REPORT ON INTELLECTUAL PROPERTY DEVELOPMENTS IN THE FIELD OF PATENTS

Prepared for meeting of the ICC Commission on Intellectual Property on 27 October 2021.

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A. Overview

Patents continue to be one of the important cornerstones of securing the value and revenue of technology driven companies. While Covid-19 also certainly has an impact on the patent system it at boosts digitization in many ways as offices and courts continue to adapt to the situation.

Covid-19 response and recovery

As previously reported, patent offices throughout the world have reacted to Covid-19 at an early stage in 2020 by generally extending official deadlines up to certain points in time. To date, in some countries these extensions have been adjusted and still apply while other countries or patent offices, such as the European Patent Office, have returned to the normal regime of due dates. Similarly, in person hearings have been postponed, and video hearing systems have been increasingly used and promoted by patent offices and courts in order to possibly prevent the build-up of major backlogs due to the pandemic. An excellent overview over the measures taken is available via WIPO's Covid-19 IP Policy Tracker.

B. International

I. WIPO

Due to the Covid-19 pandemic, the Standing Committee on the Law of Patents (SCP) had deferred its 32nd Session to December 7 to 10, 2020, and held the latter as a hybrid session online and in Geneva. The 33rd Session will only be held December 6 to 9, 2021, again as a hybrid session.

As previously reported, issues discussed in the 32nd Session were:

- i) The International Patent System: Certain Aspects of National/Regional Patent Laws, including an update of the <u>information available at the SCP Electronic Forum Website</u>.
- ii) Exceptions and Limitations to Patent Rights which included:
- discussions on the "Draft Reference Document on the Exception Regarding Prior Use" (see document SCP/32/3 and document SCP/32/3 CORR).
- iii) Quality of Patents, including Opposition Systems, which included:
 - discussions on a study on approaches to the quality of patent grant process (see document <u>SCP/31/3</u> and <u>SCP/31/3 SUMMARY</u>);

- a report of the Secretariat on a sharing session regarding the use of artificial intelligence (AI) for examination of patent applications held during the thirty-first session of the SCP, which also contained information relating to WIPO's technical assistance activities relating to use of AI as tools for patent offices (see document SCP/32/4 and document SCP/32/4 CORR).
- iv) Patents and Health, which included:
 - discussions on a review of existing research on patents and access to medical products and health technologies (see also document SCP/31/5).
- v) Confidentiality of communications between clients and their patent advisors (see document <u>SCP/32/5</u>).
- vi) Transfer of Technology, which included
 - a discussion on patent law provisions that had contributed to effective transfer of technology, including sufficiency of disclosure (see document <u>SCP/32/6</u>).
- vii) Future Work, which defined the Committee's work for the next session.

II. B+ Subgroup (Harmonization)

As previously reported, the <u>B+ Group</u> held its 13th plenary session in Geneva on October 3, 2017 (see <u>Summary of discussions</u> and <u>Statement</u>). Among others, the B+ Subgroup issued a <u>response document</u> to the Industry Trilateral (IT3: American Intellectual Property Law Association, BusinessEurope, Intellectual Property Owners Association, Japan Intellectual Property Association) "<u>Elements Paper</u>" on a possible substantive patent harmonization package, which was issued on June 1, 2017, and presented at the B+ Sub-Group/Industry Symposium held June 3, 2017 (see <u>Record of the Proceedings</u>).

Members of the B+ Sub-Group met in Geneva on the September 26, 2018, to discuss next steps for the work on substantive patent law harmonization. The B+ Sub-Group held a joint session with IT3 to discuss further work. The basis for the discussions was updated exhibits by IT3 for the topics grace period, conflicting applications, prior user rights, and prior art. These showed that progress had been made, at IT3, as agreement had been reached on both the definition of prior art and the norms governing conflicting applications (see "agreed statement").

On October 1, 2019, the B+ Group held a further plenary session in Geneva where a draft agreement on Client Attorney Privilege presented during the meeting was adopted to be further pursued for consultation. Progress from IT3 on substantive patent law harmonization was welcomed and IT3 was encouraged to develop a package of international harmonized norms (see "agreed statement").

In line with the <u>Objectives and Principles</u> of the B+ Subgroup (published May 27, 2015) activities related to partially sensitive issues, namely (a) non-prejudicial disclosures/grace period, (b) publication of applications, (c) conflicting applications, (d) prior user rights, and (e) prior art.

III. IP5 Offices

As previously reported, the <u>IP5 Industry Consultation Group (ICG)</u> comprised of representatives from the IP5 Offices (CN, EP, JP, KR, US), <u>IP5 Industry</u> (IT3 plus Korea Intellectual Property Association (KINPA) and Patent Protection Association of China (PPAC)) and WIPO International Bureau met at the EPO in The Hague on January 16, 2019, to discuss

progress in the harmonization endeavors within the IP5 Patent Harmonization Expert Panel (PHEP) and discuss potential IP5 initiatives in the area of new emerging technologies including artificial intelligence (AI).

The IP5 Offices confirmed their commitment to their ongoing dialogue with IP5 Industry (see meeting summary).

In November 2018 and June 2019 the <u>Patent Harmonization Experts Panel (PHEP)</u> of IP5 concluded their work on <u>unity of invention</u> (led by EPO, CNIPA), <u>citation of prior art</u> (led by KIPO, USPTO), and <u>written description/sufficiency of disclosure</u> (led by JPO).

On July 25, 2019 the IP5 Offices published a summary "Report from the IP5 Expert Round Table on Artificial Intelligence" held in Munich on 31 October 2018, touching on issues such as inventorship, eligibility and sufficiency of disclosure.

IV. Patent Prosecution Highway (PPH)

Since the previous report of March 2021 some new programs have started. The numerous Patent Prosecution Highway (PPH) bilateral and multilateral agreements and pilot programs (such as Global PPH, PCT-PPH, PPH MOTTAINAI) promote work-sharing among the patent offices involved and enable patent applicants to request accelerated processing of their applications on the basis of examination results of a participating office.

