

2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea

2025 FICPI Symposium

Jeju Korea



FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN





FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

Sponsor of the FICPI Korean Symposium





FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

3 April 2025 14:00-17:15



Jordan Y. KIM

Y.P. Lee, Mock & Partners

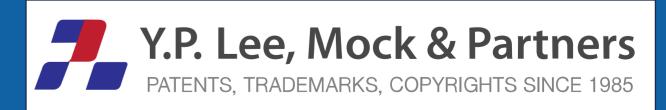
Republic of Korea

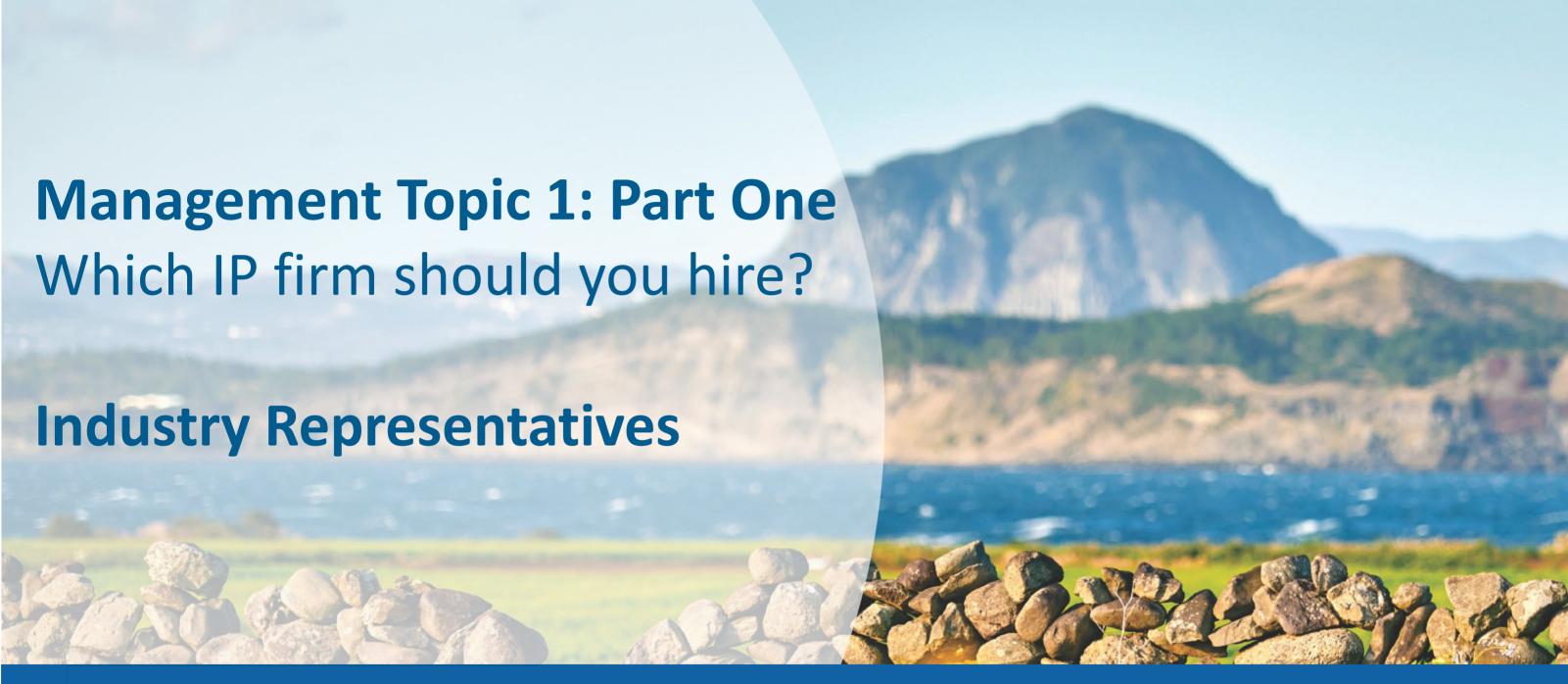


FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN







FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

3 April 2025 14:00-15:30





INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN



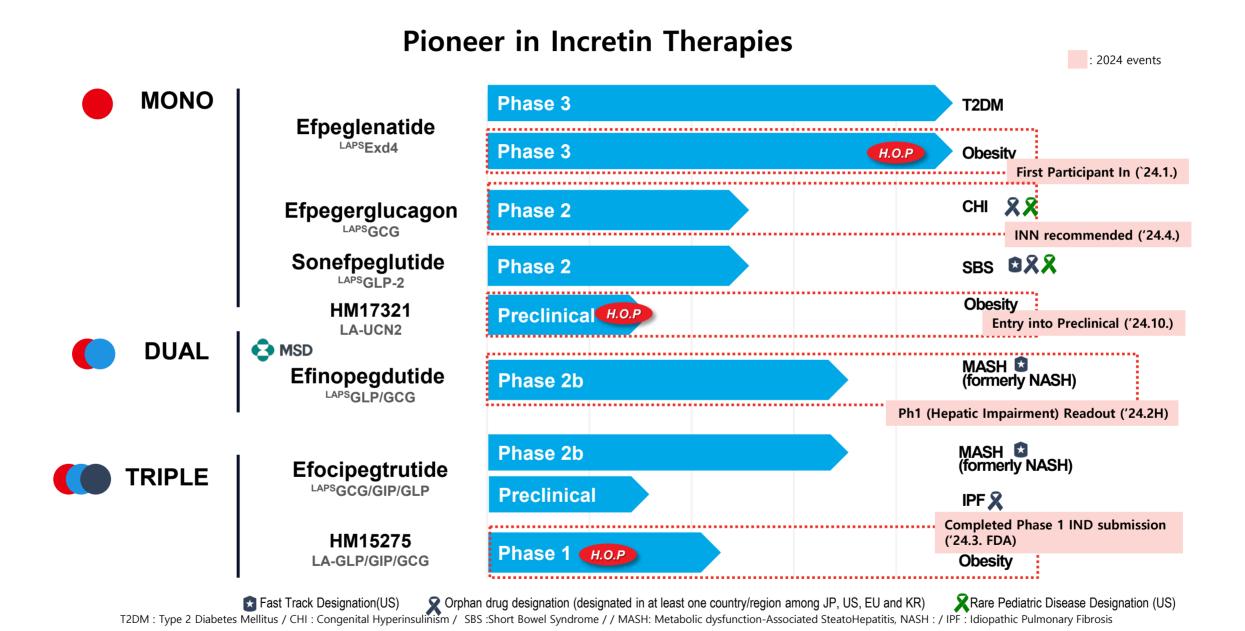
Which IP firm should you hire?

April 3, 2025



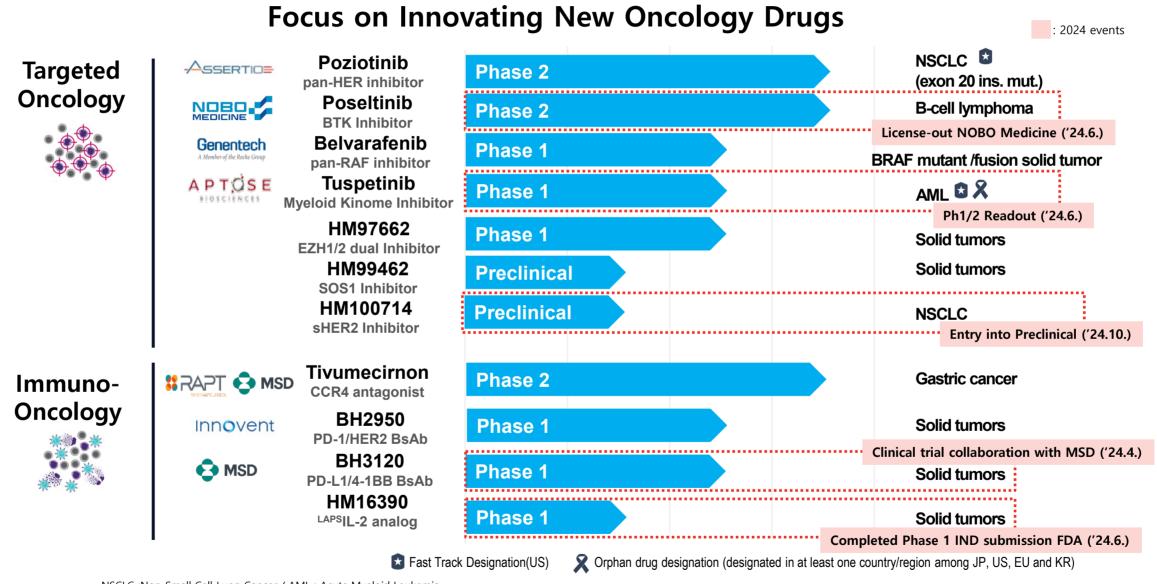
HANMI - Obesity/Metabolism Pipeline





HANMI - Oncology Pipeline





NSCLC: Non-Small Cell Lung Cancer / AML: Acute Myeloid Leukemia

Casual meeting with an IP Firm



Demonstrating Genuine Interest

✓ Researching our pipeline and engaging before meeting



Proactive Engagement

✓ Firms that reach out on significant events foster a sense of partnership

Criteria for Selecting an IP Firm



Reputation

✓ How firms handle crises and assess whether their strengths align with the work
we plan to assign

Expertise and Team Composition

- ✓ The technical backgrounds of key attorneys and ensure sufficient team capacity
- √ Former judges or examiners bring valuable insights into litigation strategies

Quality of Advice

✓ If firms provide comprehensive analyses beyond obvious points

Cross-Disciplinary Knowledge

✓ Firms capable of advising on regulatory matters related to litigation targets are particularly valuable

Working with an IP Firm



Excellent work

- ✓ Delivering high-quality work is the most important thing
- ✓ Accurate, strategic advice

Responsiveness

✓ Firms that engage in near real-time communication—especially those in similar time zones

Proactive Monitoring

✓ Firms that track global developments affecting assigned cases offer substantial added value

Cost Considerations

✓ Excessive time charges prompt reevaluation of the firm relationship

Working with an IP Firm



Understanding In-House Challenges

- ✓ Firms that seek to understand our context, deadlines, and strategic goals
- ✓ Budget-friendly analysis with valuable market insights



Story of ABL BIO



Chapter I. Overview of ABL Bio's Business and Technology

Chapter II. Defining the respective roles of inhouse attorney vs external counsel

- I. Patent prosecution
- II. Patent Portfolio management (disclosure risk management)
- III. Licensing Agreement
- IV. Due Diligence

Chapter III. Which IP firms we select, and how we collaborate with them



Chapter I.

