Generics bulletin
THE BUSINESS NEWSLETTER FOR THE GENERIC MEDICINES INDUSTRY

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Arthritis Drugs

US Celebrex ruling opens door

A key US patent protecting Pfizer's Celebrex (celecoxib) blockbuster until December next year is invalid, a Virginia district court judge has ruled. The summary judgement opens the way for generics firms to secure approval for, and to launch, the arthritis drug once six-month paediatric extensions to two other patents expire in May this year. Pfizer – which reported US Celebrex sales ahead by 11% to US$1.93 billion last year – said it would appeal.

Judge Arenda Wright Allen granted summary judgement to Actavis, Apotex, Lupin, Mylan and Teva, declaring that Pfizer's reissued US method-of-use patent RE44,048 was invalid. Pfizer, she said, "could not use the reissue process to correct its failure to file a divisional application".

Furthermore, Allen added, Pfizer had deliberately filed a continuation-in-part, not a divisional application, of an earlier patent to maximise its exclusivity for Celebrex. "Because intentional acts are not correctable via reissue, the court finds that the '048 patent violates the reissue statute as a matter of law, and is invalid." And as the '048 patent could not be considered divisional, it was also invalid due to obviousness-type double patenting in light of earlier patents.

The ruling comes 12 months after the US Patent and Trademark Office (PTO) reissued the '048 patent, and Pfizer sued the generics firms for alleged infringement.

Actavis said it "may be entitled to 180 days of generic market exclusivity, or shared exclusivity" pending final approval for its 50mg, 100mg, 200mg and 400mg capsules, which the firm expects upon expiry of paediatric extensions to US patents 5,466,823 and 5,563,165 on 30 May this year. Mylan expects to share exclusivity on the three highest strengths.

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Intellectual Property

Unitary Patent Court will face delays

Europe's Unitary Patent Court will not be operational until "the end of 2015 at the earliest", according to Alexander Ramsay, vice-chairman of the court's preparatory committee. Ramsay – who also works for Sweden's Ministry of Justice – told delegates to the European Generic medicines Association's (EGA's) 10th Legal Affairs Forum this week that his committee's previous prediction of the court starting work in early 2015 "cannot be accomplished".

Nevertheless, Ramsay insisted, substantial progress was being made towards setting up the court, which will hear infringement and validity disputes over unitary patents as well as European patents provided the patent holder does not opt out.

A training centre for judges located in Budapest, Hungary, had been inaugurated last week, he pointed out. And Sweden had recently teamed up with the Baltic States to form a regional division of the court in Stockholm with English as its operating language.

Manufacturing

Sun facility suffers an FDA import alert

Sun Pharmaceutical's active pharmaceutical ingredients (APIs) and finished-dose cephalosporins facility in Karkhadi, near Gujarat, India, has been hit by an import alert issued by the US Food and Drug Administration (FDA). This followed an inspection at the plant that revealed current good current manufacturing practice (cGMP) deficiencies.

"The company remains fully committed to compliance and has already initiated several corrective steps to address the observations made by the FDA," the Indian firm commented.

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Biological Drugs/Market Research

European doctors report by brand

One in six prescribers in Europe communicates only the international non-proprietary name (INN) when reporting adverse drug events, according to a survey of 470 doctors carried out by originators' group the Alliance for Safe Biologic Medicines (ASBM). More than half of the physicians questioned – 54% – cited both the brand and INN name, while 29% reported only the brand name.

Similarly, fewer than one in four doctors used only the INN when prescribing biological medicines, while a third used both the brand and INN name, and 30% prescribed exclusively by brand.

"Although the results showed that physicians prefer to use brand names when prescribing biological medicines and reporting adverse events," acknowledged the ASBM, "the findings around the use of INN and its meaning in the context of biosimilar products leads us to conclude that the use of distinguishable INNs for all biologics, including biosimilars, is critical to further strengthen and facilitate patient safety through effective pharmacovigilance."

Pricing & Reimbursement

Romania must amend clawback

Romania's government must immediately change the way it calculates mandatory clawbacks if the country's generics industry is to survive, Romania's generics producers' association, APMGR, has warned.

Introducing a budget-neutral cap for clawbacks on generics and other essential medicines should only be a temporary measure, APMGR insists. In the medium term, it says, generics producers which supply 70% of medicines used in Romania should be exempted from paying clawbacks.

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Free-Trade Agreements

Canada and Korea strike trade deal

A free trade agreement struck between Canada and South Korea includes "no new commitments in the area of pharmaceutical patents", according to a summary released by the Canadian government. Intellectual-property provisions in the Canada-Korea Free Trade Agreement (CKFTA) are "in line with Canada's current regime, including criteria regarding patentability and exclusions from patentability".

According to the Canadian government, the CKFTA "recognises the importance" for public health of the World Trade Organization's (WTO's) declaration on trade-related aspects of intellectual-property rights (TRIPS).

Upon the agreement entering into force, 63% of pharmaceutical tariff lines will be duty-free, the summary states, while all remaining tariffs of up to 8% will be eliminated within five years. "Products of export interest include antibiotics and anti-tuberculosis medications," it adds.