On October 26, 2021, the landscape of cooperation looked as follows (Source: <u>Patent Prosecution Highway Portal Site</u>):



V. Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)

As previously reported, on February 4, 2016, the TPP agreement was signed by twelve Pacific Rim states including Australia (AU), Brunei (BN), Canada (CA), Chile (CL), Japan (JP), Malaysia (MY), Mexico (MX), New Zealand (NZ), Peru (PE), Singapore (SG), the United States

(US), and Vietnam (VN). Ratification was underway although, to date, none of the signatories has ratified. Moreover, On January 23, 2017, US President Donald Trump signed a Presidential Memorandum to withdraw the US from the agreement, making TPP's entry into force virtually impossible.

In the meantime the remaining eleven members (see image below; source: <u>NZ Ministry of Foreign Affairs and Trade</u>) agreed on core elements of the so called Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), which was signed by all eleven CPTPP countries on March 8, 2018, in Santiago, CL.



On February 1, 2021, the UK government submitted a <u>notification of intent letter</u> to begin the CPTPP accession process. As the CPTPP contains, among others, provisions on the grace period which deviate from the provisions of the European Patent Convention (EPC), there are concerns how the UK could solve this incompatibility issue.

The signed CPTPP (see <u>CA Ministerial Statement</u>) suspended some of the provisions of <u>TPP</u>. Among the <u>suspended provisions</u> are some of the provisions of <u>Chapter 18 of the TPP</u> <u>agreement</u> which relate to Intellectual Property. Provisions relevant to the patent field (fully or partially suspended) include:

- viii) National Treatment (Art. 18.8).
- ix) Patents (Section F), including Patentable Subject Matter (Art. 18.37*), Grace Period (Art. 18.38), Patent Term Adjustment (Art. 18.46, 18.48)

VI. Europe

a. Unitary Patent and Unified Patent Court

As previously reported, the Unitary Patent and Unified Patent Court (UPC) system was on halt due to the missing ratification by Germany and the <u>withdrawal of the ratification</u> by the United Kingdom on July 20, 2020. However, the situation has changed in the meantime and the system seems on a way to actual implementation in early 2023.

While the United Kingdom, despite the decision on Brexit, had surprisingly initially ratified the UPC Agreement (UPCA) on April 26, 2018, (yet with a <u>reservation</u> to the <u>Protocol to the UPC Agreement on provisional application</u> which essentially stalled preparations for the UPC, such as recruitment of judges etc.), this has come to an end

with the withdrawal of the ratification. Hence, the UK will not be part of the UPC.

Germany, while having initially completed the parliamentary process, until recently lacked signature of the corresponding national laws by the German President, as the latter had been asked by the Federal Constitutional Court (BVerfG; FCC) to not sign until the court has decided on a constitutional complaint filed against the UPC System. The FCC (BVerfG), in its decision dated February 13, 2020, has accepted the complaint and declared the corresponding legislation void since, despite the fact that the law had been accepted unanimously by the members of the German parliament participating in the vote (as little as 35 members!), the number of positive votes did (quite obviously) not reach the required two thirds of all members of parliament required according to the view of the FCC (BVerfG). The German government thus has re-introduced the draft ratification bill into the parliamentary process, and the latter has passed both chambers on November 26 (Bundestag) and December 18, 2020 (Bundesrat). While, unsurprisingly, a further constitutional complaint had been filed with the FCC (BVerfG) on January 11, 2021, the complaint has been rejected by the FCC (BVerfG) with its decision dated June 26, 2021. In the meantime, the German President has signed the laws, and Germany has formally ratified the Protocol on the Provisional Application of the UPCA (PAP-Protocol) on September 27, 2021, which is a prerequisite for the UPC to start its set-up phase (appoint judges, set up case management etc.).

As Slovenia has also formally ratified the PAP-Protocol on October 15, 2021, there is only one further ratification missing for the PAP-Protocol to become effective and the set-up phase of the UPC to start. Sources say that it is likely that the missing ratification of the PAP-Protocol is completed by the end of 2021 with Austria being a candidate for completing the missing ratification of the PAP-Protocol.

Hence, the UPC actually seems to come to life. However, there are still some uncertainties if and when the UPC will come to life. These are, among others, the hotly debated possible "replacement" of the mandatory ratification by the UK by the ratification of another member of the UPC agreement, and the relocation of the London section of the UPC's central division. Italy has already <u>announced its candidacy</u> (with Milan as the replacement for London).

b. European Patent Office (EPO)

i. Validation Agreements

The EPO has effectively entered so called <u>Validation Agreements</u> with, to date, four states, namely Morocco (MA), Moldova (MD), Tunisia (TN), and Cambodia (KH), the agreement with the latter having entered into force on March 1, 2019. A further agreement has been signed with Georgia (GE) on October 31, 2019.

ii. Organizational

As previously reported, based on a proposal of the President of the EPO to the Administrative Council of June 9, 2017, the Directorate General (DG) structure of the EPO has been revised and the new structure has come into effect on January 1, 2018. The revised DG1 (Patent Granting Process) now has three main domains, namely (i) Mobility & Mechatronics, (ii) Healthcare, Biotechnology & Chemistry, and (iii) Information & Communications. One or two dedicated Opposition Directorates were also created in each of the three domains, which means a considerable change in the way opposition divisions are staffed. A development which still deserves attention but seems to have had no negative effects so far.

iii. Policy

As previously reported, there is an ongoing conflict of the EPO management with the EPO staff, in particular, the main EPO staff union SUEPO.

On March 16, 2016, the Administrative Council (AC) of the EPO issued a Resolution that imposed clear obligations on the parties to resolve their conflicts. In particular, the former President of the EPO (Mr. Batistelli) was requested to review staff investigation guidelines and disciplinary procedures, to suspend further decisions in disciplinary cases, to negotiate a Memorandum of Understanding with the staff unions and to speed up the structural reform of the Boards of Appeal.

