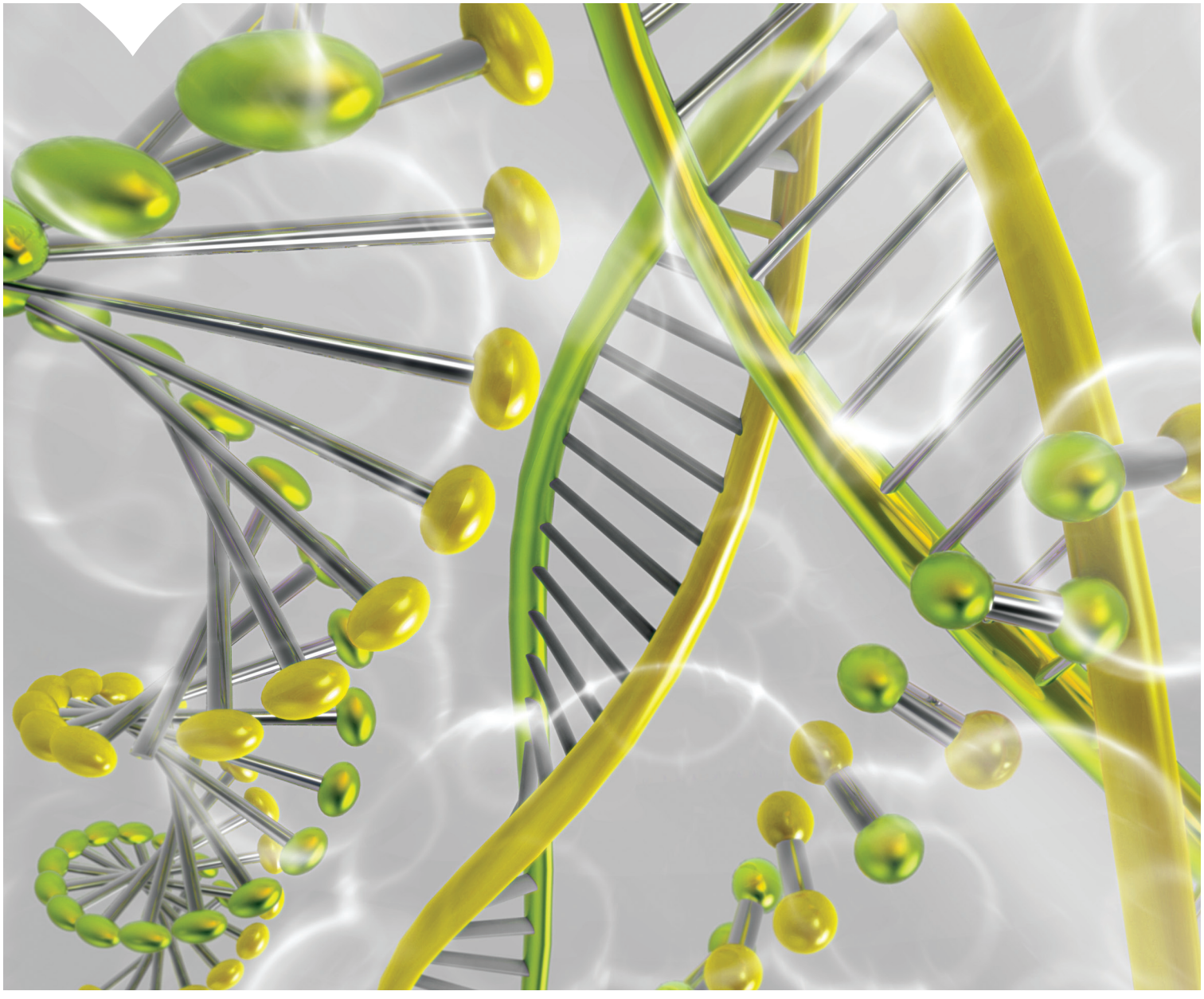
MAYER · BROWN

Summer 2013

# Life Sciences

## 2013 Legal Developments You Need to Know About



# Welcome

This is a short guide outlining some of the key legal developments in the life sciences sector in 2013.

