

Australia

“Merck Sharp and Dohme v. Sandoz”

Decision of the Federal Court of Australia
18 March 2022 – Case No. [2022] FCAFC 40

Merck Sharp & Dohme Corp. and Merck Sharp & Dohme (Australia) Pty Ltd v. Sandoz Pty Ltd

Acts Interpretation Act 1901 (Cth), Sec. 15AA; Patents Act 1990 (Cth), Secs. 2A, 13, 67, 70, 71, 72, 73, 74, 75, 76, 77, 78, 119A(1)(a)(ii), 133(2)(b), 192, 223, Sch. 1; Therapeutic Goods Act 1989 (Cth), Secs. 9A, 17, 19B, 25, 26; Patents Regulations 1991 (Cth), Reg. 6.8; Therapeutic Goods Regulations 1990 (Cth), Reg. 10

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Keywords Extension of term · Validity · Standard patent · Pharmaceutical substances · Date of commencement · First inclusion · First regulatory commencement

1. Section 70(5)(a) does not define the first regulatory approval date by reference to “registered goods” but by “first inclusion” in the Australian Register of Therapeutic Goods (ARTG).
2. Section 78 of the Patents Act provides that if the Commissioner grants an extension of term, the exclusive rights of the patentee during the term of the extension are not infringed by a person who is “exploiting” either (a) a pharmaceutical substance per se within the claimed scope of the extended patent for a purpose other than a therapeutic use; or (b) any form of the invention that is not a pharmaceutical substance per se disclosed in the specification and within the scope of the claims.
3. A first regulatory approval date should not be tied to marketing.

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