The conflict between the EPO management and the EPO staff on the management's "efficiency and productivity" initiative under the former President Batistelli seems to be still partially unresolved under the new President Campinos. As this conflict on may have an impact on the work within the EPO, this issue still deserves attention.

VII. North America

a. U.S.A.

i. U.S. Patent and Trademark Office (USPTO)

As previously reported, the USPTO, after <u>seeking comments</u>, has issued its <u>2018-2022 Strategic Plan</u>. The plan sets out the USPTO's mission-focused strategic goals: (i) to optimize patent quality and timeliness; (ii) to optimize trademark quality and timeliness; and (iii) to provide domestic and global leadership to improve intellectual property (IP) policy, enforcement, and protection worldwide.

b. Canada

i. Comprehensive Economic and Trade Agreement (CETA) and Bill C-30

As previously reported, on October 30, 2016, Canada and the European Union officially signed the CETA. The next day, proposed legislation (Bill C-30) intended to implement CETA was introduced before Canada's House of Commons and received Royal Assent on May 5, 2017.

Bill C-30 amends Canadian IP legislation. In particular, under Bill C-30, holders of pharmaceutical patents will be entitled to patent term extensions of up to two years to account for regulatory delays. Implementation of CETA will also bring further changes to Canada's IP laws including a potential end to "dual litigation" in relation to pharmaceutical patents under the Patented Medicines (Notice of Compliance) Regulations (PMNOC) and the Patent Act.

On September 21, 2017, $\underline{\text{CETA}}$ provisionally entered into force, such that most of the agreement now applies

- introduction of a notice regime by which an applicant must be notified of a missed deadline before an application is deemed abandoned;
- introduction of a mechanism allowing the addition of material contained in a priority application to a Canadian patent specification post-filing without affecting the filing date;
- c. introduction of the right to restore priority claims if a request for priority was

unintentionally omitted at first instance in certain circumstances; and

d. introduction of more flexible filing requirements, allowing applicants to file a patent application by submitting a referral to a previously filed application rather than filing a complete set of documents.

This bill received royal assent on December 16, 2014, but, to date, it is unclear when the amendments will enter into force.

VIII. South America

(see report of the Regional Ambassador)

IX. Asia

a. China

(see report of the Chinese Group)

b. India

(see report of the Indian Group)

C. Legal framework - Key IP developments

I. Europe

a. European Patent Office (EPO)

i. Law and Regulations

- 1. As previously reported, the EPO has substantially revised the <u>Rules of Procedure of the Boards of Appeal</u> (RPBA) which entered into force on January 1, 2020. The amendments relate to Art. 10, 12, 13, 14 and 15 RPBA, which form the core of the appeal procedure. The proposed amendments follow the long standing "efficiency" narrative of the EPO and aimed to restrict the appeal procedure to a mere judicial review, greatly reducing, among others, the defense options of the patentee in opposition. The new RPBA have shown to have a significant effect on the opposition procedure before the EPO, requiring more careful preparation of the first instance proceedings.
- 2. In the course of the measures related to the Covid-19 pandemic, the Boards of Appeal have transitioned to a practice that oral proceedings can also be conducted using video conferencing (VICO) technology as of January 1, 2021, even without the agreement of the parties concerned. This practice has in the meantime is also be generally codified (beyond the Covid-19 pandemic) in the new Article 15a RPBA which entered into force on April 1, 2021. According to a communication of the Boards of Appeal dated December 15, 2020, the new provision allegedly merely clarifies an existing possibility, such that the boards have been adapting their practice as regards dispensing with the need to obtain the agreement of the parties concerned even before the date of the entry into force of new Art. 15a RPBA. This is a highly controversial issue which has lead,

among others, to a referral to the Enlarged Board of Appeal (G 1/21 – see below).

3. As previously reported, new <u>Guidelines for Examination</u> entered into force on November 1, 2019, as a follow-up to the substantive amendments made in the examination procedure before the EPO with the previous Guidelines of 2017 and 2018. The amendments concern, among others, clarity of the claims, computer-implemented inventions, inventions in the field of artificial intelligence (AI), as well as to inventions in the field of biotechnology, and unity of the invention. The revision of the Guidelines is currently underway and the EPO has invited to provide comments on the latest planned revision in a <u>user consultation</u> open until April 12, 2021.

ii. Enlarged Board of Appeal Decisions and Referrals

1. Enlarged Board of Appeal (EBA) referral G 1/21: Oral proceedings by video conferencing

In decision \underline{T} 1807/15 the basic question was referred to the EBA, if, the conduct of oral proceedings in the form of a videoconference is compatible with the right to oral proceedings as enshrined in Article 116 (1) EPC if not all of the parties to the proceedings have given their consent to the conduct of oral proceedings in the form of a videoconference.

In the <u>order of the decision</u> issued on July 16, 2021, the EBA circumvented the fundamental question of the compatibility of article 15a with Article 116 (1) EPC, and restricted itself to a decision concerning a situation of oral proceedings during a "general emergency". The written decision is yet outstanding.

2. Enlarged Board of Appeal decision <u>G 1/19</u>: Inventive step of a computer-implemented simulation

In decision <u>T 489/14</u> the basic question was referred to the Enlarged Board of Appeal, if, in the assessment of inventive step, the computer-implemented simulation of a technical system or process can solve a technical problem by producing a technical effect which goes beyond the simulation's implementation on a computer, if the computer-implemented simulation is claimed as such.

In the decision of March 11, 2021, the EBA confirmed that computerimplemented simulations are patentable but ruled that the applicant must show that the invention addresses a technical issue. This decision is likely to have a wide impact in the field of computer-implemented inventions.

