

eipi Information

Institut der beim Europäischen Patentamt
zugelassenen Vertreter

Institute of Professional Representatives
before the European Patent Office

Institut des mandataires agréés près
l'Office européen des brevets

Heft · Part · Fascicule 3 September · September · Septembre 2007



Carl Heymanns Verlag

ISSN 1434-8853

2007 **3**



Institut der beim Europäischen Patentamt
zugelassenen Vertreter

Institute of Professional Representatives
before the European Patent Office

Institut des mandataires agréés près
l'Office européen des brevets

Redaktionsausschuss

Editorial Committee

Commission de Rédaction

W. HOLZER · T. JOHNSON · E. LIESEGANG · T. SCHUFFENECKER

Das Institut ist weder für Erklärungen
noch für Meinungen verantwortlich,
die in Beiträgen dieser Zeitschrift ent-
halten sind.

Artikel werden in der oder den Amts-
sprachen (deutsch, englisch, franzö-
sisch) wiedergegeben, in der bzw. de-
nen diese Artikel eingereicht wurden.

The Institute as a body is not re-
sponsible either for the statements
made, or for the opinions expressed
in the publications.

Articles are reproduced in the official
language or languages (German,
English or French) in which they are
submitted.

L'Institut n'est pas responsable des
opinions exprimées dans cette publi-
cation.

Les articles sont publiés dans celle ou
celles des trois langues officielles (alle-
mand, anglais ou français) dans
laquelle ou lesquelles ils ont été pro-
posés.

Postanschrift · Mailing address · Adresse postale

epi
Postfach 26 01 12
D-80058 München
Tel. (089) 24 20 52-0
Fax (089) 24 20 52-20
e-mail: info@patentepi.com
<http://www.patentepi.com>

Verlag · Publishing House · Maison d'édition

Carl Heymanns Verlag GmbH
Ein Unternehmen von Wolters Kluwer Deutschland
Luxemburger Straße 449
D-50939 Köln
Tel. (0221) 94 373-7000
Fax (0221) 94 373-7201
Kundenservice: Tel. (02631) 801-2222
e-mail: info@wolterskluwer.de
<http://www.heymanns.com>

Anzeigen · Advertisements · Publicité

Carl Heymanns Verlag GmbH
Ein Unternehmen von Wolters Kluwer Deutschland

Druck Printing Imprimeur

grafik + druck, München

ISBN 978-3-452-26531-9
ISSN 1434-8853

© Copyright epi 2007

Vierteljahreszeitschrift

Abonnement im Mitgliedsbeitrag enthalten,
für Nichtmitglieder € 42,00 p. a. zzgl. Ver-
sandkosten (€ 9,90 Inland / € 14,00 Aus-
land), Einzelheft € 12,60 zzgl. Versandkosten
(ca. € 2,27 Inland / ca. € 3,20 Ausland)
je nach Heftumfang. Preise inkl. MwSt. Auf-
kündigung des Bezuges 6 Wochen vor Jah-
resende.

Quarterly Publication

Subscription fee included in membership fee,
for non-members € 42,00 p. a. plus postage
(national € 9,90 / abroad € 14,00), indivi-
dual copy € 12,60 plus postage (national
about € 2,27 / abroad about € 3,20) de-
pending on the size of the issue, VAT inclu-
ded. Cancellation of subscription is reques-
ted 6 weeks before any year's end.

Publication trimestrielle

Prix d'abonnement inclus dans la cotisation,
pour non-membres € 42,00 p. a., frais d'en-
voi en sus (national € 9,90 / étranger
€ 14,00), prix à l'unité € 12,60, frais d'en-
voi en sus (national environ € 2,27, étran-
ger environ € 3,20) selon le volume du nu-
méro, TVA incluse. Résiliation de l'abonne-
ment 6 semaines avant la fin de l'année.

Table of Contents

Editorial	74	II – Contributions from epi Members and other contributions	
I – Information concerning epi		Reports	
Elections		Report on EU Symposium „The Future of the Patent Jurisdiction in Europe“, Munich 25 th -26 th June 2007 at the German Federal Patents Court, by E. Lyndon-Stanford	90
Wahl zum Rat des Instituts	75	Report on EPLA – Litigation Working Party Meeting, 27 th June 2007, by E. Lyndon-Stanford	91
Election to the Council of the Institute	79	„Les troisièmes Rencontres européennes du CEIPI“, Report by L. Nuss	92
Election au Conseil de l’Institut	82	CEIPI study course „Master of IP Law and Management“, note by the <i>epi</i> President and report on the 1 st course, by P. Rosenich	93
Discipline		Selection of PCT Receiving Office, by L. Steenbeek	95
Decision of the Disciplinary Boards of Appeal D 0025/05	86	Notice from the European Patent Office, dated 18 June 2007, concerning Spanish reservation on Chemical and Pharmaceutical Product Claims	96
Information from the Secretariat		Articles	
Next Board and Council Meetings	105	Draft European Patent Litigation Agreement (EPLA): Jurisdiction of the European Patent Court and effects of decisions, by S. Luginbuehl and E. Waage	97
<i>epi</i> Excess Liability insurance 2007/2008.	90	Orphan Drug legislation, by M. Gibson	101
Deadline 4/2007	74		
<i>epi</i> Disciplinary bodies and Committees	106		
<i>epi</i> Board	U3		

Editorial

T. Johnson (GB)

By the time our readers receive this issue, the summer will be well and truly a memory. However, unlike the effect of harmonization of IP law across Europe brought about by the EPC such harmonization did not reach the weather this year as our colleagues in the South and East sweltered in the heat while those of us in the North and West generally enjoyed at best autumnal conditions. At least British colleagues generally enjoy talking about the weather! Putting that behind us, as this Editorial is being penned (how arcane is that!) it is reported that the French government is about to ratify the London Agreement (on the application of Article 65EPC). Such a development as an implemented London Agreement will bring changes to our daily practice which will require

careful attention, though whether there will be a reduction in the cost of patenting in Europe remains to be seen. In our experience some initiatives do not always have the effect expected once they are implemented. Also implementing of the Agreement will be out of kilter with a Community Patent, still awaited, which, administered by the EPO, would if it ever comes into force eventually provide a unified (harmonised) patent jurisprudence within the area of the EU. In this regard, we commend to our readers the Report in this issue from Edward Lyndon-Stanford on the EU Symposium on „The future of European Patent Jurisdiction“ held in June at the German Federal Patents Court.

Nächster Redaktionsschluss für epi Information

Informieren Sie bitte den Redaktionssausschuss so früh wie möglich über das Thema, das Sie veröffentlichen möchten. Redaktionsschluss für die nächste Ausgabe der epi Information ist der **2. November 2007**. Die Dokumente, die veröffentlicht werden sollen, müssen bis zum diesem Datum im Sekretariat eingegangen sein.

Next deadline for epi Information

Please inform the Editorial Committee as soon as possible about the subject you want to publish. Deadline for the next issue of epi Information is **2 November 2007**. Documents for publication should have reached the Secretariat by this date.