The developments include the US Supreme Court decision on the patentability of human genes, policy-related statements on public websites, the inquiry by the French Competition Authority into the pharmaceutical sector, new regulations in the Peoples' Republic of China and proposed changes for EU rules on technology licensing.

For further information or advice, please contact your usual contact at Mayer Brown or any of the contributing attorneys whose details can be found at the end of this guide.

# US Supreme Court Rules Human Genes Cannot Be Patented, But Non-Naturally Occurring cDNA Can Be

On June 13, 2013, in an opinion delivered by Justice Clarence Thomas, the US Supreme Court ruled that a naturally occurring segment of DNA that has been isolated from the rest of the human genome by a prospective patentee is not eligible for patent protection by virtue of its isolation. In its unanimous (9-0) decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, No. 12-398 (U.S. June 13, 2013) (115 PTD, 6/14/13), the Court held that a naturally occurring DNA segment is "a product of nature" that is not patent-eligible under Section 101 of the Patent Act merely because it has been isolated. However, the Court held that complementary DNA, commonly referred to as cDNA, is patent-eligible because, when made, it is "distinct from the DNA from which it was derived."

As a result of this decision, several of Myriad's patents covering the "isolated DNA" coding for BRCA1 and BRCA2 polypeptides—the genes associated with an increased risk of breast and ovarian cancers—are effectively invalidated. In support of its decision, the Court explained that "the location and order of the nucleotides existed in nature before Myriad found them" and that Myriad did not "create or alter the genetic structure of the DNA." The Court also noted that, if valid, "Myriad's patents would give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes," and would also "give Myriad the exclusive right to synthetically create BRCA cDNA."

In reaching its decision, the Court was explicit in stating that methods for manipulating genes, new applications of knowledge about the BRCA1 and BRCA2 genes, and DNA in which the order of the naturally occurring nucleotides has been altered are "not implicated," but noted: "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." It is unclear how many issued patents may become subject to declaratory actions in federal court or to requests for reexamination before the US Patent and Trademark Office as a result of this ruling. ◆

*"Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."*

# I Said I Would Not Sue You, Therefore You Cannot Sue Me: Using Published Statements to Avoid Lawsuits

A three-judge panel in the Federal Circuit recently dismissed a suit by a coalition of organic and other non-GMO farmer and seed company plaintiffs who sought to have Monsanto's transgenic seed patents ruled invalid. In *Organic Seed Growers and Trade Association v. Monsanto Co. LLC,* 2013 WL 2460949, No. 2012-1298 (Fed. Cir. 2013), a judicial panel in the US Court of Appeals for the Federal Circuit found that the plaintiffs were not entitled to bring the lawsuit "because Monsanto has made binding assurances that it will not 'take legal action against growers whose crops might inadvertently contain traces of Monsanto biotech genes.'"

The panel ruled that a statement posted on Monsanto's website declaring that Monsanto has a policy of not bringing patent infringement lawsuits against farmers whose crops contain "trace amounts" of Monsanto's patented seeds or traits had "a similar effect" as a covenant not to sue. The Federal Circuit noted that, while the statement on Monsanto's website was sufficient to moot the present controversy under which the plaintiffs requested a declaratory judgment of invalidity and non-infringement, the statement would also "warrant the application of judicial estoppel" in the event that Monsanto was to bring suit against the plaintiffs in the future for actions that fall within the scope of the published policy.

In light of this ruling, patent holders may consider posting similar policy-related statements on their websites to protect themselves against certain lawsuits. However, when posting such statements, patent owners should bear in mind that they will likely be held to them and precluded from taking actions that run contrary to those statements. ◆

*"Monsanto has made binding assurances that it will not 'take legal action against growers whose crops might inadvertently contain traces of Monsanto biotech genes.'"*

# The French Competition Authority Launches a Wide-Ranging Sector Inquiry into the Pharmaceutical Distribution Sector

On February 25, 2013, the French Competition Authority announced the launch of a sector inquiry into the pharmaceutical sector. The Authority plans to issue its preliminary findings on or about July 2013 in order to deliver its final report and recommendations before the end of 2013.[1]

The Authority has the power to open inquiries into specific sectors to evaluate competition intensity, identify potential issues and make recommendations to improve the functioning of the market concerned.