3. Enlarged Board of Appeal decision G 3/14: Clarity objections during opposition

The Enlarged Board of Appeal of the EPO released a decision on the scope of clarity examination (Art. 84 EPC) of amended claims during opposition. The basic news is that a clarity objection is only possible (i) if an amendment leads to a lack of clarity and (ii) only to the extent that the amendment itself leads to a lack of clarity.

4. Enlarged Board of Appeal decision <u>G 1/15</u>: Partial priority

The Enlarged Board of Appeal of the EPO released this decision clarifying that an alternative in a claim, which is not covered by the priority, does not infect the entire claim, such that priority is not lost for the claim as a whole and the priority application itself does not become relevant prior art under Art. 54 (3)

EPC.

5. Enlarged Board of Appeal decision <u>G 1/16</u>: Disclaimers

In decision \underline{T} 437/14 the basic question was referred to the Enlarged Board of Appeal, if the standard referred to in \underline{G} 2/10 for the allowability of disclosed disclaimers also is to be applied to claims containing undisclosed disclaimers, and, if yes, if \underline{G} 1/03 is set aside as regards the exceptions relating to undisclosed disclaimers. The decision provides guidance of such undisclosed disclaimers and insofar conforms G 1/03.

iii. Board of Appeal Decisions

1. Board of Appeal decision <u>T 844/18</u>: CRISPR-Cas/Broad Institute, Priority, "All Applicants" approach.

In this decision the Board of Appeal confirmed the "All Applicants" approach that all applicants of a priority application or their successors had to be named as the applicants of a subsequent EP application. If this is not the case, priority is lost, which in the present case led to an intervening publication becoming novelty destroying prior art. A concise overview is given in the related EPO press release of November 6, 2020.

b. Germany

i. Law and Regulations

1. On August 18, 2021, the "Second Law for the Simplification and Modernization of Patent Law" has entered into force. Among others, the new law deals with the exceptional restriction of the right to injunctive relief under patent law for reasons of proportionality. In addition, the protection of secrets in patent litigation shall be improved. In order to better synchronize the infringement proceedings before the civil courts and the nullity proceedings before the Federal Patent Court, the law also provides for procedural changes with regard to the proceedings before the Federal Patent Court. Especially the restriction of the right to injunctive relief is a very controversial point but experts believe that the German courts will use that provision very carefully.

ii. Federal Court of Justice (BGH) Decisions

1. BGH: "Sisvel v. Haier" (FRAND)

In the above decision (No. KZR 36/17) of May 5, 2020, the Cartel Senate of the German FCJ (BGH) held that, during pre-suit negotiations, before a patent expires, implementers of standard-essential patents (SEPs) must clearly and unequivocally declare their willingness to conclude a license agreement on fair, reasonable, and non-discriminatory (FRAND) terms. If they do not, such implementers are not able to rely on the defense of anticompetitive behavior of SEP holder (abuse of a market dominant position, Art. 102 TFEU) as established in the Huawei v. ZTE decision of the Court of Justice of the European Union (CJEU) of July 16, 2015. The decision provides guidance on the obligations of an SEP holder to avoid abuse of dominance charges and on the requirements for demanding a worldwide SEP portfolio license.

iii. Regional Court (LG, OLG) Decisions

1. Munich Higher Regional Court (OLG): "Nokia v. Continental" (Anti-Anti-Suit

Injunction)

In the above decision (No. 6 U 5042/19) of December 12, 2020, OLG Munich confirmed two preliminary injunctions ("Anti-Anti-Suit Injunctions") issued by LG Munich banning Continental and its US subsidiary from applying for measures (an "Anti-Suit Injunction" before the US District Court for the Northern District of California) in prohibiting Nokia from pursuing its German patent infringement proceedings.

c. United Kingdom

i. Supreme Court Decisions

1. UK Supreme Court: "Unwired Planet v. Huawei" (FRAND)

On August 26, 2020, the UK Supreme Court issued the above highly anticipated decision (No. UKSC 2018/0214) related to the so called "Fair, Reasonable, and Non-Discriminatory" ("FRAND") licensing of standard essential patents ("SEPs"). The decision concluded that owners of patents essential to ETSI's telecommunications standards (including 2G, 3G, and 4G (LTE)) can demand that an implementer practicing a UK SEP take a license on FRAND terms to all of the patent owner's worldwide telecommunications SEPs, and can obtain an injunction should the implementer refuse.

II. North America

a. U.S.A.

i. Law and Regulations

Patent reform legislation is on its (slow) pathway. The leading bill is the "<u>Stronger Patents Act</u>" (see H.R.3666) of 2019 with identical bills pending in both the House and Senate. The bill aims to strengthen the power of an individual patent, i.e. making it harder to invalidate and easier to enforce.

As previously reported, amended <u>Federal Rules of Civil Procedure</u> became effective on December 1, 2015. They include (i) an important change to patent infringement pleading practice and (ii) notable revisions to civil discovery rules. Courts will now likely expect more detailed allegations of patent infringement (beyond the mere allegation of the existence of a patent and infringement of it). Furthermore, the scope of discovery has been limited to information that "is relevant to any party's claim or defense and proportional to the needs of the case" (proportional discovery).

ii. Supreme Court Decisions

During the past years the Supreme Court of the United States (SCOTUS) issued an impressive number of more than twenty patent law-related opinions (with an average of a total of only about 70 opinions issued by the Supreme Court per year). These opinions related to many core patent law doctrines (patentable subject matter, remedies, claim meaning, infringement). A good overview of the cases pending late 2020 may be found here.

1. "Thryv. Inc. v. Click-to-Call Technologies L.P." (Appeal Bar):

On April 20, 2020, SCOTUS issued a (7 to 2 majority) decision in <u>Thryv v. Clickto-Call</u> holding that when the PTAB grants a petition for inter partes review and

rejects a contention that the petition is time-barred, the PTAB decision cannot be appealed. This eliminates a potential way for patentees to attack petitioners.

