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Life Sciences Law & Industry Report™

Life Sciences Industry

Bloomberg BNA's Life Sciences Law & Industry Report asked its editorial advisory board members and other life sciences attorneys for their top issues for 2015. Patent eligibility for products of nature and diagnostic methods, the continued implementation of patent reform under the America Invents Act and patent litigation loomed large in their picks, as did the regulatory approval of biosimilars. Personalized medicine wasn't specifically mentioned but was an underlying theme for a number of issues.

Patents Are Back as Top Issue for 2015, Life Sciences Attorneys Say

Patents and biosimilars again will be important issues for the life sciences industry in 2015, as will health information technology and Food and Drug Administration oversight of laboratory developed tests (LDTs), life sciences attorneys told Bloomberg BNA.

The industry will continue to be concerned about the patent eligibility of natural products and diagnostic methods and the implementation of the America Invents Act, the attorneys said. They predicted that biosimilars, which have appeared intermittently on LSLR's top 10 lists since the Biosimilar Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act, finally will become a real and not just an anticipated issue when the FDA approves its first biosimilar under the BPCIA's abbreviated approval pathway in 2015.

The top 10 issues for 2015 are markedly different from those for 2014, when they were evenly split between patent-related issues and those concerning personalized medicine. None of the attorneys Bloomberg BNA talked to specifically included personalized medicine—generally defined as targeting a specific medicine in the right dose for an individual based on genetic testing—in their top 10 lists.

But this omission is deceptive. The concerns about the patent eligibility of natural products and diagnostic methods sprang from court cases that involved patents related to genetic testing. Other patent cases that will be considered in 2015, such as *Limelight Networks*, also are seen as having implications for personalized medicine. LDTs and advances in health-care technology that improve how patients and their physicians manage a patient's health are an important part of the trend toward personalized medicine. One attorney said that

Top Issues in 2015

- Patent Eligibility of Natural Products
- Diagnostic Method Claims
- Biosimilars
- Effects of Patent Reform
- FDA Lab-Developed Test Oversight
- M&As and IPOs
- Health Care IT
- Monitoring Europe and Elsewhere
- More Patent Issues
- Patient Access to Experimental Drugs

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even the movement to get patients access to experimental drugs is a ''lay translation'' of personalized medicine.

The new list of the top 10 issues for life sciences, while not referring to personalized medicine by name, indicates that it has become accepted as part of the industry's mainstream.

Patent Eligibility of Natural Products

Patent eligibility of natural products was listed as the top issue in 2015 by the most attorneys. This isn't surprising given the year-end one-two punch of a Patent and Trademark Office revised interim guidance for its examiners on the issue (*see related story in the Federal News section*), followed two days later by a decision by the U.S. Court of Appeals for the Federal Circuit that dampened the life sciences community's excitement about the revised guidance (*see related story in the Court Proceedings section*).

The guidance, effective Dec. 16, replaces the one released March 4 (8 LSLR 276, 3/21/14) that was prompted by the Supreme Court's decisions in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.* (6 LSLR 284, 3/23/12) and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (7 LSLR 622, 6/14/13). The new interim guidance also supplements a June 25 PTO guidance on *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* (8 LSLR 605, 6/27/14), which deals with business and software method patents.

Mayo held that claims for methods for administering a drug are patent ineligible as laws of nature unless there is an ''inventive step'' and *Myriad* that composition claims for isolated DNA are patent ineligible because they recite the judicial exception for products of nature.

The revision essentially is the PTO's response to criticism it received on the original *Mayo*/*Myriad* guidance. It eliminates language specifically targeting non-DNA claims, and functional differences are now to be considered by the examiners. The new guidance also provides the examiner with instructions in the two-step process that the court established in *Mayo* and clarified in *Alice*—Is the claim directed to a judicial exception, and, if so, does the claim recite additional elements that amount to significantly more than the judicial exception?—that give the examiner the option not to go to the second step. There also is a streamlined eligibility analysis in which the examiner may determine that while the claim may or may not recite a judicial exception, it doesn't ''tie up'' the exception so that others may not use it and therefore is patent eligible.

