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IPAN – MEETING 11 JANUARY 2017

PROGRESS IN PLANT SCIENCES AND BIOTECHNOLOGY, PLANT VARIETY RIGHTS AND PLANT PATENTS

THE LEGAL CHALLENGES AHEAD FOR PROTECTING INNOVATION IN PLANT
BREEDING

11 JANUARY 2017

Joel Smith, Partner IP Group, +44 7466 2331, joel.smith@hsf.com



SESSION OBJECTIVES

SHORT TERM

- BREXIT implications

MEDIUM TERM

- Increasing overlap of IPRs and regulation

LONG TERM

- Global challenges and potential responses



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BREXIT

WHAT WILL HAPPEN TO IP RIGHTS?



BREXIT - OVERVIEW

- We know Brexit means Brexit.....
- However, it will still take some time
- (~2+ years) to materialise
- Uncertainty over direction of UK's future engagement with EU post-Brexit
- £108bn agrifood industry, with over £14.8bn in agritech (engineering, precision tools, veterinary medicines, feed, crop protection and nutrition, seeds, genetics, computing, energy generation, infrastructure and machinery)
- Complex areas such as EU farming subsidies, EU research grants
- Opportunity to rebalance R&D investment and reinvigorate science in the crop protection and biotechnology sectors



BREXIT – BUSINESS AS USUAL FOR IP....

- English law will remain the dominant law for commercial contracts globally
- The English courts will remain a centre of excellence for determining disputes, governed by English law and IP disputes
- Much of existing IP law is unaffected and in the near time, our law mirrors the rest of the EU, such as UK TMs, copyright, designs etc.
- However, UK has no separate system of geographical indications (protected foodstuffs/wines), SPCs (agrochemicals)
- Future free trade arrangements with EU will set rules on parallel imports and exhaustion of rights, guidance on technology licences complying with EU competition law
- Licence agreements will need re-considering in terms of territory
- Relations with many EU regulatory bodies to be re-considered, such as EMA, EFSA etc.
- Products will still need to meet CE-marking and specific regulations, if EU bound

BREXIT – PLANT VARIETY RIGHTS

PVRs

- Current breeders favour CPVR, yet CPVR will cease to cover UK
- UK needs to provide for “equivalent” UK protection upon exit of EU
- Various options UK could adopt – better unilateral
 - Montenegro model – UK creates parallel UK right of same name, scope, registration date and term etc.
- Contingency planning - how to apply for UKPVR in meantime
 - Art 92(1) Reg. 2100/94 = rights granted contrary to CPVR ineffective
 - Get in early, 1 year grace period, otherwise novelty bar
 - Holder of CPVR must have place of business or residence in EU or appoint procedural representative

BREXIT - PATENTS

Patents

- Despite Brexit, we expect the UPC and UP to be ratified by the UK in 2017 and go live
- UPC = a pan-European system for litigating European patents before the courts, both locally and centrally. London was to be the base in the Central division for all pharma/biotechnology disputes
- UP = new unitary patent covering all 28 Member States
- Only Member States may participate in UPC, as CJEU has overall jurisdiction
- Unclear if/how UK will remain in UPC following Brexit, which may complicate matters
- EPO system out of EU framework – largely unaffected

BREXIT – EU TRADE MARKS

TM_s

- New TM regulation in effect in 2016 – CTMs → EUTMs
- Once UK exits EU, EUTMs would no longer apply to UK, though businesses may also have (or can apply for) UK TMs
- UK needs to provide for “equivalent” UK protection upon exit of EU
- Various options UK could adopt –
 - Bilateral – negotiate to remain part of EUTM system
 - Unilateral – more realistic, such as Montenegro model – automatic entry on to UK TM register.
- Complications – cluttering, may be no intention to use in UK, how to treat applications

BREXIT – TRADE SECRETS

Trade secrets

- Trade Secrets Directive adopted, due to be implemented into UK law 5 July 2018
- Aim to provide a strong, harmonised playing field for protecting innovation and investment across Europe
- Largely mirrors existing UK law, but some key differences
- Need to take “reasonable steps” to keep it secret
- Lawful acquisition, includes independent discovery, observation/study and reverse engineering (other than if prevented by NDA), whistleblowing
- Extends protection not just to “use” but also products “significantly benefiting” from the trade secret



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INCREASING OVERLAP OF IPR AND REGULATION

HOW IS LEGAL PROTECTION LIKELY TO EVOLVE?