2. "Return Mail, Inc. v. United States Postal Service" (Federal Agency not a Person):

On June 10, 2019, SCOTUS issued a (6 to 3 majority) decision in <u>Return Mail v. USPS</u> holding that a federal agency is not a "person" who may petition for post-issuance review under the America Invents Act (AIA).

3. "Helsinn v. Teva" (On Sale Bar):

On January 22, 2019, SCOTUS issued a decision in <u>Helsinn v. Teva</u> holding that pre-filing secret sales count as prior art under Section 102 of the Patent Act as revised by the America Invents Act.

4. "Oil States v. Green's Energy" (Constitutionality of Inter Partes Review):

On April 24, 2018, SCOTUS issued its (majority) decision (with dissents by Chief Judge Roberts and Judge Gorsuch) in Oil States Energy Services, LLC v. Green's Energy Group, LLC, ruling that Inter Partes Review (IPR) proceedings before an executive agency tribunal are constitutional, and the adjudication of patent validity does not have to take place in Article III federal courts.

5. "TC Heartland v. Kraft Foods" (Forum Shopping):

On May 27, 2017, in <u>TC Heartland LLC v. Kraft Foods Group Brands, LLC</u>, SCOUTS held that patent litigation venue is controlled exclusively by 28 U.S.C. § 1400(b), which restricts venue in patent cases to (1) where the Defendant resides, or (2) where the Defendant commits an act of infringement <u>and</u> has a regular and established place of business.

6. "Halo v. Pulse" (Damages for Willful Infringement):

On June 13, 2016, SCOTUS has decided in the "Halo v. Pulse" case rejecting the Federal Circuit's strict standards for obtaining enhanced damages for willful infringement, hence making it easier for patentees to obtain such enhanced damages.

7. "SCA Hygiene v. First Quality" (Laches):

On March 21, 2017, SCOTUS decided in the "SCA Hygiene v. First Quality" case that the equitable defense of laches is not available in patent cases within the six-year statutory limitations period (see 35 U.S.C. Section 286).

8. "Life Technologies v. Promega" (Component Exporter's Liability for Infringement):

On February 22, 2017, SCOTUS decided in the "Life Technologies v. Promega" case that there is no liability for infringement when a product is made in a foreign country and only one component of the infringing product is provided from the US to the foreign country.

iii. Federal Circuit Activities

Some recent decisions of the Court of Appeals of the Federal Circuit (CAFC) deal with post-issuance review under the America Invents Act (AIA):

1. "ESIP Series 2 L.L.C. v. Puzhen Life USA LLC" (Appeal Bar)

In the decision <u>ESIP v. Puzhen</u> issued May 19, 2020, the CAFC held that hat patent owners are precluded on appeal from arguing that a petitioner failed to satisfy the requirement of identifying all real parties-in-interest as required by 35 U.S.C. § 312(a)(2). Since the PTAB's finding raised an ordinary dispute regarding the application of an institution-related statute, the appellate review was barred by § 314(d).

2. "Samsung Electronics America v. Prisua Engineering Corp." (Limitation of Invalidity Arguments)

In the decision <u>Samsung v. Prisua</u> issued February 4, 2020, the CAFC held that the PTAB cannot invalidate patents during most inter partes reviews for claims that are indefinite, confirming that invalidity arguments in these proceedings are limited to anticipation and obviousness.

3. "Arthrex, Inc. v. Smith & Nephew, Inc." (APJ Appointment)

In the decision Arthrex v. Smith & Nephew issued October 31, 2019, the CAFC held that the statutory scheme for appointing Administrative Patent Judges (APJ) violates the Appointments Clause. Presently, rather than by the President, APJs are appointed by the Secretary of Commerce in consultation with the Director of the USPTO, themselves both presidential appointees.

4. "University of Minnesota v. LSI Corp. et al." (Immunity)

In this <u>decision</u> of June 14, 2019, the CAFC held that 11th Amendment Sovereign Immunity does not protect patents owned by individual states from being cancelled via inter partes review (IPR).

As previously reported, the CAFC seems to increasingly issue judgments without any opinion or explanation. A practice which is heavily criticized as in the context of:

1. "Capella Photonics, Inc., v. Cisco Systems, Inc.," (Obviousness)

In this decision of February 8, 2018, the Federal Circuit affirmed the PTAB's decision on claim construction and obviousness (issues to be reviewed *de novo* on appeal) without opinion. Capella now has <u>asked the Supreme Court</u> (SCOTUS Docket No. 18-304) to review the issue.

As previously reported, in 2015 the CAFC upheld all six of the appeals against district court decisions striking down patents under Section 101 for lacking eligible subject matter. Furthermore, according to the opinions of at least four Federal Circuit judges in 2015, the effectiveness of Section 101 challenges is unlikely to change absent intervention by either the Supreme Court or Congress.

Landmark cases of the CAFC in this respect are:

1. "Biosig Instruments v Nautilus Inc," (Indefiniteness)

In this decision of April 27, 2015, the Federal Circuit on remand from the Supreme Court applied the Supreme Court's new "reasonable certainty" standard for indefiniteness and found the claims not indefinite. Here, despite the change in law, the court reached the same conclusion it had made under the "insolubly ambiguous" standard applied before the remand from the Supreme Court.

2. "Williamson v. Citrix Online, LLC" (Means-plus-function, Indefiniteness)

In this decision of June 16, 2015, the Federal Circuit revised the law on construing means-plus-function claim limitations under 35 USC § 112 (6) and provided guidance on what disclosure must be provided in the patent specification for performing the claimed functions. The decision is of particular significance because Part II.C.1 of the opinion, regarding the standard for means-plus-function claim limitations, was considered and decided by the court "en banc".

3. "Enfish v. Microsoft" (Computer-implemented Inventions)

On May 12, 2016, the Federal Circuit issued the "Enfish v. Microsoft" decision, which found a computer-implemented invention patent eligible. In particular, this decision provides guidance as regards the first step of the "Alice" test, i.e. whether the claims are directed to an abstract idea.

