

INTELLECTUAL PROPERTY AND TECHNOLOGY NEWS

Perspectives • Analysis • Visionary Ideas

FUNDAMENTAL REFORM AHEAD FOR EUROPEAN PATENT LAW

PATENTABILITY OF ISOLATED
NUCLEIC ACID

PATENT REFORM – IS IT WORKING?

RIGHT TO PRIVACY IN JAPAN

SUPREME COURT CORNER

THE FTC GETS ACTIVIST
POST-ACTAVIS

CLAUDIA WILSON FROST NAMED AMONG LAW360'S TOP 20 MOST INFLUENTIAL WOMEN IN IP LAW



Claudia Frost

Claudia Wilson Frost has been honored by *Law360* as one of the top 20 women in the US who are most

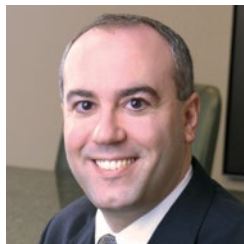
influential in IP Law. An IPT partner in the Houston office, Claudia brings tremendous experience to her role as co-chair of DLA Piper's US Patent Litigation practice.

With three decades as a trial lawyer, appellate advocate and strategist, Claudia has vast experience in all aspects of patent litigation. She has been lead or co-lead counsel in over 50 patent infringement cases in both trials and appeals throughout the US. Claudia has argued numerous *Markman* hearings, tried many patent infringement cases to verdict, represented parties in Section 337 actions in the ITC and argued significant cases in the Federal Circuit.

While most of her patent litigation clients are in the oil and gas/energy and telecommunications sectors, she also has represented technology, financial services and retail clients in patent disputes. Claudia also advises clients on international patent acquisition and enforcement strategies, either as part of ongoing litigation or independently as a business advisor. She is the go-to lawyer for clients such as Invensys Systems Inc. and Adobe Systems Inc.

For more about Claudia, see dlapiper.com/en/us/people/f/frost-claudia-wilson/

EDITOR'S COLUMN



Thomas Zutic
Partner, Intellectual
Property and Technology

Over the past year, it has been my pleasure to serve as editor of *IPT News*. I am very pleased that during my tenure *IPT News* has addressed issues in the vanguard of patent, trademark and copyright law, including those related to significant US patent reform measures; the legal landscape of the right of publicity in the context of social media; the true meaning of "intent-to-use" for purposes of US trademark opposition challenges; and the evolution of US biosimilar laws.

Now it is my great pleasure to introduce the next editor of *IPT News*, Vicky Lee. I am certain that under Vicky's leadership, DLA Piper will continue bringing you cutting-edge analysis of practical, business-focused IP and technology concerns.

In this issue, we are pleased to bring you an exciting overview of the significant changes that are on the way in European patent law. We highlight DLA Piper's recent Women in IP Law forum – a successful event drawing over 200 guests. We also look at the budding right of privacy in Japan, as well as how patents directed to genetic material are treated in jurisdictions around the world. In our Supreme Court Corner, we discuss several cases, including one relating to trademarks.

Finally, I want to thank all those who work so hard on this publication to ensure that it is timely, enjoyable and full of useful information. Your valuable work on this publication is greatly appreciated.

Happy holidays to you and your families, and we wish you all the best in 2015.

thomas.zutic@dlapiper.com



The award-winning *Intellectual Property and Technology News* is now published in the United States, Asia Pacific and EMEA regions. Find all current and past editions of the *IPT News* here: www.dlapiper.com/ipt_news/. To subscribe to this complimentary publication, please email your contact information (including your physical mailing address) to IPTnews@dlapiper.com.

You are receiving this communication because you are a valued client, former client or friend of DLA Piper. The information contained in this newsletter is for informational purposes only and should not be construed as legal advice on any matter. To unsubscribe from this mailing list, send an email to communications@dlapiper.com or send your written request to: DLA Piper, Attention: Marketing Department, 401 B Street, Suite 1700, San Diego, California 92101-4297, USA. Copyright © 2014 DLA Piper LLP (US), DLA Piper UK LLP and other affiliated entities. For questions, comments and suggestions, email us at IPTnews@dlapiper.com or contact Diane Visisel, Senior Marketing Manager, T +1 619 699 3541, diane.visisel@dlapiper.com. US Chair – Intellectual Property and Technology, John Allcock: T +1 619 699 2828, john.allcock@dlapiper.com. Editor in Chief, Thomas E. Zutic: T +1 202 799 4141, thomas.zutic@dlapiper.com. Director, Intellectual Property and Technology, Licia Vaughn: T +1 619 699 2997, licia.vaughn@dlapiper.com. DLA Piper LLP (US), 401 B Street, Suite 1700, San Diego, California 92101-4297, USA. | MRS000023623

21 DLA PIPER PATENT LAWYERS AMONG WORLD'S LEADING PATENT PRACTITIONERS

IAM Patent 1000: The World's Leading Patent Practitioners 2014 has named 21 DLA Piper lawyers to its 2014 list. IAM interviewed lawyers and clients around the world to determine who companies turn to "when only the best patent work will do."



John Allcock
San Diego and Silicon Valley



Dale Lazar
Northern Virginia



Adam Cooke
London



Mark Radcliffe
Silicon Valley



Gualtiero Dragotti
Milan



Kathryn Riley Grasso
San Diego and Washington DC



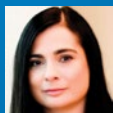
Mark Fowler
Silicon Valley



Paul Steadman
Chicago



George Godar
London



Krystyna Szczepanowska-Kozłowska
Warsaw



John Guaragna
Austin



Richard Taylor
Birmingham



Paul Gupta
New York



Stacy Taylor
San Diego and Seattle



Dr. Lisa Haile
San Diego



Jean-Christophe Tristant
Paris



James Heintz
Northern Virginia



Alexander Tsoutsanis
Amsterdam



Denise Seastone Kraft
Wilmington



Roberto Valenti
Milan



Joseph Lavelle
Washington, DC

BUILD IT AND THEY WILL COME

DLA Piper will be ten years old in January. Starting on Day 1 of the merger, we set out to be the best global IP practice in the world, and as part of that to have a strong patent litigation practice in every country of global significance. When we started there were many gaps in our lineup. Now there are none. We have highly regarded practitioners across the US (in every one of the top ten filing venues) as well as in each country of significance. The list to the left shows you just a few of these folks.