Prochaine date limite pour epi Information

Veillez informer la Commission de rédaction le plus tôt possible du sujet que vous souhaitez publier. La date limite de remise des documents pour le prochain numéro de epi Information est le **2 novembre 2007**. Les textes destinés à la publication devront être reçus par le Secrétariat avant cette date.

Wahl zum Rat des Instituts

Anfang des nächsten Jahres ist der Rat des Instituts neu zu wählen.

Wir möchten auf die Versanddaten der Dokumente, die auszufüllen sind, sowie die Fristen für den Eingang der ausgefüllten Dokumente im Sekretariat des Instituts in München hinweisen.

1. Schritt

– *spätestens am 1. Oktober 2007:*

Versand des Wahlvorschlag-Formulars zum Nominieren von Kandidaten an die Institutsmitglieder.

– *1. November 2007:*

Fristablauf für den Eingang des ausgefüllten Wahlvorschlags im Sekretariat des Instituts.

2. Schritt

– *spätestens am 30. November 2007:*

Versand der vorläufigen Kandidatenlisten an die Personen, die zur Wahl vorgeschlagen wurden.

– *10. Dezember 2007:*

Fristablauf für den Eingang schriftlicher Anträge zur Änderung der vorläufigen Kandidatenlisten im Sekretariat des Instituts.

3. Schritt

– *spätestens am 15. Januar 2008:*

Versand der Stimmzettel und der zugehörigen Wahlunterlagen an die Wahlberechtigten.

– *15. Februar 2008:*

Fristablauf für den Eingang des ausgefüllten Stimmzettels und der ausgefüllten und unterschriebenen Erklärung im Sekretariat des Instituts.

4. Schritt

– *spätestens am 14. März 2008:*

Mitteilung des Wahlergebnisses in der Ausgabe 1/2008 der epi-Information.

Die Regeln für Wahlen zum Rat sind nachstehend abgedruckt.

Regeln für Wahlen zum Rat

Regel 1: Wahlen

Die Wahlen zum Rat des Instituts der zugelassenen Vertreter werden gemäß den Vorschriften über die Errichtung des Instituts und in der nachstehend festgelegten Weise von diesem Institut durchgeführt.

Regel 2: Wahlberechtigte

2.1

Alle Personen, die in der beim Europäischen Patentamt geführten Liste der zugelassenen Vertreter bei Geschäftsschluss des Europäischen Patentamts in München am letzten Arbeitstag vor dem 15. September desjenigen Jahres eingetragen sind, das dem Jahr vorausgeht, in welchem der nachfolgende Rat sein Amt antritt („Vorjahr der Wahl“), haben das Recht, bei der nächsten ordentlichen Wahl zu wählen und zu kandidieren; andere Personen sind weder aktiv noch passiv wahlberechtigt.

2.2

Die Anzahl der Institutsmitglieder, die bei Geschäftsschluss des Europäischen Patentamts in München am letzten Arbeitstag vor dem 15. September des Vorjahres der Wahl in der Liste der zugelassenen Vertreter eingetragen sind, ist für die Festlegung der Anzahl der in jedem Wahlbezirk zu wählenden Ratsmitglieder gemäß Artikel 7, Absatz 3 der Vorschriften über die Errichtung maßgebend.

Regel 3: Wahldurchführung

3.1

Jeder Wahlbezirk, dessen Wählerschaft in der direkt vorausgegangenen ordentlichen Wahl zum Rat einheitlich oder nicht-einheitlich gewählt hat, wird in der gleichen Weise wie zum vorhergehenden Rat wählen, es sei denn, ein Wahlbezirk hat vor dem 15. September des Vorjahres der Wahl dem Sekretariat des Instituts gegenüber erklärt, dass er sich nach der in Artikel 7, Absatz 6 der Vorschriften über die Errichtung niedergelegten Weise dafür ausgesprochen habe, die andere Art der Wahl anzuwenden.

3.2

Jeder Wahlbezirk, der während der laufenden Amtszeit des Rates vor dem 15. September des Vorjahres der Wahl geschaffen wurde, hat gemäß Artikel 7, Absatz 4 und 5 der Vorschriften über die Errichtung in der Weise zu wählen, die bei seiner Schaffung zutreffend war, es sei denn, er hat vor dem 15. September des Vorjahres der

Wahl dem Sekretariat des Instituts gegenüber erklärt, dass er sich nach der in Artikel 7, Absatz 6 der Vorschriften über die Errichtung niedergelegten Weise dafür ausgesprochen habe, die andere Art der Wahl anzuwenden.

Regel 4: Wahlausschuss

4.1

Der Rat setzt während der letzten Ratssitzung, die vor dem 15. September des Vorjahres der Wahl endet, einen Wahlausschuss ein, der aus drei Institutsmitgliedern, die nicht zur Wahl stehen, besteht. Wenigstens ein Mitglied des Wahlausschusses soll wenn möglich bereits Erfahrung als Mitglied eines Wahlausschusses haben.

4.2

Die Amtszeit des Wahlausschusses endet erst mit der Einsetzung des nächsten Wahlausschusses vor der nächsten ordentlichen Wahl zum Rat.

4.3

Artikel 6.2 und 18.2 der Geschäftsordnung gelten auch für den Wahlausschuss.

4.4

Der Wahlausschuss hat bei der Wahl, für die er eingesetzt worden ist, die Einhaltung der anzuwendenden Vorschriften zu überwachen. Er hat insbesondere die gesamte Vorbereitung der Wahl, das Öffnen der Umschläge und das Auszählen der Stimmzettel zu überwachen, in Zweifelsfällen zu entscheiden, Losentscheidungen zu treffen, wann immer es diese Regeln erfordern, und über die Wahl dem Präsidenten des Rates schriftlich zu berichten.

4.5

Der Wahlausschuss tritt jeweils frühestens eine Woche, spätestens zwei Wochen nach den in Regeln 6.5 und 9.5 genannten Daten zusammen.

Regel 5: Vorbereitung der Wahl

So bald wie möglich nach dem 15. September und spätestens am 1. Oktober des Vorjahres der Wahl hat das Institut jedem Wahlberechtigten an seine Adresse gemäß der in Regel 2 genannten Liste ein Formular zur Vorbereitung der Wahl zum Rat (Wahlvorschlag), mit dem er Kandidaten vorschlagen kann, zu übersenden.

Regel 6: Wahlvorschlag

6.1

Jeder Wahlberechtigte kann auf seinem Wahlvorschlag nur für die Wahl in seinem eigenen einheitlichen Wahlbezirk beziehungsweise in seiner eigenen Gruppe seines nicht-einheitlichen Wahlbezirks sich selbst und/oder einen oder mehrere andere Institutsmitglieder, die einem beliebigen Wahlbezirk angehören können und die genau

mit Name und Geschäftssitz oder Arbeitsplatz zu bezeichnen sind, als Kandidaten vorschlagen.