But then the Federal Circuit ruled Myriad Genetics' claims on primers and methods of genetic screening are patent ineligible, utilizing language about functional differences that echoed that of the original PTO guidance (*In re BRCA1-& BRCA2-Based Hereditary Cancer Test Patent Litig.*, Fed. Cir., No. 2014-1361, 12/17/14). In this case, Myriad had asserted infringement of claims of its patents that hadn't been invalidated by the Supreme Court.

Patentability Still Uncertain. Deborah L. Lu, of Vedder Price PC, New York, told Bloomberg BNA that, unfortunately, the question as to what exactly is patentable in the aftermath of the guidance and the Federal Circuit's ruling remains largely unknown.

Rochelle K. Seide, of RKS Consulting, Boca Raton, Fla., discussed the uncertainty created by the interim guidance.

She focused on the ''markedly different'' analysis of characteristics that can include a product's structure, function and/or other properties as compared to its naturally occurring counterpart in its natural state that is part of the interim guidance's two-step process.

''The 'markedly different' test will undoubtedly be subjective,'' Seide said, ''and the question of how 'markedly different' the claimed subject matter as a whole is from what is found in nature will remain uncertain until the courts provide more clarity in the future. It is likely that more commentary from stakeholders on the new proposal will result in additional changes, since the PTO is again soliciting input from the public. Only time will tell what impact, if any, the Supreme Court's decisions and the PTO's guidelines, once adopted, will have on the biotechnology industry.''

PTO Guidance Helps. Alex Nie and Joy Nemirow of Sheppard Mullin, Washington, said, ''The 2014 Interim Guidance was seen as a step in the right direction'' but the Federal Circuit's decision ''may call into question numerous patents in the life sciences field as well as lead to additional changes to the 2014 interim guidance. The changing legal landscape also may leave innovators with uncertainty as to whether patent protection for their biotechnology patents and methods can be obtained. The upcoming new year will likely have more patent eligibility news in store.''

Lu said that, as a result of the interim guidance and the Federal Circuit's ruling, life sciences companies ''should handle natural products as they did before the interim guidance by distinguishing the product from its naturally occurring counterpart. For example, claims to isolated nucleic acid sequences may be non-naturally occurring subject matter if cloned in a vector, or expressed in a cell or organism in which it normally wouldn't be expressed. Companies may also consider curing any patents directed to natural products, as currently defined by the PTO, by reissue.''

Kevin Noonan of McDonnell, Boehnen, Hulbert & Berghoff, Chicago, exhibited a generally upbeat perspective on the recent events.

''We now have had two iterations of PTO 'Guidances' and one Federal Circuit case (Myriad, who else?) and another in the wings (*Ariosa v. Sequenom*, concerning prenatal tests). *Myriad* didn't really change much about the product-of-nature problem, but unless someone in the Administration gets a wild idea about what the court said regarding primers in obsequious adherence to what the [Federal Circuit] panel thought the Supreme

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Court said in its *Myriad* case and decides that the only products of nature that are patent eligible are ones that have been structurally changed, then the new guidance will likely calm the waters,'' Noonan said. ''The 'hand of man' standard is a good one, because it takes into account things like purification that provide novel uses.''

University Licensing Affected. Carl Gulbrandsen of the Wisconsin Alumni Research Foundation addressed the effect of the *Mayo*, *Myriad* and *Alice* decisions on the ability of universities to license their technologies to companies.

''Are these decisions going to drive down the value of university licenses?'' Gulbrandsen asked. ''The effect of these decisions is to raise the strong possibility that many university owned patents in the pharmaceutical, diagnostic and computer software fields will be invalidated, if challenged. Couple this with the new ability to challenge the validity of a patent through post-grant proceedings in the Patent Office, which are strongly biased against patent owners, and the value or strength of affected patents plummets.''

