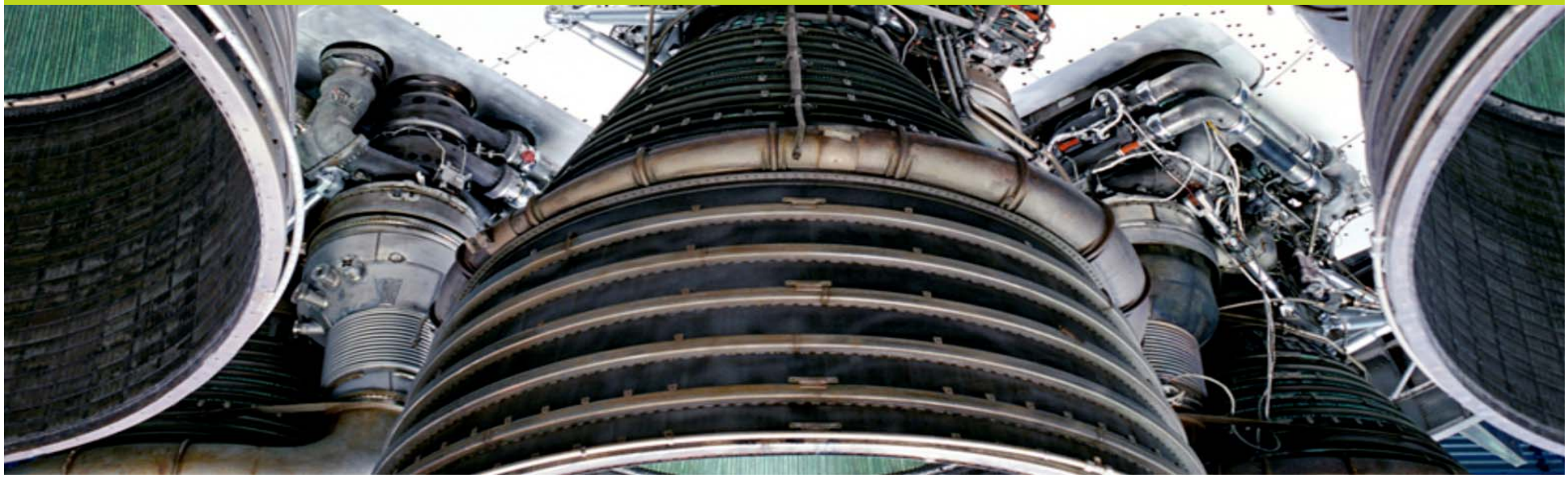
Hogan Lovells

Case study: Patenting practices and lifecycle management

Suzanne Rab, Counsel, Hogan Lovells

17 May 2010

The Fourth International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum



Case study: The facts

NEW PHARM has a product which is protected by a basic patent (Product A). The patent is due to expire in 2012.

NEW PHARM has products B, C, D and E under development and is considering whether C, D and E are patentable.

NEW PHARM is aware that generic companies are considering launching generic alternatives to Product A when it comes off patent.

NEW PHARM is considering various practices which may help to develop and extend the life of Product A.

Case study: Patenting practices and lifecycle management

#1

- File patent applications for new production processes for the production of active ingredients already covered by the basic patents for Product A

Case study: Patenting practices and lifecycle management

#2

- File patent applications for new reformulations with the aim of creating a multi-layered defence around the product towards the end of the patent protection period

Case study: Patenting practices and lifecycle management

#3

- Seek a patent for Product B to which it is intended patients will be "switched" by promotion before the expiry of the patent for Product A and then remove Product A from the market before the end of the period of patent protection for Product A

Case study: Patenting practices and lifecycle management

#4

- File patent applications for Products C, D and E

Case study: Patenting practices and lifecycle management

#5

- File patent applications for Products C, D and E with the aim of gaining an enforceable right but then withdraw the applications if they are challenged

Case study: Patenting practices and lifecycle management

#6

- Intervene in the marketing authorisation processes in Member States where generic companies are applying for authorisation, claiming that the products are inferior to Product A and less safe

Case study: Patenting practices and lifecycle management

#7

- Send letters to doctors, pharmacies and charities that are responsible for the elderly explaining the benefits of Product A and improved versions which are to become available in the near future

Case study: Patenting practices and lifecycle management

#8

- Introduce new methods of delivery and marketing for Product A as follows: (a) different strength formulations (200 mg/ 160 mg/ 145 mg); (b) different delivery methods (liquid oral, chewable); (c) improved labelling and packaging highlighting the comparative benefits of Product A in treatments for the elderly and risks of using unproven alternatives

Case study: Patenting practices and lifecycle management

#9

- Enter into an agreement with a generic company to delay its entry of a generic version of any NEW PHARM treatment until it has satisfied NEW PHARM that the product is safe

Case study: Patenting practices and lifecycle management

#10

- As in #9 but make a payment of €2 million to fund R&D by a generic company

www.hoganlovells.com