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Breaking out of the Ivory Tower—from academia to clinic

A. D. WOOLFSON

School of Pharmacy, Medical Biology Centre, The Queen's University of Belfast, 97 Lisburn Road, Belfast, Northern Ireland BT9 7BL

The ultimate goal of all research in the pharmaceutical sciences is to achieve patient benefits through improvements in the prophylaxis or therapy of disease states. It follows that the commercial exploitation of research findings will eventually be necessary in order to achieve this endpoint. It can be argued, therefore, that academic pharmaceutical research, in recognising this reality, has long since broken out of the ivory tower if, indeed, it was every resident in that location.

The progression of academic research output to the clinic and, therefore, the market, frequently involves consideration of intellectual property rights (IPR). In examining models for the conversion of academic research into marketed products, it is necessary for researchers to be aware of the types of IPR that may be generated. Typically, these may include confidential information, know-how and patents. In the latter case, timescales, including obtaining a priority date, are particularly important to maximise value and increase the commercial attractiveness of the project.

This paper presents two illustrated models for the commercial exploitation of novel drug delivery research carried out primarily within an academic setting.

Model 1: Out-licensing of IPR

In this model, there is no direct commercial sponsorship of the research programme, which is driven initially by academic curiosity and/or a perceived unsatisfied clinical need. The development of Ametop Gel (Woolfson and McCafferty, 1993) is a prime example of this model, involving university-industry technology transfer as envisaged in the 1993 UK White Paper 'Realising Our Potential'. Ametop is an effective percutaneous anaesthetic that allows painfree cutaneous procedures such as venepuncture and the harvesting of split skin grafts. It is based on the discovery of the amethocaine (tetracaine) phase-change system that allows the thermodynamic activity of a local anaesthetic base to be maximised within an aqueous delivery vehicle, resulting in a maximal drug flux through the stratum corneum such that rapid skin anaesthesia (within 30-45 minutes) of long duration (4-6 hours) is achieved. The product, which is available commercially in the UK and internationally, was developed almost entirely within an academic setting and commercialised though an out-licensing arrangement of the associated IPR.

Model 2: Co-development with an industrial sponsor: risk sharing agreements

In this model, an industrial partner defines the basic area of research, which is then further developed within the academic setting on a risk-sharing basis. The model is illustrated by reference to a partnership between the author's laboratory and a commercial sponsor to develop novel drug delivery systems with particular emphasis on women's health. Thus, the controlled and sustained delivery of a selected 17β-oestradiol prodrug from a reservoir-design elastomeric intravaginal ring (Woolfson et al., 1997) has been shown *in vivo* to give plasma oestradiol concentrations within the target physiological range, sustained for up to three months. The system resolves the apparent conflict between the enhanced hydrophobicity of the prodrug, enhancing its rate of diffusion through the device, and the need for significant *in vivo* drug solubility in the aqueous diffusion layer between device and epithelial tissue.

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Woolfson, A.D., Elliott, G.R.E. and Gilligan, C.A. (1997). Controlled and sustained intravaginal ring delivery of estradiol esters for estrogen replacement therapy. Pharm. Res. 14 (S):1128.