Overview of ABL Bio's Business and Technology



2016.02 **Established**

2018.12 Listed in KOSDAQ

7+ **Clinical Pipeline**

> 400+ **IP** assets

Core Business Domain

1/0 & CNS

- · Unmet Medical Needs
- · Mega Deal Size Market





Platform Strategy

Bispecific Antibody



- Grabody™ T Platform
- Grabody™ I Platform
- Grabody™ B Platform





Open Innovation



Integrated R&D Team



Early Licensing-out

Business Strategy

Rapid Growth & High Return

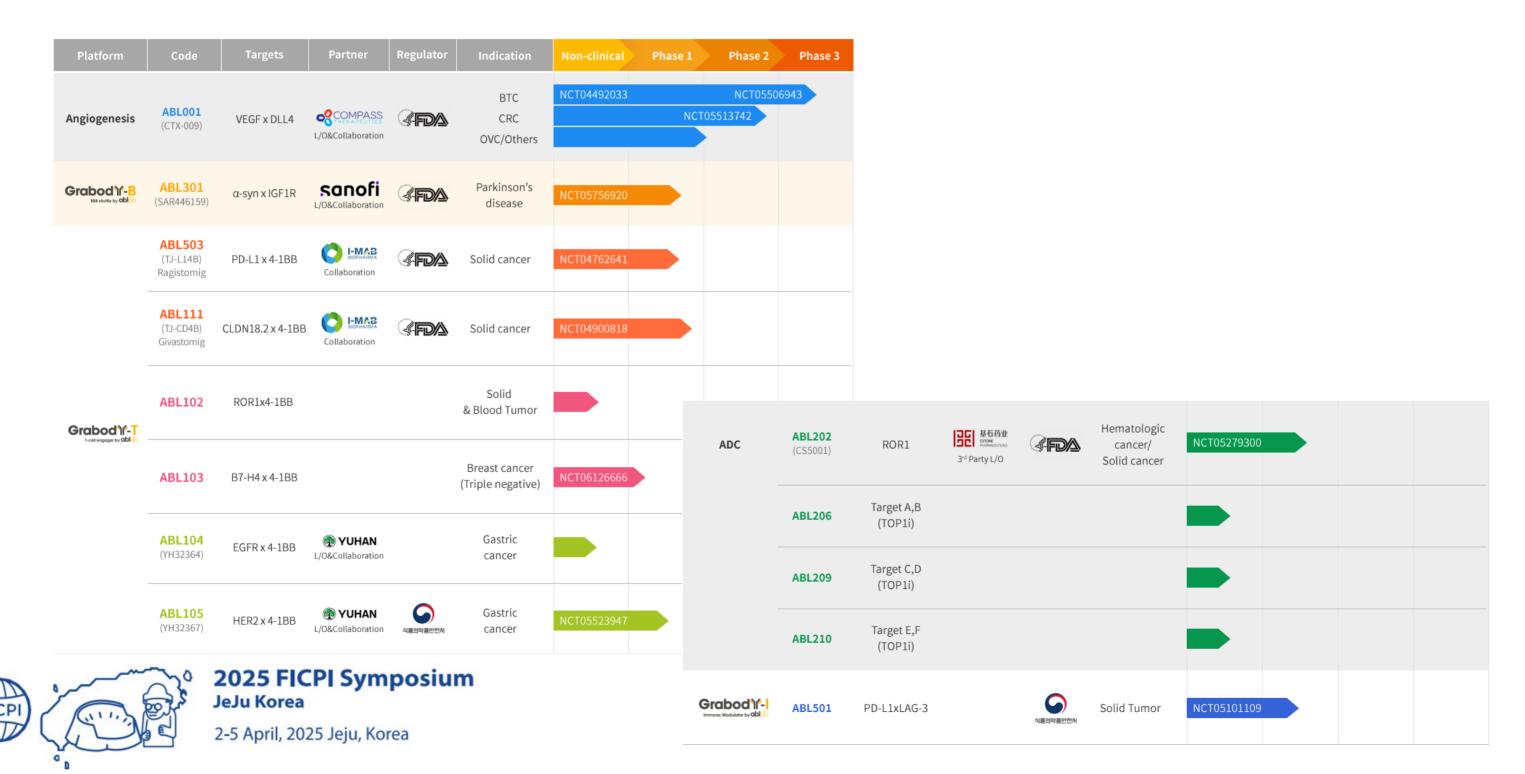
- · Financial Stability
- · Minimizing Risk
- Innovative Pipelines



2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea

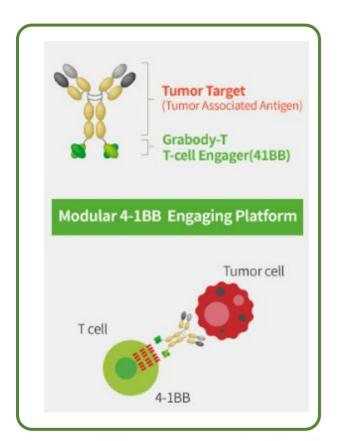






Grabod Y-T

 ABL Bio's 4-1BB antibody technology is a platform technology capable of generating various bispecific antibody-based immuno-oncology therapeutics.

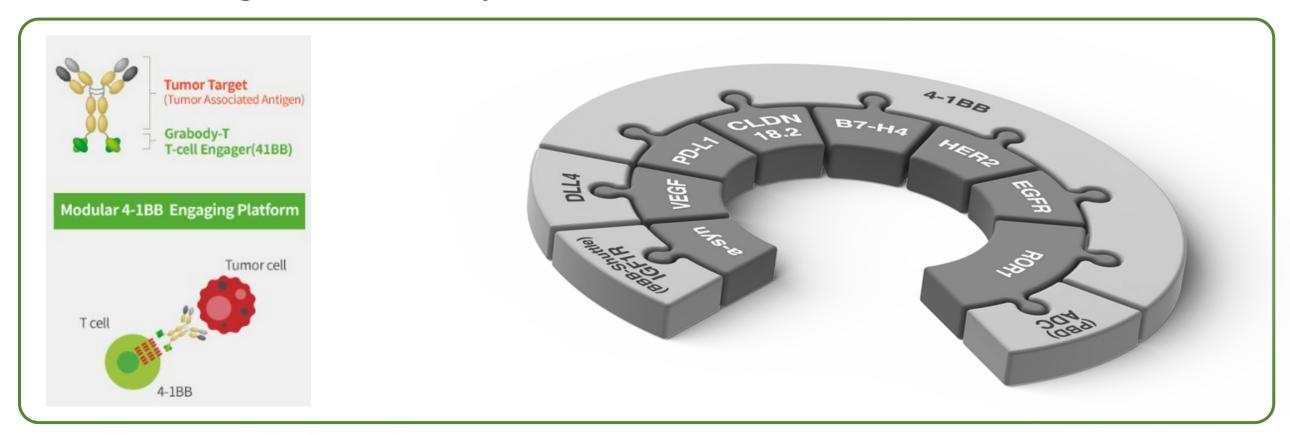


- An IO (immuno-oncology) platform based on 4-1BB agonistic
 antibodies combined with tumor-associated antigen (TAA) antibodies
 in a bispecific format.
- This format of BsAb is engineered to **trigger T cell activation only** when TAAs are present in the tumor microenvironment.
- This MOA is expected to mitigate 4-1BB related toxicity (Preclinical data suggests tumor suppression by Grabody™ T).



Grabod 1/-T

- Targets 4-1BB in the TME (tumor microenvironment).
- TME dependent 4-1BB activation.
- Various target combination potential.