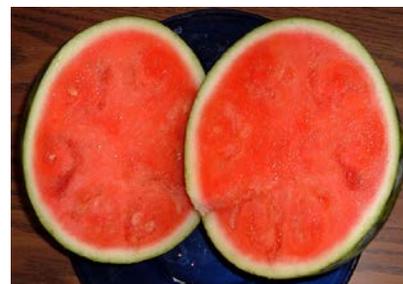


INCREASING OVERLAP

- Transformational plant breeding techniques – need for patents
- Patentability of plant related innovations unpredictable and hotly contested
- Increasing use of other IP rights in conjunction with / instead of PVRs



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PVRs and Patents



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ART 53(b) EPC

ART 4 Biotech Directive
Dir/98/44/EC

Transgenic plants v naturally occurring varieties

Products v processes *Essentially biological processes*

New breeding technologies

Other forms of protection

CRISPR

Agroinfiltration

Copyright

Trade secrets

RNAi gene silencing

Database rights

INCREASING OVERLAP

Syngenta's patent for "an improved pepper plant"
(EP 2 166 833 B1)

Claims

1. A male sterile hybrid pepper plant, which grows normal-looking edible seedless fruits throughout the whole plant, wherein said seedless fruits are **characterized by** being at least 95% seedless, wherein the "seedless" trait is controlled by a genetic determinant and is independent of the pollination and fertilization process, is independent of treatment with parthenocarp-inducing plant hormones including auxins, gibberellins and cytokines, auxin transport inhibitors, or others and/or other parthenocarp-inducing exogenous factors and/or exogenously administered parthenocarp-inducing agents such as growth regulating substances, either natural or synthetic, or plant extracts such as, for example, dead pollen extract, and is also independent of external climatic conditions and wherein the said "seedless" trait is obtainable from a pepper plant selected from the group consisting of *Capsicum annuum* AR07-F1-56-b; *Capsicum annuum* AR07-F1-87-b; *Capsicum annuum* AR07-F1-166-b; *Capsicum annuum* AR07-F1-171-X; and *Capsicum annuum* AR07-F1-172-X, grown from seeds deposited with NCIMB, Aberdeen AB21 9YA, Scotland, UK on May 26, 2008 under accession number NCIMB 41558, NCIMB 41559, NCIMB 41560, NCIMB 41561 and NCIMB 41562, respectively.

6. A method of producing seedless pepper fruits, as a food product, comprising the steps of

- i) providing a pepper plant according to any one of claims 1 to 5;
- ii) multiplying/propagating said pepper plant
- iii) allowing the plant to grow seedless pepper fruits; and
- iv) harvesting said pepper fruits;

wherein the multiplication/propagation step ii) is done by vegetative propagation.

7. Use of the seed deposited under accession number NCIMB 41 558, NCIMB 41 559, NCIMB 41 560, NCIMB 41 561 and NCIMB 41 562 for the production of parthenocarpic pepper fruits.

8. Use of a seedless fruit grown from a pepper plant according to any one of claims 1 to 5 as fresh produce, as fresh cut produce, or for processing such as, for example, canning.

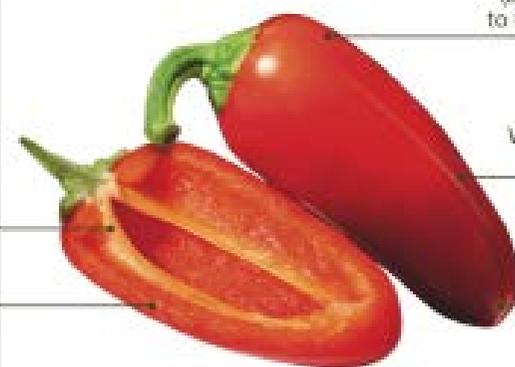
		Taste: sweet, fresh (25% sweeter compared to baby pepper reference)
Sweet, Crunchy and Seedless		Weight: 10 to 30 grams; Length: 5 to 10 cm
Color: vibrant red		Shape: Conical