6.2

Ein Wahlberechtigter darf auf seinem Wahlvorschlag nicht mehr Personen als Kandidaten vorschlagen als Ratsmitglieder für seinen eigenen einheitlichen Wahlbezirk beziehungsweise für seine eigene Gruppe seines nicht-einheitlichen Wahlbezirks zugelassen sind. Überzählige Vorschläge werden im Wahlvorschlag, vom Ende beginnend, vom Wahlausschuss gestrichen.

6.3

Vorgeschlagene Personen, die nur als stellvertretendes Ratsmitglied gewählt werden wollen, sind entsprechend zu bezeichnen.

6.4

Der Wahlberechtigte bestätigt mit seiner Unterschrift auf seinem Wahlvorschlag, dass jede von ihm vorgeschlagene Person mit ihrer Nominierung einverstanden ist und eine etwaige Wahl annehmen wird.

6.5

Der Vorschlag eines Wahlberechtigten ist nur gültig, wenn sein von ihm unterschriebener Wahlvorschlag spätestens am 1. November des Vorjahres der Wahl beim Sekretariat des Instituts eingeht.

Regel 7: Kandidatenlisten

7.1

Der Wahlausschuss erstellt aufgrund der Wahlvorschläge gemäß Regel 6 für jeden einheitlichen Wahlbezirk und für jede Gruppe jedes nicht-einheitlichen Wahlbezirks eine vorläufige Liste der von ihm zur Wahl zugelassenen Kandidaten.

7.2

Das Institut sendet spätestens am 1. Dezember des Vorjahres der Wahl jeder zur Wahl vorgeschlagenen Person jede vom Wahlausschuss erstellte vorläufige Kandidatenliste, für die diese Person vorgeschlagen worden ist, unabhängig davon, ob diese Person auf der vorläufigen Kandidatenliste aufgeführt ist oder nicht.

7.3

Nach dem Versand der vorläufigen Kandidatenlisten kann jede vorgeschlagene Person bis spätestens 10. Dezember (Eingang beim Sekretariat des Instituts) des Vorjahres der Wahl die Änderung der vorläufigen Kandidatenlisten schriftlich beantragen.

7.4

Der Wahlausschuss erstellt nach Prüfung etwaiger Änderungsanträge die endgültigen Kandidatenlisten bis spätestens 15. Dezember.

Regel 8: Kandidaten

Alle Kandidaten, die vom Wahlausschuss gemäß Regel 7.4 zur Wahl zugelassen sind, werden ungeachtet ihrer Anzahl zur Wahl gestellt.

Regel 9: Stimmzettel und andere Wahlunterlagen

9.1

Die Wahl zum Rat des Instituts wird durch Briefwahl ausgeübt. Die Stimmzettel und die zugehörigen Wahlunterlagen werden vom Institut bis spätestens 15. Januar der Wahljahres an die Wahlberechtigten zur Post gegeben.

9.2

In jedem nicht-einheitlichen Wahlbezirk erhält jeder Wahlberechtigte zwei Stimmzettel unterschiedlicher Farbe, von denen jeder für eine der beiden Gruppen dieses Wahlbezirks gilt und von denen der Wähler nur den für seine eigene Gruppe auszufüllen hat. In jedem einheitlichen Wahlbezirk erhält jeder Wahlberechtigte einen einzigen, für diesen Wahlbezirk geltenden Stimmzettel in einer dritten Farbe. Jeder Wahlberechtigte erhält zur Rücksendung des Stimmzettels einen Umschlag, der die Identität des versendenden Wählers nicht erkennen lässt und beiderseits wenigstens eine Öffnung aufweist, die die Farbe des Stimmzettels, aber nicht die Stimmabgabe von außen erkennen lässt.

9.3

Jeder Stimmzettel gibt den einheitlichen Wahlbezirk oder die Gruppe des nicht-einheitlichen Wahlbezirks, zu dem beziehungsweise zu der der Wahlberechtigte gehört, und die Gesamtzahl der ordentlichen und stellvertretenden Ratsmitglieder dieses Wahlbezirks beziehungsweise dieser Gruppe an. Er führt alle Kandidaten auf, die für diesen Wahlbezirk beziehungsweise diese Gruppe zur Wahl gestellt werden, und gibt gegebenenfalls für jeden Kandidaten an, ob er im gegenwärtigen Rat ein ordentliches oder ein stellvertretendes Ratsmitglied ist. Falls ein Kandidat eine Wahl nur als stellvertretendes Ratsmitglied anzunehmen bereit ist, ist dies auf dem Stimmzettel angegeben. Jeder Stimmzettel hat den folgenden Text aufzuweisen: *„Die Stimmabgabe für einen Kandidaten ist nur gültig, wenn der Wähler diese Stimmabgabe auf seinem Stimmzettel eindeutig erkennbar gemacht hat, beispielsweise durch Anzeichnen des Namens oder durch Streichen mindestens eines anderen Namens.“*

9.4

Jeder Wahlberechtigte erhält mit dem Stimmzettel oder den Stimmzetteln eine zu unterschreibende Erklärung, dass er selbst den Stimmzettel ausgefüllt hat. Jeder Wähler in einem nicht-einheitlichen Wahlbezirk hat auf der Erklärung zusätzlich anzugeben, ob er zu der Gruppe der freiberuflich Tätigen oder ob er zu der Gruppe der anderweitig Tätigen gehört, und zu versichern, dass er nur den für seine eigene Gruppe zutreffenden Stimmzettel zurücksendet. Wird ein Wähler von einer oder

mehreren Personen beschäftigt, die selbst freiberuflich tätig sind, so gilt auch diese Tätigkeit als freiberuflich. Der Wähler darf nur eine Art der Tätigkeit angeben. Der Wähler hat seine ordnungsgemäß ausgefüllte Erklärung gemeinsam mit dem zugehörigen Stimmzettel, der sich in dem Rücksendeumschlag befinden muss, dem Sekretariat des Instituts zurückzusenden.

9.5

Die Stimmen eines Wählers werden nur gezählt, wenn sein Stimmzettel gemeinsam mit seiner vollständig ausgefüllten und von ihm unterschriebenen Erklärung oder einer von ihm unterschriebenen Kopie davon spätestens am 15. Februar des Wahljahres beim Sekretariat des Instituts eingeht.

Regel 10: Stimmabgabe

Der Wähler hat seine Stimmen entsprechend der Anweisung auf dem Stimmzettel gemäß dem letzten Satz der Regel 9.3 abzugeben. Kein Wähler kann auf seinem Stimmzettel mehr Kandidaten gültig wählen als er insgesamt ordentliche und stellvertretende Mitglieder des Rates wählen kann. Überzählige Kandidaten werden, vom Ende beginnend, vom Wahlausschuss gestrichen.

Regel 11: Mängel der Stimmzettel

11.1

Stimmzettel, die den Willen des Wählers nicht eindeutig erkennen lassen oder denen nicht die ausgefüllte, unterschriebene und datierte Erklärung oder eine Kopie davon mit Originalunterschrift beigelegt ist oder die nicht den Angaben auf der Erklärung entsprechen, sind ungültig.