According to Gulbrandsen, many potential licensees will decide the risk of infringement is low because validity of the patents is questionable in view of these cases. ''Some potential licensee will decide it is better to run the risk of being successfully sued for infringement rather than license. Or they may choose to license but do so at rates far lower than were enjoyed by licensors prior to these decisions. Others, even those who have a license, may choose to terminate rather than continue to pay a license fee and run the risk of an infringement action because of a belief that the licensed patents could not be effectively enforced.''

Diagnostic Method Patent Claims

The initial PTO guidance covered both the *Myriad* and *Mayo* decisions. The revised interim guidance is designated as covering all patent eligibility claims including those for business and software methods. From the life sciences perspective, the revised guidance appears to provide clearer answers for composition claims than for diagnostic method claims, attorneys said.

Noonan specifically discussed the issue of diagnostic method claims for 2015.

''The Federal Circuit's latest *Myriad* decision pretty much made a hash of the *Alice* standard for applying the *Mayo* two-step patent eligibility test, and should the court continue in this vein then these claims are in serious jeopardy,'' he said.

A case to watch in the Federal Circuit is *Ariosa v. Sequenom*, Noonan said. ''If the court appreciates the logical leaps mandated by neither *Myriad* nor *Mayo* (nor *Alice*), but rather applies the *Alice* formula, that might be when maybe they come to a better decision.

''Specifically, the court should correct the idea that there must be available commercially viable alternatives at the time of patenting; this has never been the standard—indeed, the point of patenting is to leave room for competitors to enter the market (if at all) in a commercially disadvantageous position (until the patent expires, of course). Here, the district court [7 LSLR 1114, 11/15/13] was able to apply its subjective view regarding the patent because the [Supreme] Court's recent decisions provide no objective analysis or analytical tools for courts to use—it is Justice Stewart's 'I know it when I see it' pornography test applied to patent law.''

Noonan continued, ''The bigger issue (as if this wasn't big enough) is neglecting to consider patent eligibility of the claim as a whole, so that assaying a sample for a biomarker equals a law of nature, and using known techniques equals a routine, well-established and conventional and therefore NOT the 'something more' required by *Mayo*. Interpreting the claim as a whole avoids this logical trap but so far it hasn't happened.''

Biosimilars

Attorneys told Bloomberg BNA that biosimilars would be a major issue for 2015. Again, this isn't surprising because the FDA appears likely to approve the first biosimilar under the BPCIA sometime this year. There also was a flurry of dismissals of declaratory judgment actions against companies with biosimilars that tried to invalidate patents related to the brand or reference product in order to clear the field for the time when their biosimilar is approved by the FDA.

Stacie Ropka of Axinn, Veltrop & Harkrider, Hartford, Conn., said, ''Overall, it's been far more exciting for biosimilars [in 2014] than it's been for the last five [years] and is likely to be just as lively if not more in [2015].''

She noted the dismissals of *Sandoz v. Amgen* (8 LSLR 1208, 12/12/14) in the Federal Circuit and *Celltrion Healthcare Co. Ltd. v. Kennedy Trust for Rheumatology Research* (8 LSLR 1210, 12/12/14) in the U.S. District Court for the Southern District of New York. ''The Federal Circuit ruled that there is no case of controversy for a DJ [declaratory judgment action] because Sandoz hadn't even applied to the FDA for review of its biosimilar. Celltrion in the S.D.N.Y. was much closer than that, with the filing imminent, but the district court still dismissed, saying the BPCIA dispute resolution process must be followed first and that it, therefore, had no jurisdiction because the litigation was not ripe. The Federal Circuit didn't completely shut the door on DJs, but it was close.''

Ropka said that companies are seeking DJs because they may have intelligence about what the other company is doing, they may just want to hit the ground running as soon as the FDA approves a biosimilar or they want to reduce the number of patents they have to deal with.

