Members of the Biotechnology Committee – You can view the latest issue of the Biotech Buzz below and access detailed information by clicking the names and other hyperlinks. The more links below download the given article. Click here to download the entire Biotech Buzz as a pdf file.

If you want to be active in the committee, click here and indicate your interests, ideas, and contact information in your email. Alternatively, contact the Leader and Sub-Chair(s) of the particular subcommittee of interest.

BIOTECH BUZZ

January 2016

Chair’s Notes – Debora Plehn-Dujowich: … more

Announcement regarding 2016 Mid-Winter Institute Licensing/Biotech/Chem Committees CLE on Thursday January 28th from 3:30-5:30 PM:
The Licensing and IP Management of Assets, Biotechnology, and Chemical Practice Committees will present a case study on a pioneering development, subsequently patented, and ultimately successfully launched and marketed by a Fortune 100 company as a robust therapeutic for an advanced stage disease - the result of collegial exchanges between US and non-US researchers associated with different institutions, together with the efforts of a start-up company whose mission is to develop life-saving products. Our panelists will address best practices for portfolio management, institutional agreements, inventorship determinations, due diligence, in-licensing, and the ultimate resolution of disputes which can arise from the inception of research and development through various licensing exchanges, with a promise to be stimulating, engaging, and enlightening.

Speakers:
Robert D. Titus from Eli Lilly
Casie Kelly from University of California Irvine
D.C. Toedt from The Law Office of D.C. Toedt
Lisa Haile from DLA Piper
J. Michael Warner from Pfizer

Buzz Editor – Debora Plehn-Dujowich and Vicki Norton
Microsite Master – John Marquardt

Vice Chair – Vicki Norton: Vicki ponders the meaning of Life v. Promega (§ 271(f)(1)... more

Services Leader’s Notes – Carla Mouta
Biotech Patent Education – Ryan B. Chirnomas
• Ryan B. Chirnomas reports on the Trans-Pacific Partnership Agreement in U.S. more
Webinars – Carla Mouta
On February 25, 2016, we will hold a Webinar entitled What’s left under 101 after Ariosa en banc denial from 12:30 - 2:00 pm Eastern. more

**Issues Leader’s Notes – Nicholas Landau**

- **Biosimilars** – *Lynn Tyler and Kristin Connann*
  - Lynn C. Tyler reports on FDA Issues Draft Guidance on Formal Meetings with Biosimilar Sponsors [more]

- **Plant Biotech** – *Alice Martin and Mark Pickowich*
  - Humphrey Foote reports on Australia issues new Myriad Guidelines [more]

- **PTAB Actions** – *Herbert Hart and Malaika Tyson*
  - Chad Stroud reports on Inguran, LLC v. Premium Genetics, PGR2015-00017 (PTAB) [more]

- **Technology Transfer & Licensing** – *Eric Mirabel and Vladimir Drozdoff*
  - Beyond Hybrid Licenses -- Strategies for Post Patent Expiration Payments [more]

- **Hot Biotech** – *Noel Courage and Vicki Norton*
  - Alice Martin reports on the Ariosa en banc denial [more]

**Community Leader’s Notes – Ryan Chirnomas and Alice Martin**

- **International** – *David Read and Trevor Davies*
  - Gisella Barreda of Brda Abogados reports on TPP – Most important changes in the Peruvian Patent Law are really subject to the Andean Community’s permission [more]
  - Juan Rodrigo Pimentel of Arochi & Lindner reports on Opportunities for Mexico in Biotechnology Upon the Entry to the TPP [more]
  - Yoichi Watanabe, Partner of Seiwa reports on Trans-Pacific Partnership – Patent and regulatory implications for Japan. [more]

- **Regional/Social** – *Debora Plehn-Dujowich and Alice Martin*
  - There will be a Biotech Committee karaoke outing during the Mid-Winter Institute. Stay tuned for more info as the date approaches. [more]

Feel free to send comments and recommendations to a Committee Leader using the Leader’s email icon or send an email the Chair, Vice Chair, and all Leaders by clicking the envelope: [✉️]

The Fine Print: These materials are public information and have been prepared solely for educational and entertainment purposes to contribute to the understanding of intellectual property law. These materials reflect only the personal views of the authors and are not a source of legal advice. It is understood that each case is fact specific, and that the appropriate solution in any case will vary. Therefore, these materials may or may not be relevant to any particular situation. Thus, the authors and their organizations cannot be bound either philosophically or as representatives of their various present and future clients to the comments expressed in these materials. The presentation of these materials does not establish any form of attorney-client relationship with the authors or their organizations. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed.
Biotechnology
Vice Chair’s Notes

14 January 2016


In Life Technologies Corporation v. Promega Corporation, Life is asking the Supreme Court to grant certiorari on two issues relating to infringement liability under 35 U.S.C. § 271(f):

Whether the Federal Circuit erred in holding that a single entity can “actively induce” itself to infringe a patent under 35 U.S.C. § 271(f)(1).

Whether the Federal Circuit erred in holding that supplying a single, commodity component of a multi-component invention from the United States is an infringing act under 35 U.S.C. § 271(f)(1), exposing the manufacturer to liability for all worldwide sales.

After briefing by the parties, the Supreme Court asked the Solicitor General to weigh in, so there is chance the Court will grant the petition. This quick note focuses on the second question posed in Life’s petition, which asks whether the statutory requirement for supplying “a substantial portion of the components of a patented invention” can be met by supplying only a single component of a patented combination.