11.2

Bezeichnet ein Wähler auf seinem Stimmzettel einen Kandidaten mehr als einmal, so wird der Kandidat trotzdem nur einmal gezählt. Hinzugefügte Namen von Nicht-Kandidaten und Bemerkungen werden vom Wahlausschuss gestrichen. Die Gültigkeit des Stimmzettels bleibt davon unberührt.

Regel 12: Gewählte Mitglieder des Rates

12.1

Die Anzahl der Stimmen, die auf die Kandidaten entfallen, legt die Reihenfolge der Kandidaten fest, aus der sich ergibt, welche Kandidaten als ordentliche und welche als stellvertretende Mitglieder des Rates gewählt sind. Haben zwei oder mehr Kandidaten eine gleiche Stimmenzahl erhalten, so wird die Reihenfolge vom Wahlausschuss durch das Los entschieden.

12.2

Erhält ein Kandidat in zwei oder mehr einheitlichen Wahlbezirken und/oder Gruppen nicht-einheitlicher Wahlbezirke eine Stimmenzahl, die ausreicht, als ordentliches und/oder stellvertretendes Ratsmitglied in jedem dieser Wahlbezirke oder jeder dieser Gruppen gewählt

zu sein, so wird das Institut ihn so bald wie möglich hierüber informieren. Der Kandidat muss dann dem Sekretariat des Instituts umgehend mitteilen, in welchem Wahlbezirk oder in welcher Gruppe er ordentliches beziehungsweise stellvertretendes Ratsmitglied werden möchte. Versäumt er dies, wird die Frage vom Wahlausschuss durch das Los entschieden.

Regel 13: Wahlergebnis

Das Ergebnis der Wahl wird vom Institut bis spätestens 15. März des Wahljahres den Institutsmitgliedern schriftlich mitgeteilt. Diese Mitteilung enthält auch die Angabe der Stimmenzahl, die die Kandidaten erhalten haben, und das Resultat etwaiger Losentscheide.

Regel 14: Einsprüche

14.1

Institutsmitglieder, die gegen das Wahlergebnis Einwände erheben möchten, müssen ein entsprechendes Rechtsbegehren mit Begründung schriftlich fristgerecht beim Sekretariat des Instituts einreichen, wobei die Frist bei einer ordentlichen Wahl am 29. März des Wahljahres endet und das Fristende bei allen Nachwahlen vom Vorstand des Rates festgesetzt wird. Ein Rechtsbegehren, dem keine Begründung beigefügt ist, und ein solches, das nach Fristende eingeht, wird nicht berücksichtigt.

14.2

Der Präsident des Rates ernennt unverzüglich nach Eingang eines ordnungsgemäßen Rechtsbegehrens einen Wahl-Einspruchsausschuss, der aus drei Institutsmitgliedern besteht, die keine Kandidaten zur durchgeführten Wahl gewesen sind und keine Mitglieder des Wahlausschusses sind.

14.3

Die Amtszeit der Mitglieder des Wahl-Einspruchsausschusses beginnt mit ihrer Ernennung und endet mit der Erledigung der Aufgabe, für die sie ernannt worden sind. Artikel 6.2 und 18.2 der Geschäftsordnung gelten auch für den Wahl-Einspruchsausschuss. Der Wahl-Einspruchsausschuss wird den Einspruch gemäß seiner vom Rat bestimmten Zuständigkeit prüfen.

14.4

Wenn die Art des Einspruchs eine Nachwahl oder eine neue Wahl erfordert, sind die Regeln für die Nachwahl

oder neuen Wahl soweit wie möglich die gleichen wie die zu ordentlichen Ratswahlen; soweit solche Regeln nicht anwendbar sind, werden vom Vorstand des Rates geeignete Regeln aufgestellt.

Regel 15: Fristen

15.1

Das Sekretariat des Instituts hat alle bei ihm eingehenden Wahlunterlagen mit einem das Eingangsdatum aufweisenden Stempel zu versehen.

15.2

Vorbehaltlich der Regeln 15.3, 15.4 und 15.5 werden Unterlagen, die nach einem in diesen Regeln für Wahlen zum Rat festgelegten Datum beim Sekretariat des Instituts eingeht, nicht berücksichtigt.

15.3

Fällt das Ende einer Frist, die von einem Wahlberechtigten oder Kandidaten einzuhalten ist, auf einen Tag, an dem das Sekretariat des Instituts geschlossen ist, so endet die entsprechende Frist am ersten darauf folgenden Arbeitstag des Sekretariats des Instituts.

15.4

Wenn ein Wähler für den Wahlausschuss beziehungsweise den Wahl-Einspruchsausschuss zufriedenstellend nachweisen kann, dass er ein Schriftstück gemäß diesen Regeln zumindest acht Tage vor Ablauf einer Frist für den Eingang dieses Schriftstückes auf dem besten normalen Postweg, der zur Verfügung steht, an das Sekretariat des Instituts abgesandt hat, so wird dieses Schriftstück nach Eingang beim Sekretariat des Instituts als fristgerecht eingegangen angesehen, wenn zur Zeit des Eingangs andere Umstände eine Berücksichtigung dieses Schriftstückes noch erlauben.

15.5

Wenn die fristgerechte Erfüllung irgendeiner Bestimmung dieser Regeln nach Meinung des Wahlausschusses beziehungsweise des Wahl-Einspruchsausschusses durch außerhalb der Macht des Wahlberechtigten oder Kandidaten gelegene Umstände unmöglich wird, so kann der Wahlausschuss beziehungsweise der Wahl-Einspruchsausschuss anordnen, dass die Erfüllung zu einem anderen Termin angenommen werden wird.

Election to the Council of the Institute

At the beginning of next year, the Council of the Institute is due to be elected for its new term.

We would like to inform you of the mailing dates of the documents which have to be completed as well as of the deadlines for receiving the completed documents at the Secretariat of the Institute in Munich.

1st step:

– by 1st October 2007 at the latest:

Mailing of the nomination form for the nomination of candidates to the members of the Institute.

– by 1st November 2007:

Deadline for receiving the completed nomination form at the Secretariat of the Institute.

2nd step

– by 30th November 2007 at the latest:

Mailing of the provisional lists of candidates to the persons nominated for election.

– by 10th December 2007:

Deadline for receiving requests in writing for corrections of the provisional lists at the Secretariat of the Institute.

3rd step

– by 15th January 2008 at the latest:

Mailing of the ballot papers and related documents to the electors.

– by 15th February 2008:

Deadline for receiving the completed ballot paper together with the completed and signed declaration form at the Secretariat of the Institute.

4th step

– by 14th March 2008 at the latest:

Publication of the results of the election in **epi** Information 1/2008.

The Rules for election of Council are published hereafter.

Rules for Election of Council

Rule 1: Elections

Elections to the Council of the Institute of Professional Representatives are carried out by this Institute, in accordance with the Founding Regulation and in the manner laid down below.

