Debating access to medicines

Contrasting viewpoints on the role and impact of IP rights on access to medicines were expressed in a panel during Pharma Day yesterday. The issue was discussed in the context of the 2016 UN High Level Report on Access to Medicines and the issues it explores relating to increasing access in developing nations and regions around the world.

“In my view this report has some problems, beginning with the assessment of the legitimacy,” said Roberto Ribeiro of Sanofi in Brazil. “Not only with the people who participated but also the lack of a more holistic view in terms of approaching the real issues in the lack of access to medicine.”

Ribeiro noted that 95% of the medicines that are considered essential by the World Health Organization are off patent. “So you are talking about only 5% of medicines becoming a problem, and that problem may not necessarily be linked to patents,” he said, referencing taxes, distribution and other areas.

“So if you look at the overall picture – the forest, not the trees – you will see there is an evolving system towards progressing and improving the conditions. In fact, it is a concern on the industry side to always discuss access and to seek new medications. But the single minded view that was brought up by this report really needed a holistic view.”

Tahir Amin of I-MAK in the US had a more negative view of the role of IP. He said the report is a culmination of a problem that has been existing since the enactment of TRIPS. “I think just to attack the report on the basis that it is distorting or contorting the basis is a bit disingenuous. What it does is actually captures some of the heated debate that has gone on in the last 20 years around access to medicine,” he said.

Amin said that IP practitioners wanting to take IP out of the conversation around problems accessing medicine serves to “stoke fear instead of taking part in positive and constructive debate”. He added: “The IP community should take it upon themselves to try to address those imbalances or else we lose what is positive about the system.”

The issue of evergreening of medicines was discussed, with Amin giving strong criticism. He said companies try to keep the patent cliff as far on the horizon as possible, such as through taking an old formulation off the market and putting a new one on (known as product topping in the US). “The argument in response to that is, ‘Well you can just use the old drug.’ Well, unfortunately marketing doesn’t work like that because what drug companies do is tell the doctors to prescribe the new version. So the patent system enables the marketing system,” said Amin.

He added: “To say there isn’t a problem with evergreening is disingenuous. I get it: it is how medicines work. Companies want to maintain their monopoly. But it is also distorting what I think of as the true potential of the patent system. As lawyers we are all responsible for it. Not just the pharmaceutical lawyers. It is the lawyers that file these patents. It’s the patent examination systems that are designed to try and curb these kinds of patents but either don’t have resources or have incentives in the wrong place because patent offices are designed to grant patents.”

Amin said US examiners only have 18 hours to examine a patent. This means the issue gets addressed through litigation. He added 68% of secondary patent are invaliditated when challenged, while a further 15% have patents. It’s the patent examination systems responsible for it. Not just the pharmaceutical companies, but the USPTO from 25 to 15 months.

María Holtman, USPTO representative, introduced another accomplishment of IPS: the Global Dossier, which can be used as a single point of access for all patent information from IP offices around the world. It removes language barriers, and allows applicants to receive alerts with any change in their patent’s status.

Holtman said applicants often ask if offices can look at collective prior art. She revealed: “We’re looking at it, and we’re going to convene in November this year to look at practical solutions to see if we can reduce the burden on applicants.”

Bo Li, SIPO representative, updated the group on IPS’s Global Classification Initiative, which focuses on harmonising internal classification schemes and adapting them to emerging technologies such as AI, 3D printing, and others.

Rigopoulos shared some other goals: “We’re looking into ways we can reduce workload and costs for all of you filing applications. We will also continue to attach great importance to quality, and to continuously improve timeliness. Last but not least, we will improve coordination of our activities with stakeholders.”
London calling in 2019!

With this year’s Congress finishing up today, you may already be wondering what you will be getting up to at next year’s event. The 2019 Congress will take place in London from September 15-18.

The Queen Elizabeth II Centre is located opposite the Houses of Parliament in Westminster, and within easy walking distance of numerous hotels and centrally located attractions.

The host group is already busy working on putting together a great event. “London 2019: What’s not to like?” says Justin Watts, President of the UK Group of AIPPI and Partner at WilmerHale. “The UK group looks forward to welcoming everyone to the London 2019 Congress, and to sharing with them all the IP, legal, business and cultural opportunities that London and the UK offers. The London IP community is a diverse, forward looking, creative and open group, and growing rapidly. We’re privileged to have a close and continuous dialogue with our government, IP office, judges, financial community, authors and creators, users and consumers and the AIPPI Congress will be a great opportunity to see that network of stakeholders in action.”