Attention Deficit Hyperactivity Disorder Drugs

Actavis strikes Daytrana deal

Actavis will be able to launch a US generic version of Noven Pharmaceuticals' Daytrana (methylphenidate) transdermal patch from 1 September 2015 under the terms of a patent-litigation settlement agreed between the two companies.

"Noven will grant Actavis a non-exclusive, royalty-bearing licence to market its generic Daytrana", Actavis said, adding that the launch depended on securing approval from the US Food and Drug Administration (FDA) for the generics firm's abbreviated new drug application (ANDA). Actavis believes it may be entitled to 180-day exclusivity for its version of the attention deficit hyperactivity disorder treatment as one of the first to file an ANDA.

Citing IMS Health data, Actavis said Daytrana had US sales of around US$98 million in 2013.

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Intellectual Property/Manufacturing

EGA demands action on SPCs

Urgent action from the European Commission is needed on patent extensions to allow European producers to compete equally with other manufacturers, according to the European Generic medicines Association (EGA). "The supplementary protection certificate (SPC) unfairly blocks our industry from exporting to the rest of the world and encourages the delocalisation of our production," the EGA's director-general, Adrian van den Hoven, told delegates to association's 10th Legal Affairs Forum earlier this week. The association wants to amend the SPC Regulation to permit "advanced manufacturing" for export during the SPC term.

Highlighting efforts to improve a patent's 'inventive step', the EGA's government affairs and intellectual-property manager, Lidia Mallo, said the EGA was "engaged in a constructive dialogue with the European Patent Office to address deficiencies in the granting of pharmaceutical patents that, if abused, can delay competition in the single market".

The EGA also called for "more guidance on what is authorised in a patent settlement" in light of the Commission's actions over certain patent deals.

Manufacturing/Biological Drugs

Alvotech finesses its biotech production

Alvogen's newly-formed biosimilars affiliate, Alvotech, has formed a manufacturing partnership with California-based Finesse Solutions. The deal will give Alvotech access to "world-class, scalable, flexible and cost-efficient manufacturing and laboratory technology through Finesse's turnkey SmartFactory good manufacturing practice (GMP) manufacturing platform suite".

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Preliminary Results

Adcock faces 'bumpy road ahead'

Adcock Ingram's sales during its current financial quarter ending 31 March 2014 have "shown no improvement" over the prior-year period as of the end of February, while its generic and OTC portfolio sales "remain of concern" and are "significantly behind those of the corresponding period", the South African firm has reported to shareholders. "Gross profit as a percentage of sales remains under extreme pressure," the firm added, pointing to a combination of an "unfavourable revenue mix, rand depreciation … and certain facilities running significantly below capacity, particularly oral liquids".

"The road ahead is likely to be bumpy," predicted Adcock, which revealed costs associated with its failed takeover by Chilean firm CFR Pharmaceuticals – called off earlier this year – were expected to reach ZAR140 million (US$12.8 million).

Parkinson's Disease Drugs

Amerigen celebrates first US approval

Amerigen has secured its first marketing authorisation from the US Food and Drug Administration (FDA) after the agency approved the firm's abbreviated new drug application (ANDA) for a rival to Valeant's Lodosyn (carbidopa).

Retirements

Korman to call it a day with Mylan

Mylan's chief operating officer, Harry Korman, will end his 18-year association with the US firm when he steps down from the role on 1 July. "Harry has been an important part of the leadership team that helped successfully transform Mylan from a US-based generics business into a leading global pharmaceutical company," Mylan commented.

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Strategic Alliances

Sandoz expands programme in Africa

Sandoz will this year begin supplying Egypt's Ministry of Health with an additional "life-saving anti-tuberculosis medicine". The agreement struck by the firm – which already has a portfolio of three tuberculosis drugs in the country – will run for two years.

Meanwhile, Sandoz' German affiliate – 1A Pharma – has struck a three-year development partnership "aimed at increasing access to high-quality, affordable medicines" in Ghana. Local firm La Gray Chemical Company forms part of the venture, and will receive training and support from Sandoz.

Promotions

Takeda picks Platford for emerging markets

Takeda will on 1 April promote Giles Platford – who currently leads the firm's Middle East, Turkey and Africa (META) region – to head the firm's commercial operations and emerging markets business. Last month, the firm's head of emerging markets, Jostein Davidsen, agreed to join Swiss company Acino as chief executive officer by 15 May "at the latest" (**Generics *bulletin***, 7 March 2014, page 30).

Genitourinary Drugs

Par goes after Hyperion's Ravicti

Par has submitted an abbreviated new drug application (ANDA) containing a paragraph IV certification for a generic rival to Hyperion Therapeutics' Ravicti (glycerol phenylbutyrate) 1.1g/ml oral liquid. The US firm's ANDA alleges invalidity against two of the urea-cycle disorders treatment's three patents – US patents 8,642,012 and 8,404,215 – that protect Ravicti until September 2030 and March 2032 respectively.

Mergers & Acquisitions

Mallinckrodt completes Cadence deal

Mallinckrodt has completed its US$1.4 billion acquisition of Cadence Pharmaceuticals. The deal – which was announced earlier this year (**Generics *bulletin***, 7 March 2014, page 9) – gives Mallinckrodt access to Cadence's Ofirmev (acetaminophen) injectable, as well as providing the firm with "an expanded presence in the US hospital channel".