By way of background, Melissa Schwaller provided an excellent summary of the Federal Circuit’s decision, in a Biotech Committee Case Law Review, at http://www.aipla.org/committees/committee_pages/Biotechnology/caselaw/Shared%20Documents/Caselaw_Buzz_201501.pdf. Briefly, § 271(f)(1) imposes infringement liability for supplying in or from the United States “all or a substantial portion of the components of a patented invention,” in such manner as to “actively induce the combination of such components outside of the United States.” After a jury found Life liable for willful infringement of five patents, including a kit claim in U.S. Patent No. RE 37,984, the district court granted JMOL of non-infringement. The Federal Circuit reversed, holding that the ’984 patent was infringed under § 271(f)(1), even though Life

---

1 Life has been acquired by Thermo Fisher Scientific.
shipped only one of five components of the patented kit to its own manufacturing facility in the UK, where all five components were combined. Judge Prost dissented in part from the Federal Circuit’s majority opinion, urging that § 271(f)(1) requires an infringer to “actively induce” another to combine the components of the patented invention, such that a single entity cannot “actively induce” itself to infringe a patent under 35 U.S.C. § 271(f)(1).

In this discussion, I leave open the question about whether Supreme Court precedent cited by Judge Prost, such as Microsoft v. AT & T, or Limelight v Akamai support her interpretation of § 271(f), and focus instead on the issue of whether a single commodity product can constitute a “substantial portion of the components of a patented invention.”

Claim 42 of the ’984 patent recited a kit “for analyzing polymorphism in at least one” DNA locus, the kit comprising 5 components, including primers, a PCR polymerizing enzyme, dNTPs, a buffer and template DNA comprising a simple or cryptically simple nucleotide sequence:

a) at least one vessel containing a mixture of primers constituting between 1 and 50 of said primer pairs;

b) a vessel containing a polymerizing enzyme suitable for performing a primer-directed polymerase chain reaction;

c) a vessel containing the deoxynucleotide triphosphates adenosine, guanine, cytosine and thymidine;

d) a vessel containing a buffer solution for performing a polymerase chain reaction;

e) a vessel containing a template DNA comprising

i) a simple or cryptically simple nucleotide sequence having a repeat motif length of 3 to 10 nucleotides and ii) nucleotide sequences flanking said simple or cryptically simple nucleotide sequence that are effective for annealing at least one pair of said primers, for assaying positive performance of the method.

According to the Federal Circuit opinion, Life shipped Taq polymerase (component “b”) of a kit to its UK facility, while the remaining components were manufactured and combined with the Taq polymerase in the UK. In addition, the opinion noted that Promega did not assert infringement under 271(f)(2) because “Taq polymerase is ‘a staple article or commodity of commerce suitable for substantial noninfringing use.’”

Life’s petition for certiorari reiterates two arguments previously rejected by the Federal Circuit; namely, (1) reference in § 271(f)(1) to “components” in plural form requires an infringer to supply more than a single component of a patented combination; and (2) a comparison of the provisions of § 271(f)(1) with § 271(f)(2).

2 The remaining four patents-in-suit were held invalid for lack of enablement.
indicates that § 271(f)(1) governs when an accused infringer supplies multiple components of a patented combination, whereas, § 271(f)(2) governs liability for supplying a single component (it imposes liability for supplying “any component of a patented invention that is especially made or especially adapted for use in the invention.”) The petition further argues that because § 271(f)(1) excludes liability if the single component is “a staple article or commodity,” Life’s offshore supply of Taq polymerase—a single, commodity product—cannot be the basis for liability under § 271(f)(1).

If the Supreme Court grants certiorari it will be interesting to see if the Court interprets the phrase “substantial portion” of the components as a numerical term (e.g. can a single component be a “substantial portion” of a 5 component combination? Or only 3 or more?).

Alternatively, will the Court rule that it is appropriate to take into account considerations of “how important or central” the component is to the invention” as the Federal Circuit did in its decision? Moreover, if it is appropriate to take into account how important or central the supplied component is to the invention in determining whether an accused infringer has supplied a “substantial portion” of components, should technical and/or patent considerations weigh into that analysis? The Federal Circuit relied in part on technical considerations in determining that the Taq polymerase was a “substantial portion” of the kit, stating essentially that but for Taq polymerase, “the genetic testing kit recited in the [‘984] patent would be inoperable because no PCR could occur.” The Federal Circuit’s view may have been influenced by the evidence in the case which included an admission by Life’s own witness that the Taq polymerase was one of the “main” and “major” components of the accused kits. Going forward, it will be interesting to see if other factors are considered in the “substantial portion” analysis under § 271(f)(1), such as whether a component was cited by the patentee during prosecution as a patentable distinction from cited art. Finally, another possible factor that could be raised is based on the rationale of the dissenting Justices in the Deepsouth Packing Co., Inc. v. Laitram Corp., who indicated that manufacture abroad of even “only one vital part” of a patented combination might have altered their view that infringement liability should have been imposed under the facts of that case. This might suggest that if a “vital” component is omitted from the supplied components, the remaining components cannot constitute a “substantial portion” of the components of a claimed combination.

Vicki Norton

---

3 Deepsouth is the Supreme Court case which spurred Congress to expand infringement liability by enacting § 271(f)(1), in order to close the loophole caused by the majority’s ruling that an accused infringer wasn’t liable for infringement, even though the accused infringer supplied all of the components of a patented combination to a third party, with instructions on how to combine the components).
Vicki Norton is the Co-Leader of the Global Life Sciences Interdisciplinary Group, and Co-Chair of the Life Sciences Division of the Intellectual Property Group at Duane Morris LLP.

