IPPro LifeSciences

ISSUE061
20.01.2016 WEDNESDAY
www.ipprolifesciences.com

The primary source of global intellectual property life sciences news and analysis

Pay-for-delay deals at a low, says FTC

Pharmaceutical companies in the US entered into substantially fewer pay-for-delay patent settlements in 2014, according the US Federal Trade Commission (FTC).

The total number of pay-for-delay deals filed with the FTC fell to 21 in 2014 from 29 in 2013.

The FTC attributed the drop to the 2013 Actavis decision, in which the US Supreme Court held that pay-for-delay deals are to be subject to standard 'rule of reason' anti-trust scrutiny, meaning that courts must consider evidence that these agreements harm consumers.

The FTC received 40 pay-for-delay filings in 2012 prior to the Actavis ruling.

Despite the number of filings increasing to 160 in 2014, compared to 145 in 2013, the number that were pay-for-delay deals decreased.

Some 21 of the patent settlements filed with the FTC in 2014, which covered 20 different branded pharma products with combined annual US sales of approximately $6.2 billion, potentially involved 'pay for delay' terms such as payments to the generic manufacturer and restrictions on marketing.

Continued on p2

Apotex free to produce Daiichi's Benicar drug

Apotex did not infringe a Daiichi Sankyo-owned patent covering blood pressure drug Benicar (olmesartan) because it was disclaimed, a US district court has ruled.

The US District Court for the Northern District of Illinois ruled on 8 January that Apotex's planned generic version of Benicar does not infringe Daiichi's disclaimed patent.

The decision could reduce the exclusivity period held by rival generics manufacturer Mylan, which also sought to produce a generic version of Benicar.

The US Supreme Court declined to hear a petition in November 2015 that could have allowed Mylan to delay Apotex's planned generic version.

Continued on p2

USPTO to decide CRISPR/Cas9 dispute

The US Patent and Trademark Office (USPTO) has weighed in on a CRISPR/Cas9 technology dispute between two inventors.

The USPTO initiated an interference on 11 January between the Broad Institute of MIT and Harvard and the University of California, whose scientists both claim to be the inventors of the same CRISPR/Cas9 technology and have filed patent applications.

Judge Deborah Katz has been appointed to manage the interference.

Feng Zhang of the Broad Institute of MIT and Harvard and Jennifer Doudna of the University of California, both claim to have invented the technology, which relates to CRISPR-Cas9 gene editing in animal cells.

Continued on p2

Matters of import

Alireza Behrooz of Merchant & Gould and Nick Phillips of Edwin Coe

What is the EU's position on parallel goods?

Nick Phillips: There is a very large body of case law that has been developed over the years in relation to the issue of parallel imports in Europe. The basic position in Europe is that the doctrine of exhaustion of rights applies to anything first marketed in Europe.

In other words, once a product has been put on the market anywhere in Europe with the intellectual property owner's permission, then it can be sold in any other European country without infringing the rights of the IP owner.

The legal issues in parallel imports have largely related to the extent that goods (often pharmaceuticals) can be repackaged or relabelled from one European country to another and the extent to which so-called 'grey goods' can be brought into Europe from outside of Europe. For example, if I sell Migraleve for migraines in Germany, then repackage it for regular headaches and not migraines in the US, that's when the issues arise.

What about the US?

Alireza Behrooz: Federal regulatory authorities assist to restrict parallel imported pharmaceuticals into the US pursuant to federal laws and regulations. Thus, for example, pharmaceutical shipments discovered in the inbound stream by Customs and Border Protection (CBP) are referred to the federal Food and Drug Administration (FDA).

Moreover, federal legislation such as the Food, Drug, and Cosmetics Act (FDCA) also restricts the importation of "American goods returned". by prohibiting any person other than the original manufacturer from importing a prescription drug that was originally manufactured in the US and sent abroad.

Phillips: We understand that parallel imports into the US are a big problem and the US courts have had to grapple with the question of the international exhaustion of rights and the first sale doctrine, ie, whether goods put on the market with the IP owner's permission outside of the US can then lawfully be brought into the US in much the same way as the courts have had to deal with this in the EU.

Where is the US focusing in terms of pharmaceuticals?