John Allcock
Partner
Global Co-Chair and US Chair, Intellectual Property and Technology

When we started on this project, we did not know that there would be a Unified Patent Court, but our instinct was that it would be increasingly important to have global patent capability. As the articles in this issue note, with the UPC, for the first time, a single court in Europe will have the ability to grant a European-wide injunction and damages based on sales throughout Europe. For those of us who, over the years, have litigated patent cases involving large product sales in various countries, this is a game changer. Europe will become a much greater factor in strategic decisions in patent disputes of any magnitude.

DLA Piper stands ready to help clients – right now – with planning a patent strategy to best take advantage of this dramatic change in the global patent landscape. And we will be there in the future if disputes arise, ready with our tight-knit group of focused, experienced patent litigators across the globe.

john.allcock@dlapiper.com

PATENTABILITY OF ISOLATED NUCLEIC ACID: US VS. AUSTRALIA

By Dr. Lisa Haile, Nicholas Tyacke, Eliza Mallon and Louis Italiano

Patents directed to genetic material have been the subject of significant public discourse and legal challenge worldwide, leading to a divergence of governing law between jurisdictions and heightened industry uncertainty in the US, especially in the molecular diagnostics area.

SUBJECT MATTER ELIGIBILITY

Subject matter eligibility in the US is based on Section 101: “Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter...may obtain a patent....”

Until recently, as long as the subject matter fell within one of the four statutory classes and involved human intervention, it was patent eligible.¹

Patentable subject matter in Australia must be a “manner of manufacture.” The guiding test was established by the High Court of Australia in *National Research Development Corporation v. Commissioner of Patents* (1959), which held a product that amounts to an “artificially created state of affairs” (something which, but for human intervention, would not exist) and which also has economic significance constitutes a “manner of manufacture.”

These respective principles were applied to isolated genetic material by the US Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (2013) and the Full Court of the Australian Federal Court (“FFC”) in *D’Arcy v. Myriad Genetics Inc.* (2014).

THE MYRIAD BRCA GENE PATENTS IN SUIT

Nine composition claims from three patents were at issue in the US *Myriad* case, but ultimately, in both the US and Australia, only the threshold subject matter eligibility test for patentability was considered.

THE US MYRIAD DECISIONS

The US Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.* ruled last year in a unanimous 9-0 decision that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.” 133 S. Ct. 2107, 2111. “To be sure, [Myriad] found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.” *Id.* at 2117.

In the US, *Myriad* has been extended beyond the patentability of genes, creating a roadblock to the patentability of other naturally occurring biologics. The USPTO has begun to examine and consistently reject patent claims for proteins, stem cells and other biologics under the *Myriad* test. In many instances, unless a DNA or protein sequence is claimed in combination with a detectable label, or linked to a solid support, the claims are rejected as lacking patentable subject matter under *Myriad*.

THE AUSTRALIAN MYRIAD DECISIONS

Applying a broader test than in the US, the FFC held that “the isolated nucleic acid, including cDNA, has resulted in an artificially created state of affairs for economic benefit”² and therefore the claimed product is patentable subject matter.

The FFC stated that “the analysis should focus on differences in structure and function [of the isolated molecule] effected by the intervention of man and not the similarities” (at [155]).

An application has been made to appeal the FFC decision to the High Court. In the meantime, isolated genetic material remains patentable subject matter in Australia.

USPTO GUIDELINES

Earlier this year, the USPTO issued “Guidance for determining subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, and natural products,” setting out guidelines to determine subject matter eligibility.

Particularly constraining, the Guidelines state that a “claimed product must be both non-naturally occurring and markedly different from naturally occurring products.”

A revision of the Guidelines is expected to provide that, in addition to examining structural differences, functional differences must be considered in assessing whether a claim is directed to a product that is different from a naturally occurring product.³

In contrast, the Australian Patent Office continues to grant patents over isolated genes with known functions, as long as such patents do not fail for lack of novelty or inventive step.

AMBRY

Following the US case, a number of Myriad's competitors, including Ambry Genetics, announced their intent to market their own versions of Myriad's BRCA diagnostic test. Myriad instigated proceedings against those parties in the District of Utah, alleging such tests would infringe patent claims that had not been struck down, including:

- "Primer claims" directed to single-stranded DNA primers used in the polymerase chain reaction process for replicating BRCA1 and BRCA2 genes; and
- "Method claims" directed to techniques for screening BRCA genes for mutations by comparing patient sequences with ordinary "wild-type" sequences.

The district court denied Myriad's motion for a preliminary injunction, finding the primer claims may not constitute patentable subject matter because they may fall within the ambit of claims to mere isolated DNA, and that the method claims may be rejected in light of the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories*.

Myriad appealed to the Federal Circuit, arguing primers are essentially the same as cDNA, which the Supreme Court found to be patent-eligible. Myriad further argued its methods are applications of the discovery of the BRCA gene sequences, which the Supreme Court has held are patent-eligible. A decision has not yet been delivered.

CONCLUSION

Isolated nucleic acid sequences are patentable in many jurisdictions, among them Australia, Canada, China, Europe, Japan, Russia and South Korea, but not in the US.

The US biotech industry requires certainty rather than the uncertainty introduced by the *Myriad* decisions and the USPTO Guidelines. The current chaotic environment is disincentivizing research and development by US companies of new and useful diagnostic or therapeutic products from subject matter of biological origin.

Meanwhile, the Australian Patent Office and Australian judiciary's preparedness to leave such subject matter exclusions to the legislature provides a more certain environment, conducive to research, development and investment.

