.2 months**

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# The Issue (II)

- **Similar practice re P&R authorities in relation to**
  - patent infringement (most frequent)
  - bioequivalence
  - safety (907)

- **Claims arguably irrelevant**
  - patent protection "is not a criterion to be considered" (916)
  - bioequivalence and safety assessed as part of MA process
    - "all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. The difference between originator and generic products resides in the procedure to prove safety and efficacy … Any campaigns which put this fact in question ignore the key principles for marketing authorisations" (954)

# The Law

- ***AstraZeneca* (1st Abuse)**
  - misleading submissions to public authorities that result in extension of exclusivity potentially abusive
- ***AstraZeneca* (2nd Abuse)**
  - a dominant company "cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors"

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# Thank you!

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