Behrooz: US concerns with pharmaceutical grey goods have mainly revolved around issues relating to consumer safety as well as to the impact such imports could potentially have in stifling innovation. Regarding the former, the government has found it difficult to

> "US concerns with pharma grey goods have mainly revolved around issues relating to consumer safety as well as to the impact such imports could potentially have in stifling innovation"

Alireza Behrooz, Partner, Merchant & Gould PC

be able to guarantee the safety and efficacy of these goods due to the limited logistical as well as financial resources that are required to effectively monitor and evaluate them.

The public safety challenges are invariably further exacerbated by the ever-present counterfeit market that serendipitously attempts to continuously infiltrate the market along with such genuine goods.

In addition, opponents of parallel imports are concerned that the lower costs, although arguably of some immediate benefit to the individual consumer, undermine and distort the very economic and business models that ultimately drive innovation in the pharma industry (for example, research and development), which could have unintended consequences and a far greater negative impact on public health and welfare down the road.

Do grey goods threaten the IP of pharmaceutical companies, if at all?

Phillips: The main way in which grey goods threaten the IP of pharmaceutical companies is that they risk damaging their brands if goods of a different formulation and packaging with different look and feel are imported into a country.

There can also be issues where instructions are incorrectly or badly translated. With prescription pharmaceuticals, this is generally less of a risk than with other products because, in addition to the IP rights, there are usually also regulatory barriers to entry, meaning that anyone wishing to sell the pharmaceutical goods in the UK (or other countries of Europe) will need to be licenced by the regulator to do so.

Behrooz: A recent example of a court case in the context of test strips helps illustrate the threat to trademarks—the case of Abbott Laboratories et al v Adelphia Supply USA et al in the US District Court for the Eastern District of New York.

There, Abbott's request for a preliminary injunction was granted as Abbott made the case that the likely confusion of its domestic US customers over the international strips would cause damage to Abbott's goodwill and reputation.

So, for example, the differences (instructions, symbols, contact information, and the like) between the two strips, which were not refuted, would likely lead to user frustration and/or misuse, and therefore Abbott is likely to lose goodwill and suffer reputational harm when a domestic user receives international test strips.

Moreover, the domestic sale of the international product can interfere with the company's ability to control its reputation through quality-control procedures.

Grey goods can also dilute pharma marks through association. The marks can be considered 'tarnished' with a mislabelled product (ie, the international strips) that is likely to confuse consumers and which fails to give them the instructions and customer support to which the user is accustomed. In fact, one of the claims for relief by the plaintiff in the Abbott case was federal trademark dilution under Section 43(c) of the Lanham Act.

Will we see a rise in grey goods, as wholesalers seek to profit from cheaper drugs?

Phillips: There is a large disparity in the prices of pharmaceuticals across the EU and this in itself leads to there being a healthy business in parallel imported pharmaceuticals. Price differentials outside of Europe are likely to be greater still and so grey imports are commercially attractive.

However, grey goods are possible for the rights owners to guard against by tightening up their distribution and labelling arrangements to make it clear that these goods cannot be sold outside of the territory they are intended for. There are also regulatory hurdles to the import of some pharmaceuticals into European countries.

Behrooz: Likely not in the US, absent changes in federal legislation relating to drug importation. Moreover, even in those instances where individual states have attempted to loosen control of drug importation by passing state laws in order to allow their residents to legally buy drugs from foreign sources, the possibility of preemption by federal law has posed a challenge.

For example, earlier this year, a federal judge in the US District Court of Maine declared that the FDCA, which creates a regulatory scheme that sets limits on the importation of prescription drugs from other countries, preempts the 2013 Maine Pharmacy Act (MPA) Amendments pursuant to the Supremacy Clause of the US Constitution.

Maine's MPA Amendments, which exempted certain entities from the licensing requirement, had provided in part that an "entity that contracts to provide or facilitate the exportation of prescription drugs from a licensed retail pharmacy [that is located in Canada, the UK, Australia or New Zealand that meets its country's statutory and regulatory requirements] may provide or facilitate the provision of prescription drugs from that pharmacy by mail or carrier to a resident of this state for that resident's personal use". **IPPro**

> Grey goods risk damaging pharma brands if goods of a different formulation and packaging with different look and feel are imported into a country

Nick Phillips, Partner, Edwin Coe LLP