Dr. Lisa Haile is a partner based in San Diego. She is Co-Chair of the Global Life Sciences Sector and concentrates on patent prosecution and IP strategy. Reach her at lisa.haile@dlapiper.com.

Nicholas Tyacke, a partner based in Sydney, is an patent litigator admitted to practice in both Australia and the US. Reach him at nicholas.tyacke@dlapiper.com.

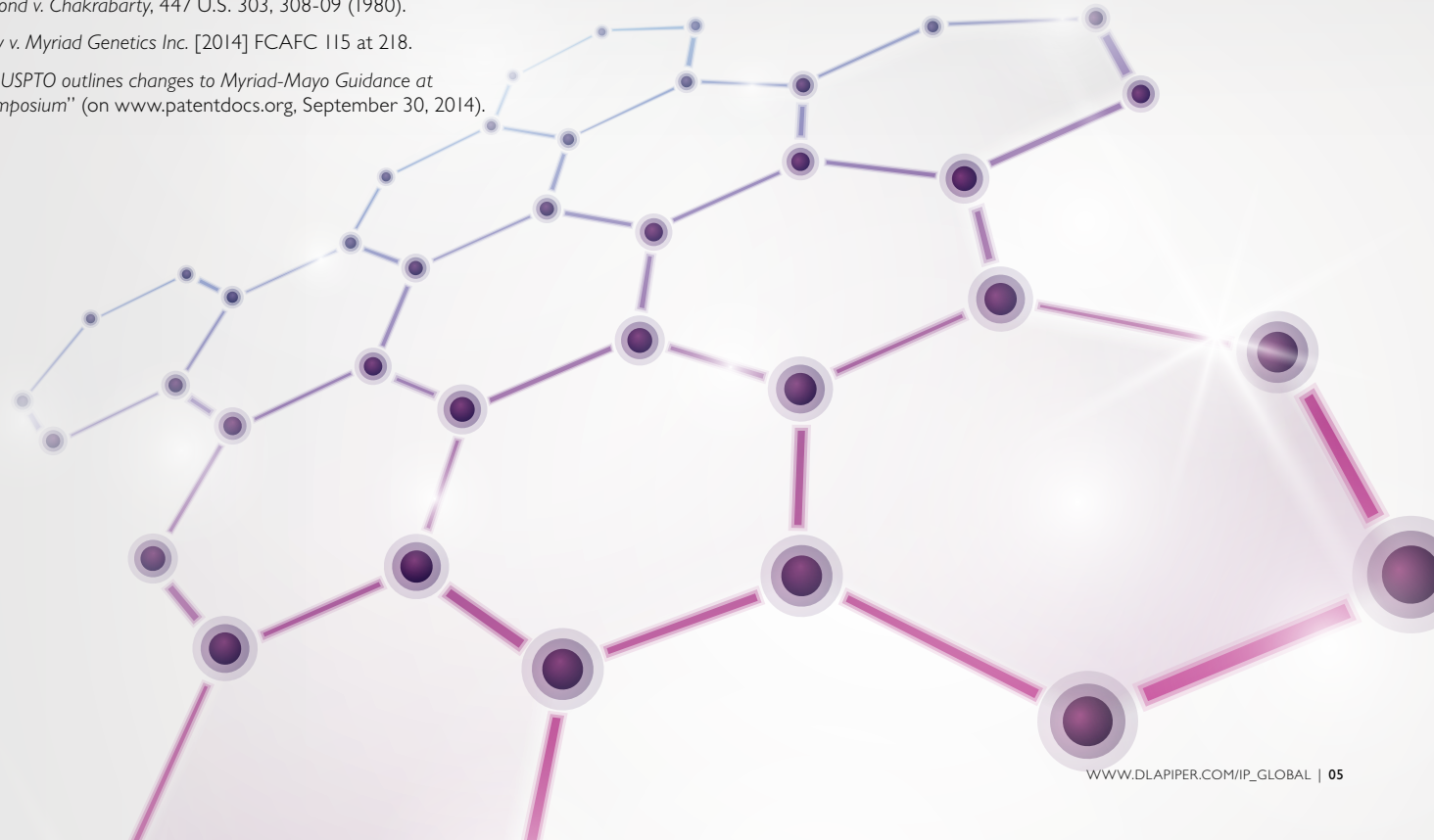
Eliza Mallon is a senior associate in DLA Piper's IPT group, based in Melbourne. Reach her at eliza.mallon@dlapiper.com.

Louis Italiano is a graduate in the IPT practice, based in Melbourne, and may be reached at louis.italiano@dlapiper.com.

¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980).

² *D'Arcy v. Myriad Genetics Inc.* [2014] FCAFC 115 at 218.

³ See "USPTO outlines changes to *Myriad-Mayo* Guidance at *BIO Symposium*" (on www.patentdocs.org, September 30, 2014).



WOMEN IN IP LAW: PATENT REFORM – IS IT WORKING?

By Licia Vaughn

DLA Piper's eighth annual Women in IP Law CLE Luncheon co-sponsored by the Association of Corporate Counsel and Leading Women in Technology, focused on the consequences of patent reform and IPRs and their impact on district court litigation.

Showcasing women as leaders in the IP and Technology field, the popular annual Silicon Valley event attracted approximately 200 guests.

Addressing this year's topic – "Patent Reform – Is It Working?" – were Marta Beckwith, Vice President Legal, Aruba Networks; Alexa King, SVP, General Counsel and Corporate Secretary, FireEye; Elizabeth Miller,

GC, Milwaukee Tool; and DLA Piper IPT partners Claudia Wilson Frost (Houston), Denise Seastone Kraft (Wilmington) and Christine Corbett (Silicon Valley). DLA Piper's Director of Intellectual Property and Technology, Licia Vaughn (San Diego), led the program.