Inter Partes Review. Ronald M. Daignault of Polsinelli, New York, said, ''The Federal Circuit mentioned specifically that it was not addressing Sandoz's ability to bring a DJ action once it files its application with the FDA. Sandoz may do that in 2015, and this case could therefore resurface. But another option is Inter Partes Review before the PTO where there is no court jurisdictional hurdle. By filing its DJ complaint, Sandoz clearly wanted to begin the process of clearing the patent barriers ahead of it. As a result of the Federal Circuit's decision in *Amgen*, life sciences companies in the biosimilar space will give greater consideration to filing an IPR petition if they want to take a proactive approach and address patent issues earlier in their product development timelines. As the biosimilar world evolves further in 2015, we are getting closer to the first lawsuit under the BPCIA, but we may also see the initiation of IPR proceedings in the wake of *Amgen*.''

Ropka noted, ''Here's the interesting thing. Sandoz refused to do the information exchange that the BPCIA requires. It took an interesting strategy. It protected its manufacturing information rather than going through the patent dance in the exchange of information required by the BPCIA. It therefore limited the number of patents that can be asserted against it and may get to litigation sooner than later. The downside is that something hidden could pop out after you've gone to market. I think some people are hoping the court will force Sandoz to turn over the data.''

Celltrion reportedly has filed with the FDA for its Remicade biosimilar, which is a monoclonal antibody, Ropka said. ''The FDA is now going to have to tell us how biosimilarity is achieved for complicated molecules. People are not sure what has to be done. But it's clear from Celltrion's litigation filings how closely it was working with the FDA, and the biosimilar has been approved in other countries. It's almost like the FDA has done a mini-review. The rumor is the FDA could approve it in 12 months.''

Naming Convention. Another issue in 2015 is the naming convention for biosimilars, Ropka said.

''The brand name [reference product companies] want the biosimilars to have unique names, the biosimilar companies want to use the chemical name but the brands say biosimilars are not interchangeable. It's no surprise that biosimilars want to use the chemical name,'' she said. ''If you can't use the chemical name, you'll have to do some marketing to make sure your biosimilar is substituted. But Celltrion already has its own unique name that it uses in Europe, so this won't come up with Celltrion.''

Effects of Patent Reform

While eligibility issues mostly dominated life sciences patent discussions in 2014, attorneys told Bloomberg BNA that the effect of the America Invents Act patent reform law will be more fully felt in 2015.

Lu of Vedder Price said that many pending applications in biotechnology are beginning to shift to AIA-filed examinations and that it will be interesting to see how the patent office handles this dichotomy.

''There is likely to be confusion especially for continuing patent applications that are transitional applications and which contain claims that are directed to both pre and post AIA subject matter. In this instance, it is advisable to avoid such transitional applications, by, for example, preparing separate continuation applications—one that only contains pre-AIA claims and one with post-AIA claims. Unfortunately, once an application is accorded AIA status, it cannot revert to pre-AIA status. It is also important to ascertain the differences in what is considered prior art under pre-AIA or post-AIA.''

Seide of RKS Consulting said that the AIA created proceedings to challenge the validity of patents in the PTO that are administered by the Patent Trial and Appeal Board (PTAB), ''which is constituted by panels of administrative patent judges, many of whom are former clerks at the Federal Circuit.'' Seide said that one of the challenges, inter partes review (IPR), is a trial at the PTAB to review whether one or more claims in an issued patent is invalid under 35 U.S.C. §§ 102 (novelty) or 103 (obviousness) in view of previous patents or printed publications.

''While there were more than 2,000 petitions to institute post-grant proceedings, less than 15 percent involved patents in the life sciences, but this number is growing, especially among generic companies seeking to invalidate patents on branded drugs they are looking to genericize through an Abbreviated New Drug Application (ANDA),'' Seide said.