Watts promises the event will be a great opportunity to deepen knowledge of IP, push the policy agenda forward, and develop contacts and business in one of the world’s greatest business cities.

“We've had a fantastic time in Cancun, enjoying the hospitality and vitality of the Mexican group,” he adds. “London, which is a vibrant, diverse and welcoming city, is the perfect place to build on the great success of the Cancun Congress. We can see how AIPPI is rejuvenating, for instance with more younger members, and we look forward to taking that further next year.”

Keep calm and Congress on

The timing of the London Congress is interesting, to say the least, with Brexit occurring in March next year and (potentially) progress on the Unified Patent Court.

“This is likely to be one of the first global conferences in the UK, post Brexit,” says Calum Smyth, Chair of the London Planning Committee and Global Head of IP at Barclays. “Given AIPPI’s spirit of collaboration, it provides the perfect setting to work together with our international members on further harmonising laws across numerous countries and trading blocks. The conference will take place against a backdrop of a vibrant and innovative London – a city that supports creative arts and technology companies alike – from the West End theatre district and the BBC to a thriving software and FinTech community.

“London is a major business centre and home to many global law firms so delegates can usefully combine AIPPI activity with business meetings before and after the conference.”

The timing of the Congress provides a good opportunity for the UK IP community to underline its relationships with AIPPI members around the world.

“The Brexit vote shook the IP profession across the UK and Europe,” says Annsell Merelle Ward, Member of the London 2019 Planning Committee and Senior Associate at Bristows and IPKat. “Immediately after the vote, UK IP professionals made clear to our European colleagues that our close bonds would not waiver despite the outcome – but that they would grow stronger. AIPPI Congresses do a huge amount to promote and foster these global connections across our close IP community. Hosting the Congress next year in London gives the UK a fantastic opportunity to showcase that, irrespective of the ongoing politics, the UK is a dynamic global hub of technology and creativity, with a strong IP profession that celebrates our robust ties with our global IP colleagues and friends.”

She notes that London is steeped in IP, having been the heart of science and creativity for centuries. “Attendees will be able to walk the historic winding lanes and alleyways of an ancient city that gave birth to the Statute of Anne and the Statute of Monopolies – the foundations of IP systems throughout the world. What better place to host the high calibre of IP debate and development that is the hallmark of the AIPPI Congress?”

“The London Planning Committee has been hard at work helping to plan a spectacular and exciting Congress for attendees. We have some exciting plans up our sleeve which we look forward to sharing when we welcome you all to London next year!”

Biosimilars: do you wanna dance?

The Biologics Price Competition and Innovation Act in the US, which created a pathway for biosimilar approval, is still in its infancy. Recent years have seen litigation start to provide some clarity on the Act’s complicated provisions, however, with about a dozen biosimilars being approved so far.

Many questions remain. During the biosimilars panel of yesterday’s Pharma Day, Mark Stewart of Eli Lilly discussed one important consideration: whether to engage in the so-called patent dance – a schedule of steps under which both parties may disclose and exchange certain information relating to potential patent disputes once an application has been accepted by the FDA.

“If the statistics are an indication, I think the ones dancing are having more fun,” said Stewart, who has seen 70% of applicants actually choosing to participate in the dance, most going all the way through and some doing at least the initial steps.

One reason an applicant would choose to dance is that with biosimilars there is no list of patents that an applicant can look at to determine if they have an issue, unlike the Orange Book with small molecules. “So the only way an applicant can really get an indication of the entire patent state that a product sponsor may serve against them is to participate in the dance, send the product sponsor their application and additional information, and then get a list of patents. If there are a lot of patents at issue it may be to your benefit to dance,” said Stewart.

Reasons not to dance include if there are only a few patents at issue or if there are many secondary patents that are low hanging fruit. “There is also some concern about all the disclosure requirements and playing your hand early,” said Stewart. “I think that eventually all comes out but there may be a reason you would want to hold that back, maybe settlement discussions.”

Neil Trueman of Mundipharma gave the European perspective. “In Europe there is no patent linkage-type system. For a biosimilar patent or biological patent you are going to fight it in pretty much the normal way as for any other patent battle – small molecule or indeed in other fields. You are depending on your permanent injunctions to keep your exclusivity.”