In recent years, the Authority has been very active on this front, publishing reports covering sectors like online commerce, auto spare parts, online advertising and food retail, with a strong impact on pending and/or subsequent public and private enforcement actions.

## The Scope of the Inquiry

In the roadmap which has just been published, the Authority explains that the investigation will assess whether and how recent regulatory evolutions have effectively fostered competition in this sector. The inquiry will focus on the competitive structure and practices at each level of the distribution chain of pharmaceutical producers, wholesalers and pharmacists.

- The Authority first intends to assess the scope for competitive pricing on medicines that are reimbursed and the investigation will include the whole pricing formation process between producers, wholesalers and pharmacists, as far as non-reimbursed medicines are concerned. The wholesaling system applicable in France, with "grossistes-répartiteurs" between producers and pharmacists, will also be investigated, including cross-border aspects (competitive pressure exercised by wholesalers through imports from/exports to other Member States). The Authority has started to address this subject with an opinion n°12-A-18, released on July 20, 2012, recommending that restrictions to such cross-border trade be limited to the necessary minimum.
- The inquiry will also cover practices likely to delay generic entries and could eventually include recommendations to originator companies to adopt "internal prevention programs" to avoid anticompetitive practices as well as recommendations to improve regulations to stimulate competition between originator and generic medicines. It may be noted that the Authority is currently investigating several cases concerning complaints against originator companies (see decisions n°10-D-16 and 09-D-28).
- Non-reimbursed medicines are also included in the scope of the investigation considering the recent price evolution of those products, and the Authority will notably assess the reality of price competition between manufacturers, as well as price and service competition at the level of pharmacists.

*"[T]he Authority will notably assess the reality of price competition between manufacturers, as well as price and service competition at the level of pharmacists."*

- The Authority will finally focus on the development of online sales. In a recent opinion (Avis n°12-A-23), it has advocated extending French legislative proposals transposing the EU Directive N°2011/62 to all medicines that are not subject to medical prescription. This recommendation has not been followed so far, but the entry into force of these new provisions was suspended for legality issues by the French Administrative Supreme Court on February 14, 2013. The sector inquiry will also provide an opportunity to assess how the Directive has been transposed in other Member States and conditions that need to be ensured for the proper development of online sales.

## The Implications of a Sector Inquiry

As it has done in a number of cases — and will do so here — the Authority first publishes preliminary findings for comment before issuing its final inquiry report based on the information gathered through requests for information and hearings conducted by its investigation services.

The final report details the relevant competition assessment to be made of a number of practices in the sector at hand and includes specific recommendations to companies and/or the Government where legislative or regulatory changes appear necessary. If potentially uncompetitive practices are uncovered, individual infringement proceedings can also be opened by the Authority.

The Authority's inspection powers do not explicitly apply to sector inquiries, with the consequence that inspections — as this was done in the EU pharmaceutical inquiry — are not expected here, but companies are to cooperate with the inquiry and to provide all information requested for that purpose. The provision of incorrect or misleading information or a refusal to provide the information requested might expose companies to a fine of up to 5% of their global total turnover under article L 464-2, V of the Commerce Code.

## Lessons Learned from the EU Pharmaceutical Sector Inquiry

Like the EU pharmaceutical sector inquiry (2008–2009), the French investigation will address practices delaying the entry of generic products, but it will largely focus on pricing and distribution issues, whereas the EU inquiry was rather IP-oriented.

To date, the European Commission has opened several formal procedures under Article 102 TFUE (abuse of dominance) against practices that might have had the object or effect of delaying the entry of generic drugs (COMP/39.612 – Perindopril, COMP/39.226 – Citalopham, COMP/39.686 – Modafinil, COMP/39.685 – Fentanyl).

Following up on the recommendations of its final report, the European Commission also launched three successive patent settlements monitoring exercises designed to identify potentially problematic settlements from an antitrust perspective, in particular, those that limit generic entry against payment from an originator to a generic company.

Finally, the Commission recommended the introduction of an EU patent and a

unified specialised patent litigation system to improve the fragmented patent system which currently causes legal uncertainty in patent disputes all over the EU, a project which is about to become reality. ◆

## Endnote

1 Link to the Decision n°13-SOA-01 dated 25 February 2013 launching the sector inquiry: http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=483&id_article=2051.