''In this regard, an IPR is an attractive, faster (proceedings are expected to take no more than one year) and less expensive way due to limited discovery to try to invalidate the patent, since the burden of proof in the PTO—preponderance of the evidence—is lower than that in federal courts—clear and convincing evidence,'' Seide said.

''However, this may not always be an advantage for a generic pharmaceutical challenger, since in the first Final Written Decisions in an IPR in the context of a dispute under Hatch-Waxman [1984 law that created an abbreviated approval pathway for non-biologic generic drugs] between generic (Amneal) and brand companies (Supernus and Galderma), the PTAB upheld the brand's patents covering the drug Oracea. While IPRs have become widely used for technology patents, they are being used increasingly in Hatch-Waxman challenges by generic companies seeking a separate route to invalidate patents in addition to litigation in federal court. Despite the decision in the Oracea case, I don't expect this approach to abate any time soon,'' Seide said.

IPR Cost Issue. WARF's Gulbrandsen said that an issue for universities is the frequency with which they get pulled into IPR proceedings and the cost and fairness to the patent owner of such proceedings.

''IPR proceedings were argued to be necessary to inexpensively invalidate weak patents that arguably should not have been issued by the PTO. In practice, it results that the proceedings are not inexpensive. On the average the cost through decision by the PTAB is $300,000 and if appealed, through appeal $1.5 million,'' Gulbrandsen said.

''The statistics as of the end of 2014 show that almost 2,000 IPR petitions were filed. Eighty percent of the petitions are granted. Of the IPRs adjudicated at trial in 2014, 77 percent resulted in every challenged claim being canceled, 10 percent resulted in some claims being canceled and only 13 percent of the adjudications resulted in all of the challenged claims being upheld. Former Federal Circuit Chief Judge Randall Rader referred to the PTAB as the death squad for patents [at the American Intellectual Property Law Association's Oct. 25, 2013, annual meeting in Washington]. It is unlikely that many research universities would file a petition for IPR as universities do not make a product or have a reason to challenge another's patent though an IPR proceeding, particularly considering the cost of IPR trials,'' Gulbrandsen said.

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''Given the cost of [IPR] proceedings and the bias against patent owners, it is likely many universities would choose to abandon the patent rather than bear the cost.''

—CARL GULBRANDSEN, WARF

On the other hand, he added, it is likely that many university patents will be challenged in IPR proceedings, either by licensees who would rather not pay royalties or by defendants of an enforcement action involving a university patent. ''Given the cost of such proceedings and the bias against patent owners, it is likely many universities would choose to abandon the patent rather than bear the cost. If this is in fact what will happen, innovation will suffer.''

IPR Trolls. Steve Maebius of Foley & Lardner said that a new problem in the wake of the AIA is the phenomenon of ''IPR trolls.''

Maebius said, ''Due to the fact that the PTO uses a different evidentiary standard and a different claim construction standard—broadest reasonable interpretation—a patent owner who has just successfully defended a patent in litigation may be vulnerable to an IPR based on the same prior art that was used unsuccessfully in litigation. However, the reverse is not true: a defendant who is unsuccessful in IPR cannot challenge the same patent in court over the same references. Because of this loophole, legislative fixes are starting to be discussed that could be seen in 2015.''

While there will be continued attention on implementing patent reform legislation from 2010, attorneys acknowledged that more reform of the patent law is in the works.

Sarah Rouse Janosik of Onyx Pharmaceuticals, South San Francisco, Calif., said, ''Patent reform appears at the top of the legislative agenda for 2015. Topics addressed in legislative patent reforms may include a presumption of attorney fee shifting, broadening of post-issuance review proceedings, heightened pleading requirements, patent ownership transparency, and nationalization of trade secret law. Congressional efforts to fight patent trolls and forms of abusive patent litigation will also likely continue in 2015.''

FDA LDT Oversight

Due to advances in lab technology, LDTs have significantly increased in sophistication and utility. An LDT is a type of in vitro diagnostic (IVD) test measuring any of a wide variety of analytes that is designed, manufactured and used within a single laboratory.