Tips for creating winning surveys

It is possible to create an international standard for survey methods in trade mark cases? This is the question a panel of survey experts and judges tackled at a panel yesterday afternoon. It will also be considered by AIPPI and various national groups over the coming months, because it is a study question for next year that will hopefully be transformed into a resolution in London.

Yesterday’s discussion may give them a headstart with the questions. In some courts, like Argentina, survey evidence is inadmissible because experts often don’t agree, and it can seem like the value of surveys is not worth the cost of time and money. On the other hand, “Surveys can be the most powerful pieces of evidence, if conducted properly,” asserted the EUIPO’s Ricardo Nunes Ferreira.

Still, the panel agreed that if surveys are submitted as evidence, they should always be complemented by other evidence. Judge Jian Li, from China’s Supreme Court, added: “Surveys should not be the only proof; and they are subjective, so the court is sceptical. In my view, the ultimate issue is not admissibility, but rather weight.”

The weight given to survey evidence is highly variable, depending on jurisdiction and individual judges. Justice Henry Carr of the UK High Court shared his stance: “I don’t feel likelihood of confusion surveys are terribly useful, and with enhanced distinctiveness, I generally feel I can work it out for myself. But it’s a shape or a colour, I think surveys could be of considerable value to see if people really see it as an indicator of origin.”

Almut Pflüger, a survey expert, gave some guidelines for creating surveys that stand up in court: appropriate survey method (face to face is better than online); correctly defined relevant public (as narrow as possible); representative sample (keeping in mind age/race/sex/gender/consumer habits); sufficient sample size (1,000 for most litigation, 1,500-2,000 for the Trademark Office); coherent, unbiased questionnaire written by a neutral third party; and an independent, well-reputed research institute undertaking quality interviewing.

Pflüger said: “Surveys should help judges and juries get a sense of what the public thinks, but they should keep in mind it’s only one piece of the whole puzzle.”
Is the US or Europe the weakest link for copyright cases?

The good news is that the panelists at yesterday’s morning “Linking into the digital era” session were optimistic that the case law in this area is heading in the right direction. The bad news is that this positive trend could easily be derailed.

In recent years, courts on both sides of the Atlantic have struggled to balance copyright owners’ rights and internet users’ freedom of information and expression in the context of linking. Linking is a broad term inclusive of embedding, deep linking, hyperlinking and framing.

US case law on copyright and linking goes back to the 2007 case Perfect 10 v Amazon, in which Perfect 10 sued Amazon for violating its display right because Google displayed thumbnails of its images in its search results. The Ninth Circuit found that presentation of images not stored on Google’s servers was fair use, and the “server test” was born.

Two important cases since then have rejected the server test: Leader’s Institute v Jackson (Northern District of Texas, 2017) and Goldman v Breitbart (Southern District of New York, 2018). In the Leader’s Institute case, the court reasoned that the Copyright Act does not make possession of the infringing work a requisite for infringement.

Goldman emphasised the difference between the facts in Perfect 10 in which Google’s “display” simply helped users navigate to the copyright owner’s website, and the facts in this case, in which each defendant took steps to ensure that the images were viewable on their pages. The court found that this constituted a “process,” which is covered by the Copyright Act and constitutes infringement.

At the moment, these differing circuit court decisions stand. Ken Adamo, partner at Kirkland & Ellis, thought it was unlikely the Supreme Court would take up the question, particularly right now. In the meantime, forum shopping is an option, which Adamo called “one of the few advantages of litigation in the United States.” When personal jurisdiction is available, Adamo recommended: “If you’re a rights-owner, go to New York or Dallas. If you’re on the other side and you want the server test, you can file a declaratory judgement to get yourself in the Ninth Circuit.”

Adamo said the situation is “stable for now,” though harmonisation between the circuit courts would be desirable. The Supreme Court could theoretically pick it up, but more likely the Ninth Circuit could change its mind. While the panel of judges may not directly contradict its precedent, it might be able to argue they should use the test from New York if the fact pattern is different enough from Perfect 10.

Both Leader’s Institute and Goldman were decided on summary judgement, so the issue has not yet reached a jury. When that happens, Adamo believes the rights-holder has an advantage with an American jury, particularly in cases with uncertainty or complicated facts. However, he warns: “If you get past summary judgement and people listen to what’s happening in Europe, the law could shift unexpectedly.”