The panelists noted that in enacting the AIA, Congress sought a more efficient and streamlined system that would provide a timely and cost-effective alternative to litigation. Citing August 2014-end statistics from the USPTO, the panelists reported that since IPRs became available in September 2012, 1,700 have been requested and 211 CBM petitions have been filed. Since the conference, those numbers have risen. As of August 28, 2014, about 80 percent of IPR petitions have been instituted and about 85 percent of IPR reviews have resulted in at least one patent claim being cancelled or amended.

Discussing stays of district court litigation pending IPR, Denise Kraft said that since the adoption of the AIA, approximately 55 percent of all contested motions to stay pending IPR have been granted. In addition, numerous cases have been stayed pending IPR by agreement of the parties.



IP lawyers from many prominent Bay Area companies filled the room

Discussing the impact of estoppel on district court litigation, Liz Miller and Claudia Frost noted the AIA provides that after a decision by the PTAB, the petitioner in an IPR may not assert in court or the ITC that a patent claim involved in the IPR "is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review."

The PTAB is creating estoppel case law, narrowing issues by finding certain grounds for invalidity "redundant" or "cumulative" in view of other grounds and explaining this action as required by 37 C.F.R. § 42.1(b) for the "just, speedy and inexpensive resolution of every proceeding."

Estoppel only applies to a petitioner and its related companies, which means that in a consolidated case, there could be a way around estoppel. A non-IPR defendant could raise an IPR defendant's estopped arguments in district court; in this way, the IPR defendant might benefit from those arguments. Panelists noted that some cases have conditioned a district court stay on all defendants agreeing to be estopped (even those not filing the IPR).

Christine Corbett discussed the impact IPRs may have on damages and willful infringement. In pre-AIA cases, courts held that if a claim is cancelled or substantively amended during a PTO review and the patent is reissued with new or amended claims, then the patentee cannot recover past damages on that claim. Pre-AIA, the Federal Circuit affirmed a district court ruling that a plaintiff was not entitled to damages for infringement during the period before the grant of reexamined patent claims where



Panelists from left to right: Licia Vaughn (San Diego), Denise Seastone Kraft (Wilmington), Alexa King (SVP, General Counsel and Corporate Secretary, FireEye), Marta Beckwith (Vice President Legal, Aruba Networks), Elizabeth Egasti Miller (General Counsel, Milwaukee Tool), Christine Corbett (Silicon Valley) and Claudia Wilson Frost (Houston)

the claims were substantively amended. Thus, it is reasonable to expect that IPRs which change the scope of a patent and its claims will have an impact on the scope of damages liability in a district court case.

Likewise, the institution of an IPR could impact willful infringement. To prove willfulness, the patentee must demonstrate that the accused infringer's invalidity positions were objectively unreasonable. Pre-AIA, courts held that when the USPTO requires amendments or cancels a claim during review, this demonstrates the reasonableness of the invalidity positions, and the willful infringement claim fails as a matter of law.

However, cases also confirm that a grant of a request for reexamination alone does not establish a likelihood of invalidity and that the entirety of the record must be reviewed for willfulness.

Post-AIA, it is reasonable to expect that where the PTAB requires amendments or cancels a claim during an IPR, the district court in related federal court litigation may find no liability for willfulness because the invalidity positions were not objectively unreasonable. Yet simply because an IPR petition is granted cannot alone be dispositive of objectively reasonable behavior.

Panelists spent a good deal of time talking about some of the patent reforms that did not appear in the AIA, including a provision requiring the losing party to pay the prevailing party's attorneys' fees. Yet the panelists noted there were some recent and promising opinions out of the District of Delaware and the Northern District of California having similar effect by awarding attorneys' fees against parties filing or maintaining frivolous cases, and awarding case terminating sanctions for a plaintiff failing to conduct a reasonably adequate pre-suit investigation.

Licia Vaughn, based in San Diego, is DLA Piper's Director of Intellectual Property and Technology. She practices IP litigation and functions as the practice group manager for the IPT practice in the US. Reach her at licia.vaughn@dlapiper.com.



Attendees enjoy connecting and networking at this annual Silicon Valley luncheon



EUROPEAN PATENT LAW: FUNDAMENTAL REFORM AHEAD

By Dr. Markus Gampp

The European Union member states are preparing to introduce a new European Patent with Unitary Effect and a single Unified Patent Court with divisions located throughout Europe.

With this package of broad patent reforms, the significance and the scope of patent litigation in Europe is expected to increase substantially. By creating a truly unitary European patent protection system, with a supporting court system, the EU is making its patent enforcement system much more attractive and globally competitive.

From both legal and economic perspectives, the new system, particularly the new Unified Patent Court (UPC), is the biggest game-changer in European patent law in history, bringing about fundamental changes for patentees, defendants, their counsel, judges and everyone involved in patent litigation in Europe.

STATUS QUO AND REFORM OBJECTIVES

Patent protection for inventions may currently be achieved in Europe on two paths: either through national patents, which are valid and provide protection only in the respective granting member state, or through a European Patent, granted by the Munich-based European Patent Office. The present European Patent is not a single uniform IP right providing protection across the entire EU. Rather, it must be validated with each respective national patent office and then only exists as a bundle of national patents. When infringement occurs, the patentee must bring separate actions before courts in every single relevant jurisdiction. Similarly, the defendant must endeavor to have the patent invalidated separately in every jurisdiction. This system is not only costly and burdensome for the parties, but also bears the inherent risk of conflicting decisions.

The imminent introduction of the European Patent with Unitary Effect and the creation of the Unified Patent Court aim to create homogenous, EU-wide patent protection. Under the new system, it will be possible to obtain an injunction against an infringing product valid across the entire EU (i.e., in all the participating member states) with just one legal action. For companies, this puts the vast majority of the single European market at stake in future patent litigation in Europe, thereby significantly increasing the economic and strategic importance of such cases.

THE EUROPEAN PATENT WITH UNITARY EFFECT

The new European Patent with Unitary Effect will be based on the existing European Patent. To be afforded the protection of the unitary effect, the patentee must apply for this patent during application for or subsequent to the grant of a European Patent. The European Patent Office will continue to be the competent body for examination and granting of such patent applications, as well as for handling opposition proceedings.