Although the FDA historically has used its enforcement discretion to not impose premarket review and other applicable requirements for LDTs, in July 2014, it published a framework and subsequent draft guidance that proposed more FDA oversight for LDTs due to concerns about unsupported claims, lack of appropriate controls yielding erroneous results and falsification of data (8 LSLR 773, 8/8/14).

Nathan A. Beaver of Foley & Lardner, Washington, noted that the FDA's proposal has been both supported and vehemently opposed by different industry sectors, leading to congressional hearings as well as numerous public comments.

''The FDA has indicated its intent to now enforce certain device requirements for LDTs, along with device manufacturer requirements for laboratories that create them. In the draft guidance, the FDA proposes continued enforcement discretion for applicable pre-market review requirements towards low-risk LDTs (Class I devices), 'traditional' LDTs (those produced within the historical model of low-volume manufacturing intended for clinical use), LDTs for rare diseases and LDTs for unmet needs,'' Beaver said. He added that the FDA has indicated that it will institute a risk-based, phased-in approach to enforcing the premarket review requirements for high-risk and moderate-risk LDTs.

''The agency envisions this approach as enhancing health care by ensuring safety and effectiveness of these IVD tests,'' Beaver said. ''FDA's proposal is not yet final, and with a battle brewing next year, this is by no means settled as to the final outcome. I expect both industry as well as Congress to influence the final outcome and as a result, 2015 will be an important year for determining how, and if, LDTs will be regulated differently by FDA.''

Personalized Medicine. Carol A. Pratt of K&L Gates, Portland, Ore., said, ''LDTs are so fundamental to the development of personalized medicine. Personalized medicine is not typical drug development. One of its tenets is the development of slivers of new information and then acting quickly on them. That works from a medical, scientific and investor perspective, but a 501k [application for FDA approval of a medical device] is not consistent with this process.''

''The arguments against expanded FDA oversight of LDTs have some merit,'' she said. ''And yet the FDA still has made the decision to move forward.''

''If this is going to be done, the final guidance will have to be instituted quickly because there will be a ton of comments and it will take time to sort them out. It will be interesting to see if the FDA pushes this through, responds to them and goes to final guidances. Or will it stall? They sometimes do. People are looking to see when and if the FDA goes to final guidance or whether it will take a different avenue,'' Pratt said.

More M&As, IPOs

Pratt said there is likely to be continued merger and acquisition (M&A) and initial public offering (IPO) activity for life sciences companies in 2015.

''In 2014, I did more of this kind of work than the last 10 years combined,'' Pratt said. ''In looking over those deals, what becomes important is the regulatory overlay. In all of them, the impact of regulations became critical. It's usually been the case that companies haven't worried about regulatory issues in merging or acquiring or being acquired. But it has become really important to consider them early on in due diligence. Otherwise, you can get very deep in the weeds only to find that the deal won't go forward, the metrics are impacted, the price point can plummet and the reserves set aside can be affected.''

Companies with an exit strategy must remember that they are under a microscope during due diligence, Pratt

said. ''It's necessary, then, especially in a robust M&A field, to move regulatory due diligence early in the process, and this is true across all sectors of life sciences.''

Health Care IT

A number of attorneys noted there has been an explosion of innovation in health-care information technology at the same time as the FDA is trying to develop a policy that doesn't kill innovation while also fulfilling the agency's mandate not to imperil patient safety.

Janosik of Onyx Pharmaceuticals said, ''An increase in the application of medical devices, including network-enabled features that report to users and/or health care providers, is expected in 2015.''

''This expansion not only provides an opportunity to offer improved, lower-cost care, but changes the traditional engagement model between patients and providers. In 2015, the development of medical devices to evaluate and monitor a user's health status will continue,'' she said. ''Current innovations include the facilitation of diabetes management using glucometers connected to or integrated within smart phones as well as medication vials and sharps containers digitized to detect usage in order to estimate medication adherence. The use of patient-reported input platforms in public social media and various patient portals is also expected to increase in 2015.''