DuaneMorris®
Much has been made in the news about the recently finalized Trans-Pacific Partnership (TPP) trade agreement. The TPP is an agreement signed by trade representatives from twelve Pacific Rim countries: United States, Canada, Mexico, Australia, Singapore, Malaysia, Japan, Chile, Peru, Vietnam, New Zealand, and Brunei. China and Korea are not parties to the agreement at this time. The TPP has the potential to impact many aspects of commerce, not the least of which is intellectual property. While the majority of the discussion in the patent world has been focused on the TPP’s provisions relating to data exclusivity and biologics, this was covered discussed in an article by Kristen Connarn that appeared in the December 2015 Biotech Buzz.

This article will take a look generally at the TPP’s general patent provisions in Chapter 18. First, Article 18.37 governs patent eligible subject matter, and indicates that patents shall be available “in all fields of technology.” However, exclusions are permitted in paragraphs 3 and 4:

1. Subject to paragraphs 3 and 4, each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step and is capable of industrial application.

2. Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.
3. A Party may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that such exclusion is not made merely because the exploitation is prohibited by its law. A Party may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

   (b) animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes.

4. A Party may also exclude from patentability plants other than microorganisms. However, consistent with paragraph 1 and subject to paragraph 3, each Party confirms that patents are available at least for inventions that are derived from plants.

Note that although parties may “exclude from patentability plants other than microorganisms,” on its face, the TPP states that patents must be available at least for inventions that are “derived from plants.” Fortunately, the TPP does not explicitly incorporate the line of reasoning of the Supreme Court’s recent §101 jurisprudence. However, the broad language of paragraph 3 regarding “*ordre public* or morality” seems to leave patent eligibility open to different interpretations from Party to Party.

Next, Article 18.38 essentially passes on the AIA’s grace period to other Parties:

Each Party shall disregard at least information contained in public disclosures used to determine if an invention is novel or has an inventive step, if the public disclosure

   (a) was made by the patent applicant or by a person that obtained the information directly or indirectly from the patent applicant; and

   (b) occurred within 12 months prior to the date of the filing of the application in the territory of the Party.

Although this grace period may be compatible with similar grace periods in countries such as Canada and Australia, amendment of patent laws may be necessary in some countries with stricter novelty requirements.

In Article 18.46, the TPP provides for a patent term adjustment system similar to that in the U.S.P.T.O., and requires compensation for unreasonable delays. An
unreasonable delay is regarded as more than five years from filing in the territory or more than three years after a request for examination. Time periods not attributable to the local patent office or attributable to the applicant are excluded from the delay period. Article 18.46 also permits, but does not require, expedited examination procedures.

Similarly, Article 18.48 provides for patent term adjustment as compensation for unreasonable curtailment of patent term due to the marketing approval process for pharmaceutical products. This is similar to §156 patent term extension for FDA delays in the U.S. However, no specifics are provided as to what time period is considered unreasonable.

Of course, this is just the tip of the iceberg. As noted above, the biologics and data exclusivity aspects of the TPP will be discussed in a separate article. The full text of the intellectual property chapter of the TPP can be found here:


However, all of this may be irrelevant, at least in the short term. The TPP becomes effective only after it is (a) ratified by all member countries, or (b) ratified by at least six countries representing 85% of the GDP of the signatories, within 2 years of signature of the agreement (which has not yet occurred). Being that the U.S. represents about 60% of the GDP of the signatories, ratification will not happen without the U.S. Since 2016 is an election year in the U.S. and the TPP is politically controversial, it is quite unlikely that the TPP will be ratified in the near term.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.

**Ryan Chirnomas** is a partner at Westerman Hattori Daniels and Adrian LLP. He can be reached at (202) 822-1100 or rchirnomas@whda.com
Webinars Subcommittee
January 2016
Contributor: Carla Mouta

Webinars

We have several Biotech Webinars planned for the Spring:

- **Feb 25 (CLE):** What’s Left Under 101 After Ariosa En Banc Denial
- **March 10:** Patent Eligibility Around The World: Latin America
  - Luis Diego Castro (CASTRO & PAL ABOGADOS, Costa Rica)
  - Ignacio Sanchez Echagüe (Marval, O’Farrell & Mairal, Argentina)
  - Rodrigo Calderon (Uhettof, Mexico)
  - Leonor Magalhães Galvão (Magellan IP, Brazil)
- **March 16 (CLE):** Trade Secrets in Biotech, Biosimilars and Medical Devices
  - Victoria Cundiff (Paul Hastings)
  - Elizabeth Howard (Orrick)
  - Austin Wang (Hologic)
  - Debora Plehn-Dujowich (Prismatic Law Group, PLLC)
- **April 7:** Biosimilars Around the World: Europe
- **May 25:** Patent Eligibility Around The World: Europe and Australia

The list of speakers for the other Webinars is being finalized, but we have already received confirmation that the USPTO will have a representative speaker at the Feb 25, 2016 Webinar on Section 101. Debora Plehn (Prismatic Law Group, PLLC) will present at the March 16, 2016 Webinar on Trade Secrets and Holger Tostmann (WALLINGER RICKER SCHLOTTER TOSTMANN) will present at the April 7, 2016 Webinar on Biosimilars in Europe.

To Register visit:
We welcome volunteers who would like to help organize upcoming webinars. Please contact Carla Mouta at the e-mail noted below.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.

http://www.finnegan.com/CarlaMouta/
carla.mouta@finneghan.com
BIOTECH BUZZ
Biosimilars Subcommittee
January 2016
Contributor: Lynn C. Tyler

FDA Issues Final Guidance On Formal Meetings With Biosimilar Sponsors

Late last year, the FDA issued a final guidance on meetings with biosimilar product developers, titled "Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants." The guidance discusses the different types of such meetings and procedural matters such as requesting, rescheduling, cancelling, conducting, and documenting the meetings.