THE UNIFIED PATENT COURT

The centerpiece of Europe's patent reform is the Agreement on a Unified Patent Court, signed by 25 EU member states in early 2013. The UPC will make it possible to enforce, attack and defend a patent before one single

VIEW FROM THE US

By Claudia Wilson Frost



While a radical departure from prior practice in the EU, the concept of

a European Patent with Unitary Effect will be familiar to US practitioners. That is because the Unitary Patent (UP) System is an “all eggs in one basket” system – much like that in the US, where the USPTO is the only agency authorized to issue US patents and an issued US patent is applicable and enforceable in all 50 states.

Even after the UP system goes into effect, however, patent holders and applicants may opt out of the system for many years. Inventors can choose to have patents under the UP system, the existing EPU system or a country's national system. Moreover, not all EU countries have agreed to be bound to the UP system – most notably Italy, Spain and Poland.

As a result, multinational companies will have a broad variety of European patent enforcement and acquisition strategies available even after the advent of the UP system. Some suggest that for important inventions, all three systems should be used, with the applicant patenting differently in each system so that only part of the portfolio is in the UP system.

The Unified Patent Court will also be familiar to US practitioners in concept because it is similar to the US federal court system, which has exclusive jurisdiction over patent cases and the ability to issue binding decisions and injunctions across the US. The UPC will be able to decide both infringement and invalidity cases, and its decisions and injunctions will be binding in all countries that have signed on as member states to the UPC agreement.

Unlike the US court system, however, the UPC will be a specialized patent court system. To take part, countries must sign up. There will be a new set of procedural rules based on European best practices, and sitting judges will be redeployed and, as necessary, trained in patent law.

Moreover, in the undoubtedly bumpy transitional period to come, we all should remember that, while the system has many familiar aspects, it is largely being created from scratch.

Partner and Co-Chair of Patent Litigation
Claudia Wilson Frost, based in Houston, has three decades of experience as a trial lawyer, appellate advocate and strategist, including in all aspects of patent litigation and enforcement. Reach her at claudia.frost@dlapiper.com.

THE UK AND FRANCE

By Adam Cooke and Jean-Christophe Tristant



The introduction of a unitary patent and a unified patent court system is viewed as a

very exciting prospect. Somewhat paradoxically, however, the introduction of the UP will mean that three types of patents will become available in Europe: national patents; so-called European bundle patents; and UPs. During the transitional period, litigation of European bundle patents may take place not only before national courts, but also before the UPC. Initially therefore, the system will be more complex than at present.

For existing holders of European patents, one of the key issues will be whether to opt out of the UPC system during the seven-year transitional period. Depending upon the amount of the opt-out fee, this would be a prudent step for “crown jewel” patents because it would avoid the risk of pan-EU patent revocation by an inexperienced new court. An opt-out may generally be withdrawn, thereby allowing pan-EU enforcement of that same patent at a later date.

An issue for patent applicants will be whether to choose unitary protection upon grant rather than to choose a European bundle patent. The answer will in part depend upon the geographical scope of protection needed for the technology in question and of course the cost of renewal fees. As to the latter, a European bundle patent gives greater flexibility: some territories can be “dropped” during the life of the patent, with consequent cost savings.

At first instance, the seat of the UPC central division will be in Paris, with sections in London and Munich. Broadly, London will deal with chemical and life sciences patents, Munich with mechanical engineering and Paris with electronic and ICT. These courts will also deal with infringement cases transferred by local or regional divisions as well as infringement cases where there is no UPC division in the member state in question. This could well lead to a concentration of patent litigation in France, the UK, and Germany.

If the litigation process before the UPC is efficient, and if the UPC is able to make decisions quickly, predictably and consistently, it will be a great success. The quality of the judges, facilities, administrative support and level of funding, as well as the amount of fees charged will all be key elements. But we in the UK and France are optimistic. There is a real commitment among all parties to make it work.

.....
Based in London, Adam Cooke, a partner in DLA Piper's IPT group, focuses on multijurisdictional patent litigation, especially in the life sciences and high technology sectors. Reach him at adam.cooke@dlapiper.com.

Based in Paris, Jean-Christophe Tristant, a partner in DLA Piper's IPT group, concentrates on litigation and licensing IP rights with particular emphasis on patent litigation. Reach him at jean-christophe.tristant@dlapiper.com.

court, with effect for all participating member states. The UPC will have jurisdiction not only for the new Unitary Patents, but also for the existing European Patents, pending patent applications and Supplementary Protection Certificates. The Court of First Instance is composed of local divisions (set up in individual member states), regional divisions (which can be set up jointly by member states that do not wish to establish a local division of their own) and the central division, which will be based in Paris, London and Munich. The appellate court will be set up in Luxembourg. Local jurisdiction in individual cases will be determined among the local and regional divisions, taking into account the place of infringement or the defendant's seat.

In principle, the local and regional divisions have competence to handle infringement suits, while the central division shall handle invalidity actions. However, under the new system, an invalidity action may also be brought before the local or regional divisions as a countersuit to a pending infringement action. Thus, while the UPC retains the principle of bifurcation known from the German system, in practice many cases are expected to be handled as combined infringement and validity proceedings before the same division.

Once it is up and running, the UPC will have exclusive jurisdiction for such cases. An exception exists in two respects for the European Patents, patent applications and Supplementary Protection Certificates existing at that point in time. First, for a transition period of initially seven years, the UPC and the national courts will have alternative jurisdiction. Second, the patentee may declare to opt out of the jurisdiction of the UPC, either for individual patents or entire portfolios. By declaring an opt out, the patentee can prevent his patent from being declared invalid by the UPC with effect for all participating member states. On the flip side, however, the patentee thereby also deprives himself of the possibility to obtain an injunction for infringement of the patent with pan-European effect.

This puts the burden on patent holders – not only European, but all global companies with important European Patents in their portfolios – to evaluate whether and for which patents opting out of the jurisdiction of the UPC provides strategic advantages. Some large industrial European patent holders have announced that they intend to test the new system using a part of their patent portfolios.