Rule 2: Electors

2.1

All persons entered in the list of Professional Representatives maintained by the European Patent Office at the close of business of the European Patent Office in Munich on the last working day before 15th September of the year preceding the year in which the succeeding Council will take office („pre-election year“) shall be electors having the right to vote and to be candidates in the next ordinary election for the succeeding Council, and no other person.

2.2

The number of members of the Institute entered in the list of Professional Representatives at the close of business of the European Patent Office in Munich on the last working day before 15th September of the pre-election year shall be decisive for determining the number of Council members to be elected in each constituency, according to Article 7, paragraph 3 of the Founding Regulation.

Rule 3: Voting

3.1

Every constituency which voted unitarily or non-unitarily in the immediately preceding ordinary election to the Council and not having indicated to the Secretariat of the Institute before 15th September of the pre-election year that it has decided, in the manner envisaged by Article 7, paragraph 6 of the Founding Regulation, to adopt the other method of voting, shall vote in the same manner in the election of the succeeding Council.

3.2

Every constituency created during the current term of office of the Council and before 15th September of the pre-election year shall vote in the manner that was appropriate at its creation, pursuant to Article 7, paragraphs 4 and 5, of the Founding Regulation, unless it has indicated before 15th September of the pre-election year to the Secretariat of the Institute that it has decided, in the manner envisaged by Article 7, paragraph 6, of the Founding Regulation, to adopt the other manner of voting.

Rule 4: Electoral Committee

4.1

During the last Council Meeting, before the 15th September of the pre-election year, the Council shall set up an Electoral Committee consisting of three members of the Institute who shall not stand for election, and at least

one of whom should, if possible, have experience within a previous Electoral Committee.

4.2

The term of the Electoral Committee shall continue until the setting up of the next Electoral Committee for the next ordinary election of Council.

4.3

Articles 6.2 and 18.2 of the By-Laws are also applicable to the Electoral Committee.

4.4

For the election of Council for which the Electoral Committee has been set up, the Electoral Committee shall supervise conformity with the applicable Rules. The Electoral Committee shall in particular supervise all the steps relating to preparation for the election, the opening of the envelopes, the counting of the votes, shall decide in cases of doubt, shall draw lots whenever required by these Rules, shall declare the result of the election, and shall prepare a written report to the President of the Council on that election.

4.5

The Electoral Committee shall meet not before one week from and two weeks later than the respective dates mentioned in Rules 6.5 and 9.5.

Rule 5: Preparation for the Election

As soon as possible after 15th September and no later than 1st October of the pre-election year, the Institute shall send to each elector at his address as in the list referred to in Rule 2 a nomination form in preparation for the election of Council in which he may make nominations for candidates for election to Council.

Rule 6: Nomination

6.1

Only for his own unitary constituency or group of a non-unitary constituency, every elector can nominate himself and/or one or more other member(s) of the Institute, including those from another constituency, as candidate(s) for election, providing he identifies him/them by name and place of business or employment on his nomination form.

6.2

An elector shall not nominate on his nomination form more persons for election than the maximum number of Council members that is determined for his own unitary constituency or his own group of his non-unitary constituency. Nomination(s) beyond the determined number shall be struck from his nomination form from the end towards the beginning by the Electoral Committee.

6.3

A nominated person, who is only prepared to stand as a substitute, shall be so indicated.

6.4

An elector who has signed his nomination form thereby confirms that each nominee accepts his nomination and election, if elected.

6.5

To be valid, a signed nomination form shall be received by the Secretariat of the Institute no later than 1st November of the pre-election year.

Rule 7: Lists of candidates

7.1

For each unitary constituency and each group of each non-unitary constituency, the Electoral Committee shall prepare from the persons nominated, according to the provisions of Rule 6, a provisional list of candidates for election.

7.2

No later than 1st December of the pre-election year, the Institute shall send to each person nominated for election to Council the provisional list(s) drawn up by the Electoral Committee for the or each constituency for which he has been nominated. Persons whose nomination was disregarded shall also receive those provisional list(s).

7.3

After the provisional list(s) has/have been sent, any person nominated may request in writing correction of such provisional list(s). Any such request shall be received by the Secretariat of the Institute at the latest by 10th December of the pre-election year.

7.4

The Electoral Committee shall consider any such request and shall then draw up final lists of candidates for election until 15th December.

Rule 8: Candidates

All candidates appearing on final lists drawn up according to Rule 7.4 shall be put forward for election, regardless of their number.

Rule 9: Ballot Papers and related documents

9.1

The election of the Council shall be carried out by postal vote. At the latest by the 15 January of the election year, the Institute shall send ballot papers and related documents by post to the electors.

9.2

In every non-unitary constituency each elector will receive two ballot papers of different colour, applicable respectively to the two groups of that constituency, of which he will complete only the one applicable to his own group. In every unitary constituency each elector will receive a single ballot paper applicable to that constituency and of a third

colour. Each elector will receive an envelope for returning the ballot paper, suitable for concealing the returning elector's identity, and with at least one opening on both sides, which allows identification of the ballot paper by colour, but not the content of the ballot paper.

9.3

Each ballot paper will indicate the unitary constituency or the group of a non-unitary constituency for which that ballot paper is valid, and the total number of representatives and substitutes for that constituency or group. The ballot paper will indicate all the candidates standing for election to the respective constituency or group of a non-unitary constituency, and, where applicable, for each of them whether he is a representative or substitute of the current Council, and whether a candidate wishes only to stand for election as a substitute. Each ballot paper must include the following text: *„The vote for a candidate shall only be valid when the elector makes it clear on his ballot paper that he has voted for that candidate, particularly by putting a sign or mark against the name of that candidate, or by striking out the name(s) of (an)other candidate(s).“*

9.4

Each elector will receive with the ballot paper(s) a declaration for the elector to declare that he himself has completed the ballot paper. In addition, each elector in a non-unitary constituency shall on the declaration declare that he is a member of the group in private practice, or in the group of another capacity, and that he has only returned the ballot paper applicable to his own group. Employment in a private practice firm shall be considered as being in the group in private practice. An elector is permitted to indicate on the declaration only one kind of practice. The elector shall return the duly completed declaration, together with the related ballot paper, which ballot paper must be in the envelope provided, to the Secretariat of the Institute.

9.5

The votes of the elector will only be counted if his ballot paper together with his completed and signed declaration, or a photocopy thereof (provided the signature is original), is received by the Secretariat of the Institute no later than 15 February of the election year.

Rule 10: Voting

An elector shall vote as directed on the ballot paper according to the last sentence of Rule 9.3. No elector may validly vote on his ballot paper for a number of candidates exceeding the determined number of representatives and substitutes, taken together, for whom he may vote. Votes cast exceeding the determined number will be struck from a ballot paper from the end towards the beginning by the Electoral Committee.

Rule 11: Ballot Deficiencies

11.1

Ballot papers which do not clearly allow a determination of the intention of the elector, or which are not accompanied by the completed, signed and dated declaration, or by a photocopy thereof on which the signature is original, or which do not correspond with the declaration, are null and void.

