Rethinking pay for delay

Yesterday's Pharma Day session 1 began with moderator Jérémie Jourdan, partner at White & Case in Brussels and Paris, raising objections to how IP regulators characterise 'pay for delay'. He offered an alternative title of 'patent settlement agreement where parties settle based on different elements of litigation'.

"But I'm afraid it doesn't have the same nice ring to it as 'pay for delay,' said Mr. Jourdan.

Pay for delay is a controversial technique whereby pharma innovators pay generic companies to delay bringing their drug to market. This method of avoiding litigation is a red flag for regulators interested in enforcing anti-competition laws.

Mr. Jourdan argued that rather than seeing pay for delay as a means to protect an undeserved monopoly, it should be reframed.

"One part of litigation is the right to settle; if there is the opportunity the company should be able to do so," said Mr. Jourdan. "IP rights do not provide immunity from competition law. Rather, the competition law protects the consumer, and it is in the public interest to remove bad patents with pay for delay."

Erin Dunston, shareholder at Buchanan Ingersoll & Rooney in Pittsburgh, described the origins of pay for delay as the ominous paragraph IV of the US Drug Price Competition Act. Under paragraph IV, generic companies assert to the FDA that their proposed generic product is free to enter the market either because the originator's listed patent(s) are invalid or they are not infringed by the proposed generic product. Innovators then have 30 days to bring a case against the generic company to obtain a "30-month stay" in which the generic product cannot be approved by the FDA, and thus cannot be brought to market. Instead of litigating, some manufacturers simply decide to pay their competitor to go away.

"The stakes are very high, and it is tempting for the brand to pay the generic to stay off the market," said Ms. Dunston. "The phrase 'reverse settlement' has come about when the brand pays the generic."

The US Supreme Court ruled in 2013 in *Actavis v FTC* that patent protection does not override antitrust law. In that case the size of the settlement, $30 million per year to delay the rollout of a generic medication, was deemed too steep and unbeneficial for society.

With the ruling, the courts said the size of the damages relative to the payer's expected costs was an important criterion for establishing anti-competitive behaviour. You can pay your competitor to stay off the market, but it better not be an outrageous sum of money, it seems.

Takanori Abe, partner and founder of Abe & Partners in Osaka, humorously told the audience that Japan has no history of pay for delay because of the country's corporate culture.

"They are afraid of offending the Ministry of Health so we have zero cases in Japan," he said.

The panel concluded the session by asking what sort of payment for damages is acceptable.

"Does the size of damages matter?" asked Mr. Jourdan. "If you don't get a benefit, why would you settle? You only settle if you get something."