EU copyright law on linking is very different from US law. Stefan Naumann, partner at Hughes Hubbard & Reed, explained: “They don’t get into the technical setup of the system to transmit copyrighted works; they get into the weeds of copyright law itself.”

The laws are found in Articles 3 and 5 of the EU Copyright Directive, which include a provision that the right to prohibit communication to the public is not exhausted the first time it is used. This is important to the nature of the internet.

In 2018, the CJEU decided two cases – Svenson and BetWater – which established that hyperlinking, framing and embedding do not require authorisation of the copyright owner because they are not considered a “communication to the public.”

While these two 2014 cases have not been directly overturned, the six CJEU cases between 2016 and 2018 have taken the law in a different direction, and each have improved upon the former. “All of these cases find a rule that the next case – deliberately or inadvertently – works around, and the more current case refines and rebalances it,” Naumann explained. The six relevant CJEU cases are: GS Media, Reha, Widlems, Ziggo, Vust, and Remckhoff.

Without going into the detail of each case, some specific principles that were established in the EU include: providing hyperlinks to copyright-protected content constitutes infringement if the hyperlink circumvents restrictions on the content – such as a paywall – or if it is associated with making a profit. If there is a profit, it creates a rebuttable presumption that the user knew the work infringed.

The most up-to-date status of the law is reflected in the Remckhoff case, in which a German high school student turned in an essay that included a picture of a travel agency she had downloaded online. The school published it on its website. The photographer saw the post, and sued the school for €400. On appeal, the photographer was awarded €300. The photographer wouldn’t accept it so the case went to the CJEU.

The court found that, because the student had downloaded the photo and reuploaded it instead of simply linking to it, a disconnect was created between the photographer’s original publication of the photo and the school’s subsequent publication on its website. Because the photographer had been deprived of control over their work via this disconnect, the photographer won the case.

“Not to be facetious,” Naumann said, “but you really do need to consult a lawyer if you’re doing business in the EU that has to do with communicating to the public, because it is complicated and evolving.”

Naumann concluded: “Even though the court’s reasoning doesn’t necessarily work the way IP should work, it does stand its ground. They are consistent, and working toward a solution. Despite everything, I’m optimistic.”
The shape of marks to come

There is also a consumer protection element to why 3D marks are important to protect; if shapes are not protected, consumers could be misled about the origin of the products they buy. For these reasons, 95% of the Study Question respondents agreed that 3D shapes should be registrable.

However, problems that applicants for 3D trade mark registrations most often run into are distinctiveness and functionality. It has been very difficult for 3D trade mark owners to prove shapes' distinctiveness, which is defined as indicating products' source to the average consumer.

The EU has said in its case law that average consumers are not used to making assumptions about the origin of products based on their shape. Verschuur says that in their reports for AIPPI, many groups agreed that "a reevaluation of this assumption would be very welcome". Specifically, 90% said 3D shapes should be inherently distinctive or be able to acquire distinctiveness.

Functionality is the most common ground for refusal and invalidity for 3D marks. If a mark is "exclusively functional," it may not be granted a registration. This language has been interpreted strictly so far, but there is room to open up. For example, the shape of Lego's building brick was invalidated in the EU on functionality grounds. Later, Lego's figurines were successfully registered despite their technical function because parts of the figurines were not functional.

Rights holders can run into a competition issue when their 3D mark is functional in some way, because shapes often serve a functional purpose that competitors may need to emulate. Another exclusion ground for 3D marks in the EU is if the shape results exclusively from the "nature of the goods". Some 85% of respondents agreed that this should continue to be a ground for refusal and invalidity, although the French group commented that it is difficult to define because a shape resulting from the "nature of the goods" will often be either functional or not distinctive, as it has the same shape as other goods. The UK group also found this ground to be redundant.

Another exclusion ground for 3D marks is if their shape is exclusively necessary "to obtain a technical result". The vast majority agreed that marks should be refused or invalidated on this ground without much controversy.

The French group commented that the substantial value ground should be eliminated. The substantial value invalidity ground should be eliminated.

There was no consensus in respondents' reports on which exclusion grounds should be overcome by acquired distinctiveness. In many jurisdictions, exclusion grounds apply even when a mark has been found to be distinctive. The EU Trademark Directive, for example, specifies that grounds for refusal and invalidity cannot be overcome based on acquired distinctiveness. But this is not always the case. In Australia, for example, it is possible for a 3D mark to be valid based on acquired distinctiveness even in the presence of functionality because the test is about an "inherent capacity to distinguish".