11.2

If an elector votes on his ballot paper more than once for a candidate, that candidate will be counted only once. Added names of persons who are not candidates and remarks shall be deleted by the Electoral Committee without prejudice to the validity of the ballot paper.

Rule 12: Elected Members of Council

12.1

The number of votes received by the candidates determines whether they are elected either as representatives or as substitutes, and in what order. If an equal number of votes is received by two or more candidates, their order will be decided by lots drawn by the Electoral Committee.

12.2

If a candidate receives in two or more unitary constituencies and/or groups of non-unitary constituencies a number of votes sufficient for being elected, as a representative and/or as a substitute, in each of those constituencies or groups, the Institute shall inform him accordingly as soon as possible, and he must then promptly advise the Secretariat of the Institute in which one he chooses to become a representative or a substitute, as the case may be, failing which the question will be decided by lots drawn by the Electoral Committee.

Rule 13: Election results

At the latest by 15th March of the election year, the Institute shall send the result of the election by post to its members, indicating the number of votes received by all candidates and the result of any drawing of lots, if applicable.

Rule 14: Objections

14.1

Members of the Institute wishing to object to the election result shall submit their written requests with a reasoned statement to reach the Secretariat of the Institute at the latest by a date which for an ordinary election is 29th March of the election year and for any by-election will be set by the Board of the Council. Any request without a reasoned statement will not be taken into consideration; neither will a request reaching the Secretariat of the Institute after the respective date be taken into consideration.

14.2

After a correctly made request has been received by the Secretariat of the Institute, the President of the Council shall promptly designate an Electoral Objections Committee consisting of three members of the Institute who were not candidates in the disputed election and who are not members of the Electoral Committee.

14.3

The term of the Electoral Objections Committee shall continue until the completion of examination of the objections for which it was designated. Articles 6.2 and 18.2 of the By-Laws are applicable to the Electoral Objections Committee. The Electoral Objections Committee shall examine the objections in conformity with terms of reference fixed for it by the Council.

14.4

If the nature of the objections requires a by-election or new election, the Rules governing that election shall as far as possible be the same as those governing ordinary elections to Council and where those Rules are not applicable, Rules will be set by the Board of the Council.

Rule 15: Time Limits**15.1**

The Secretariat of the Institute shall stamp all papers concerning the elections received by the Institute with a stamp giving the date of receipt.

15.2

Any paper reaching the Institute after any respective date set by the Rules for election of Council shall be ignored, excepting as provided for in Rules 15.3, 15.4 and 15.5 hereafter.

15.3

If any time limit which must be observed by an elector or candidate falls on a day on which the Secretariat of the Institute is closed, that time limit shall extend until the first working day of the Secretariat of the Institute thereafter.

15.4

If an elector can prove to the satisfaction of the Electoral Committee or the Electoral Objections Committee respectively that he posted any paper referred to in these Rules to the Secretariat of the Institute by the best normal postal service available at least eight days before a time limit for receipt of that paper, the paper shall, after receipt by the Secretariat of the Institute, be deemed to have been received in time, if at that time of receipt other circumstances still permit account to be taken of that paper.

15.5

If compliance with any provision of these Rules by the date set is, in the opinion of the Electoral Committee or the Electoral Objections Committee respectively, rendered impossible by circumstances outside the elector's or candidate's control, the Electoral Committee or the Electoral Objections Committee respectively may rule that compliance by another date will be accepted.

Election au Conseil de l'Institut

Au début de l'année prochaine, le Conseil de l'Institut doit être renouvelé pour un nouveau mandat.

Nous vous informons ci-après des dates d'envoi des documents à remplir et des dates auxquelles ces documents devront être retournés au secrétariat de l'Institut à Munich.

1ère étape

– au plus tard le 1er octobre 2007:

Envoi du formulaire de candidature pour la nomination de candidats aux membres de l'Institut.

– 1er novembre 2007:

Date limite de réception du formulaire de candidature au secrétariat de l'Institut.

2ème étape

– au plus tard le 30 novembre 2007:

Envoi des listes provisoires de candidats aux personnes dont la candidature a été proposée.

– 10 décembre 2007:

Date limite de réception, au secrétariat de l'Institut, de toute requête écrite visant à apporter une correction sur les listes provisoires de candidats.

3ème étape

– au plus tard le 15 janvier 2008:

Envoi des bulletins de vote et documents annexés aux électeurs.

– 15 février 2008:

Date limite de réception du bulletin de vote dûment rempli ainsi que du formulaire de déclaration, dûment rempli et signé, au secrétariat de l'Institut.

4ème étape

– au plus tard le 14 mars 2008:

Communication des résultats des élections dans *epi* Information 1/2008.

Les Règles pour l'élection au Conseil sont publiées ci-après :

Règles pour les élections au Conseil

Règle 1: Elections

Les élections au Conseil de l'Institut des mandataires agréés sont organisées par cet Institut en application du Règlement de création et de la manière précisée ci-dessous.

Règle 2: Electeurs

2.1

Toute personne qui est inscrite sur la liste des mandataires agréés, tenue par l'Office européen des brevets, à l'heure de fermeture de l'Office européen des brevets à Munich le dernier jour ouvrable avant le 15 septembre de l'année précédant celle au cours de laquelle le nouveau Conseil entrera en exercice („année pré-électorale“), aura la qualité d'électeur ayant le droit de voter et d'être candidat pour la prochaine élection ordinaire au nouveau Conseil, et ce à l'exclusion de toute autre personne.

2.2

Le nombre des membres à l'Institut inscrits sur la liste des mandataires agréés à l'heure de fermeture de l'Office européen des brevets à Munich le dernier jour ouvrable avant le 15 septembre de l'année pré-électorale, sera pris en considération pour fixer le nombre de membres du Conseil qui seront élus dans chaque circonscription, conformément à l'article 7, paragraphe 3 du Règlement de création.

Règle 3: Vote

3.1

Toute circonscription ayant voté suivant le système à collège unique ou à double collège lors des élections ordinaires immédiatement précédentes au Conseil, et n'ayant pas indiqué au Secrétariat de l'Institut avant le 15 septembre de l'année pré-électorale que, en vertu de l'Article 7, paragraphe 6 du Règlement de création, elle a décidé d'adopter l'autre système, devra voter suivant le précédent système aux élections du nouveau Conseil.

3.2

Toute circonscription créée avant le 15 septembre d'une année pré-électorale pendant la durée d'exercice du Conseil devra voter suivant le système applicable à la date de sa création en vertu de l'Article 7, paragraphe 4 et 5 du Règlement de création, à moins qu'elle n'ait indiqué au Secrétariat de l'Institut avant le 15 septembre de l'année pré-électorale que, conformément à l'Article 7, paragraphe 6 du Règlement de création, elle adoptera l'autre système.

Règle 4: Commission Electorale

4.1

Lors de la dernière réunion du Conseil prenant fin avant le 15 septembre de l'année pré-électorale, le Conseil devra désigner une Commission Electorale constituée de trois membres de l'Institut qui ne se présentent pas aux élections. L'un d'entre eux au moins devrait avoir si possible une expérience antérieure au sein d'une Commission Electorale.