The proceedings before local divisions will be held in general in the official language of the member state where the respective local division is seated. Due to the high number of patent cases being brought in Germany each year, Germany will be the only member state to host four local divisions (based in Munich, Mannheim, Düsseldorf and Hamburg). Debate about the use of English as a permissible second language for proceedings is ongoing. At the regional divisions, the participating member states are free to decide their official languages. For example, Sweden, Estonia, Latvia and Lithuania have agreed that English will be the language of their joint future Nordic-Baltic Regional Division seated in Stockholm. Generally, parties are free to agree, with the consent of the court, on the language of the patent as the language of the proceedings. At the central division, the language of the patent, which is currently English for the vast majority of European patents, will always be determinative.



OUTLOOK

As of the date of publication, 24 of the 28 EU member states are fully participating in the new system. Only Spain and Croatia do not participate at all, while Poland and Italy participate partially. Spain filed two complaints against various aspects of the patent reform package with the European Court of Justice. The first was dismissed and the second is still pending. The Agreement on a Unified Patent Court will enter into force after ratification by at least 13 participating member states, which must include Germany, France and the UK. Until then, a set of procedural rules is being created, the (currently 17th) draft of which is far advanced. Some practical questions must be resolved, including selection and training of judges, the implementation of a unitary IT system and the specification of court fees.

Against this background, the UPC is currently not expected to be fully operational before 2016. Then, in the first few years, the new system will come with considerable legal uncertainty. Many of the new material and procedural provisions will require interpretation, and the quality of the local and regional divisions scattered across Europe will initially be difficult to assess. It likely will take some time until reliable lines of case law have been established.

In view of the substantially increased significance of these cases, there are interesting times ahead for European patent law – and for all involved.

THE GERMAN PERSPECTIVE

By Dr. Markus Gampp



Arguably, Germany is the jurisdiction which has the most to lose with the introduction of the UPC. The German patent infringement courts have built a reputation of offering an attractive combination of quality, speed and a certain patentee-friendliness, which has made Germany a cornerstone of recent global patent disputes. More patent cases are filed in Germany each year than in all other EU member states combined.

Against this background, the reform project around the UPC was initially met with a certain degree of skepticism in Germany. However, in the long process of drafting the governing regulations, many concerns were addressed, and preparations are now well under way to have adequate structures in place when the UPC takes up its work. As to procedural aspects, the UPC will have an option for bifurcation of infringement and validity proceedings modeled after the German system.

To ensure judicial continuity, in particular regarding the quality and efficiency that clients have come to expect from German patent courts, it will be helpful that many, if not all, of the experienced German patent judges become judges in the UPC's four German local divisions, as is expected. Munich will also be hosting a section of the central division and will continue to be the seat of the European Patent Office.

Public debate continues on how to make the German local divisions even more attractive to prospective users, perhaps most importantly by permitting English as a second language for proceedings. Germany is expected to ratify the UPC Agreement in early 2015, at the latest, allowing the required ratifications to be completed in time for the currently anticipated start of the UPC by early 2016.

Dr. Markus Gampp, LL.M. is a partner in DLA Piper's Intellectual Property and Technology practice, based in Munich. Reach him at markus.gampp@dlapiper.com.

THE ITALIAN POSITION

By Gualtiero Dragotti



From a foreign perspective, it is not easy to understand the difference between UP and UPC. If you are Italian, the distinction is extremely clear, as Italy joined the newly established unified patent court system (the UPC) but did not participate in the enhanced cooperation procedure that led to the unitary patent (the UP).

Italy's peculiar position is probably going to change, as it can be hardly justified in logical terms. However, for the time being, this unusual distinction provides interesting opportunities for patent owners.

To get protection in Italy, it still will be necessary to go through the traditional routes: validating a European patent or filing a national application. If the scope of the claims coincides with those of the corresponding UP, those patents can be litigated before the Italian courts without the risk that the outcome of any litigation will affect patent protection in the rest of the EU.

This leads to a sort of litigation test ground, having the advantage of being located in a country participating in the UPC, whose judges will be therefore perfectly aware of UPC case law and practice (the Italian local UPC court will be located in Milan, where the major national IP Specialized Section is located).

Anyone interested in testing the strength of a patent without risking the protection it provides in the EU at large should consider the opportunities offered by the peculiar Italian situation. Of course, a number of issues could play a role in construing these kinds of actions (from the opt-out transitional regulations to the rules on international competence), but the intricacies of the new system and the existence of some differences and borders, even within an ever more unified territory, may be advantageously exploited.

Gualtiero Dragotti is a partner in DLA Piper's IPT practice, focusing on patents and the protection of innovation. He is based in Milan. Reach him at gualtiero.dragotti@dlapiper.com.



RIGHT TO PRIVACY STILL TENTATIVE IN JAPAN

By Lawrence Carter, Matthew Dougherty and Ryo Takizawa

In early October, the Tokyo District Court ruled in the case of a plaintiff who claimed his privacy rights had been violated because Google search engine results of his name included news articles suggesting he had a criminal past.

The plaintiff also alleged he had received death threats because of these suggestions, making his claim for damages immediate and actual.

Judge Nobuyuki Seki found that some of the results infringed on the plaintiff's personal rights and that the plaintiff had suffered actual harm as a result. Granting a provisional injunction against Google Inc., the judge ordered Google to delete certain search results mentioning the plaintiff – of 237 search results, he ordered Google to delete 122.

This case bears some similarities to the landmark ruling by the European Court of Justice in May that search engines need to remove the link between search results and a web page if it contains information an individual deems should be “forgotten.” That broad ruling increases the

rights of private individuals to remove themselves from search results, making search results less reliable. The ruling could impact day-to-day operations of Internet companies and could have deep implications for any service using third-party data sources containing personal data.