Specifically, Verschuur anticipates clashes around "to what extent it should be possible to overcome the 'nature of the goods' and 'substantial value' refusal/invalidity grounds through acquired distinctiveness."
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DUBAI (UAE)
Suites 401-402, Al-Hawai Tower Sheikh Zayed Road, Dubai
Tel: +971-4-3437 544
Fax: +971-4-3437 546
Email: Dubai@UnitedTm.com

JORDAN (Amman)
Suite 7, 2nd Floor Chicago Building, Al Abdali
Tel: +962-6-5630888
Fax: +962-6-563089
Email: Jordan@UnitedTm.com

LEBANON
6th Floor, Burj Al-Ghazal Bldg., Tabaris, Beirut, Lebanon
Tel: +961-1-21 5373
Fax: +961-1-21 5374
Email: Lebanon@UnitedTm.com

OMAN
Suite No. 702, 7th Floor Oman Commercial Centre, Ruwi
Tel: +968-24-787555, 704788
Fax: +968-24-794447
Email: Oman@UnitedTm.com

QATAR
Villa # 40, Al Amir Street Al Mirdas Area, Doha, Qatar
Tel: +974-444 3083, 444 3093
Fax: +974-444 7311
Email: Qatar@UnitedTm.com

SAUDI ARABIA
Behind Maktaba Al Shawwaf
30th Street-Olaya, Riyadh 11444
Tel: +966-11-4616157, 4655477
Fax: +966-11-4616156, 4622134
Email: SaudiArabia@UnitedTm.com

OMAN
58, Rue Ibn Batouta, PPT. No. 4, 1 er Estage, Casablanca, Morocco
Tel: +212-522206096
Email: Morocco@UnitedTm.com

SUDAN (Khartoum)
Flat No.1, 3rd Floor, Al Hurraya St. Shalai Al Deen Brothers Bldg.
Tel: +249-183-740634
Fax: +249-183-796031
Email: sudan@UnitedTm.com

TANZANIA
Shauri Moyo Area, Pugu Road Dar-Es-Salaam
Tel: +255-222862900
Email: Tanzania@UnitedTm.com

SHARJAH (UAE)
Suite 203, Al Buhairah Building Buhairah Comiche, Sharjah
Tel: +971-6-5722742
Fax: +971-6-5722741
Email: UAE@UnitedTm.com

SRI LANKA
105, Hunupitiya Lake Road, Colombo 02, Sri Lanka.
Tel: +94 11 4322790-1
Email: srilanka@UnitedTm.com

YEMEN
6th Floor Ideal Clinic Building Hadda Street, Sana’a, Yemen.
Tel: +967 181 9642
Email: yemen@UnitedTm.com
Pressure is increasing on pharmaceutical companies to be transparent about big data, whereas some may prefer to keep it as a trade secret, said Myra McCormack of Johnson & Johnson in the US. She was speaking on the big data panel during Pharma Day yesterday.

“There is certainly pressure for companies like Myriad or Johnson & Johnson or Sanofi to move to transparency with these large databases. There is going to be a lot of pressure on both sides to see how big data is going to be managed for diagnostics,” said McComack.

An example of the problems that can emerge came last week when Memorial Sloan Kettering Cancer Center got bad press after it was revealed it had entered into a relationship with a small start-up company to give exclusive access to many tissue samples it had collected over the years.

Peter Damerell of Powell Gilbert UK said the real potential from big data will come when it starts to be amalgamated into many different areas.

“It is only when you start combining all this data and putting it all in the mix, processing it and coming up with new ways of analysing it that we are going to see the benefit. If companies try to segregate these data sets and try and keep them separate, we are not going to see anything like the promise that is expected.”

McCormack discussed the IP protection implications of big data for pharma. A data set is usually just an anonymised set of data. “You could imagine you could protect it by copyright but I don’t know why you would,” she said. “So I think the dataset itself would likely be protected by trade secret to the extent that there is any value in the data set itself being protected.”

She continued: “What is more valuable would be the algorithms that are created. Then we walk into Alice and more recently Enfish, which limit your use of protection for algorithms, but computer-generated information can still be protected in the US. I think the bigger way we would do this is probably by trade secret and then protecting by patent that output of the dataset analysis. It could be a method for identifying a clinical trial population within these characteristics, for example.”