According to the guidance, there are five types of meetings leading to the approval of a biosimilar application, summarized as follows:

1. **Biosimilar Initial Advisory meeting** is an initial assessment limited to a general discussion regarding whether licensure under the biosimilar pathway is feasible for a particular product, and, if so, general advice on the expected content of the development program.

   Initial advisory meetings should take place within 90 days of FDA’s receipt of a written request and a meeting package.

2. **BPD Type 1 meeting:** A Biosimilar Biological Product Development (BPD) Type 1 meeting is a meeting that is necessary for an otherwise stalled BPD program to proceed.

   Examples of a BPD Type 1 meeting include:
   - Meetings to discuss clinical holds
   - Special protocol assessment meetings
   - Meetings to discuss an important safety issue
   - Dispute resolution meetings as described in 21 CFR 10.75 and 312.48
BPD Type 1 meetings should occur within 30 of receipt of a written request and meeting package.

3. **BPD Type 2 meeting:** A BPD Type 2 meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where the FDA will provide targeted advice regarding an ongoing BPD program.

Type 2 meetings should occur within 75 of receipt of a written request and meeting package.

4. **BPD Type 3 meeting:** A BPD Type 3 meeting is an in-depth data review and advice meeting regarding an ongoing BPD program.

   Examples of submission for a BPD Type 3 meeting include:
   - Comprehensive analytical similarity data that permit the FDA to make a preliminary evaluation of analytical similarity
   - Full study report(s) for a clinical study(ies)

Type 3 meetings should occur within 120 of receipt of a written request and meeting package.

5. **BPD Type 4 meeting:** A BPD Type 4 meeting is a meeting to discuss the format and content of a biosimilar biological product application or supplement to be submitted under the biosimilar pathway.

Type 4 meetings should occur within 60 of receipt of a written request and meeting package.

The guidance includes detailed discussion of the contents of both a meeting request and a meeting package.

The guidance states that “meetings will be chaired by an FDA staff member and will begin with introductions and a statement of the agenda.” The guidance discourages presentations by the sponsor and recommends that, before the end of the meeting, the FDA and the sponsor or applicant summarize the important discussion points, agreements, clarifications, and action items.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.

*Lynn C. Tyler* is a partner in the Intellectual Property Department of Barnes & Thornburg LLP. He is a registered patent attorney and concentrates his practice in intellectual property litigation and FDA counseling.
Introduction

Much has been written about the Australian High Court’s decision in *D’Arcy v Myriad Genetics Inc* [2015] HCA (“the Myriad decision”).

This article considers the impact of the decision, and subsequent IP Australia examination guidelines, specifically on the patenting of plant biotech inventions in Australia.

Re-cap on the High Court decision

On 7 October 2015 the High Court of Australia ruled that isolated nucleic acid sequences that encode proteins, or fragments thereof, as found in nature are no longer patent eligible subject matter.

This is a similar decision to that made in the US Supreme court case (*Association for Molecular Pathology v. Myriad Genetics, Inc.*) in June 2013, except that the Australian court went a step further and found that cDNA is also not patent eligible.

The rationale behind the Australian decision is that the informational content, rather than structural content, is the substance of the invention in a claim to an isolated nucleic acid sequence, and that this “information” is not “made” (created or modified) by human action merely through isolation.

IP Australia’s reaction to the decision?

Those familiar with US practice will be aware that following the Myriad US Supreme Court decision, the USPTO issued guidelines significantly extending the scope of excluded subject matter, far beyond that considered by the court. The USPTO exclusions cover virtually any naturally occurring biological products including nucleic acid and protein sequences, biomolecules and micro-organisms, regardless of whether they are isolated. This has caused great consternation in the biotech industry. Thankfully, from the patentee’s perspective, IP Australia have reacted more conservatively.

On 15 December 2015, following public consultation, IP Australia issued guidelines (found here) on the examination of patents in light of the Australian Myriad decision. These guidelines were incorporated into the Examiner’s Manual of Practice and Procedure on 11 January 2016.
Brief summary of some key points from the guidelines

The guidelines specifically exclude isolated naturally occurring DNA and RNA (whether human, non-human, coding or non-coding) from patent eligibility in light of the Myriad decision, in short because they are considered to relate in substance to “information” and have not been “made”.

In addition, claims to cDNA, synthetic nucleic acids, probes, primers, and isolated interfering/inhibitory nucleic acids are excluded from patentability if they merely replicate the genetic information of a naturally occurring organism.

Uses of such excluded nucleic acids however, can still be patentable.

The guidelines assert that other subject matter which may be affected by the Myriad decision but not expressly excluded from patentability should be assessed on a case by case base with consideration of the following factors:

1. What is the substance of the claim (not merely its form)?
2. Has the substance of the claim been "made" or changed by man, or is "artificial"?
3. Does the invention have economic utility?
4. Does the invention as claimed represent a new class of claim?

The guidelines state that the following subject matter remains patentable:

- Recombinant or isolated proteins;
- Pharmaceuticals and other chemical substances;
- Methods of treatment;
- Methods of applying herbicides; and
- Applications of computer technology.

The guidelines also state that plants, isolated micro-organisms and isolated naturally occurring biomolecules can be patentable, although consideration should be given to whether these are “made”.

The guidelines indicate that isolation can render micro-organisms and biomolecules “made” presumably because IP Australia do not consider that such subject matter relates in substance to “information” in the same way as isolated nucleic acid sequences according to the Myriad decision.

What does this mean for patenting plant biotech inventions in Australia?