Notably, after the "Alice" decision, the "Enfish v. Microsoft" decision and the "DDR Holdings v. Hotels.com" decision are the only Federal Circuit cases which found computer-implemented inventions patent eligible.

b. Canada

i. Law and Regulations

1. New Patent Rules and Amendments to the Patent Act

As previously reported, in implementing the Patent Law Treaty (PLT), ratified by Canada on July 30, 2019, new Canadian Patent Rules and associated amendments to the Patent Act have come into force October 30, 2019. They intended to provide applicants more flexibility in their filings. However, the amendments also reduce the national phase entry deadline from 42 months (still applicable but now subject to a fine) to 30 months from the priority date and shorten prosecution deadlines.

2. Intellectual Property Enforcement Guidelines

As previously reported, on March 31, 2016, the Competition Bureau released its <u>Intellectual Property Enforcement Guidelines</u> after an extensive public consultation process held in 2015. The draft addresses conduct involving patent assertion entities and industry standard patents.

ii. Court Activities and Decisions

1. "Dow v. Nova" (Accounting of Profits Remedy)

In its decision of September 15, 2020, in Dow v. Nova (2020 FCA 141) the Canadian Federal Court of Appeal affirmed the decision of July 5, 2017, in The Dow Chemical Company v. Nova Chemicals Corporation, (2017 FC 637) where the Federal Court of Canada has awarded the successful plaintiff (Dow) over CAD 644 million plus interest, as compensation for patent infringement. This represents the largest monetary award for patent infringement ever granted in a Federal Court judgment. The award was based on a combination of a reasonable royalty for the pre-grant publication period of the patent, an accounting of profits for the post-grant period, and an accounting of "springboard profits" for a period of time following expiry of the patent.

2. "Canmar Foods Ltd v TA Foods Ltd" (Prosecution History Estoppel)

On September 25, 2019, in <u>Canmar Foods v TA Foods</u> (2019 FC 1233), the Federal Court held that representations made by a patentee during prosecution of a foreign patent application constituted admissible evidence under Section 53.1. The Court recognized that Section 53.1 only specifies using Canadian prosecution file histories to rebut positions taken on claim construction, and makes no reference to prosecution histories from other jurisdictions. Notwithstanding, the Court found that it could consider the U.S. Application prosecution history as part of a purposive construction of the claims in issue, based on the "extraordinary circumstances" identified by the Court in the case.

3. "AstraZeneca Canada Inc v Apotex Inc" (Promise Doctrine)

On June 30, 2017, the Supreme Court of Canada delivered an important and highly anticipated unanimous decision in <u>AstraZeneca Canada Inc v Apotex Inc</u> (2017 SCC 36), by rejecting the "Promise Doctrine" and clarifying the requirement for patent "utility" in Canada. The "Promise Doctrine" previously applied by Canadian Courts had imposed a further requirement that, to be patentable, the invention must fulfil any "promise" set out in the specification.

4. "Eli Lilly v. Mylan" (Markush Groups and Alternatives in Patent Claims)

As previously reported, in a previous decision "Abbott Laboratories v Canada (Minister of Health)" ("Abbott I"), 2005 FC 1095, the Federal Court distinguished Markush groups from alternatives and defined a Markush claim as a claim to the entire group. In "Abbott I", the Federal Court concluded that an entire Markush claim was invalid because some of the solvents in the Markush group lacked utility. In the May 2015 decision "Eli Lilly v. Mylan" the Federal Court now seems to take the opposite approach. The "Eli Lilly v. Mylan" decision has been appealed to the Federal Court of Appeal, which may clarify the issue.

5. "Mylan v. Eli Lilly" (Obviousness-type Double-Patenting, Distinction between Prior Art and Common General Knowledge)

On April 20, 2016, the Federal Court of Appeal issued the "Mylan v. Eli Lilly" decision. The Federal Court of Appeal dismissed the appeal and clarified the test for obviousness-type double-patenting and addressed the relevant date for the double-patenting analysis. The Court also made important remarks on the use of prior art as well as and on the distinction between prior art and common general knowledge.

III. South America

(see report of the Regional Ambassador)

IV. Asia

a. China

(see report of the Chinese Group)

i. Supreme People's Court (SPC) Decisions

1. "Huawei v. Conversant" (Anti-Suit Injunction)

In September 2020, the SPC issued a preliminary anti-suit injunction in Huawei v. Conversant restraining Conversant from enforcing a German judgment (LG

Düsseldorf) of August 27, 2020, setting a FRAND fee which was more than 18 times higher than the ones set earlier in a case (initiated earlier than the German case and requesting to set a FRAND rate) before the Jiangsu Nanjing Intermediate Court. According to the SPC enforcement of the Düsseldorf judgment would have a negative impact on the case pending in the Chinese court, and the injunction was necessary to prevent irreparable harm to Huawei, as the damage to Conversant by granting the injunction is significantly smaller than the damage to Huawei if not granting injunction. Further; the injunction would not harm public interest or international comity.

ii. Intermediate People's Court (IPC) Decisions

1. "Xiaomi v. InterDigital" (Anti-Suit Injunction)

On September 23, 2020, the Wuhan Intermediate Court issued an anti-suit injunction in Xiaomi v. InterDigital restraining InterDigital from enforcing a possible injunction issued in India (Dehli High Court). The court provides essentially similar reasons as the SPC in the above case.

The Dehli High Court, in the meantime, has issued an anti-anti-suit injunction on October 9, 2020.

b. India

(see report of the Indian Group)

i. Dehli High Court Decision

2. "InterDigital v. Xiaomi" (Anti-Anti-Suit Injunction)

On September 23, 2020, the Chinese Wuhan Intermediate Court issued an antisuit injunction in Xiaomi v. InterDigital restraining InterDigital from enforcing a possible injunction issued in India (Dehli High Court). The court provides essentially similar reasons as the SPC in the above case.