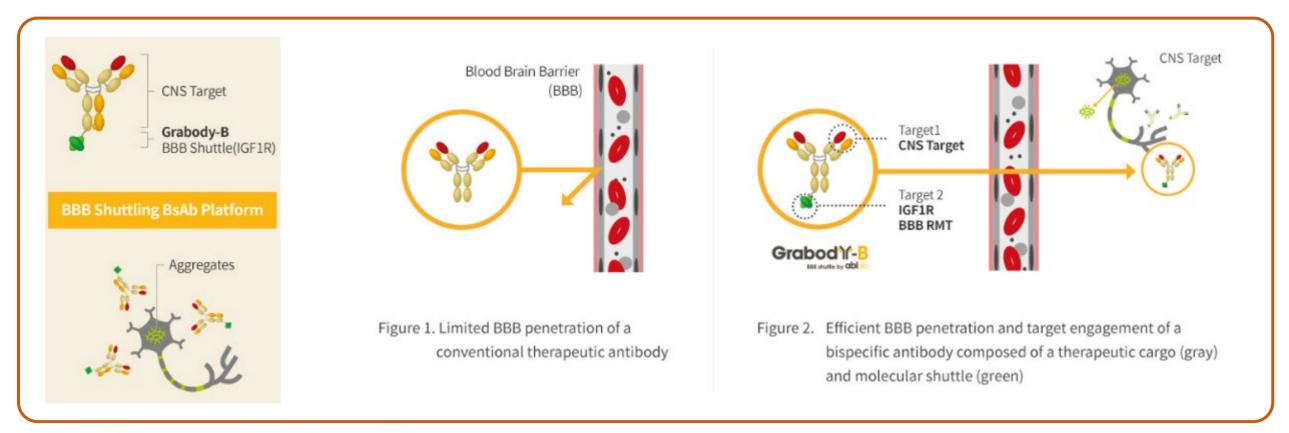






Grabod\('-B

- Targets IGF1R protein in the brain.
- Designed to overcome BBB-penetrance challenges of traditional antibody.
- Applicable for various neuro disease associated pathogens







The Business Direction of ABL Bio:

- Licensing out of platform technologies and drug candidates at pre-clinical or clinical stages
- Partnering with leading global pharmaceutical companies
- Utilizing early-stage publications and disclosures to facilitate strategic collaborations



Challenge arising from Platform/Partnering Business

- A series of similar patents under genus (overlapping subject matter).
- Obviously, this genus/species situations creates doble patenting challenges.
- From an in-house perspective, early disclosure further complicates the filing and prosecution of subsequent patent applications.
- Needs to file genus patent application first and have the genus patent application goes first in the prosecution.
- Further, joint inventors or assignees (often arising from collaboration) may invite ODP rejection. USPTO may view the later application as an obvious variation of the earlier one.



IP Spectrum across different targets

	Patent Family	Applicant/ Owner	Status
Genus Patent	F1. IGF1R mono Ab	ABL	1 st Priority date
Species Patents	F2. Target 1 x IGF1R F3. Target 2 x IGF1R	Collaboration with Company A	 2nd Priority date 2nd Priority date
	F4. Target 3 x IGF1R	Collaboration with Company B	3 rd Priority date
	F5. Target 4 x IGF1R		3 rd priority date



IP Spectrum in a project's time span

Composition-of-matter patent (covering Antibody)

Composition-of-matter patent (covering Product)

Method of use (covering dosing regimen)

Method of use (covering biomarker)

Method of use (manufacture)

Formulation



2025 FICPI Symposium JeJu Korea



Implications for hiring outside counsels (ABL's perspective)

- Leveraging its platform technology, ABL creates diverse improved technologies.
- Comprehensive IP consideration matters across the full scope of R&D and business; prosecution, due diligence, and partnering transaction.
- ABL engages outside counsel based on platform or grouped projects with shared technical aspects.
 - Several IP firms for respective platforms or groups.
 - Long standing relationship allows them to deepen understanding of ABL's technology and business strategy.
 - Would need to have resources to handle hundreds of patent families in the same group.

Chapter II.

Respective roles of inhouse attorney vs external counsel at ABL Blo

Roles of IP attorney from ABL's perspective



- I. Patent prosecution
- II. Patent Portfolio management(disclosure risk management)
- **III. Licensing Agreement**
- IV. Due Diligence

3.1 Expected Roles for Patent Prosecution



Where inhouse attorney Leads

- Outlines or drafts the specifications.
- Prepares data sets.
- Ensures alignment with company's R&D and IP strategy.

Where outside counsel Leads

- Fills in the missing parts and completes applications.
- Provides guidance on the prosecution trends across jurisdictions.

Common oversights

- Delegating the entire first draft to an external attorney.
- Failing to explain the company's portfolio or strategy.
- Lack of a clear agreement
 on the cost structure.
 (potentially leading to inflated fees
 due to excessive page count)

3.2 Expected Roles for IP related Agreement abliciones



(Licensing, Collaboration, Material Transfer Agreement, etc)

Where inhouse attorney Leads

- 1st round review.
- Hear voices from different departments. (BD, legal, IP, and R&D)
- **Ensures internal** alignments.
- Finalize the review.

Where outside counsel Leads

- 2nd round review.
- Provides guidance on specific points (e.g. areas that requires specialized expertise).

Common oversights

- A purely legal-to-legal review (lacking IP, R&D, or BD perspectives).
- Failing to define key objectives and areas for compromise (which could lead to a no man's land or a deadlock).

3.3 Expected Roles for IP Due Diligence



(inhouse attorney responding to IP DD request, as potential licensor)

Typical IP DD request inquires:

- Lists of Patents
- Chain of ownership, Existence of true inventorship
- Territories covered or to be covered by the patents
- FTO analysis (infringement aspect)
- Any 3rd party rights
 - that are contractually engaged (e.g. any 3rd party having royalty receiving rights?)
 - that are otherwise required for commercialization (e.g. needs additional license?)

3.3 Expected Roles for IP Due Diligence



(inhouse attorney responding to IP DD request, as potential licensor)

Where inhouse attorney Leads

- Drafts the initial response.
- Ensures internal alignments.
 (BD, legal, IP, and R&D)
- Finalize the review.

Where outside counsel Leads

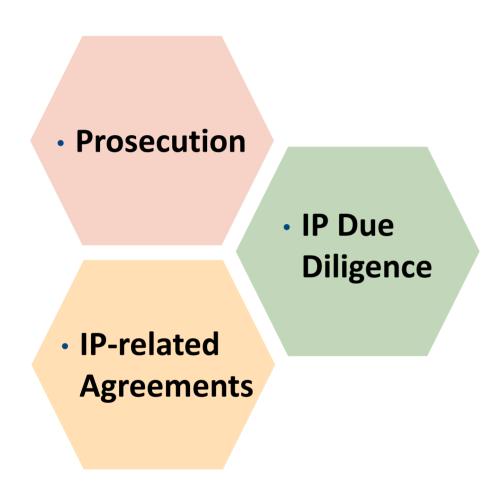
- Reviews and provides advice on the inhouse draft.
- Fills the gaps with thoroughness and objectivity.

Common oversights

- A purely legal-to-legal review (lacking IP, R&D, or BD perspectives).
- Failing to define key
 objectives and areas for
 compromise (which could lead
 to a no man's land or a deadlock).

3.4 Respective Roles – Balanced Approach





- ABL Inhouse sets the frames and ensures alliances with strategy.
- Outside counsels provides high specialty in details and objectivity.
- ✓ While the directions may differ, the expertise of each group is crucial to successful performance.
- ✓ ABL's goal must be a starting point, and effective communication is a key to success.

Chapter III.

- (1) Which IP firms we select, and
- (2) How we collaborate with them





- What is expected at minimum
 - Certain level of technical expertise in biologics (general prosecution practice in main jurisdictions, life-cycle IP management in biologics, etc)
 - Administrative resources to handle a big number of cases under a same patent family.

Group	Technology	National entries
1	Antibody (target A), Composition of matter	10+
2	Modified antibody (target A), composition of matter	10+
3	Bispecific antibody (targets AxB)	10+
4	Method of manufacture	10+
5	Method of use for treating disease A	10+
6	•••	10+

3.2 How we collaborate with IP firms



- Finding a single perfect IP firm is challenging due to rapid technological changes;
 therefore, ABL seeks flexibility and adjustment.
- ABL's entire IP portfolio is divided into several groups, and external attorneys are assigned to each group for management.
- Global prosecution management is conducted through attorneys in Korea.
- For advisory groups, ABL operates several attorney pools, depending on the nature of IP matters or technology.
- Fees are not ABL's primary consideration. ABL first decides to work with a firm if the firm meets minimum expectations, and once ABL finds a good partnership is built, then negotiates the detailed fee structure with the firm.
- The goal is to maximize internal and external collaboration. ABL doesn't expect inhouse roles from external attorneys.

3.2 How we collaborate with IP firms



- Case_#1.
 - ABL engaged a U.S. firm for IP due diligence in connection with a licensing-out transaction.
 - During the process, the firm also drafted a provisional patent application (in addition to ABL's existing patent portfolio), as the need for a new application became evident.
 - Currently, the entire patent portfolio is being managed by the Korea-based IP firm,
 which has been overseeing it from the beginning
 - Working with a U.S. attorney does not necessarily result in a better technical understanding. Ultimately, effective communication is key to deepening technical comprehension, and it is crucial for the in-house patent attorney to lead the process in alignment with the company's strategy.

3.2 How we collaborate with IP firms



- Case_#2.
 - Increasing Trend of ODP Issues in US Patent Applications
 - Lack of clear guidelines for ODP Objection, because ODP is a relatively recent examination trend.
 - Opinions among US agents are not consistent. Nevertheless, prompt feedback and coordination are essential to find the optimal response within the statutory deadline.
 - With a pool of multiple counsels, ABL was able to successfully respond the ODP.





FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

General Requirements/Considerations

☐ PROFESSIONAL EXPERTISE

- Patent Drafting/Prosecution
- Trademarks/Copyrights
- Litigations
- Consulting/Counseling
- ☐ REASONABLE FEES
- ☐ GOOD COMMUNICATIONS
 - Professional & Administrative
 - Solution-Oriented



2025 FICPI Symposium JeJu Korea

Specific Needs & Objectives

- ☐ DESIRED OUTCOMES (NO ONE-SIZE-FITS-ALL)
 - Tailored Legal Solutions
 - Risk Management (vs Risk Elimination)
 - More than Problem Identification
 - Safeguard the Client's Interests Proactively
 - Trusted Business Advisor
- WILLINGNESS TO ADAPT
 - Willingness to Work with the Client's System
- ☐ SPECIFIC BUDGET & COST CONSIDERATIONS

Interviews & Proposals

- ☐ UNDERSTANDING OF THE BUSINESS AND INDUSTRY
 - Tailored for Specific Situations
- NOT AN EXAM
 - OK to Ask
- ☐ CANDIDNESS & TRANSPARENCY
 - OK to Say No
 - No Need to Hesitate to Correct

Ongoing Re-Evaluation

- **☐** WILLINGNESS TO ADAPT
 - Correct or Follow
- ☐ COMMUNICATIONS
 - Solve Together (vs Explain)
 - How (vs Why)
 - Administrative





INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN



Introduction

- KT (Korea Telecom)
 - 1st Landline Operator and 2nd Mobile Operator in KR, having 140-yr history
 - SEPs holders
 - Int'l Filing to secure (potential) Overseas Market and/or for Licensing Business
- KINPA (Korea Intellectual Property Association)
 - Represents over 200 Korean IP Owners
 - Big, med & small sized Members in IT, Elec., Mech., Chem., Pharm., Food, etc.
 - Has Annual Conference in Fall with over 1,000 visitors; the Biggest IP Event in KR





5 Criteria KT uses when selecting IP Firms

Bi-lingual Ability

Reliability

Expertise

Conflict

Price

Fluency in Korean

Reputation; No negligence

Domain Knowledge

Loyalty; Size doesn't Matter

Annually Review: 11 Categories & 25 Check points





Criteria in Details

- Bi-lingual Ability
 - Firms having attorneys who are Korean or Korean descent PREFERRED
- Reliability and Expertise
 - Much Experience with Korean Clients in KT's Subject Matters
 - Good Reputation in KINPA
 - Absolutely NO Client Attrition due to Negligence
- No Conflict
 - Firms having Now NO Competitive Clients in KT's Subject Matters PREFFERED
 - No Need to be BIG; Team Size Sustainable by KT also enough



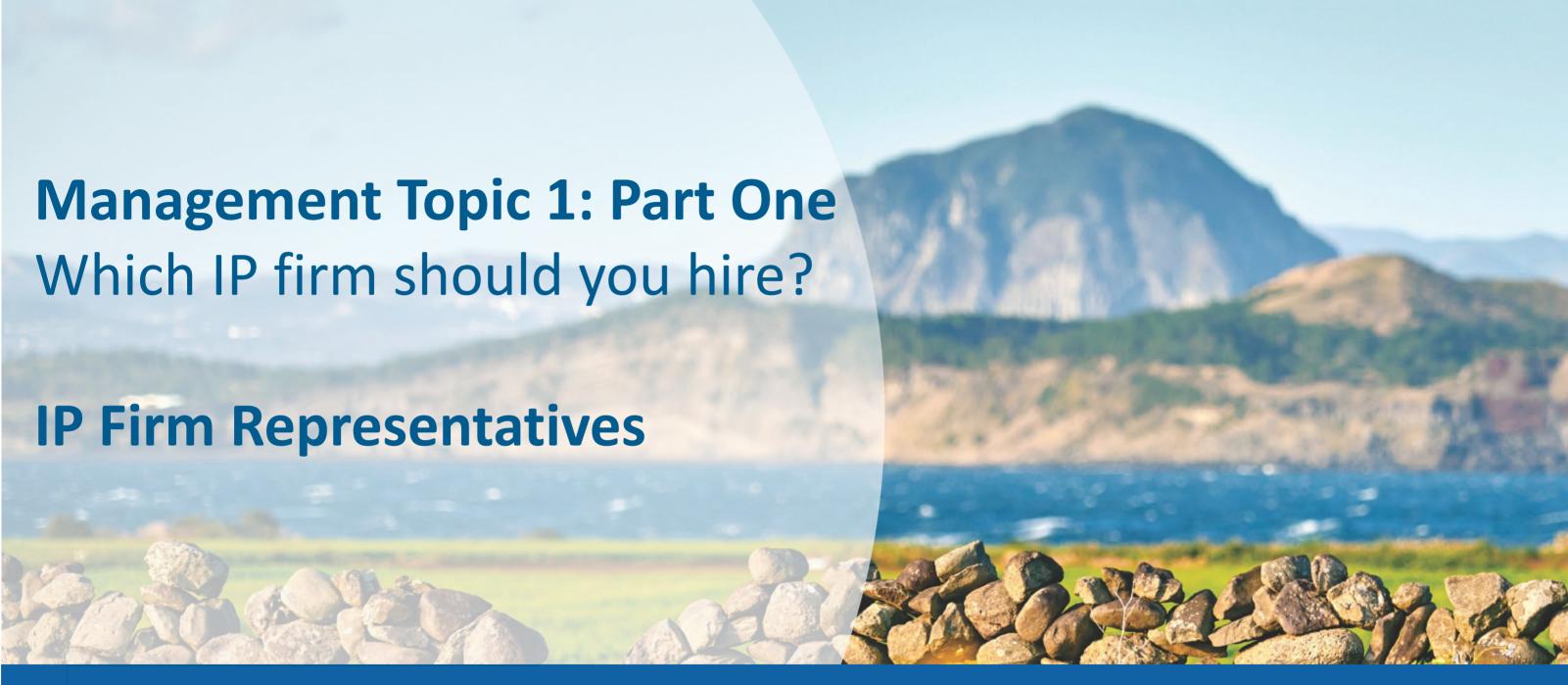


Performance Review

- Yearly Review done by Prosecution Team every January
- Compliance to KT Standard Operation Procedure, mainly regarding Due Dates
- Quality Review pursuant to KT Rules done by In-house Counsels
- Expertise in National Practice and Advanced Consultation is Valued
- Performance over Years Monitored in comparison with Similar Cases of our Competitors









FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

3 April 2025 15:45-16:45







- Meeting requirements from corporate clients in the ESG area
 - What is ESG?
 - Why is this important to IP firms?
 - Our experience
- What effect might this have on who we choose to work with?
 - Clients we want to work for
 - Attorney firms we choose to work with

What is ESG?



- ESG is a framework used to assess an organisation's business practices and performance on various sustainability and ethical issues, providing a way to measure business risks and opportunities in those areas
- Three pillars of ESG are
 - Environment this assesses how a company takes responsible actions to preserve the environment - includes impact on climate change, resource use, energy efficiency, waste and pollution management, and biodiversity conservation
 - Social this is how a company manages its relationships with its employees, suppliers, customers, and the communities in which it operates includes factors such as diversity and inclusion, human rights, labour standards, health and safety, and community relations
 - Governance this assesses the leadership, policies and structures that guide a company's actions
 covers, among others, executive remuneration, board diversity and structure, business ethics,
 compliance, risk management, and shareholder rights

Why is this important to IP firms?



- It is important to ALL businesses!
- Most countries have, for example, carbon neutral strategies
- Many industries are also adopting a similar focus, and requiring this of their suppliers, including law firms

Korea's Carbon Neutral Strategy



The Republic of Korea moves towards the goal of carbon neutrality by 2050. The Korean New Deal will serve as a stepping stone to reach carbon neutrality by 2050. Korea will harness green innovations and advanced digital technologies to create synergies between the Green New Deal and the Digital New Deal, the two pillars of the Korean New Deal. Korea will also take decisive action especially in supporting and investing in the development of innovative climate technologies to achieve carbon neutrality by 2050.

Tackling climate change requires global efforts and collective engagement. Korea will lead by example to help the international community jointly make efforts to reach carbon neutrality by 2050.

December 2020, https://unfccc.int/sites/default/files/resource/LTS1_RKorea.pdf



The Pharmaceutical Industry - PREMIER



VISION

Contributing to a sustainable future by proactively managing the environmental impact of medicines.

MISSION

- 1.Develop tools to identify and predict potential environmental impacts associated with the use of human medicines.
- 2. Explore the feasibility of greener drug design and development with associated guiding principles.
- 3. Develop a framework to prioritise the environmental assessment of existing medicines based on risk.
- 4. Generate environmental data for up to 25 existing medicines based on their potential environmental risk to validate the prioritisation framework.
- 5.Launch an evidence-based transparent, public and easily accessible database collating physico-chemical and environmental properties (ecotoxicity, e-fate) as well as relevant metadata for human medicines.
- 6.Create a novel information and assessment guiding system to support regulators, water managers and other stakeholders in identifying and managing any potential environmental risks associated with the patient use of medicines.
- 7. Provide stakeholder guidance on how to use the PREMIER data, tools and assessment system in practice.







- We were already worked with a global biopharmaceutical company (due to acquisitions of our clients), but in 2019 they wanted to create a small panel of IP firms in USA and Europe to use for all their work
- In our initial conversations, as well as discussing our IP capabilities, they asked about our ESG initiatives, with a particular focus on diversity
- At that time, we were just beginning our ESG journey across a number of areas
 - We had started Inclusion training for all partners and managers
 - We appointed our Chief Diversity Officer, Dr Robert Andrews, in 2022





- As our ESG journey continued, we began to evaluate external agencies that can could help measure our progress, particularly in the environmental space
- In 2021, this same client asked us to submit to Ecovadis (a sustainability ratings agency)
 and to work towards establishing a Science Based Target for CO₂ reduction
- We received our first Ecovadis score and ranking in 2022 Silver
 - The first UK based European IP firm to achieve this goal
- In 2023 we retained Silver, and improved our score to move from the 70th to 83rd percentile of the 90,000 companies evaluated worldwide

Ecovadis



- Founded in 2007, they have grown to be the pre-eminent sustainability ranking organisation
- Their ranking system measures a broad range of areas, not just environmental sustainability
 - Environment
 - Labour & Human Rights
 - Ethics
 - Sustainable Procurement



How did we do in 2024?