It appears that following the both Myriad decision, and the IP Australia guidelines, much of the subject matter of plant biotech inventions should remain patentable.

While isolated nucleic acid sequences *per se* as they occur in nature will not be patentable, the following subject matter will likely remain patentable:

- Modified nucleic acid sequences
- Chimeric nucleic acid sequences (e.g. a coding sequence linked to heterologous promoter)
- Isolated polypeptide sequences
- Plant cells and plants transgenic for naturally occurring, modified or chimeric sequences.
- Plants (including non-transgenic plants, if “made” (bred or created via human activity)
- Methods for producing transgenic cells and plants.
- Methods for producing altered phenotypes in transgenic plants
- Methods for editing the genome of plants to introduce new phenotypes
- Methods for producing recombinant products in plant cells and plants
- Pure cultures of (naturally occurring) bio-protection organisms (e.g. bacteria)
- Modified bio-protection organisms (e.g. bacteria)
- Bio-protection methods using naturally occurring or modified organisms

Ultimately it will be for the courts to decide how the Myriad decision is applied, but there should still be many ways to capture plant biotech related inventions as patent eligible subject matter in Australia. It will of course be important to include claims, in patent specification destined for Australia, that are likely to define patent eligible subject matter.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.

For further information please contact the author (humphrey.foote@ajpark.com) who specialises in protecting plant-related IP in Australia, New Zealand and the rest of the world.
On December 22, 2015, the Patent Trial and Appeal Board (“the PTAB”) instituted post-grant review (“PGR”) on the grounds that all claims of U.S. Patent No. 8,933,395 (“The ‘395 patent”) were more likely than not either anticipated or unpatentable as obvious over the prior art.

Perhaps more importantly, the PTAB determined that the application was not entitled to a filing date earlier than March 16, 2013 (even though it claimed priority to an application filed before that), and was thus subject to the PGR provisions of the America Invents Act (“AIA”).

The ‘395 patent relates to an apparatus and method for multiple laminar flow cytometry. Inguran petitioned to institute PGR in June 2015, 6 months after the patent granted in January 2015, contending that the specification is not enabling and the claims are indefinite under 35 U.S.C. § 112(a) & (b), respectively, and that the claims are anticipated by or unpatentable as obvious over the prior art.

Premium Genetics, however argued that the patent was not subject to PGR because it claimed priority back to an application filed in 2004 and therefore does not fall within the PGR provisions of the AIA.

This was one of the first PGR petitions filed with the PTAB. While the standard for instituting a PGR trial is higher than it is for an IPR trial (more likely than not (PGR) v. a reasonable likelihood (IPR)), PGR may be instituted based upon any condition of patentability (except for best mode), while an IPR may be instituted only upon any ground under §§ 102 and 103.

Because Premium Genetics argued that the ‘395 patent was entitled to a 2004 priority date, the PTAB had to determine if PGR was actually available. PGR is limited to those patents with an effective filing date on or after March 16, 2013. The application for
the ‘395 patent was filed January 2014 and claimed priority back to an application filed in 2004.

Inguran argued that the subject matter of the limitations in the independent claims 1 and 2 was not disclosed until the January 2014 filing. The PTAB found that while the subject matter of claim 1 was properly disclosed in the earlier patent application, the subject matter of claim 2 was not. The PTAB then concluded that claim 2 had an effective filing date after March 16, 2013. Accordingly, the PTAB held that the ‘395 patent was subject to the AIA first-inventor-to-file provisions.

In reaching its decision, the PTAB relied on the plain language of the statute which reads:

“shall apply to any application for patent, and to any patent issuing thereon, that contains or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after the [March 16, 2013] effective date . . . ; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.”

AIA § 3(n)(1), 125 Stat. at 293.

As one can see, the statute is very specific in making the AIA provisions applicable to any patent that contains a claim that has an effective filing date on or after March 16, 2013.

When the PTAB turned to review of the grounds of unpatentability, it was not persuaded that the patent claims failed to comply with the enablement or definiteness requirements. It concluded that Inguran failed to provide a meaningful analysis of the Wands factors or demonstrate that undue experimentation was necessary to practice the claimed invention. The PTAB did, however, determine that all claims were more likely than not unpatentable as being anticipated and/or obvious in light of the prior art.

In summary, it should be noted that patent applications which continue from applications filed before March 16, 2013, may nonetheless be subject to the AIA provisions and thus vulnerable to PGR. As this case illustrates, if just one claim contains subject matter not properly disclosed in an application filed prior to March 16, 2013, the entire patent may be subject to the broader PGR unpatentability proceedings.
Chad K. Stroud, Ph.D., is an associate at McAndrews, Held and Malloy. He has a background in biochemistry, biotechnology, and nutritional sciences, and he can be reached at cstroud@mcandrews-ip.com or at 312-775-8000.
Beyond Hybrid Licenses -- Strategies for Post Patent Expiration Payments*

Respondent Marvel Entertainment's corporate predecessor agreed to purchase petitioner Stephen Kimble's patent for a Spider-Man toy in exchange for a lump sum plus a 3% royalty on future sales. The agreement set no end date for royalties. As the patent neared the end of its statutory 20-year term, Marvel sought a declaratory judgment in federal district court confirming that it could stop paying Kimble royalties, under the holding of *Brulotte v. Thys Co.*, 379 U. S. 29 (1964) in which this Court held that a patentee cannot continue to receive royalties for sales made after his patent expires. The district court granted relief, and the Ninth Circuit affirmed. The Supreme Court held that *stare decisis* required it to "adhere to Brulotte," meaning Marvel did not have to continue to pay royalties.