Pratt, however, sounded the ever-increasing concern of regulatory uncertainty, this time for health IT.

''The FDA issued guidance on software programs, and MDDSs [medical device data systems] have tentacles that reach into the integrated health care system. The FDA is to exercise enforcement discretion on medical device [data] storage. This is saying, 'These are medical devices, but we're not holding you responsible.' ''

''Investors say, 'This is not enough for us.' It creates uncertainty because if it turns out that there are significant safety risks down the road, the FDA retains the authority to regulate,'' she said.

''There is uncertainty, and uncertainty creates havoc. A coalition wrote Congress asking that it decide these are not medical devices and that the FDA umbrella be taken out all together. I'll be surprised if that happens but it will be an interesting bellwether,'' Pratt said.

Monitoring Europe, Elsewhere

After noting all that is going on for life sciences in the U.S., some respondents also described the importance of events in Europe and other countries.

Janosik said that implementation of the EU Unitary Patent System (8 LSLR 233, 3/7/14) initially was projected to occur in 2015. Although implementation now appears unlikely before the spring of 2016, 2015 will bring finalization of the system one step closer, she said.

''Under the Unitary Patent System, a single patent, granted by the European Patent Office (EPO), will be offered in addition to already-existing national patents. This unitary patent will be effective across the EU and enforceable with a single court ruling. The Unitary Patent System would establish accepted languages for patents and create a Unified Patent Court (UPC), with headquarters in Paris, for hearing patent disputes. In addition, a specialized branch of the UPC, located in London, will be established to handle all pharmaceutical and life sciences cases. Many issues related to the Unitary Patent System will be addressed in 2015, such as setting of costs and maintenance fees,'' Janosik said.

Trans-Pacific Partnership. Noonan of McDonnell Boehnen commented on the Trans-Pacific Partnership agreement (8 LSLR 367, 4/18/14). It addresses intellectual property and is being negotiated by the U.S. and Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore and Vietnam.

''I don't know if this will be an issue because I don't know what it says—nor does anyone. The negotiators are being very secretive about it. And this is what motivates the conspiracy theorists and anti-patent folks, particularly regarding pharmaceuticals. From what has been leaked it doesn't look like a sea change but there's no way to know until it is released. This does make important the issue of whether Congress will give President Obama 'fast track' authority to enter into the treaty. If it is 'pro-business' then the Republican Congress should want it, but this will go up against their unwillingness to give the President anything not forced upon them at gunpoint.''

More Patent Issues

Nie and Nemirow of Sheppard Mullin noted that there were some patent decisions in 2014 that didn't involve patent eligibility whose effects are likely to be felt in life sciences in 2015.

Double Patenting. They said that *Gilead Sciences, Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208 (Fed. Cir. 2014), is a noteworthy case involving obviousness-type double patenting (ODP) that also may have a significant impact in the life sciences field, particularly where prosecution of multiple patent applications in the same family or related families is common (8 LSLR 1217, 12/12/14).

In *Gilead*, the Federal Circuit held that a patent that issues after, but expires before, another patent can qualify as a double patenting reference for that other patent. The court further said that the patent expiration dates should control, not the issuance dates. The Federal Circuit also said in *AbbVie, Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014), that the doctrine of ODP continues to apply where two patents that claim the same invention have different expiration dates (8 LSLR 866, 9/19/14).

''If these cases are interpreted broadly,'' Nie and Nemirow said, ''a reconsideration of a patent portfolio strategy for moving forward and a review of current granted patents may be wise.''

They gave as an example a parent patent that receives significant patent term adjustment (PTA) while its subsequent continuation applications in the direct family have shorter or no PTA. ''While the parent and its continuation applications all share the same priority date, the parent would expire later due to its PTA. Under a broad reading of *Gilead*, these later-issued but earlier-expiring continuation applications may serve as a basis for an ODP rejection. On the other hand, perhaps one can argue that this scenario is distinguishable from *Gilead*'s facts, where the patents at issue were not in the same family, and from *Abbvie*, where the patents

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(though related) claimed different priority dates, thereby leading to different expiration dates.''