Following a huge amount of work in all areas, we received:



How did we do in 2024?



- We scored 81 out of 100
- Top 1% of all 130,000 rated companies and in our category of 'legal and accountancy' worldwide
- One of only 4 legal and accountancy firms to achieve a platinum medal in the UK (KPMG / PWC / Weightmans) and 13 worldwide.





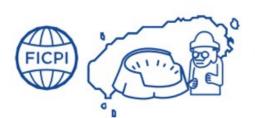
What did we do to achieve this? (1)



- Overall Score (81)
 - Up from 56 in year 1 and 62 in year 2
 - Strong external profile
 - UN Global Compact
 - Strong measures & reporting
- Environmental (90)
 - Carbon Reporting
 - Validated Net-zero targets
 - ESOS
 - Sustainability Champion (Dr Eleanor Maciver, 2022) & Group
 - Net Zero Transition Plan
 - Waste management







What did we do to achieve this? (2)



- Labour & Human Rights (80)
 - Great Place To Work
 - My Learning
 - Career development Frameworks
 - Chief I&D Officer
 - I&D Group
 - Communities Program
 - I&D Programme
 - The HIVE

- Ethics (80)
 - New improved policies
 - Quantitative objectives
 - Cyber Essentials
- Sustainable Procurement (80)
 - New policy & process
 - Strong reporting











Our experience (3)



- Our 2025 contract with this company includes clauses:
 - to disclose Sustainability-related information to the client to enable them to report
 - to take a proactive role to improve out performance in terms of sustainability and that of our suppliers
 - to provide an Ecovadis rating, and if below 45, undertake to improve it
 - to publicly report our environmental actions to CDP Climate annually
 - to commit to Science Based Targets initiative (SBTi) by submitting a letter to SBTi within 6 months and setting a science-based target and will within 24 months
 - to reduce our use of non-renewable and non-recyclable resources and the emission of Green House Gasses from our operations and our supply chain (with specific 2030 targets for reduction
 - to provide diversity data on our company and maximise inclusion of small and diverse owned businesses where opportunities exist, including, for example, those owned by minorities or any others who are socially disadvantaged



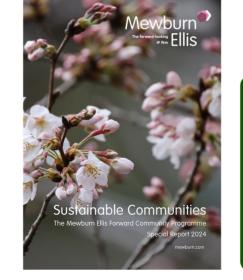


- It has become part of our companies DNA
- Now embodied in two of our mission statements:

Committed to inclusion Passionate about Sustainability

- We are more interested in working for companies who care about our sustainability
- Likely to become a consideration in the attorneys we instruct

Scan this code to read our Sustainable Communities 2024 report











FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

McDonald Hopkins

Agenda

- 1. Introduction
- 2. How are we selected by our clients?
- 3. US IP attorney perspectives: How do we select or foreign agents?





Introduction

My Background

- 25 years in private practice
- US clients
- European & Japanese Clients
- Primarily Large Corporate clients





How are we selected?

Non-Competitive Selection

- Cold Calls and Referrals: Sometimes clients come to us
- Pitches: We are sometimes lucky enough to be given the opportunity to pitch our services through an introduction.

Competitive selection

- Requests for Proposals (RFPs): Occasionally, we are called on to participate in a formal competitive selection process





How are we selected?

Our Experience with RFPs

- We can learn a lot from participating in this process
- What do clients want from their law firms?
- We reviewed about 20 RFPs from the past 10 years to find out.

McDonald Hopkins

Expertise in the Laboratory Industry Generally

Our laboratory industry practice is among the largest of such legal practices in the country. Within the laboratory space, we have provided assistance and continue to serve several hundred laboratories across the country, ranging from some of the largest laboratory providers in the country, to specialty laboratories, to hospital laboratories, to academic medical center laboratories, and to smaller regional or local laboratory providers. Our firm has represented more than 300 clinical laboratories nationwide. We work with clinical, anatomic, molecular/ genomic, toxicology, and specialty laboratory and pathology providers. Our laboratory industry team consists of lawyers dedicated to the clinical laboratory sector. Our professionals are well-grounded in the unique challenges and opportunities applicable to laboratory providers and hospitals providing laboratory services. We also work with national, state, and local professional and industry associations and societies to provide support to such associations and societies, to remain aware of trends affecting pathology providers and laboratories. Our attorneys also serve on the boards of such associations and societies and often engage in thought leadership in the laboratory industry by speaking at conferences, participating in webinars, and writing for laboratory focused publications. Website links to representative though leadership materials can be found at the

Expertise in Laboratory Business Arrangements and Laboratory Compliance

Our firm has extensive experience advising on healthcare-related business arrangements. We have represented laboratories and hospitals in structuring laboratory and/or pathology ventures, provider networks, pathology and laboratory services agreements, and laboratory/hospital affiliations. Our healthcare regulatory team works on every laboratory M&A transaction and focuses on areas such as CLIA standards, state laboratory laws, government and private payor reimbursement policies and billing rules, federal and state fraud and abuse rules and regulations, STARK compliance, and HIPAA rules and

In addition to M&A transactional work, the laboratory industry team has a depth of experience in advising laboratory clients through the life cycle of the business. On a day to day basis the laboratory industry team supports laboratory clients navigating the structure and negotiation of service arrangements, consulting on sales representative training and compensation arrangements, counseling on laboratory billing and reimbursement coverage and denial issues, and out of state licensure considerations with the increased adoption of telehealth and digital pathology. In addition, our team has been involved in more complex projects such as, but not limited to, advising on the establishment of joint venture entities to provide laboratory services, evaluating billing policies and strategy for hospital patient versus outreach patient laboratories, defending laboratories against payment suspensions and DOJ/OIG investigations, supporting laboratories through various ransomware and security incidents, and preparing laboratories for FDA's oversight of LDTs. Members of our team are considered thought leaders and are consulted by industry associations to assist in litigation and legislative strategic planning on matters that are anticipated

One of our key differentiators is that our team includes the perspective of attorneys who have served as in-house counsel for laboratories and hospitals.

mcdonaldhopkins.com



2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea



An inside look: What do clients ask us on RFPs?

We found a wide variety of questions.

- How many total offices does your firm have?
- Who is the proposed attorney team?
- What are the backgrounds/biographies of the proposed attorney team?
- What are your proposed rates (pricing)
- Do you offer discounted rates?
- Do you offer alternative fee arrangements?
- Who will be the primary contact for this engagement?
- What is your customer service approach/philosophy?
- Please provide the address and phone numbers of all your office locations
- Describe your firm's values
- Describe your firm's commitment to diversity, equity, and inclusion
- Which of the following X services does your firm have experience with?
- Provide relevant experience/representative matters related to X services
- Provide an overview of the firm's services (for each specific relevant service)
- How many total attorneys does your firm have (# of partners, # of associates)
- What are other aspects of your firm you wish to highlight for this proposal?
- How does your business align with potential client's mission and operations?
- Describe your firm's approach to staffing a case
- What sets your firm apart from others?
- How would your firm tailor services to the specific needs of the organization?
- How many years has the firm been in business?
- Do you have any known legal or business conflicts that could restrict your firm's representation of potential?
- What systems do you have in place for finance, billing and budgeting, conflicts, What is the average response time for phone calls? docket management, and document management functions?
- Who are the firm managing partners?
- Do you utilize an electronic billing system?
- How is the work of associate attorneys supervised?
- Describe your firm's management structure

- Has any attorney in the firm ever been disciplined by any State Bar association?
- Describe your firm's history
- Describe your firm's pro-bono work
- Does your firm have a formal attorney performance review program?
- Does the firm require diversity training for all attorneys and staff members? (if so, please elaborate)
- Describe the firm's method of assigning work
- Describe your conflict check process
- What are the language capabilities of the firm?
- Does the firm have a disaster/business continuity plan?
- What are the cities and states where attorneys who are members of the area of practice are located?
- Please list all of your licensed courts of admissions firm-wide?
- How do you ensure legal work of a partner is meeting professional standards?
- Has any disciplinary action been taken against the firm in the past X years
- Does the firm have a quality assurance program or peer review process? If so, please explain
- Please provide specific attorney references
- Will your firm use any outside vendors related to this engagement?
- What is your firm's ESG policy
- Do you have licensed attorneys in each state (yes/no)?
- Do you have licensed litigators in each state (yes/no)?
- What is the average response time for emails?
- Does your firm have a special classification? (Woman-owned business, Minority-Owned Business, etc.)
- Provide the firm's organizational chart
- What percentage of your firm's management are either women and/or

minority/diverse?

- What percentage of your attorneys are women? Minority/diverse?
- What is the law school graduation year for each of the members of the proposed attorney team?
- Identify all names the firm has used at any time, including the dates each name
- Has your firm been involved in any recent significant organizational changes (mergers, ownership changes)?
- Is the firm Mansfield Certified?
- For a specific area of practice, how many partners and how many associates?
- What is the current total case volume by practice area?
- What is the average lifespan of a case by practice area?
- Describe the firm's international experience
- Has your firm experienced a recent staff reduction?
- What type of case is the firm most likely to take?
- Does the firm conduct background checks on all employees
- Does the firm employ non-attorneys?
- Does the firm employ summer interns/law students
- Please indicate the size of your staff (by office), indicating full or part-time for each of: Attorneys, Partners, Associates, Paralegals, Law clerks, Secretaries, Other staff, Counsel
- Please indicate how many attorneys and paralegals you have hired over the
- What is the average caseload an associate/partner is responsible for?
- Please explain all physical security at all office locations
- Has the firm ever had a data breach?
- Describe the firm's and individual attorney's social media profiles
- Please provide information about the firm's insurance



2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea



An inside look: What do clients ask us on RFPs?