This decision has spurred considerable interest in ways for patentees to better allocate the risks and rewards associated with commercializing inventions by allowing a more extended payment period—beyond patent expiration—but avoiding the strict prohibition against post-patent expiration royalties under Brulotte and Kimble. The Court itself provided several means of such avoidance, including the following:

- "Brulotte poses no bar to *business arrangements other than royalties* -- all kinds of joint ventures..."
- "Brulotte allows a licensee to *defer payments* for pre-expiration use of a patent into the post-expiration period..."
- "Under Brulotte, *royalties may run until the latest-running patent* covered in the parties' agreement expires"
- "[P]ost-expiration royalties are *allowable so long as tied to a non-patent right* -- even when closely related to a patent."

Bundling patent with non-patent rights will often provide the most-flexibility for structuring payments that extend beyond patent expiration. Among the categories of things which can qualify as "a non-patent right" are: trade secrets, confidential
information, materials (biological materials, compounds, compositions of matter, machines), know-how, and other technology. Typically, the royalty rate will be reduced at patent expiration to reflect the different royalty rate for the technology. There is no prohibition in *Kimble* on this traditional means of extending royalties.

When a patent, however, is the only licensed asset, *Kimble* leaves open fewer alternatives, which “may not offer the parties the precise set of benefits and obligations they would prefer.” For example, the licensor may obtain common stock in the licensee. But when the licensee is a non-publicly traded company, the licensor takes on added risk that it may have no opportunity to realize value from such equity. Preferred stock or bonds are subject to less risk than common stock, allow for post-expiration payment, and allow for payment whether or not the licensee is successful. The licensee, however, may not be able to structure a deal in this way.

At first glance, *Kimble* could appear to sharply curtail flexibility in how a straight patent license might be structured to avoid the consequences of the Brullote rule. However, the narrow grounds on which Kimble was decided leave a fair number of options open. As the Court repeatedly stressed, the issue of *stare decisis* required Court to decide only a specific, narrow question: “[t]he sole question presented here is whether we should over rule Brullote” and “all the decision bars are royalties for using an invention after it has moved into the public domain…A court need only ask whether a licensing agreement provides royalties for post-expiration use of a patent. If not, no problem; if so, no dice.” Confined to post-expiration royalties, the Court’s holding may in practice turn out to have less of an impact on licensing than first advertised.

Notably, the Court declined to extend its particular concern about post-expiration royalties as improperly restricting use of an invention now in the public domain to any deferred payment structure. As the Court noted, while an extended royalty term continuing past expiration coupled with a lower royalty rate “may allocate the risks and rewards associated with commercializing inventions—most notably, when years of development work stand between licensing a patent and bringing a product to market…parties can often find ways around Brullote to achieve those same ends.”

Perhaps most useful is in the Court’s express endorsement of amortization. In doing so, the Court draws a practical distinction between post-patent expiration royalties (prohibited) and contractual arrangements allowing a licensee to defer payments past the expiration of a patent (permitted). In other words, although royalties only accrue prior to expiration, the timing of payment of them can be at the licensee’s discretion: i.e., either before or after patent expiration. In such case, the licensee would normally defer payment until after patent expiration. For example, royalties can be structured as installment payments, which accrue before expiration, but which continue on for a fixed term even after the patent expires.

And licensees might creatively envision additional deferred payment structures beyond the particular examples described in Kimble. For example, deferred payments can be
structured to time such payments to risk allocation milestones. A large upfront license fee that accrues upon license execution, could at the option of the licensee, be deferred in part, becoming payable only upon some milestone event, such as drug approval or clinical trial success. Alternatively, an upfront license fee could be paid in installments over a fixed term in which particular installment payments would be payable only if certain trigger events had taken place. While potentially more complex than simple royalty arrangements, such alternatives may well offer sufficient options to “bring patent holders and product developers together and ensure that inventions get to the public.”

Nothing herein should be construed as legal advice or legal representation.

drozdoff@cshl.edu, Vladimer Drozdoff, Cold Spring Harbor Laboratory

eric@emirabel.com, Eric P. Mirabel, JD, LLM

*Based on a Presentation of the same name to the LES, 2015 Annual Meeting by: Patrick Gattari (McDonnell Boehnen Hulbert & Berghoff LLP); Steven Ferguson (NIH Office of Technology Transfer); David Crichton (J & J); Rob McInnes (DibbsBarker (Australia)).
December 2, 2015
Contributor: Alice Martin


On November 30, 2015, the Federal Circuit denied Sequenom’s Petition for an en banc rehearing of the June 12, 2015 decision holding the asserted claims of U.S. Pat. 6,258,540 invalid under 35 U.S.C. §101, dashing any hopes that an en banc panel of the Federal Circuit would undo the damage done in the 3 judge panel decision.

By way of background, the earlier decision continued the judiciary’s attacks on diagnostic patents by holding Sequenom’s fetal DNA prenatal diagnosis patent invalid.

The June 2015 ruling by the 3 judge panel

Citing the Supreme Court’s Mayo opinion and the Myriad decision, the Federal Court affirmed the District Court findings that U.S. Pat. 6,258,540 was invalid under 35 U.S.C. §101:

Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art.


However, the decision appeared to go beyond the Mayo and Myriad holdings.

The claims at issue were directed to a noninvasive prenatal diagnostic test based on detection of paternally inherited “cell-free fetal DNA (cffDNA)” in maternal blood samples. This paternal DNA was previously not known to be present, or detectable in maternal blood, and was not present in nature at levels suitable for diagnosis. The test is useful for example, to detect fetuses at risk for X-chromosome linked to genetic disorders, e.g. some forms of muscular dystrophy and hemophilia. The invention was to amplify the cffDNA to levels useful for diagnosis, and to detect paternal markers. In nature, paternal DNA is not amplified in maternal blood.