4.2

L'exercice de la Commission Electorale se poursuit jusqu'à la mise en place d'une nouvelle Commission Electorale en vue de la prochaine élection ordinaire du Conseil.

4.3

Les dispositions de l'Article 6.2 et 18.2 du Règlement Intérieur sont aussi applicables à la Commission Electorale.

4.4

Pour l'élection pour laquelle elle a été désignée, ladite Commission veillera au respect des règles en vigueur. Elle supervisera toutes les tâches préparatoires afférentes à l'élection, le dépouillement du scrutin, tranchera en cas de doute et effectuera en tant que de besoin les tirages au sort prévus par les présentes règles; elle annoncera les résultats de l'élection et établira un compte-rendu de celle-ci à l'attention du Président du Conseil.

4.5

La Commission Electorale se réunit au plus tôt une semaine après et au plus tard deux semaines après les dates visées aux Règles 6.5 et 9.5.

Règle 5: Préparation de l'élection

Dès que possible, après le 15 septembre de l'année pré-électorale, mais au plus tard le 1er octobre de cette même année, l'Institut enverra à chaque électeur, à son adresse indiquée sur la liste visée à la Règle 2, un formulaire de candidature destiné à la préparation de l'élection du Conseil, grâce auquel chaque électeur peut soumettre des candidatures.

Règle 6: Proposition de candidatures

6.1

Exclusivement pour sa circonscription à collège unique, ou son propre groupe dans le cas d'une circonscription à double collège, tout électeur peut soumettre sa propre candidature et/ou celle d'un ou de plusieurs autres membres de l'Institut, même provenant d'une autre circonscription. Les candidats doivent être dûment identifiés sur le formulaire de candidature par leur nom et leur lieu d'établissement ou d'emploi.

6.2

Un électeur ne doit pas soumettre sur son formulaire de candidature plus de candidatures à l'élection qu'il n'y a de sièges disponibles de membres du Conseil dans sa propre circonscription si celle-ci est à collège unique, ou son propre groupe si la circonscription est à double collège. Au-delà du nombre de sièges disponibles, les candidatures en trop seront biffées du formulaire de candidature de bas en haut par la Commission Electorale.

6.3

Les personnes dont la candidature est proposée et qui sont disposées à siéger en tant que membres suppléants uniquement, doivent être identifiées en tant que telles.

6.4

L'électeur qui a formulé une proposition de candidatures confirme par sa signature sur le formulaire de candidature que chaque candidat accepte sa candidature et son élection, le cas échéant.

6.5

Pour être valable, le formulaire de candidature doit parvenir dûment signé au secrétariat de l'Institut au plus tard le 1er novembre de l'année pré-électorale.

Règle 7: Listes des candidats

7.1

Pour chaque circonscription à collège unique et pour chaque groupe des circonscriptions à double collège, la Commission Electorale établit à partir des propositions de candidatures une liste provisoire de candidats conformément aux dispositions de la Règle 6.

7.2

Au plus tard le 1er décembre de l'année pré-électorale, l'Institut transmet à chaque personne dont la candidature a été proposée la ou les listes provisoires qui la concernent, et ce dans toutes les circonscriptions à collège unique et tous les groupes des circonscriptions à double collège pour lesquels sa candidature a été proposée. L'Institut fait également parvenir ces listes aux personnes dont le nom n'a pas été retenu par la Commission Electorale pour y figurer.

7.3

Après que les listes provisoires ont été transmises, toute personne dont la candidature a été proposée peut demander leur correction par écrit. Une requête à cette fin, doit parvenir au secrétariat de l'Institut au plus tard le 10 décembre de l'année pré-électorale.

7.4

La Commission Electorale statue sur les requêtes en correction et établit ensuite les listes définitives de candidats à l'élection jusqu'au 15 décembre.

Règle 8: Candidats

Tous les candidats dont les noms apparaissent sur les listes définitives visées à la Règle 7.4 sont présentés aux élections, au mépris de leur nombre.

Règle 9: Bulletins de vote et documents annexés

9.1

L'élection au Conseil s'effectue par correspondance postale. Au plus tard le 15 janvier de l'année de l'élection, l'Institut adresse les bulletins de vote et documents annexés par voie postale aux électeurs.

9.2

Dans toute circonscription à double collège, chaque électeur recevra deux bulletins de vote de couleur distincte, respectivement valables pour chacun des groupes de cette circonscription, et il ne devra remplir que le bulletin valable pour son propre groupe. Dans toute circonscription à collège unique, chaque électeur recevra un seul bulletin de vote valable pour cette circonscription, dans une troisième couleur. Chaque électeur recevra une enveloppe permettant de remettre le bulletin de vote sans révéler l'identité de l'électeur, et comportant au moins une ouverture sur les deux faces permettant de reconnaître la couleur du bulletin de vote mais non d'identifier son contenu.

9.3

Chaque bulletin de vote mentionne pour quelle circonscription à collège unique ou quel groupe d'une circonscription à double collège il est valable, ainsi que le nombre total de l'ensemble des représentants titulaires et suppléants pour cette circonscription ou ce groupe. Il indiquera en outre tous les candidats qui sont présentés dans la circonscription à collège unique ou le groupe de la circonscription à double collège considérés, et le cas échéant, pour chacun d'entre eux, s'il est représentant titulaire ou suppléant au sein du Conseil précédent, et si le candidat souhaite son élection uniquement en qualité de membre suppléant. Chaque bulletin de vote comprend en outre la mention suivante: „Le vote en faveur d'un candidat sera réputé valable uniquement lorsque l'électeur montre clairement sur le bulletin de vote qu'il a voté pour ce candidat, notamment à l'aide d'un signe ou d'une marque en regard de son nom, ou en biffant les

noms d'un ou des autres candidats qu'il ne souhaite pas élire."

9.4

Chaque électeur reçoit avec le ou les bulletins de vote une déclaration au moyen de laquelle il déclare avoir rempli lui-même le bulletin de vote. Pour les circonscriptions à double collège, chaque électeur indique en outre s'il appartient au groupe de la profession libérale ou s'il exerce à tout autre titre, et qu'il renvoie seulement le bulletin de vote de son propre groupe. Si un membre exerce son activité auprès d'un employeur qui exerce lui-même à titre libéral, cette dernière sera également considérée comme relevant de la profession libérale. Un électeur n'est autorisé à mentionner qu'un seul titre d'exercice. L'électeur renvoie au Secrétariat de l'Institut la déclaration, dûment remplie, ainsi que le bulletin de vote, lequel doit être préalablement inséré dans l'enveloppe jointe.

9.5

Le vote d'un électeur ne sera compté que si le bulletin de vote et la déclaration, dûment remplie et signée, ou une photocopie de celle-ci, portant une signature originale, parviennent au Secrétariat de l'Institut au plus tard le 15 février de l'année de l'élection.