Some questions were asked more often.

- How many total offices does your firm have?
- Who is the proposed attorney team?
- What are the backgrounds/bios of the proposed team?
- •What are your proposed rates/prices?
- Do you offer discounted rates?
- Do you offer alternative fee arrangements?
- Who will be the primary contact for this engagement?
- What is your customer service approach/philosophy?
- Provide the addresses/phone numbers of your offices
- Describe your firm's values
- Describe your firm's commitment to DEI
- Which of the following X services does your firm have experience with?
- Provide relevant experience/representative matters related to X services
- Provide an overview of the firm's services (for each specific relevant service)
- How many total attorneys does your firm have (# of partners, # of associates)?
- •What are other aspects of your firm you wish to highlight for this proposal?

- How does your business align with potential client's mission and operations?
- Describe your firm's approach to staffing a case
- What sets your firm apart from others?
- How would your firm tailor services to the specific needs of the organization?
- How many years has the firm been in business?
- Do you have any known legal or business conflicts that could restrict your firm's representation of potential?
- What systems do you have in place for finance, billing and budgeting, conflicts, docket management, and document management functions?
- Who are the firm managing partners?
- Do you utilize an electronic billing system?
- How is the work of associate attorneys supervised?
- Describe your firm's management structure
- Has any attorney in the firm ever been disciplined by any State Bar association?
- Describe your firm's history
- Describe your firm's pro-bono work
- Does your firm have a formal attorney performance

review program?

- Does the firm require diversity training for all attorneys and staff members? (if so, please elaborate)
- Describe the firm's method of assigning work
- Describe your conflict check process
- •What are the language capabilities of the firm?
- Does the firm have a disaster/business continuity plan?
- What are the cities and states where attorneys who are members of the area of practice are located?
- Please list all of your licensed courts of admissions firmwide?
- How do you ensure legal work of a partner is meeting professional standards?
- Has any disciplinary action been taken against the firm in the past X years
- Does the firm have a quality assurance program or peer review process? If so, please explain
- Please provide specific attorney references
- •Will your firm use any outside vendors related to this engagement?



2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea



An inside look: What do clients ask us on RFPs?

We noticed that 20 of them were asked the most often.

- How many total offices does your firm have?
- Who is the proposed attorney team?
- What are the backgrounds/bios of the proposed team?
- What are your proposed rates/prices?
- Do you offer discounted rates?
- Do you offer alternative fee arrangements?
- Who will be the primary contact for this engagement?
- What is your customer service approach/philosophy?
- Provide the addresses/phone numbers of your offices
- Describe your firm's values
- Describe your firm's commitment to DEI
- Which of the following X services does your firm have experience with?

- Provide relevant experience/representative matters related to X services
- Provide an overview of the firm's services (for each specific relevant service)
- How many total attorneys does your firm have (# of partners, # of associates)?
- What are other aspects of your firm you wish to highlight for this proposal?
- How does your business align with potential client's mission and operations?
- Describe your firm's approach to staffing a case
- What sets your firm apart from others?
- How would your firm tailor services to the specific needs of the organization?





An inside look: What do clients ask us on RFPs?

These 20 questions fell into 5 general categories

1. BASIC FIRM INFORMATION

- Who will be the primary contact for this engagement?
- Address and phone numbers of all your office locations
- How many offices does your firm have?
- Who is the proposed attorney team?
- Backgrounds/biographies of the proposed attorney team
- Total number attorneys (partners/associates) in firm

2. FIRM MANAGEMENT

- What is your customer service approach/philosophy?
- Firm's values
- Firm's commitment to DEI
- Describe your firm's approach to staffing a case

3. COST

What are your proposed rates (pricing)?

- Do you offer discounted rates?
- Do you offer alternative fee arrangements?

4. EXPERIENCE/OFFERINGS

- Provide an overview of each the firm's service offerings
- Which of the following X services does firm have experience with?
- Describe experience/representative matters for those X services

5. MARKETING OPPORTUNITIES

- List other aspects of your firm you wish to highlight
- How does your business align with potential client's mission and operations?
- What sets your firm apart from others?
- How would you tailor your services to the potential client's specific needs?



McDonald Hopkins

An inside look: What questions matter most?

We surveyed the partners in our firm. 18 had experience with RFPs.

Questions:

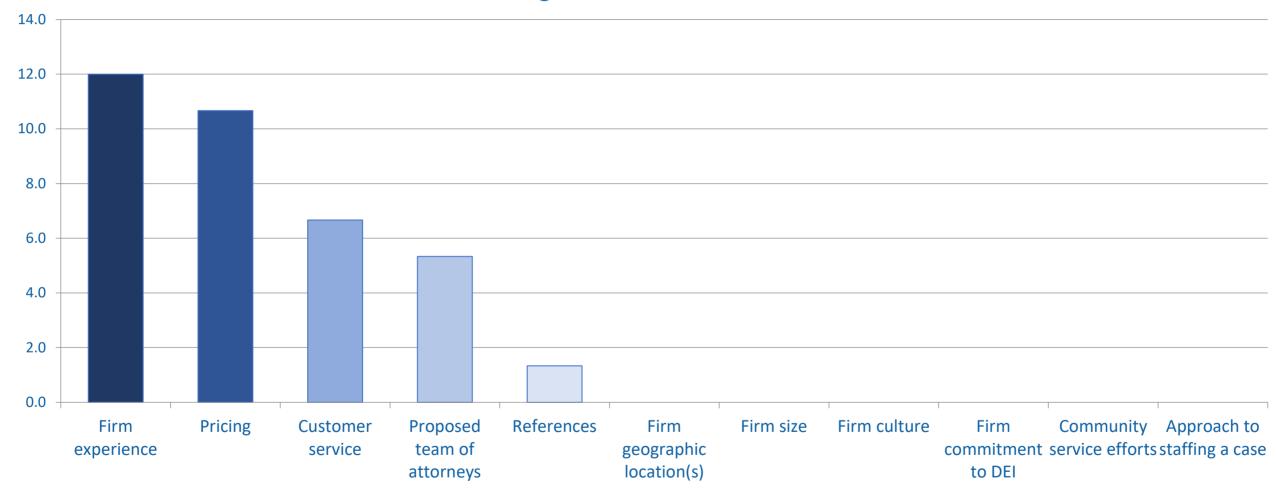
- 1) Rank the 3 most important criteria prospective clients use to evaluate RFPs
- 2) Why is a proposal not successful?
- 3) Rank the 5 most important factors in both winning and retaining a client?





Survey: What We Considered Most Important

1) From the list below, please rank the 3 most important criteria businesses/organizations to evaluate RFPs

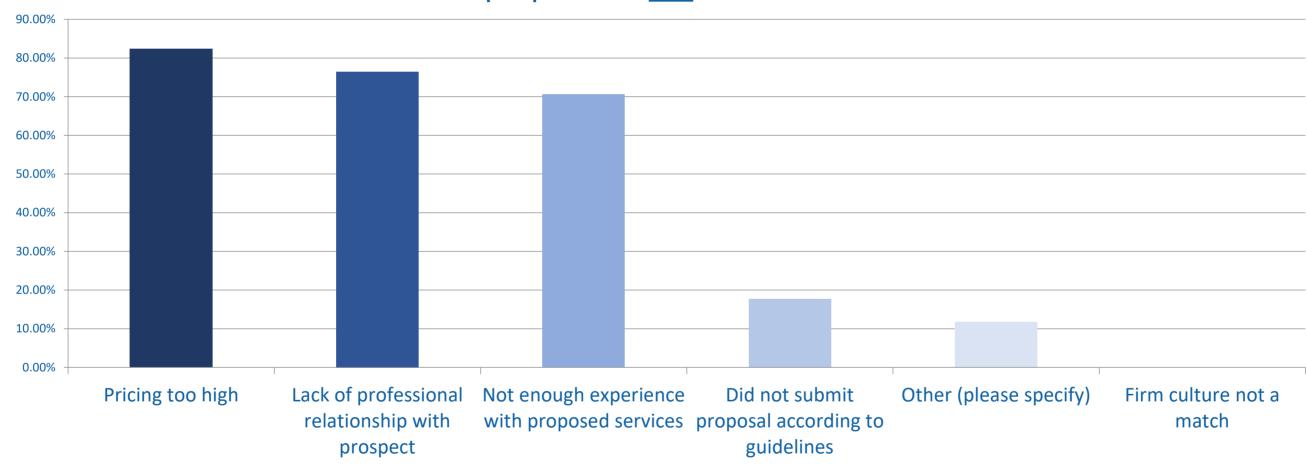






Survey: Why Did We Lose Bids?

2) In your experience, what are the reasons that a proposal is <u>not</u> successful?