It appeared that in reaching its holding, the court missed the reality of the problem facing innovation in biotechnology, in that detection and application of diagnostic biomarkers to develop the personalized medicine sought after by the public, depends on many “conventional and routine” laboratory techniques. The court’s decision would
imply that laboratory techniques used for biological inventions would themselves have to be novel and patentable.

Although acknowledging that claims at issue were method claims, which are “generally eligible subject matter” and that claims should be considered as a whole, the court pronounced that the claimed method begins and ends with a natural phenomenon, therefore is not patent eligible.

In reaching its holding the court did not consider that the method does not exist in nature, and is not a natural phenomenon or an abstract idea, but stated “the claims are directed to naturally occurring phenomenon.” In addition, the court ignored the fact that “paternally inherited DNA” does not exist isolated or amplified in nature. The court further discounted one argument for patent eligibility, that claims do not preempt a natural product, nature phenomenon, or abstract idea.

The Federal Circuit also rejected Sequenom’s arguments that the claims should be found patent eligible because there was no preemption.

While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. (Page 14, Decision)

Id. at 1379.

Judge Linn wrote a separate concurring opinion in the June ruling by the 3-judge panel to note his reluctance to join in “the opinion invalidating the claims of the '540 patent” and noting that he was doing so “only because I am bound by the sweeping language of the test set out in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. ____, 132 S.Ct. 1289, 182 L.Ed.2d 321 (2012).” Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015).

The denial of the petition for en banc rehearing

The only positive takeaway from the November 30th ruling was that the decision to deny Sequenom’s petition was not unanimous.

Judge Newman dissented, taking the position that the Supreme Court’s decisions in Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012), and Association for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013) were distinguishable because unlike the claims at issue in those cases, “In the case now before us, the claimed method was not previously known, nor the diagnostic knowledge and benefit implemented by the method.”

Judge Lourie wrote a separate concurring opinion (joined by Judge Moore), to express a view similar to that expressed by Judge Linn’s concurring opinion in the original 3-judge panel decision:

In sum it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court.
Judge Dyk also wrote a concurring opinion, indicating that he agreed the claims at issue should be invalid, but offering a Pyrrhic victory of sorts, by suggesting that a narrowly drawn claim based on working data might be patent eligible:

My proposed approach would require that the claimed application be both narrow in scope and actually reduced to practice, not merely “constructively” reduced to practice by filing of a patent application replete with prophetic examples.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.

Alice O. Martin is a partner in the Chicago office of Barnes & Thornburg LLP. She is a member of the Intellectual Property Department where she concentrates on international patent prosecution, litigation opinions and due diligence investigations. Dr. Martin’s practice covers biotechnology, agriculture-plants and animals, medical compositions and devices, laboratory equipment, genetics, treatments and assays for various diseases, surgical techniques, tissue culture methods, stage equipment, computer systems, business methods and waste management and monitoring.
**BIOTECH BUZZ**

**International Subcommittee**

January 2016

Contributor: Gisella Barreda, BRDA ABOGADOS

**TPP – Most important changes in the Peruvian Patent Law are really subject to the Andean Community’s permission**

When talking specifically about Patent Law, the TPP could bring some changes in the Peruvian Patent Office’s interpretation of the law and the internal procedures, however, the real changes required by the TPP might not be possible due to the existence of the Andean Community.

The TPP could force the National Authority to grant more patents for inventions derived from plants (which currently, although possible under Peruvian national law, does not occur very often). It could also help make the application procedure go faster by requiring the national authority to issue more publications before the 18 months term, when so requested by the applicant, which, even if possible under the current law, is very uncommon. This agreement could also contribute to the communication between DIGEMID, the Peruvian National Office in charge of approving the marketing of pharmaceutical products, and a patent owner, in order to create a system that could give notice to the patent owner when someone wants to market their patented product, communications that have existed in the past and are possible under the current law.

However, even though the abovementioned examples could help improve the Peruvian patent system, these are not real changes because they are all matters that have already been discussed internally and that are possible under the current law. The real improvements that the TPP seeks are the extension of the term of protection of pharmaceutical patents when there has been an unreasonable delay during the prosecution for the patent or when there has been an unreasonable delay in the marketing approval process, situations that the current Peruvian law does not allow. Even though Peruvian law allows an extension of the term of protection of a patent due to unreasonable delays during the prosecution, this extension is specifically prohibited in the case of pharmaceutical patents.

Given that the law regulating Intellectual Property in Peru is not a national law, but an Andean Community Decision, an international agreement that obliges Bolivia, Colombia, Ecuador and Peru, Peru itself cannot modify it. Therefore, in the TPP, Peru only obliges to make its best efforts to obtain a waiver from the Andean Community.
and, if the Andean Community refuses, there will be no change in the law and there will be no extension in the protection period for pharmaceutical patents, even if there are unreasonable delay in the prosecution or the marketing approval.

It is important to mention that it is not easy to obtain a waiver from the Andean Community. The last time a modification to the Intellectual Property law was requested two member countries (not just one like in the present case) were interested in the modifications and it was still not an easy negotiation. Being this the case, chances of obtaining a waiver to allow Peru to modify the law in accordance to the TPP are not very high.

In conclusion, specifically regarding patent law, TPP may help improve national procedures that are already accepted by our law, but it does not force the Peruvian national authority to make the changes that really matter in order to obtain a more adequate patent protection, specifically for the pharmaceutical patents, since changing the law is not up to Peruvian authorities. Peru is not actually obliging itself to make a change, but to make its best efforts to obtain it. Being this the case, it is possible that very important patent requirements in the TPP will not occur in Peru.