Image source: Luciano Fioramonti, Presentation on "Angello™ sweet and seedless pepper" Fresh Congress 2012

Currently under Opposition for patentability before EPO

Monsanto's patent for a "broccoli type adapted for ease of harvest" (EP 1 597 965 B1)



The opposition is supported by around 45.000 signatures

Other opposition to such patents...

INCREASING OVERLAP

How will the IP rights overlap affect key plant breeder activities?

Research & Development

- Patent thickets - more rights to consider and navigate around to protect oneself from infringement
- Potentially lost exceptions due to overlap with other IP rights (in terms of breeders' rights, farmers' right...)

Licensing

- Negotiating, finalising more complex and robust licensing arrangements spanning different types of IP rights, not just PVRs
- Potential movement towards FRAND-type licensing

FRAND licensing

- Fair, Reasonable And Non-Discriminatory terms
- Compulsory for "standard essential patents" (SEPs) mainly in technology and telecom
- Standards set by standard-setting organisations (SSOs) – ETSI
- 2G, 3G, 4G telecom standards



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251
standards

Potential standards for PVRs?

Mandatory nutritive / safety
gene sequences

Biological standards for
size, productivity

INCREASING OVERLAP

Challenges in the short- to mid-term

Regulatory interventions (UK/EU/International)

- Increased level of scrutiny likely over plant variety development activities / licensing activities
 - Cartagena Protocol
 - UK/EU Food safety-type regulations
 - UK/EU Product liability-type regulations
 - UK/EU Consumer protection legislation
- GMOs – Advantage Britain after Brexit?

Competition / Anti-trust challenges (UK/EU)

- TFEU Art 101, 102 challenges:
 - Art 101 – cartels and anti-competitive agreements
 - Art 102 – abuse of dominant position in market
- EU Commission & UK Competition & Markets Authority (“CMA”)
- Balance between patent protection and distortion of competition in the market needs to be achieved in order to allow overlapping IP protection for plant breeding

CASE STUDY

Lundbeck v Generics (Sept 2016)

GSK v Generics (May 2016)

- CJEU upheld EU Commission decision on “pay-for-delay” agreements
- Breach of Art 101 – delay of generic drug by agreement between patent proprietor and generics
- Seminal case upholding fines imposed by EU Commission (~ €145 mn)
- Fines also imposed upon GSK by CMA for similar agreements
- Increasingly robust and vigilant competition authorities



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FUTURE GLOBAL CHALLENGES

WHAT EMERGING ISSUES MUST WE TAKE NOTE OF?



FUTURE GLOBAL CHALLENGES

What may the future hold?

