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UNIVERSITEIT VAN PRETORIA
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TRAINING COURSE:
INTELLECTUAL PROPERTY RIGHTS
AND
PHARMACEUTICAL PRODUCTS AND PROCEDURES

PANEL DISCUSSION:
ASSESSING/ADDRESSING CONTENTIOUS ISSUES

Saturday 14 February 2009 at 11:30 – 12:30

CASE STUDY 2: REGISTRATION OF GENERIC PRODUCTS

2. **CASE STUDY FACTS:**

In two recent cases in India, the patent owners of two patents in respect of two original drugs, OY and OZ, applied to the High Court to stop the Indian registering authority (DCGI) from processing two applications for marketing registration of two generic versions, GY and GZ. The Indian patent law has a Bolar provision.

In the first of the cases it was argued that sales of the generic drug GY would cause financial prejudice to the owner of the patent in respect of the original drug OY, should the generic drug GY be marketed.

In the second of the cases the Court instructed the registering authority to take note of the existence of patents in respect of a drug and not to grant marketing approval for any drug falling within a patent.

Questions

2.1 Would an application for marketing approval in respect of a generic equivalent GY or GZ, or the preparatory experimental and other work for purposes of an application for marketing approval constitute an infringement of the patent in respect of the original drug OY or OZ where there is a Bolar provision? Would the marketing approval process constitute an infringement in South Africa?

Refer: Patents Act, 1978 section 69A.

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2.2 Does the so-called Bolar provision have a basis in the TRIPS Agreement?
Refer: TRIPS Article 30.

2.3 Does the Bolar provision permit sales of the generic drug during the patent term of the original drug, once marketing approval has been given for the generic drug? Does the law in SA have a provision or principle that would prevent or at least delay early sales of a generic equivalent?
Refer: Patents Act, 1978 section 69A.

2.4 Would such a practice by the registering authority, ie not to grant marketing approval for any drug falling within a patnet, not negate the purpose of the Bolar provision?
Refer: SA Patents Act section 69A

2.5 Would it be good practice, eg in SA, to require of the registering authority to take cognisance of the existence of relevant patents in assessing the registrability of a medicine?