# New Regulations in the PRC

There has been increasing concern about the quality of pharmaceuticals and health care products marketed in the Peoples' Republic of China (PRC), partly due to a number of scandals in recent years and growing public concern about the quality and availability of health care.

## Advertising

Advertising in the health care sector has been growing steadily in recent years and is thought to be worth more than RMB 80 billion. In March 2007, the PRC State Food and Drug Administration (SFDA) and State Administration of Industry and Commerce (SAIC) jointly issued the Examination and Placement Standards of Pharmaceutical Advertisements and Pharmaceutical Advertisements Examination Rules to regulate the contents, production and release of pharmaceutical advertisements in China.

The SFDA has recently undertaken a study into online advertising and sales of pharmaceutical products. As a result of the investigations carried out in 2012, 435 administrative notices or orders were issued in connection with advertising, and 83 pharmaceutical-related websites were completely shut down. The clear message is that the SFDA is taking compliance with advertising regulations more seriously than perhaps has been the case in the past.

In April 2013, the SFDA, together with other government bodies, published an Official Notice regarding a new round of investigations that are scheduled to end in July 2013 covering health care advertising in newspapers and periodicals, on websites and on broadcast media, such as radio and television stations. It is clear that there will be much greater scrutiny of advertising going forward.

## Consolidation Objectives

On January 22, 2013 the National Development and Reform Commission issued a Guidance Paper aimed at encouraging greater consolidation within the PRC pharmaceutical sector. This set out the government objective of restructuring the industry so that, by 2015, the combined revenues from the top 100 pharmaceutical companies will represent more than 50 percent of the market in terms of sales. The top 20 companies engaged in the sale of what are known as "essential pharmaceuticals" will account for 80 percent of all

*"The clear message is that the SFDA is taking compliance with advertising regulations more seriously than perhaps has been the case in the past."*

such sales. It should be noted that essential pharmaceuticals are those listed in the catalogue of essential drugs published by the Ministry of Health and subject to regulation by the National Development and Reform Commission.

### Illegal Activities

Responding to increased concern about compliance with the requirements of law, the SFDA introduced measures on January 8, 2013 designed to reward the reporting of illegal activities involving food and pharmaceuticals. These new provisions set aside public money to fund payments of up to RMB 300,000 per case to reward members of the public submitting information concerning the illegal development, manufacture or circulation of drugs, medical devices, health food or cosmetics. These new measures follow similar regulations introduced in October 2012, which made available online resources allowing members of the public to report regulatory offenders.

### Review of Approval Procedures

On December 31, 2012 the SFDA introduced proposals to encourage the development and approval of innovative pharmaceuticals and high-demand generics. Innovative pharmaceuticals are those that target critical illness and result in the creation of Chinese-owned IP. High-demand generics are those that treat rare and special diseases, have a pediatric application or have clinical demand that exceeds supply in the market. The new measures introduce proposals that reduce approval times by adjusting current standards and technical review requirements. They also improve efficiency by allowing applicants to provide supplementary materials as their research progresses. The proposals introduce the option of giving high-demand generics a "fast track" priority review procedure, thereby reducing the time required for approval and streamlining clinical trial controls. ◆

## Changes in the Pipeline for EU Rules on Technology Licensing

The European Commission has moved a step closer to adopting tougher antitrust rules on technology licensing and is seeking public comment on them. Some of the proposals are specifically aimed at life sciences businesses.[1]

The second round of consultation with citizens, public authorities, organizations and the business community closed in mid-May 2013.

The proposal will replace the current "safe harbor" rules aimed primarily at patent and know-how licences, contained in the EU Technology Transfer Block Exemption Regulation, which expires on April 30, 2014, after having been in place for 10 years. The old regime will continue after it expires to protect most pre-existing agreements that complied with it.

Most of the proposed changes would cut down the scope of the "safe

harbor," exposing licenses to greater risk of being found anti-competitive and potentially unenforceable in their entirety. For example, there are changes to the maximum allowable market shares for parties to licensing agreements.