KEY CONCERNS

Protection of Biodiversity / Traditional Knowledge

Population growth and Food security

MODES OF ACCESS TO RESOURCES

Benefit-sharing

Community ownership of natural resources

Traditional forms of IP protection / licensing

LEVELS OF INTERVENTION

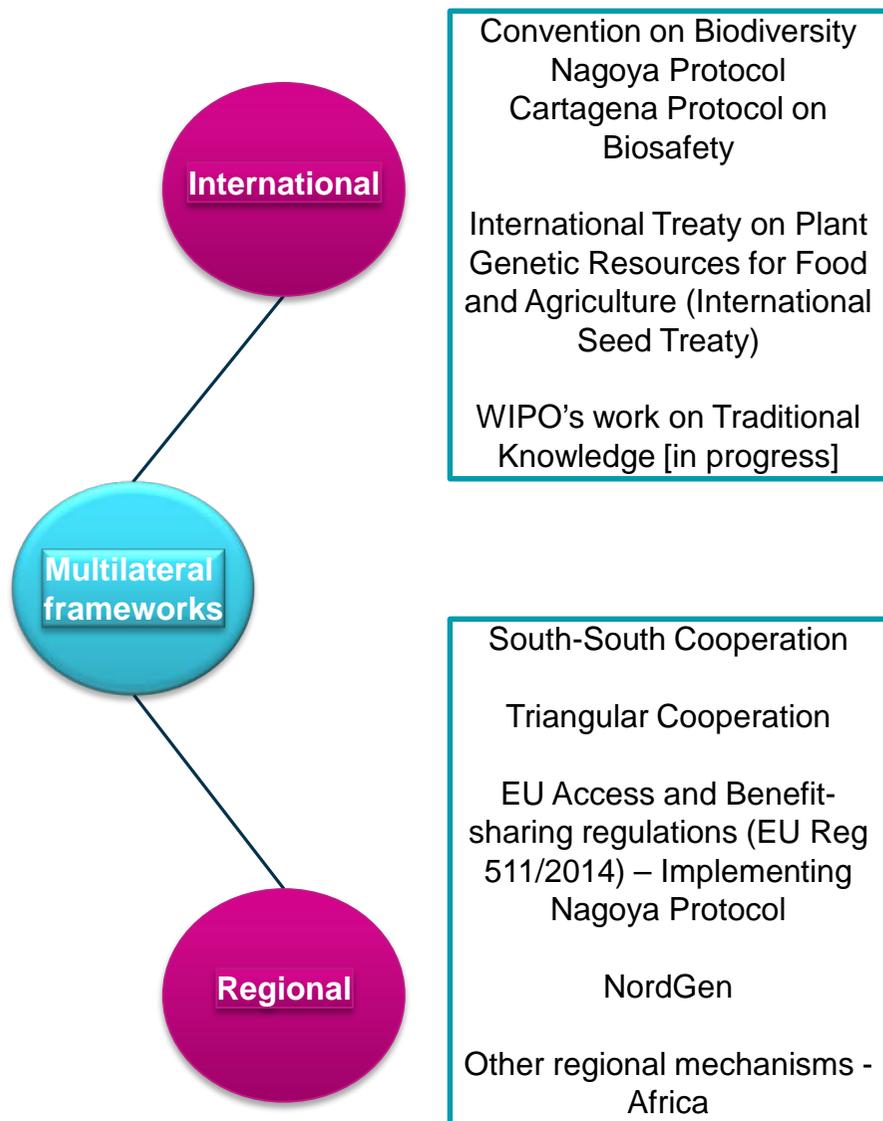
MULTI/INTER-NATIONAL

Regional / International conventions and agreements

AD-HOC INTER PARTY

Bespoke MTAs or benefit-sharing arrangements

FUTURE GLOBAL CHALLENGES (2)



Common themes

General steer away from individual proprietorship models to community ownership / benefit-sharing models

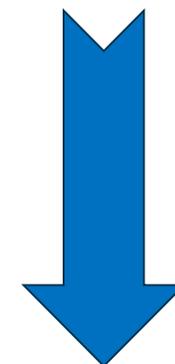
Availability / non-availability OR flexibilities in IP protection

Differences in needs/attitudes between developed/developing countries. For example:

- Emphasis on disclosure of origin to prevent “biopiracy” especially in developing countries
- “Good faith” exception for contamination of farmer’s land by protected plant variety (Thailand)
- Special protections for developing countries’ interests