The Dehli High Court, in the meantime, has issued a related anti-anti-suit injunction on October 9, 2020.

c. Japan

i. Law and Regulations

1. Amendments to the Patent Law driven by the Fourth Industrial Revolution

The amendments have passed the parliament on May 10, 2019, and were published on May 17, 2019. They will be enacted within one year but the date of enactment is yet to be determined. A short overview of the amendments may be found here. Other amendments have already entered into force. The amendments include:

On-Site Inspection by Expert

The infringement court will be able to order on-site inspection at the defendants site by an appointed expert.

Extension of the Grace Period

Effective as of June 9, 2018, the grace period has been extended from six

months to one year.

Reduction in Patent Fees and Charges for SMEs etc.

The fees for the request for examination, the annuities (for years one through ten), and the fees for international applications shall be reduced for SMEs etc. by 50%.

2. Previous Partial Revision of the Patent Act

As previously reported, on January 19, 2016, the Cabinet approved Act No. 55, such that it entered into force on April 1, 2016. The revision related to the following patent issues:

- Re-introduction of post-grant opposition.
- Employee invention system:

Employee inventors shall be entitled to claim a financial or other benefit for an invention. The right to obtain a patent on an employees' invention can be vested in the employer from the outset via an agreement between the employer and the employee.

- Reduction of renewal fees by 10%
- New provisions in accordance with the Patent Law Treaty (PLT)
 - (i) The time limit for submitting a translation of a preliminarily filed English-language subsequent patent application in Japan is extended by 2 months to 4 months following expiry of the 12-month priority period according to the Paris Convention. Where this time limit is missed, the JPO will issue a notification requesting the applicant to perform the omitted act within a period to be specified.
 - (ii) If a patent application contains a defect which would lead to a non-remediable loss of rights, such as missing specification pages, or when the applicant's name is not given, the JPO will henceforth issue a notification requesting the applicant to correct the defect within a period to be specified.
- 3. As previously reported, on June 5, 2018, the JPO released "Guide to Licensing Negotiations involving Standard Essential Patents".
- 4. As previously reported, in early 2016, the Japan Patent Office (JPO) has outlined a number of measures it will pursue to improve the office's efficiency and to encourage small-to-medium enterprises (SMEs) to file for protection for their intellectual property. This approach has been confirmed early 2017.
 - > The commissioner for the JPO (Mr. Ito) announced that JPO will appoint another 100 examiners on a full-time basis in an attempt to speed up prior art searches and the granting of patents. The intention is to create the "world's fastest and highest quality examination system".
 - Furthermore, JPO has announced additional support for SMEs in the form of subsidies for foreign applications and infringement claims.

ii. Court Decisions

1. "MTG v. Five Stars"

On February 28, 2020, the IP High Court issued a decision in MTG Co., Ltd. v. Five Stars Co. Ltd., where the court increased the damages award to the patentee using a new calculation model based on lost profits. The Patent Act allows courts to use the number of infringing products sold multiplied by the price paid by consumers per product. The court increased the damages award in finding that the damages calculation should consider the entire profits lost per sale and not just the portion attributable to the invention.

2. "Debiopharm vs. Towa Pharmaceutical"

On January 20, 2017, the IP High Court issued a judgment regarding infringement actions filed in the context of pharmaceutical products based on patent rights under patent term extension.

3. "Teva v Kyowa Hakko Kirin" and "Teva v Tori Limited" (product-by-process claims)

As previously reported, the Supreme Court of Japan decisions "Teva v Kyowa Hakko Kirin" and "Teva v Tori Limited" have changed the standards applied in Japan regarding product-by-process claims, bringing it more in line with the related practice in Europe. Changes to Japanese patent law are also planned under a new bill recently approved by the Japanese Diet.

Following the decisions, the Japanese Patent Office (JPO) has changed its practice regarding the examination of product-by-process claims. Under the new guidance, JPO will object that a product-by-process claim lacks clarity unless it was "impossible" or "impractical" to define the product by anything other than a reference to method or process features. On November 25, 2015, corresponding Handling Procedures for Examinations involving Product-by-process Claims have been published by JPO.

4. "Maxacalcitol" Case (Doctrine of Equivalence)

On March 24, 2017, the Supreme Court of Japan affirmed a decision of the Japanese IP High Court in favor of the originator of "Maxacalcitol" against several generic manufacturers finding infringement of the process patent under the Doctrine of Equivalence (DOE). Although the Japanese IP High Court has rarely applied DOE, it was applied here further explaining the requirements No. 1 (non-essential part) and No. 5 (special circumstance) the five requirements test established with the "Ball Spline Bearing" case.

d. South Korea

i. Law and Regulations

- As previously reported, two major amendments to the Patent Act were signed into law on February 4 and March 3, 2016, respectively, that have entered into force March 1, 2017. The amendments include a number of important changes to South Korea's patent procedures, including:
 - A new patent cancellation system replacing the previous invalidation system for non-interested third parties and applicable for patents registered as of March 1, 2017. A non-interested third party can now only file a request for cancellation with the Intellectual Property Trial and Appeal Board (IPTAB) up to six months after publication of the patent and based on prior art rejection grounds. Remarkably, an IPTAB decision not to cancel