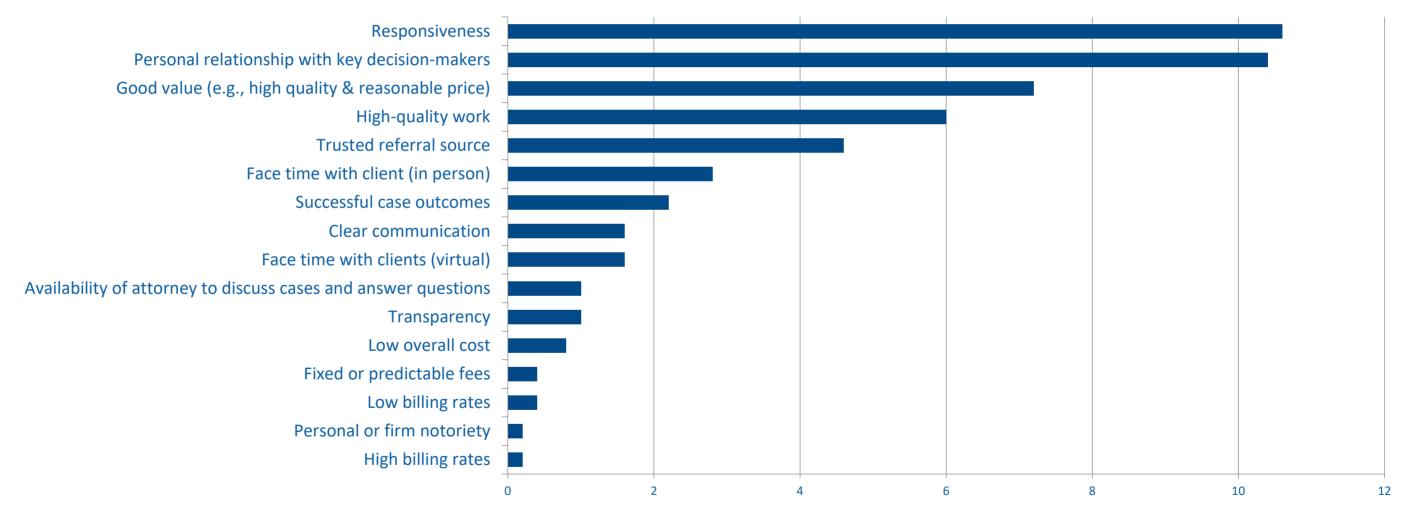






Survey: How do we win & keep clients?

3) From your <u>personal experiences</u> with clients, rank the <u>5 most important</u> factors both in <u>winning engagements</u> and in <u>retaining clients</u>

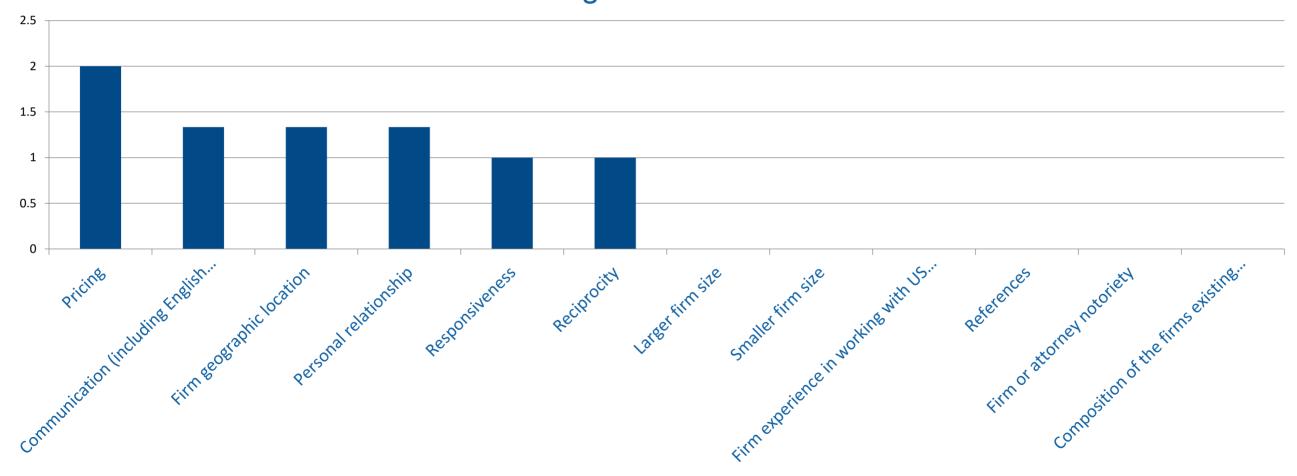






Survey: How do we choose a foreign firm?

From the list below, please rank the 3 most important criteria you consider when selecting a foreign law firm to represent your clients or act as a local agent in overseas matters.







Thank you.







Vice President & Patent

Attorney

Soei Patent & Law Firm

Japan





FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN



Introduction

- Patent Attorney qualified as an IP litigator, and acts as vice president of SOEI Patent
 & Law Firm in Japan.
- B.S. in chemistry and biomaterials from the University of Tokyo, MBA from Bond University (AU) and Juris Doctor from Toin University of Yokohama (JP)
- Over 25 years as an IP Attorney at SOEI after 12 years as a researcher at 3M Company
- Extensive experience in providing IP education to companies and universities
- Serving as a councilor of the Japan Patent Attorneys Association
- Co-author of the following English publications:
 - "Infringement of Second Medical Use Claims A global study focusing on skinny label"
 - "Pharmaceutical Test Data Exclusivity: A Multi-Jurisdictional Survey"





Which IP firm should you hire? - Perspective of IP Firm -

Prerequisite Requirements (for patents):

- (1) No conflicts
- (2) Good technical understanding and sufficient experience
- (3) Costs commensurate with the work

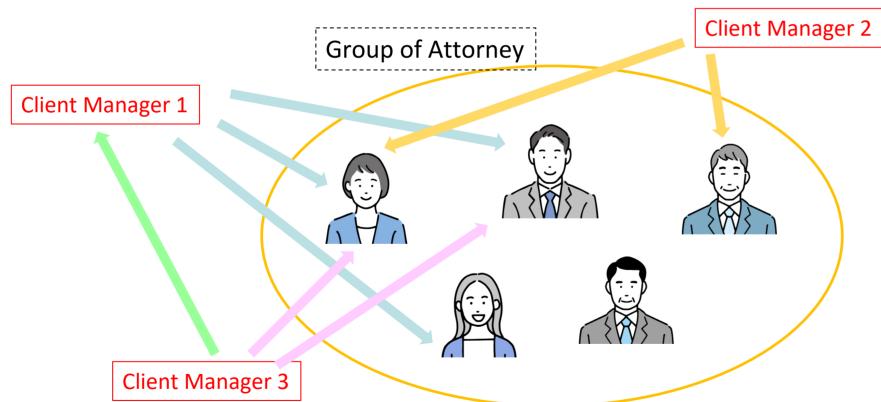
Given that the above Prerequisite Requirements are met, the following points are important:

- (4) Organization
- (5) Method of Operation
- (6) Responsiveness (especially when problems arise)



Organization and Method of Operation -our firm-

- > 116 JP attorneys, 2 US attorneys, 2 CN attorneys, 1 CA attorney (about 310 members in total)
- Filing 4000+ domestic patent cases and 4000+ foreign patent cases annually
- Our organization is flat, with no hierarchical structure and no divisions such as mechanical, electrical, or chemical departments.
- We conduct our operations centered around the client manager assigned to each client.



- (1) One client manager is assigned to each client.
- (2) Client manager is responsible for the best results for that client.
- (3) Client manager can assign work to any attorney.
- (4) Appraisal is made by peer, manager and client.
- (5) Attorneys who do not perform high-quality work are not given new cases.

2025 FICPI Symposium JeJu Korea

Organization and Method of Operation -our firm-

- ➤ No assistant for each attorney
- Administrative work is done in groups.
- ≥26 IT engineers are developing internal IT systems.

Administrative Group

Domestic Group (domestic work for clients in Japan)

Inbound Group (domestic work for foreign clients)



Foreign Filing Group (foreign filing for clients in Japan)

Foreign Prosecution Group (foreign work after filing for clients in Japan)

Crossdepartmental management system

Utilization of Al

Organization and Method of Operation

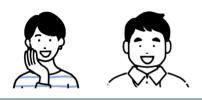
- reliability of clerical work-

(A) Group Administration



Group of attorneys



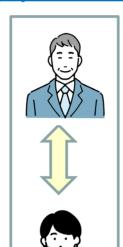


Group of administrative staff



IP Office, Client

(B) Administration by Assistant





Assistant A

Assistant A does work only for attorney A.





Good in terms of mutual understanding.

IP Office, Client

However, quality of work tends to depend on the quality of the assistant.



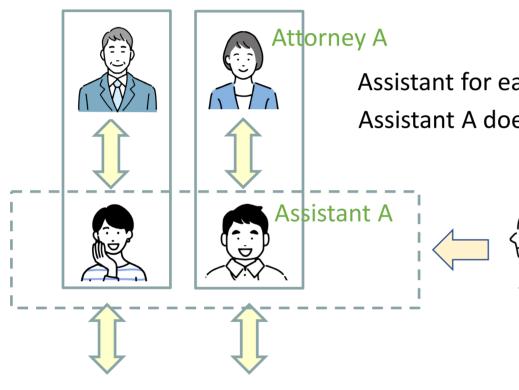
2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea

Organization and Method of Operation

- reliability of clerical work-

(C) Combination of (A) and (B)



Assistant for each attorney

Assistant A does work only for attorney A.

The administrator manages the entire team of assistants (utilizing computer systems, etc.).

We prefer style (A) or (C). IP Office, Client



2025 FICPI Symposium JeJu Korea

Good Technical Understanding and Sufficient Experience

Office visits and meetings at international conferences are important sources of information on firms.

However, the people we meet there are not the ones actually doing the work.





We are sometimes disappointed with the quality of work, which may contradict our impressions at the meeting.