However, despite the Tokyo decision, it is still unclear whether Japanese courts will adopt and recognize a “right to be forgotten.” This case was decided in a provisional trial at the district court level. It has not been considered by Japanese appellate courts or the Japanese Supreme Court. In a separate case earlier this year, a court in Kyoto dismissed a claim filed against Yahoo! Japan because the plaintiff in that case actually did have a criminal record.

The right of privacy from search results is therefore not settled in Japan, and whether a Japanese court will find that search results infringe on personal rights may depend, in part, on whether the search results are accurate and/or part of the public record. Resolution of this question will likely require a ruling from the Japanese Supreme Court.

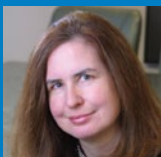
Lawrence Carter, a senior associate in the Corporate group based in Tokyo, focuses on employment matters and advises on corporate, M&A and real estate matters. Reach him at lawrence.carter@dlapiper.com.

Matt Dougherty, an associate in DLA Piper's Corporate group, has been involved in many cross-border transactions assisting US and Japanese corporations. He is based in Tokyo and admitted to practice in Colorado. Reach him at matthew.dougherty@dlapiper.com.

Ryo Takizawa, an associate in DLA Piper's Corporate group based in Tokyo, focuses on employment disputes, as well as Japanese data privacy law. Reach him at ryo.takizawa.dlapiper.com.

FOUR DLA PIPER PARTNERS NAMED AMONG TOP 250 WOMEN IN IP

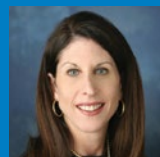
Managing IP has named Ann Ford (Washington, DC), Claudia Wilson Frost (Houston), Lisa Haile (San Diego) and Christina Martini (Chicago) among its 2014 Top 250 Women in IP.



Ann Ford



Claudia Wilson Frost



Dr. Lisa Haile



Christina Martini

THE FTC GETS ACTIVIST POST-ACTAVIS



By Dr. Erica Pascal and Karen Kwok

In 2013, the FTC left its mark on the pharmaceutical industry when the Supreme Court ruled in *FTC v. Actavis* that settlement agreements for patent infringement suits between branded and generic drug companies are not immune from antitrust scrutiny. These settlement agreements, referred to colloquially as “pay for delay,” often negotiate the terms by which the generic drug will enter the market relative to the expiration of patents covering the drug. The Supreme Court held that a rule of reason analysis should apply to antitrust claims. For example, antitrust issues may arise where settlement involves a large and unjustified reverse payment and a “risk of significant anticompetitive effects.” *Actavis*, 133 S. Ct. 2223, 2237 (2013).

Since *Actavis*, direct and indirect purchasers of pharmaceuticals have brought antitrust claims against branded and generic drug companies. Purchasers allege they have been harmed by the settlements between these companies. They claim that settlement terms, such as delaying a generic’s launch while promising to keep competing generics off the market, result in higher marketplace prices. Ironically, generic and branded companies now find themselves on the same side of the issue, defending the validity and competitive nature of their settlement agreements.

Actavis left open questions as to what constitutes “payment” between the companies and whether the magnitude of particular payments is sufficient to trigger antitrust issues. District and appellate courts are addressing these questions, with different results.

While the exchange of money clearly falls within the ambit of “payment” under *Actavis*, the high court’s ruling did not directly address other forms of consideration for litigation settlement. Examples of non-monetary exchanges include agreement by the generic company to delay launch of its drug until an agreed-upon future date; a promise by the branded company not to launch an authorized generic version; and an agreement between the companies to allow the generic company to distribute and sell the branded form of the drug until the generic version launches.

Do any of these exchanges constitute reverse payment? Courts have reached different outcomes, and even within the same circuit results are not uniform. The District of New Jersey has held that a reverse payment is limited under *Actavis* to a monetary reverse payment. The same district court later ruled that non-monetary consideration could be construed as a reverse payment, at least as sufficient to survive the pleading requirements. The Eastern District of Pennsylvania has concluded it was “not prepared at this point to accept [the defendant’s] argument that only a large cash payment

from the patentee to the generic is subject to antitrust analysis under *Actavis*.”¹ The District of Rhode Island, however, concluded “*Actavis* should be applied only to cash settlements, or to their very close analogues.”² The most definitive case yet on this other side of the coin is the District of Massachusetts’s *In re Nexium (Esomeprazole)* decision. Although the court sits in the First Circuit with the District of Rhode Island and its case was decided after *Loestrin*, it affirmatively held that a promise to refrain from launching an authorized generic constitutes “payment” under *Actavis*.³ At least three additional cases await determination of whether a “no authorized generic” promise should be considered a reverse payment under *Actavis*.

In view of this uncertainty, the FTC has not sat quietly on the sidelines. It has actively interjected itself into a number of pending cases. In *Lamictal*, plaintiff wholesale purchasers of the drug appealed to the Third Circuit after the district court dismissed their claims. The FTC filed an *amicus* brief and request for oral argument. The Third Circuit granted the FTC ten minutes of oral argument. The FTC also filed *amicus* briefs in cases pending in the Eastern District of Pennsylvania and in the District of New Jersey. In the former, the court refused to consider the FTC’s brief.

In each of its filed briefs, the FTC has made strong statements against “no authorized generic” agreements, arguing they are “a vehicle for sharing monopoly profits.” The FTC contends that through these agreements the “brand-name drug company...forfeits the revenues it could otherwise make by selling an authorized generic” and “consumers, meanwhile, are forced to pay supra-competitive prices for the first filer’s generic product.” The FTC website features similarly strong claims, declaring, these “pay-for-delay” patent settlements effectively block all other generic drug competition for a growing number of branded drugs.”

In contrast, the FTC’s views on the negotiated date for market entry of the generic drug are much more permissive. In the FTC’s view, merely setting a launch date before the patent expiration suggests nothing “other than arms-length bargaining between adverse parties.” And in the recent *In re Nexium* trial, the jury found that the agreement between the branded company and the generic drug maker, setting a delayed launch date for the generic version of Nexium, was not an antitrust violation.