The case law may be in flux, Nie and Nemirow said, because Gilead has petitioned the Supreme Court to review the Federal Circuit's decision (8 LSLR 1217, 12/12/14). Natco's response to the petition was due Jan. 5, 2015, ''and the industry will likely be interested in whether *Gilead* can be construed narrowly or even overturned in 2015.''

Method Patents. Nie and Nemirow also highlighted the Supreme Court's decision in *Limelight Networks, Inc. v. Akamai Technologies, Inc.* (8 LSLR 989, 10/3/14). ''It did not come as a big surprise but can have profound impact in the personalized medicine industry, even though the case related to computer systems,'' they said.

The personalized medicine industry had already been hit by the *Mayo* decision. Under *Mayo*, diagnostic claims reciting a routine screening step aren't patent eligible as diagnostic correlations are natural phenomena. To deal with patent-eligibility issues under *Mayo*, some life science patent practitioners added more method steps to diagnostic claims.

''Such a strategy is not necessarily successful,'' Nie and Nemirow said. ''Under *Akamai*, unfortunately, such a strategy may create enforceability problems, as each of the method steps, such as screening and therapy administration, can be carried out by different parties, none of whom would be liable for infringement. In reversing the Federal Circuit's decision, the Supreme Court criticized that 'the Federal Circuit's analysis fundamentally misunderstands what it means to infringe a method patent.' The Supreme Court, however, appears to be making case law that further sets the U.S. patent law apart from the rest of the world, in particular Europe. For instance, diagnostic claims are in general patent eligible in Europe and infringement can be found even when a party carries out substantially all of the claimed steps.''

Claim Construction Review. Daignault discussed *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, which the Supreme Court will decide in 2015 and rule on whether the Federal Circuit should review a district court's claim construction rulings de novo or under the clearly erroneous standard (7 LSLR 813, 8/9/13; 8 LSLR 807, 8/22/14).

It is unlikely that the Supreme Court will simply affirm the Federal Circuit and adopt a bright-line rule that all aspects of claim construction should be reviewed de novo or that a district court's ultimate construction should be reviewed under the clearly erroneous standard, Daignault said.

''Whatever direction the Supreme Court heads, the most significant impact will be how parties frame the claim construction issues in the district courts and in the Federal Circuit. Parties will argue over what constitutes an issue of fact versus an issue of law,'' he said.

''The claim construction process will not become less costly,'' Daignault said. ''In high-stakes life science patent infringement cases, parties will continue using experts in the claim construction process, but the evidence an expert offers will get caught up in standard of review and framework the Supreme Court will try to enunciate. After the Supreme Court's ruling in *Teva* this year, there will be plenty of nuances and factual scenarios left for litigators and the Federal Circuit to address.''

Patient Access to Experimental Drugs

Pratt of K&L Gates flagged what she called the ''bubbling up'' of efforts to get terminal patients access to experimental drugs.

''Five or six state laws about this have or will be passed. One has to ask, how did this issue coalesce to the state level? It's an interesting mix of states, and they form a launch pad for other states.''

''Why is this happening now? It's part of the conceptualization of personalized medicine, sort of a lay translation,'' she said. ''The patients are saying the best drug for me is probably the most recently developed and not one that is FDA approved. This puts pressure on the FDA to be nimble.''

''It will be interesting to see how this translates on the federal level. This is moving control over available therapies further down, shifting it away from Big Pharma and the FDA to patients, consumers, providers,'' Pratt said.

Beaver, Daignault, Gulbrandsen, Janosik, Lu, Noonan, Pratt and Seide are members of the Life Sciences Law & Industry Report Editorial Advisory Board.

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