It is necessary not only to get an impression of management, but also to evaluate the daily work ability of practitioners.







Number: Total number of office actions received (Total for 3 years)

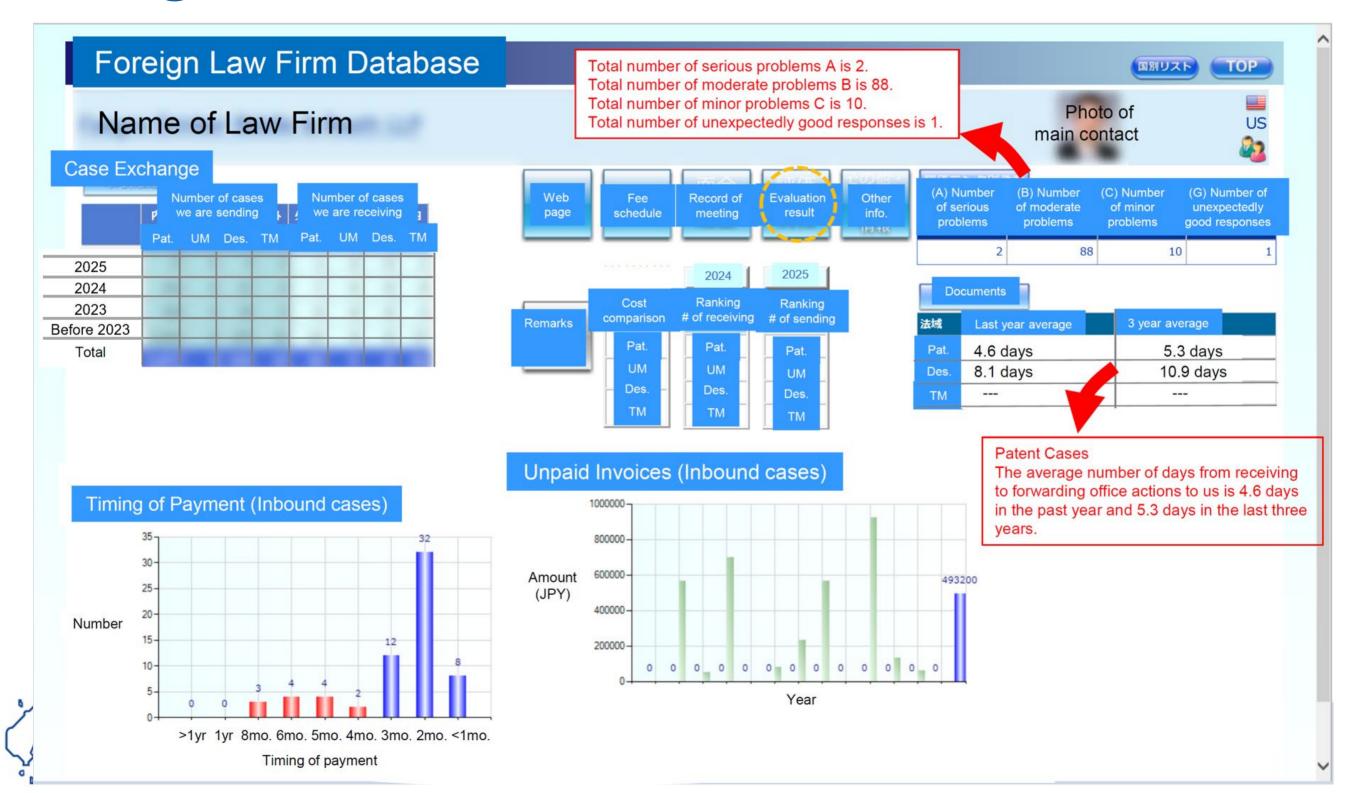
Speed: Average number of days from receiving to forwarding office actions to us (Total for 3 years)



2025 FICPI Symposium JeJu Korea

2-5 April, 2025 Jeju, Korea

The data entered by our administrative staffs upon receiving documents is automatically reflected and aggregated. The numbers change in real-time.



By clicking , the following analysis shows up.

Our Ref.	Item	Date of Letter	Date of Receipt	Evaluator	Quickness	Quality of Content	Ease of understanding
FP23-0123-00US-XYZ	First OA	2024/1/28	2024/2/9	Attorney A	5 (Good)	3 (Average)	3 (Average)
FP23-0003-00US-XYZ	First OA	2024/3/11	2024/6/17	Attorney B	3 (Average)	3 (Average)	3 (Average)
FP22-1101-00US-XYZ	Final OA	2024/6/15	2021/6/28	Attorney C	3 (Average)	5 (Good)	5 (Good)
FP22-0568-00US-XYZ	QPIDS	2024/9/14	2024/9/28	Attorney D	3 (Average)	3 (Average)	3 (Average)
FP22-0218-00US-XYZ	First OA	2024/9/17	2024/9/27	Attorney E	1 (Poor)	3 (Average)	3 (Average)
FP22-0155-00US-XYZ	First OA	2024/10/4	2024/10/12	Attorney A	3 (Average)	3 (Average)	3 (Average)
FP21-0039-00US-XYZ	Final OA	2024/10/6	2024/10/13	Attorney C	3 (Average)	3 (Average)	3 (Average)
FP21-0006-00US-XYZ	First OA	2024/11/5	2024/11/12	Attorney B	5 (Good)	5 (Good)	5 (Good)

Best 5 > 4 > 3 > 2 > 1 Worst



Average Filing Fee vs. Average Prosecution Fee





Responsiveness

1. Understanding the Characteristics of Japanese Clients

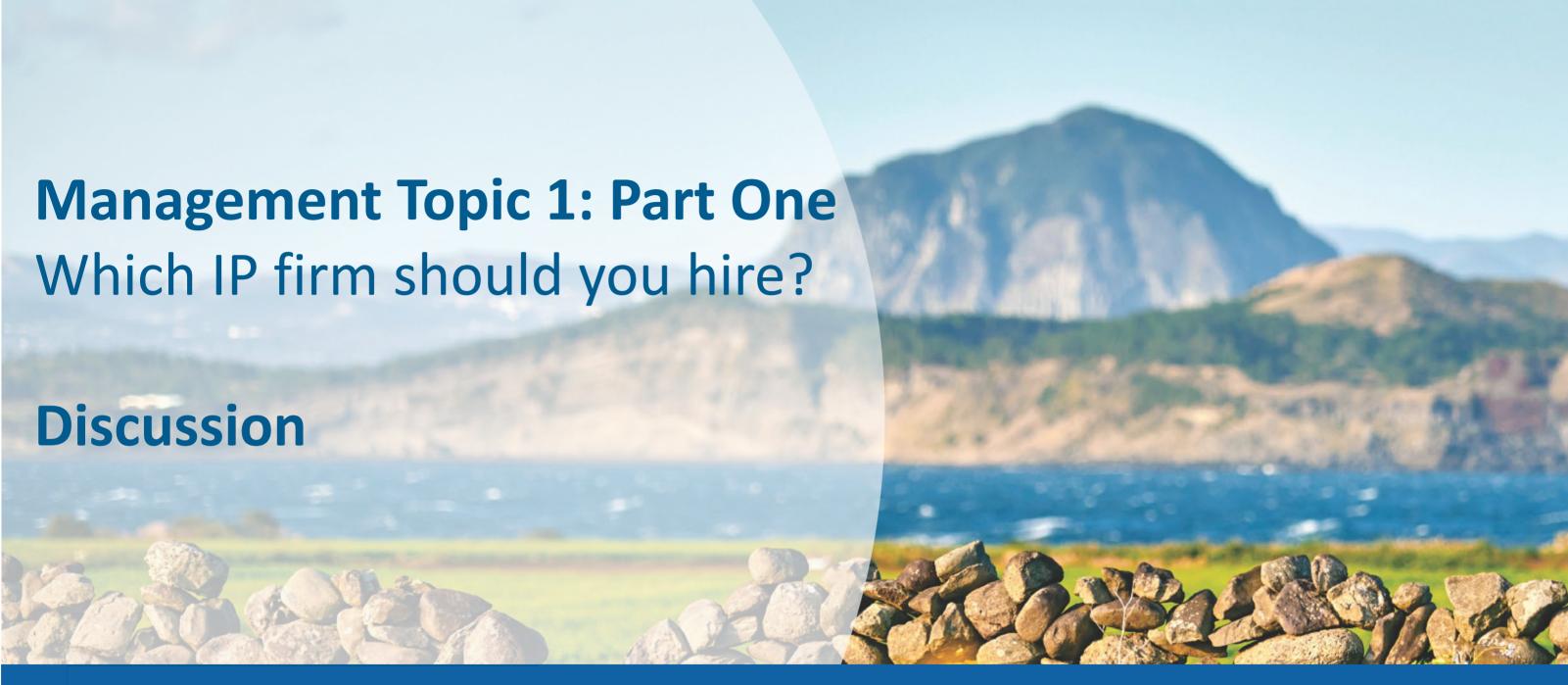
- They do not prefer last-minute responses.
- They appreciate consistent timing in responses.
- They are concerned about the speed of email acknowledgments and replies.
- They prefer invoices to include a breakdown, not just the total amount.

2. Assignment of Work

- Please assign work to the most suitable personnel, considering their expertise.
- The attorney we are in contact with does not need to monopolize our work.

3. When Troubles Arise

- If a problem occurs, please report it immediately.
- Do not conceal any problems.
- Since the responsible attorney may sometimes be reluctant to acknowledge their responsibility, we would like to know their supervisor so that we can consult with him/her.





FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

3 April 2025 16:45-17:15