IN brief

Courts defer ruling on science

A lawsuit between rival companies over false advertising has ended with the US Court of Appeals concluding that the courts are not the appropriate forum to resolve scientific disputes. The US Court of Appeals, Second Circuit (Court) in June ruled that a scientific study to evaluate a pharmaceutical product then cited in marketing material could not be attacked as “false advertising” because such studies are protected as free speech under the First Amendment. The lawsuit was brought by ONY of Amherst, New York, against Chiesi Farmaceutici, of Parma, Italy. Both companies make surfactants for lining the surfaces of lungs of premature infants or other patients with respiratory distress syndrome. In 2006, Chiesi hired physicians and other specialists to develop data to show the effectiveness of its product, and they later presented their findings online at several conferences and published those findings on September 1, 2011 in the peer-reviewed *Journal of Perinatology* (10.1038/jp.2011.125). With qualifications, the authors, who disclosed their relation with Chiesi, concluded that the Chiesi product is superior to the competing ONY product, and the company later touted those conclusions in a press release. ONY objected to the study and its presentations, and then in December of that year brought a lawsuit, claiming false advertising and selective mention of some of the data among other alleged damages and harm, but not claiming that the data were fraudulent or fabricated. Instead, ONY claimed that the “inferences drawn from those data were the wrong ones.” However, the Court states that such scientific matters are best left to “other members of the relevant discipline or specialty,” noting that if conclusions are drawn from nonfraudulent data, and if there is legitimate ongoing scientific disagreement, there are no grounds for a claim of false advertising. The Court also concluded that Chiesi’s press release was okay because, even though laudatory of the company’s product, it did not distort or misstate the conclusions of the study it cites. In sum, ONY’s disagreement with that study and its conclusions is not a matter to be settled by lawsuit, but a matter of scientific dispute that is better settled by more research and debate among scientific experts.

Jeffrey L Fox

IN their words

“[The ban on Monsanto 810 transgenic corn was enacted] not because we refuse progress, but in the name of progress.”

President François Hollande confirms that France will defy the ruling by the French Council of State overturning a

moratorium on the cultivation of transgenic corn. (*Agence France-Press*, 2 August 2013)

Box 1 Onyx team—is it a keeper?

With the transaction not yet finalized, neither Onyx nor Amgen has commented on how many of Onyx’s 900 employees, particularly its 459 R&D staff, will become part of the new organization. Analysts believe that Amgen will want to retain many within this talented team. Those involved in Kyprolis and oprozomib development will be particularly critical, given that the big biotech lacks this specific experience in-house. “If Amgen is interested in continuing to expand the proteasome inhibition space, the researchers at Onyx would be great people to keep,” says a former Onyx employee, who requested anonymity. “Some senior, operational roles in development may be duplicated at Amgen, while individuals running critical day-to-day activities are more likely to be retained.”

The R&D team is led by Pablo Cagnoni, who became executive vice president, global research & development and technical operations, in March 2013. Before his time at Onyx, Cagnoni built up strong credentials in oncology drug development, playing a role in the development and approval of numerous cancer drugs at Basel-based Novartis Oncology, Allos Therapeutics in Westminster, Colorado, and OSI Pharmaceuticals in Melville, New York. Onyx’s head of research is Christopher Kirk, who played a key role in the discovery and early development of Kyprolis at Proteolix. Many others from Proteolix’s R&D team also transferred to Onyx after the 2009 acquisition. Onyx’s research team has been focused on research around carfilzomib, other proteasome inhibitors, and other targets in the pathway.

Much of the development efforts have centered on Kyprolis, but there is also work being done on the oral proteasome inhibitor oprozomib and expanding Nexavar’s indications. The company’s head of clinical development is senior vice president Barbara Klencke, who joined Onyx in 2011, and led the regulatory process for Kyprolis’ FDA approval.

“Onyx’s top management may go off to other companies or retire, it depends how much Amgen wants to fit Onyx into their culture, but R&D people associated with the proteasome inhibitor franchise will likely stay,” says analyst Gene Mack at Brean Capital in New York. “It is hard to say what Amgen will do with Onyx’s other early-stage pipeline.”

In a US Securities and Exchange Commission document posted online on August 27, Onyx says that Amgen intends to retain the biotech’s S. San Francisco location. Employment-related decisions have not been made yet.

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developed by Cambridge, Massachusetts-based Millennium Pharmaceuticals. Kyprolis is being compared against Velcade in multiple phase 3 head-to-head studies, including in newly diagnosed disease, where Velcade is commonly used. So far, Kyprolis is approved only for use as a third-line agent, after patients have failed Velcade and an immunomodulatory drug like Summit, New Jersey-based Celgene’s Revlimid (lenalidomide), although some US doctors are already using it off-label in earlier settings. “Kyprolis’ ultimate share in earlier lines of treatment is the wild card in the acquisition,” says analyst Nicholas Bishop of Cowen & Company in New York.

“For me and my colleagues, carfilzomib [Kyprolis] would have to show a great enough benefit in terms of efficacy and side effects in clinical trials to make it worth the higher cost and greater inconvenience to administer,” says S. Vincent Rajkumar of the Mayo Clinic in Rochester, Minnesota, given that it requires twice-weekly intravenous injection instead of once-weekly subcutaneous injection. The advantages are, that as a more specific proteasome inhibitor, certain side-effects like neuropathy appear to be less frequent, and single-arm phase 2 data suggest that it could lead to higher response rates than with Velcade.

Even if Kyprolis bests Velcade, competition could still come from the newer drugs on the horizon, including Takeda’s oral proteasome inhibitor, ixazomib, as well as novel agents, such as anti-CD38 antibodies and epigenetic drugs that have been the focus of other recent deals. For example, Celgene recently made a \$100-million investment in Boston-based Acetylon for its histone deacetylase 6 (HDAC6) inhibitor, ACY-1215, which could lead to an acquisition; elsewhere, the New Jersey biotech flagship partnered with Munich-based MorphoSys, paying \$92 million (and a \$60-million equity stake) to jointly develop MOR202, an anti-CD38 monoclonal antibody, and in another deal, New Brunswick, New Jersey-based pharma giant Johnson & Johnson paid Genmab, of Copenhagen, \$55 million upfront, with an \$80-million equity stake, to license its anti-CD38 antibody daratumumab.

In the meantime, it looks like in Kyprolis, Amgen has acquired a rising star. As Sagar Lonial of Emory University in Atlanta, puts it, “Although we know that carfilzomib will have a place in multiple myeloma, the optimal time and place in the disease are being defined and refined right now.”

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