Damerell noted the issues of ownership and consent will become increasingly important.

“If we are able to move forward in this area it has got to be with the consent of the people whose data is collected,” he said. “I am not sure it matters whether they own it as long as they are aware that it is then being used for these types of drug development and diagnostic studies. I suspect at the moment there might be quite a lot of pushback on that. People have some scepticism of the motivations of the pharmaceutical industry in gaining this sort of data, and whether it is really for the general well-being of the world or whether it is more commercial, and I think people have huge scepticism with technology companies.

“We are trying to get to a situation where people would be comfortable with that data being used, almost certainly in some kind of anonymised way, to try and come up with more and better drugs. And I think if we try and do that without the informed consent of those people, it is going to get very messy very quickly.”
Meet the new Executive Director

Arno Hold reflects on his first few weeks at AIPPI, and how his background has prepared him for the role

How is the new job going? After officially starting at the end of August, I have been involved in the final part of the preparation for the 2018 World Congress in Cancun together with the excellent and hard-working General Secretariat team in Zurich. Furthermore, I have received a lot of help from an extremely supportive Bureau. As you can imagine, I am on a steep learning curve. But so far, everybody is extremely supportive in this uphill battle, and they all do it by reaching out their hands, not by pushing me upwards.

What attracted you to AIPPI? The Executive Director role caught my interest as it allows me to apply both my interdisciplinary background in IP protection as well as my experience in international multi-stakeholder management. AIPPI is different from other professional associations as it does not focus on lobbying but on providing substantive output to current and future issues in the IP world.

Where do you see future challenges for AIPPI and/or the global IP system? Today's globalised and interconnected world is characterised by volatility, uncertainty, complexity and rapid technological changes. These changes will have a radical impact on the existing IP landscape and will pose major challenges for the development, harmonisation and enforcement of IP rights. Within this highly dynamic environment, AIPPI strives to remain a body of IP professionals to which Inter-Governmental Organizations (IGOs), Government Organizations (GOs), Intellectual Property Offices (IPOs), relevant trade and business organizations and other Non-Government Organizations (NGOs) turn for expertise, guidance and support.

What do you see as your biggest challenges in your role? One of the major tasks will be the implementation of the Strategic Plan for 2017-2020, which includes, among others, the continuous improvement of the quality and impact of AIPPI’s Annual Work Programme as well as an increase of the level and quality of member services. Moreover, AIPPI strives to pursue a targeted membership growth, with a particular focus on recruiting young members and members from industry. The General Secretariat will coordinate closely with our National and Regional Groups to apply state-of-the-art communications and marketing tools. AIPPI will further strengthen its external relations in order to raise awareness and increase the visibility of its work.

The responsibilities of the Executive Director will include the following. Firstly, he will closely coordinate with various AIPPI bodies to implement AIPPI’s strategy and policy decisions. Secondly, the Executive Director will further develop AIPPI’s relations with external partners in the IP world. This includes international and regional IP organisations such as the World Intellectual Property Organization (WIPO) the World Trade Organization (WTO) and the European Patent Office, but also national Intellectual Property Offices (IPOs), trade and business organisations as well as NGOs dedicated to IP protection. Thirdly, the Executive Director will play an integral part in supporting AIPPI’s National and Regional Groups.

How much progress has been made on the 2017-2020 Strategic Plan so far? The Association’s Strategic Plan 2017-2020 has been established over the last years. As a next step, the overall objectives in this Strategic Plan have to be prioritised, and further broken down into tangible goals, clear responsibilities, properly sequenced milestones, and budgetary impact.

What were you looking forward to at the Congress? This Congress is a unique chance for me to meet with as many members, national and regional groups and external stakeholders as possible. I can only commend the Mexican group as well as all other involved partners for the excellent organisation of this extraordinary event. Personally, I look forward to the closing dinner and hope nobody will show up in a “white tie” dress instead of wearing the traditional Guayabera.

Interview
### TODAY’S SCHEDULE

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### SAVE THE DATES!

Details of upcoming AIPPI World Congresses:
- London, UK: September 15-18 2019
- San Francisco, CA, USA: dates tbc (2021)
- Hangzhou, China: dates tbc (2020)
- Yokohama, Japan: dates tbc (2023)
- Istanbul, Turkey: dates tbc (2022)