Nothing herein should be construed as legal advice or legal representation.

_Gisella Barreda is a partner at BRDA Abogados in Peru_

/http://www.brdaabogados.com/
Opportunities for Mexico in Biotechnology Upon the Entry to the TPP

Last October 5, in the city of Atlanta, the representatives of 12 countries that as a whole represent approximately 40% of the global GDP, completed the negotiations of the TPP. The contents therein agreed will cause for the legislations of the member countries to be amended so as to keep consistency with the new provisions which are not currently included. Mexico, as a member, has the opportunity to improve the Industrial Property Law and the Regulations on Health Inputs, among others, in biotechnological pharmaceutical products matter.

As a general panorama, the Mexican authorities have estimated that during the first 5 years of enforceability, this treaty would increase 150,000 million dollars international commerce in our country and a 1.3 percentage points in the GDP growth. This treaty will be signed by Mexico next February 4, and shall be submitted to the Senate for ratification process, aiming for several discussion forums. It is worth mentioning that there is a clause which provides that if after two years of the signature of the TPP there are six member countries that have concluded their ratification before their legislative authorities, and which comprise 85 percent of the region’s GDP, the agreement shall automatically take effect.

The aspects that must be modified in the different laws with respect to biotechnological medicaments are: (i) patent protection term adjustment for patent office unreasonable delays which are clearly defined by article 18.46.4; (ii) patent protection term adjustment for unreasonable curtailment in granting the marketing authorization; (iii) strengthening the linkage system between these two authorities for making the measures described in article 18.51 enforceable; and (iv) the protection of data related to the security and efficiency of biotechnological medicaments during a period that, for Mexico, pursuant Article 18.52.1, is optional between:

- eight years, or
- five years along with additional mechanisms for assuring a balanced commercialization between the new biological product (reference) and a
possible biosimilar medicament, even recognizing the circumstances in the marketplace.

According to the Director General of COFEPRIS, the food and drug administration in Mexico, the procedural approach between both options must be embodied in our national laws, but it could be defined in a case by case basis, molecule by molecule basis, and change from one to another, which is allowed by the agreement.

The approach to follow will be assessed so as to reach a balance that the Mexican representatives always sought in the recent TPP negotiations. On one hand, the Mexican government keeps view of the need for promoting the investment in biotech innovation. On the other hand, as any government in the world, it must guarantee the vulnerable population’s access to better medicines at more affordable prices. This is according to the efforts that said entity has made in the last five years, whereby it lowered the healthcare sector’s total expenditure in medicines from 32 to 28 percent.

Regarding the protection of data for conventional pharmaceutical medicaments, the period that was established is of five years, such as the one that Mexico has already established and which does not represent further changes in the regulations.

All in all, the TPP execution opens the opportunity for modifying the Industrial Property Law so as to harmonize the agreements reached in the TPP, identifying, among others:
- applying Article 4 to provide the Mexican Patent Office (IMPI) with capacities such that, when it deems it applicable, same may request for expert reports and opinions from other government entities;
- clarifying articles 16 and 19 about non-patentable and non-protectable subject matter;
- modifying the current patent protection term foreseen by article 23;
- adapting article 86bis related to the protection of data about security and efficiency including the distinction with agricultural chemical, pharmaceutical and biologic products;
- strengthening the linkage system between IMPI and COFEPRIS comprised by article 47bis of the IPL regulations; and
- defining public patentability guidelines, particularly in the matter of medical uses, formulations and administration methods.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.
Juan Rodrigo Pimentel is associate and head of the patent prosecution area at Arochi & Lindner. 
http://www.arochilindner.com
Trans-Pacific Partnership – Patent and regulatory implications for Japan

Having studied the Intellectual Property chapter of the Trans-Pacific Partnership (TPP) Agreement, it appears that the changes required in Japan to meet the TPP for which Biotech practitioners will be interested are as follows:

- Extend the Grace Period to 12 months (Article 18.37 of Chapter 18)
  Under the current patent law, the grace period for filing a patent or a design application from the date which the invention being disclosed (exceptions to lack of novelty) is 6 months).

- Adopt a Patent Term Adjustment system for Patent Office delays (Article 18.46)
  Currently, Japan has no relevant system.

- Set the data protection period of an agricultural chemical product to at least 10 years from the date of the marketing approval (Article 18.47)
  Currently, for an agricultural chemical product such as a pesticide, there is no limitation on the data protection period, which means that presently the data can be protected permanently.

Nothing herein should be construed as legal advice or legal representation. Click here for an expanded disclaimer.

Yoichi Watanabe is a Senior Partner at Seiwa Patent & Law in Tokyo Japan
BIOTECH BUZZ

Regional/Social Subcommittee

January, 2016

Contributor: Alice O. Martin

Mid-winter Meeting Social Gathering-Karaoke Night

If you are attending the Mid-winter Meeting in La Quinta, CA, please join us for Karaoke Night on Thursday January 28th at 9:00 pm PDT at the Neill’s Lounge at 80956 CA-111, Indio, CA 92201 in Indio (760) 347-1522. Some will arrive after the AIPLA dinner.

Look out for an email with more information as the date approaches.

If you are planning on attending, please email me at alice.martin@btlaw.com

For those who can’t/won’t sing, cheering and applauding are always welcome, so no excuses for not joining us!

Alice O. Martin, Ph.D., J.D.

Barnes & Thornburg LLP

One North Wacker Drive, Suite 4400, Chicago, IL 60606
Tel: 312-214-8316. Fax: 312-759-5646. Email: alice.martin@btlaw.com