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Second medical use patents – enforcement in harmony or conflict with the regulatory system?

Norway

Amund Brede Svendsen, partner, Advokatfirmaet Grette DA

Legal sources

- Regulatory legislation
- The Patents Act
- No judicial decisions in Norway
- Little literature on the subject
- Decisions from other European countries

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Regulatory framework

- Statens legemiddelverk (Norwegian Medicines Authority, NoMA) issues MAs, decides on prices and substitutability
- MA (Medicines Regulation sec. 5-8)
  - Criteria: quality, safety and effect
- Substitutability (Pharmacies Act sec. 6-6)
  - Assessment of similarities in composition/effect

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Regulatory framework, cont.

- Pricing: the stepped price model (*Trinnprismodell*) Graded pricing (Medicines Regulation sec. 12-14)
  - Automatic if «stable generic competition»
- Reimbursment (Medicines Regulation sec. 14-10)
  - Reimbursment for off label use
  - Exception for indications protected by patent
  - Patent rights not mentioned elsewhere in regulations

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NoMA study report (2013)

- Focus on reducing costs
- NoMA 2013 study report on the substitution system and document, market and patent protection:
  - NoMA does not consider itself competent to assess patent rights
  - NoMA presupposes that generic manufacturers have strong incentives to avoid infringing patent rights
  - NoMA suggests that patent rights should only be taken into accounts where patent owner and generic manufacturer agree on patent scope, or where an enforceable judgment is in place
- Prior practice (Pramipexol, Klopidogrel) suggests negative attitude.

MoHCS policy after NoMA's study report

- Ministry of Health and Care Services policy (2014) states that:
  - Assessing whether a patent covers an indication is not difficult
  - NoMA is to respect patents when deciding substitutability
  - A granted patent is to be presumed valid, even if generic manufacturer contends it is not
  - Difficulties that pharmacies may have in determining intended use is not a reason for NoMA not to try to avoid substitutions that infringe
  - It will be hard to develop routines to assess with regard to patent rights any amendment in the indications of all existing substitutable drugs
  - It is to be expected that patent owner who thinks a *new indication* is protected by patent will notify NoMA

In practice

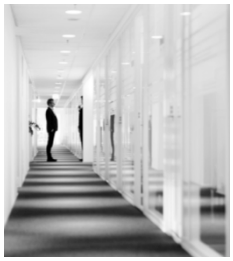
- Information in national database (FEST) about protected indications
  - So far only one medicine on list: Aclasta/zoledronic acid (for osteoporosis)
- Hearings regarding substitution for new medicines/indications
- Doctors normally prescribe by brand name
- Indication normally mentioned for refundable prescriptions, often not mentioned for non refundable prescriptions
- Pharmacies are not required to ask patients about intended use - patients not obliged to answer if asked
- No accessible information as to whether prescribed drug is intended for use in combination with other drugs

Conclusion

- Skinny labelling may be countered by informing NoMA of patent rights
- Patent holder must be vigilant and inform NoMA of patent rights
- «Blind spots» for pharmacies exist

Discussion points

- Pharmacies liable?
- Other third parties liable? – Doctors, hospitals, LIS?
- Does generic manufacturer have a duty to prevent infringement?
- Preventing stable generic competition



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Further reading

Pharmaceutical Pricing and Reimbursement Information – PPRI Pharma Profile Norway 2015:
http://www.legemiddelverket.no/English/price_and_reimbursement/Documents/PPRI_Pharma_Profile_Norway_20150626_final.pdf

NoMA study report (in Norwegian):
http://slv.no/Nyheter/Blaa_resept_og_pris/Documents/2013-4-April/Rapport%20-Byttbare%20legemidler%20med%20ulike%20indikasjoner_20130403.pdf

MoHCS letter of 3 March 2014 (in Norwegian):
http://slv.no/Nyheter/Blaa_resept_og_pris/Documents/2014-6-Juni/Oppfølging%20av%20rapport%20om%20byttbare%20legemidler%20med%20ulike%20indikasjoner.pdf

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THANK YOU!

Amund Brede Svendsen
E-mail: amsv@grette.no
Phone: +47 911 73 945

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