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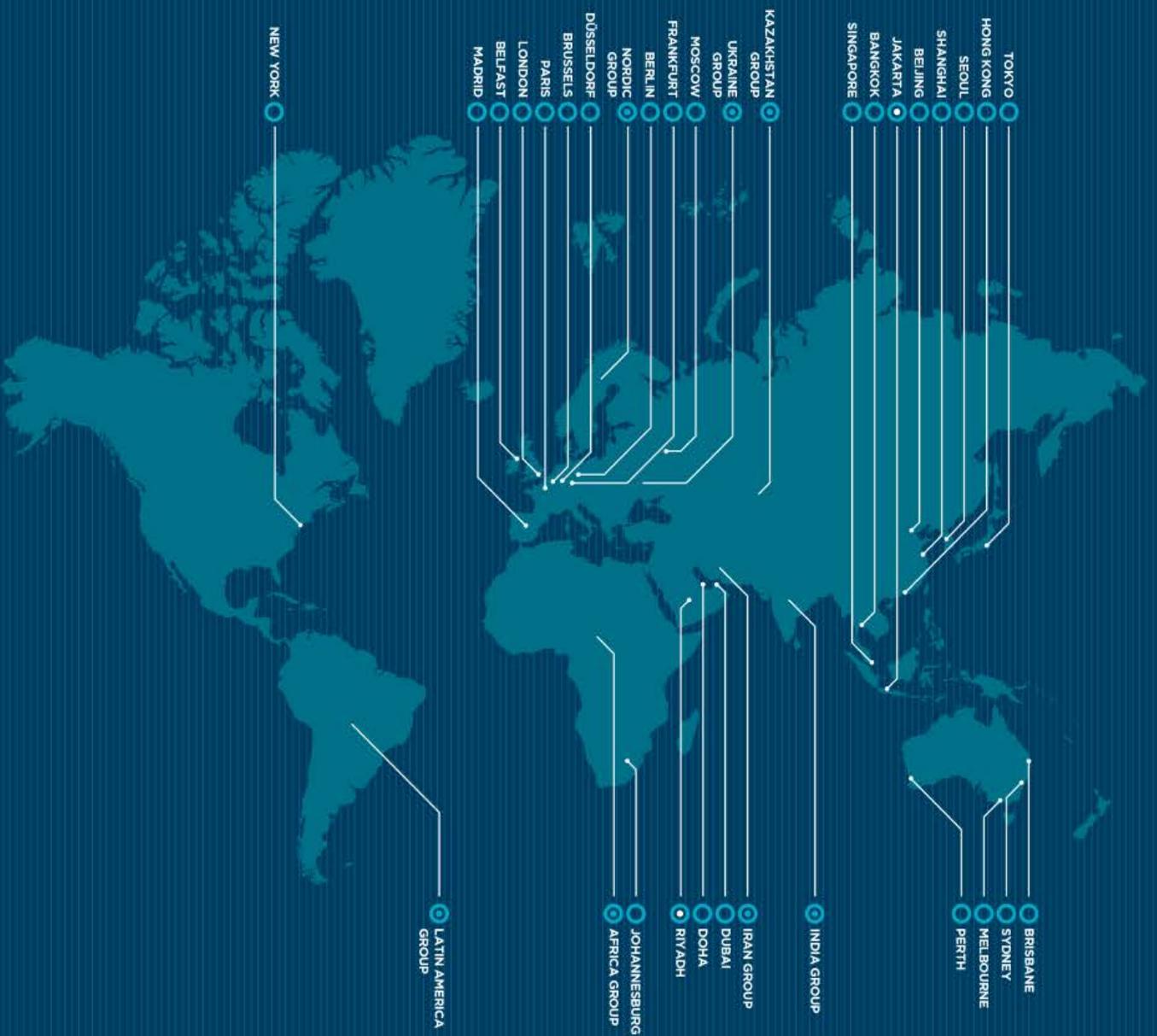
EXAMPLE – THE NAGOYA PROTOCOL TODAY

- Nagoya Protocol in force 12 October 2014 on access and benefit sharing.
- Regulation (EU) 511/2014 in force 12 October 2015 and Commission Regulation (EU) 2015/1866
- Applies to genetic resources – plant, animal, microbial or other origin containing functional units of hereditary
- Utilisation in EU (though may be other obligations under national regimes) – i.e. R&D, including through use of biotechnology
- Country of origin of genetic resources must be a signatory state (82 parties) and asserted sovereignty
- Triggers due diligence requirements, record-keeping and seek PIC (prior informed consent) and MAT (mutually agreed terms) contracts, if and when needed.
- Identity checkpoints and audits.
- Complicates FTO searches – risk that unable to launch products or conduct externally-funded research in NP states
- Undermines breeders' and research exemptions
- Limits ability to patent “in form received”, triggers declaration of source and origin in IP applications and market authorizations, plus requires royalties to be paid
- Significant reputational risk (biopiracy label) and risk of criminal sanctions for non-compliance
- Sectoral guidance documents – e.g. plant breeding