So where does the line get drawn between anti-competitive “payments” and arms-length negotiations? In the milieu of multiple plaintiffs, differing views within the jurisdictions and now the FTC’s activism, the line is likely to remain fuzzy for some time.

Dr. Erica Pascal, an IPT partner based in San Diego, focuses on patent litigation in the life sciences area. Reach her at erica.pascal@dlapiper.com.

Karen Kwok worked as a summer associate at DLA Piper and will join the firm in 2015.

¹ *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 ECF 534, Order at 4.

² *Loestrin 24 Fe Antitrust Litigation*, 2014 WL 4368924 at *10-11.

³ 968 F. Supp. 2d at 392.



SUPREME COURT CORNER



RECENT DECISIONS



CASES TO WATCH



Kimble v. Marvel Enterprises, Inc.


Patent Licensing - Cert. Pending

Issue: Whether the Supreme Court should overrule *Brulotte v. Thys Co.*, which held “a patentee’s use of a royalty agreement that projects beyond the expiration date of the patent is unlawful *per se*.”

In *Brulotte v. Thys Co.*, 79 U.S. 29 (1964), the Supreme Court found “a patentee’s use of a royalty agreement that projects beyond the patent expiration date is unlawful *per se*” as an improper extension of the patent monopoly.

Petitioner Kimble patented a toy based on a Marvel comic book hero in 1991. During the appeal of Kimble’s patent infringement action, Kimble and Marvel agreed to settle the case in exchange for Kimble assigning the patent and other IP rights to Marvel, and Marvel paying a lump sum and running royalty. Under the agreement, the royalty would not end or reduce in rate when the patent expired. Years later, when Kimble sued Marvel for breach of the settlement agreement, the district court found the royalty was based, at least in part, on the assigned patent, and, thus, uncollectible under *Brulotte*. The Ninth Circuit “reluctantly” affirmed.

Kimble argues *Brulotte* should be reversed because post-expiration patent royalties do not extend the patent monopoly and because *Brulotte* discourages pro-competitive licensing practices. Marvel argues *Brulotte* is a narrow rule reaching only those agreements in which royalties accrue post-expiration, thus preventing patent misuse.

 **B&B Hardware, Inc. v. Hargis Industries, Inc.**

Trademark - Argument: Dec. 2, 2014

Issue: Whether a Trademark Trial and Appeal Board's (TTAB) finding of a "likelihood of confusion" precludes the alleged infringer from arguing no likelihood of confusion in a district court trademark infringement case.

Petitioner B&B owns the registered trademark SEALTIGHT; respondent Hargis manufactures a similar product and sought the trademark SEALTITE. B&B filed an opposition to Hargis's trademark with the TTAB. The TTAB denied Hargis's trademark because it was "substantially identical" to B&B's and was "used on closely related products" such that it would cause a likelihood of confusion. But in a co-pending trademark infringement litigation, the district court did not afford the TTAB's decision preclusive effect. The Eighth Circuit affirmed, finding the TTAB's likelihood of confusion test and the applicable burden of persuasion distinct from the Eighth Circuit's.

On appeal, B&B argues that the Eighth Circuit's decision diverges from that of the Second, Third and Seventh Circuits, which afford a TTAB likelihood of confusion finding preclusive in some circumstances, and that of the Fifth and Eleventh Circuits, which give the TTAB's decision deference. B&B notes that the TTAB and Federal Circuit give preclusive effect to district court findings of likelihood of confusion in the reciprocal instance. Hargis responds that all circuits agree the weight a district court should give a TTAB decision depends on the facts of the case. Further, Hargis argues district courts cannot afford presumptive preclusive effect to a TTAB likelihood of confusion analysis because its analysis differs materially from those of the different circuits.

 **Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.**

Patent - Argument: October 15, 2014

Issue: Whether the Federal Circuit's standard of reviewing a district court's factual findings in support of claim construction *de novo* is correct in view of Fed. R. Civ. P. 52(a).

This case raises the long-debated question of whether a district court's factual findings supporting a claim construction are entitled to appellate deference. The oral argument focused heavily on three key questions: (1) Is claim construction different? (2) What is a fact? (3) How much would deference matter anyway?

On the first question, some justices expressed concern that a *de novo* standard creates an anomaly by treating appellate review of fact-finding in one area – claim construction – differently from all other areas. For example, Justice Stephen G. Breyer asked, "Where are we going if we start carving out one aspect of the patent litigation?" Other justices, however, suggested claim construction might warrant different treatment. For example, Chief Justice John Roberts observed that deference could result in appellate endorsement of different constructions from different district courts on a "public patent that is going to bind a lot of other people."

On the second and third questions, Justice Samuel B. Alito asked whether it was even worth struggling to distinguish factual questions from legal questions in the claim construction context. Citing a study that suggested most appellate outcomes would be the same under either a deferential or a non-deferential standard of review, he asked, "Is it worthwhile as a practical matter?" If the Supreme Court affirms the Federal Circuit's *de novo* standard, there will of course be no need to grapple with these questions further. But if the Supreme Court institutes a deferential standard, these questions will take center stage.

Stan Panikowski, a partner in DLA Piper's Patent Litigation group based in San Diego, focuses on IP, antitrust, appeals and other areas of business litigation. Reach him at stanley.panikowski@dlapiper.com.

Andrew Stein, an associate based in Washington, DC, defends companies against patent troll litigation in federal district courts. Reach him at andrew.stein@dlapiper.com.

Brian Biggs, an associate based in Wilmington, Delaware, represents clients across many technical fields in patent litigation. Reach him at brian.biggs@dlapiper.com.

Attorney Advertising



TOP THREE: PATENT LITIGATION

When you have a patent dispute that can only be solved in the courtroom, DLA Piper has the trial strength and technical depth to guide you through. *Corporate Counsel's Annual Patent Litigation Survey 2014* ranked DLA Piper among the top three most active US firms, based on number of new district court patent case filings. We are honored that clients around the globe trust us with their patent matters.