- a patent cannot be appealed under the new system, while a decision cancelling the patent can be appealed.
- Easier proof of patent infringement and damages. Under the amended Patent Act, materials may no longer be withheld from court simply because the defendant claims that they contain trade secrets if the requested materials are necessary to prove infringement or damages. However, the defendant may request limitation of the scope of materials to be produced or persons allowed access to the produced materials after demonstrating to the court that the materials contain trade secrets. Failure to produce the materials may now expressly result in the presumption that the facts related to these materials are proven. These provisions apply to patent infringement actions filed as of June 30, 2016.
- A shortened period for requesting examination (from five to three years) for applications filed as of March 1, 2017.
- New ex officio re-examination system, under which an examiner, if clear rejection grounds are found after allowance but before registration, may withdraw the decision to grant a patent ex officio and reopen examination. The new ex officio re-examination procedure will apply to applications that are allowed as of March 1, 2017.
- 2. A revised Korean Patent Act has become effective on July 9, 2019. The revision introduces punitive damages for patent infringement and shifts the burden of proof in patent infringement litigation to an accused infringer. More precisely:
 - the courts may award punitive damages up to treble the actual damages for willful infringement;
 - > the burden of proof in a patent infringement litigation may be shifted to the defendant to require the defendant (denying infringement) to produce their actual product or process.
- 3. Consolidation of Jurisdiction over IP Infringement Cases

As previously reported, on November 12, 2015, the Korean National Assembly passed amendments to the Korean Civil Procedure Act and Court Organization Act (i) to consolidate jurisdiction over infringement cases involving certain intellectual property rights (i.e., patents, utility models, trademarks, designs, and plant variety rights) with five district courts, and also (ii) to reorganize intermediate appeals of IP Infringement Cases which will now be heard exclusively by the Patent Court.

4. Amendments to South Korea's patent prosecution procedures

As previously reported, amendments to South Korea's patent prosecution procedures came into force on July 29, 2015.

> Waiver of Declaration Requirement for 12-month Grace Period

Under the amended provisions disclosures made by an inventor less than 12 months before the patent filing date will not be considered prior art. Before the amendment, applicants had to submit specific documents in this respect.

Divisional Applications after Notice of Allowance

Previously, a divisional application could be filed only in response to an office action. Thus, once a notice of allowance had been issued, a divisional application could not be filed anymore. Under the amendment, applicants can now file divisional applications after receiving a notice of allowance, up to three months from receiving the notice or until the application is registered, whichever is earlier. This eliminates the need to file unnecessary back-up divisional applications, allowing applicants to file applications based on the prosecution outcome of the parent application. The new divisional practice is available for notices of allowance received on or after July 29, 2015.

5. Expedited Examination for "Fourth Industrial Revolution" (4IR) Technologies

KIPO has announced that, under the revised Enforcement Decree of the Korean Patent Act (effective on April 24, 2018), expedited examination will be available for patent applications related to "Fourth Industrial Revolution" (4IR) technologies such as artificial intelligence, internet of things, 3D printing, autonomous vehicles, cognitive robotics, Big Data and cloud computing. The goal is a reduction of the time for examination to about six months (compared to the conventional average of 18 months).

ii. Court Decisions

1. Patent Term Extensions

Numerous generics manufacturers have filed challenges to the validity of patent term extensions ("PTEs") in South Korea over the past few years. In November 2017, the South Korean Supreme Court rejected two of the major validity issues raised, and upheld the validity of numerous PTEs. Since then several Patent Court and Intellectual Property Trial and Appeal Board (IPTAB) decisions were issued in this context, a summary of which may be found <a href="https://example.com/here-ex

In a recent case dealing with PTEs, the Supreme Court (Case No. 2017 Da 245798) on January 17, 2019, held that the scope of the protection conferred by a PTE is not restricted to only the specific salt of the original drug (here: solifenacin succinate) but can be extended to cover an alternate salt (here: solifenacin fumarate).

2. Active Legitimation of Licensee to File Invalidation Suit

The Supreme Court (Case No. 2017 Hu 2819) on February 21, 2019, held that the licensee of a patent is also an interested party that can file an invalidation suit against a patent.

Doctrine of Equivalents

In a decision (2017Hu479) issued December 22, 2017, the South Korean Supreme Court clarified and substantially broadened the scope of the doctrine of equivalents emphasizing a functional approach where deviating structures can still be considered equivalent as long as the differences are conventional and the basic purpose of the invention is still achieved.

4. Assessment of Inventive Step Requires Consideration of the Problem Solved

South Korean courts reviewing patentability and validity typically gave less weight to the specific technical problem the patent-in-suit intended to solve. Recently, there are indications that this view may change in favor of patentees.

This change manifested in the decision in a South Korean Patent Court case (2013Heo1313) of January 28, 2014. The decision is expected to lead to more courts to take into account the unique technical problems addressed by particular patents, which in turn should lead to greater affirmance of patent validity. It is seen that more and more courts in patent cases ask the parties to submit a patent map or other patent landscape analysis to better understand the context in which particular inventions were developed.

5. Construction of Product-by-Process Claims

As previously reported, the Supreme Court of South Korea, in a recent decision modified the court's approach to evaluating product-by-process claims by indicating that only the structure and properties of the product not the process are relevant to a patentability inquiry, without exception. However, the court has also stated that all descriptions in a patent including those in relation to the process recited in a product claim are relevant when defining the structure and properties of the final product. Thus, presumably, the process must still be considered when assessing novelty and inventive step of a product-by-process claim.

This decision resolves a number of inconsistent previous Patent Court decisions.

6. Patentability of a Dosage Regimen

As previously reported, the South Korean courts have long held that a known drug treating a known disease with a new dosage regimen is unpatentable subject matter. In a significant *en banc* decision, the Supreme Court reversed this precedent, thereby settling the debate on this aspect of South Korean patent law.

D. Forums or institutions to look out for

As a general note, all the organizations, legislative and official bodies mentioned above are worth keeping an eye on.

E. ICC initiatives relevant to this specialty

As in the past, ICC will engage with organizations, such as WIPO, patent offices, such as the EPO and the USPTO, and governments to provide input to their projects and initiatives. Examples in the field of patents are:

- 1. Participation in the WIPO SCP sessions.
- 2. Continuation of the dialogue with the EPO and other patent offices.

As in the past, ICC will strive to create awareness and understanding of the importance of patents to the economy. This will happen by corresponding initiatives but also by publications such as the IP Roadmap.