*"Two common ways of legitimately circumventing antitrust restrictions are to be excluded under the new rules...."*

Two common ways of legitimately circumventing antitrust restrictions are to be excluded under the new rules, unless they can be justified on a case-by-case basis.

Any provision entitling the licensor to terminate the licence if its licensee challenges the IP in question within the EU (e.g., if the licensee brings a revocation action against a licensed patent) would fall outside the safe harbor. It is already not possible to prevent the licensee from an outright attack on the IP, but a common way around this has been to terminate the license, so that the licensee, like any other company, must take the risk that it will be left without the license that it needs if its attack fails.

Currently, a licensor cannot insist on owning improvements to its IP made by the licensee, but it can achieve a similar result by insisting that these be exclusively licensed back to it where those improvements are "non-severable" — meaning that the improvements cannot be used without also infringing the underlying patent or disclosing the underlying know-how. This carve-out from the antitrust rules is also set to disappear from the "safe harbor," so that, at most, a licensor looking to bring all of its license terms within the scope of the exemption could require only a non-exclusive license of improvements, leaving the licensee free to exploit them.

The proposal also amends the guidelines accompanying the Exemption Regulation, in particular those relating to settlement agreements. While these can often be pro-competitive, the draft-revised guidelines note that "pay for delay" clauses (often found in settlements between innovators and generic producers of pharmaceuticals), and others where a licensee takes payment in exchange for more restrictive settlement terms, might well be anti-competitive. It is clear that the European Commission has the life sciences industry in its sights. ◆

## Endnotes

1 The new proposal can be accessed at http://ec.europa.eu/competition/consultations/2013_technology_transfer/index_en.html.

# About the Life Sciences Group

Mayer Brown is a leading provider of legal services to a broad range of participants in the global pharmaceuticals, biotech and medical device industries. We offer the legal and technical experience and global awareness needed to understand the opportunities offered and challenges presented to these industries.

Our clients within the life sciences industries range from start-ups to some of the largest pharmaceutical and medical device companies in the world. We also represent a significant number of regional, national and global banks, investment banks, financial institutions, funds and other investors in capital markets and finance transactions.

Our Life Sciences Group consists of a multidisciplinary team of lawyers with extensive industry knowledge and experience. The group comprises lawyers from across the firm's practices, including our Mergers & Acquisitions, Corporate & Securities, Banking and Finance, Private Investment Funds, Intellectual Property, Litigation & Dispute Resolution, Antitrust & Competition, Government/Global Trade, Tax and Transfer Pricing, Environmental, and Regulatory, Compliance and Market Access practices.

Our Life Sciences Group includes dual-qualified lawyers with additional degrees in medicine, pharmacy, biochemistry and biology. This scientific approach helps our team to quickly understand the business and scientific needs of our clients and provide them with tailored advice.

Our geographic reach and on-the-ground presence in most of the world's key business and finance centers allows us to assist our clients with structuring and executing cross-border transactions and handling other transnational legal matters. Our experience working with life sciences companies and participating in leading industry organizations across the sector provides our lawyers with valuable insights in dealing with the legal and regulatory challenges facing these industries.

Philip O. Brandes
Global Co-Chair

Adem Koyuncu
Global Co-Chair

Joseph A. Mahoney
Global Co-Chair

# Contributing Attorneys


**Sarah Byrt**
Partner
Intellectual Property
+44 20 3130 3832
sbyrt@mayerbrown.com

**Nathalie Jalabert Doury**
Partner
Antitrust & Competition
+33 1 53 53 36 37
njalabertdoury@mayerbrown.com

**Ian K. Lewis**
Partner
Corporate & Securities
+86-10 6599 9266
ian.lewis@mayerbrownjsm.com

**Christopher C. Mackey**
Associate
Intellectual Property
+1 312 701 8755
cmackey@mayerbrown.com

**Vera A. Nackovic**
Partner
Intellectual Property
+1 312 701 8115
vnackovic@mayerbrown.com

**Deborah Schavey Ruff**
Partner
Intellectual Property
+1 312 701 8601
druff@mayerbrown.com

**Kristine M. Young**
Associate
Intellectual Property
+1 312 701 8162
kyoung@mayerbrown.com