FUTURE GLOBAL CHALLENGES (3)

Other arrangements

- Using standard Material Transfer Agreements:
 - [NordGen](#) – Nordic council of ministers – standard transfer agreements for seed requests (under International Seed Treaty)
- [Bioversity International](#) – Effective conservation of genetic resources and use through - Community seedbanks, local initiatives
 - [International Licensing Platform](#) – Prototype patent “clearing house” for life sciences industry (based on similar model for vegetable seed industry)
 - Open participation (no need to be vegetable breeders, as long as they can license in-scope patents)
 - Standard Licensing Agreement
 - “All in” or “pull in” mechanisms
 - “Baseball arbitration”
 - MFN-type clause



- Herbert Smith Freehills office
- Associated office
- Group

BANGKOK

Herbert Smith Freehills (Thailand) Ltd
T +66 2657 3888
F +66 2636 0657

BEIJING

Herbert Smith Freehills LLP Beijing
Representative Office (UK)
T +86 10 6535 5000
F +86 10 6535 5055

BELFAST

Herbert Smith Freehills LLP
T +44 28 9025 8200
F +44 28 9025 8201

BERLIN

Herbert Smith Freehills Germany LLP
T +49 30 2215 10400
F +49 30 2215 10499

BRISBANE

Herbert Smith Freehills
T +61 7 3258 6666
F +61 7 3258 6444

BRUSSELS

Herbert Smith Freehills LLP
T +32 2 511 7450
F +32 2 511 7772

DOHA

Herbert Smith Freehills Middle East LLP
T +974 4429 4000
F +974 4429 4001

DUBAI

Herbert Smith Freehills LLP
T +971 4 428 6300
F +971 4 365 3171

DÜSSELDORF

Herbert Smith Freehills Germany LLP
T +49 211 975 59000
F +49 211 975 59099

FRANKFURT

Herbert Smith Freehills Germany LLP
T +49 69 2222 82400
F +49 69 2222 82499

HONG KONG

Herbert Smith Freehills
T +852 2845 6639
F +852 2845 9099

JAKARTA

Hiswara Bunjamin and Tandjung
Herbert Smith Freehills LLP associated firm
T +62 21 574 4010
F +62 21 574 4670

JOHANNESBURG

Herbert Smith Freehills South Africa LLP
T +27 11 282 0831
F +27 11 282 0866

LONDON

Herbert Smith Freehills LLP
T +44 20 7374 8000
F +44 20 7374 0888

MADRID

Herbert Smith Freehills Spain LLP
T +34 91 423 4000
F +34 91 423 4001

MELBOURNE

Herbert Smith Freehills
T +61 3 9288 1234
F +61 3 9288 1567

MOSCOW

Herbert Smith Freehills CIS LLP
T +7 495 363 6500
F +7 495 363 6501

NEW YORK

Herbert Smith Freehills New York LLP
T +1 917 542 7600
F +1 917 542 7601

PARIS

Herbert Smith Freehills Paris LLP
T +33 1 53 57 70 70
F +33 1 53 57 70 80

PERTH

Herbert Smith Freehills
T +61 8 9211 7777
F +61 8 9211 7878

RIYADH

The Law Office of Nasser Al-Hamdan
Herbert Smith Freehills LLP associated firm
T +966 11 211 8120
F +966 11 211 8173

SEOUL

Herbert Smith Freehills LLP
Foreign Legal Consultant Office
T +82 2 6321 5600
F +82 2 6321 5601

SHANGHAI

Herbert Smith Freehills LLP Shanghai
Representative Office (UK)
T +86 21 2322 2000
F +86 21 2322 2322

SINGAPORE

Herbert Smith Freehills LLP
T +65 6868 8000
F +65 6868 8001

SYDNEY

Herbert Smith Freehills
T +61 2 9225 5000
F +61 2 9322 4000

TOKYO

Herbert Smith Freehills
T +81 3 5412 5412
F +81 3 5412 5413