Règle 10: Vote

Chaque électeur doit voter suivant les instructions figurant sur le bulletin de vote, conformément à la dernière phrase de la Règle 9.3. Aucun électeur ne peut valablement marquer sur son bulletin de vote plus de candidats que le nombre total des représentants titulaires et suppléants, pris dans leur ensemble, pour lequel il est autorisé à voter. Au-delà du nombre autorisé, les noms des candidats sont biffés de bas en haut par la Commission Electorale.

Règle 11: Bulletin nuls

11.1

Sont considérés comme nuls et sans valeur les bulletins de vote qui ne permettent pas de déterminer clairement l'intention de l'électeur, ou ceux qui ne sont pas accompagnés de la déclaration, dûment remplie, signée et datée, ou d'une photocopie de celle-ci portant une signature originale, ainsi que ceux qui ne correspondent pas à la déclaration.

11.2

Si un candidat se voit attribuer plusieurs fois la marque d'un électeur sur un bulletin de vote, celle-ci ne sera prise en compte qu'une seule fois. Les noms additionnels de personnes non-candidates et les remarques seront bariés par la Commission Electorale sans préjudice de la validité du bulletin de vote.

Règle 12: Membres du Conseil élus

12.1

Le nombre des voix recueilli par les candidats détermine leur ordre d'élection qui détermine si ceux-ci sont élus au Conseil en tant que représentant titulaire ou en tant que suppléant. Si un nombre égal de voix a été recueilli par deux ou plus de candidats, ces derniers sont départagés par tirage au sort organisé par la Commission Electorale.

12.2

Si un candidat recueille, dans deux ou plus de deux circonscriptions à collège unique et/ou groupes de circonscriptions à double collège, un nombre de voix suffisant pour être élu dans chacun de ces circonscriptions ou groupes, en tant que représentant titulaire et/ou suppléant, l'Institut devra l'en informer dès que possible. Le candidat devra alors indiquer à bref délai au Secrétariat de l'Institut dans quelle circonscription ou quel groupe il choisit de devenir représentant titulaire ou, le cas échéant, suppléant, faute de quoi la question sera tranchée par tirage au sort organisé par la Commission Electorale.

Règle 13: Résultat de l'élection

Au plus tard le 15 mars de l'année électorale, l'Institut communiquera par écrit le résultat de l'élection à tous les membres, en indiquant le nombre de voix recueillies par chaque candidat et, le cas échéant, le résultat des tirages au sort qui auront été effectués.

Règle 14: Contestation du résultat

14.1

Les membres de l'Institut désirant contester le résultat d'une élection devront soumettre par écrit une requête au Secrétariat de l'Institut, accompagnée d'un mémoire exposant leurs objections, de manière qu'ils lui parviennent au plus tard le 29 mars de l'année électorale lorsqu'une élection ordinaire est concernée, et, dans le cas d'une élection complémentaire, à une date qui sera fixée par le Bureau du Conseil. Si la requête en contestation parvient au secrétariat de l'Institut après cette date, ou si elle n'est pas accompagnée d'un mémoire exposant les objections soulevées, celle-ci ne sera pas prise en considération.

14.2

Dès la réception de la requête en contestation, le Président du Conseil devra désigner dans les plus brefs délais une Commission des Contestations de l'élection constituée de trois membres de l'Institut qui n'ont pas été candidats dans l'élection contestée, ni membre de la Commission Electorale.

14.3

L'exercice de la Commission des Contestations de l'élection se poursuit jusqu'au complet achèvement de son devoir. Les dispositions des Articles 6.2 et 18.2 du

Règlement Intérieur sont applicables à la Commission des Contestations de l'élection. La Commission des Contestations de l'élection devra traiter les contestations conformément à ses attributions fixées par le Conseil.

14.4

Si la nature des objections impose une élection complémentaire ou une nouvelle élection, les Règles régissant ces élections seront, autant que possible, les mêmes que celles qui régissent l'élection ordinaire au Conseil, sous réserve de l'application de Règles spécifiques fixées par le Bureau du Conseil.

Règle 15: Délais

15.1

Le secrétariat de l'Institut pose un cachet d'arrivée portant la date de réception sur tout document relatif aux élections qui arrive au secrétariat de l'Institut.

15.2

Tout document arrivant au secrétariat de l'Institut au-delà des dates prescrites par les présentes Règles ne sera pas pris en considération, à l'exception de ceux visés aux Règles 15.3, 15.4 et 15.5 ci-après.

15.3

Si le dernier jour d'un délai qui doit être observé par un électeur ou un candidat tombe sur un jour de fermeture

du secrétariat de l'Institut, alors le délai est prorogé jusqu'au jour ouvrable suivant du Secrétariat de l'Institut.

15.4

Si un électeur peut prouver de façon convaincante à la Commission Electorale ou la Commission des Contestations de l'élection respectivement qu'il a effectué l'envoi d'un document quelconque prescrit par les présentes Règles par courrier postal à l'adresse du Secrétariat de l'Institut dans les meilleures conditions normales possibles, au moins huit jours avant la date limite de réception de ce document, ce dernier sera considéré à sa réception par le Secrétariat de l'Institut comme ayant été reçu dans le délai fixé si, lors de sa réception, aucune autre circonstance ne s'y oppose.

15.5

Si la Commission Electorale ou la Commission des Contestations de l'élection respectivement estime que des circonstances indépendantes de la volonté d'un électeur ou d'un candidat ont empêché ce dernier de respecter l'une quelconques des exigences des présentes Règles à une date fixée, celle-ci peut décider que le respect de cette exigence à une autre date devra être accepté.

Decision of the Disciplinary Board of Appeal of 15 November 2006 (D 0025/05)

Dear Colleagues,

On behalf of our Disciplinary Committee I may inform you about the recent decision of the Disciplinary Boards of Appeal D 0025/05.

It was established that the defendant/appellant had failed to pay an annual fee in due time, failed to notice and report to the client of the non-payment and requested for payment of the next renewal fee. The Board has confirmed that it was appropriate to issue a reprimand by the responsible Disciplinary Chamber of our Committee.

Please note, that the Chambers of our Committee are advised to follow that decision in similar cases. Please remember, that more serious penalties are available, if members of our institute misbehave and cause damages to others.

The Chairman of *epi* Disciplinary Committee

Paul Rosenich

Decision of the Disciplinary Board of Appeal of 15 November 2006 (D 0025/05)

Appellant: N.N.

Decision under appeal: Decision of the Disciplinary Committee dated 17 June 2005

Composition of the Board:

Chairman: P. Messerli

Members: E. Dufasne

H. Preglau

C. Onn

A. V. Huygens

Summary of Facts and Submissions

I. The present appeal concerns the decision of the EPO Disciplinary Committee of 17 June 2005 to issue X with a reprimand.

II. The European Patent Attorney Y (the Complainant) had entrusted the firm Z with the validation in Spain of the Spanish counterpart of the European patent pub-

lished under Nr. ... 85 and with the further payment of renewal fees for this patent. In its turn, the firm Z entrusted the Spanish European patent attorney X therewith.

On 23 July 2002, Z sent to X „Annual fee payment instructions“ for the (n)th renewal fee of the concerned patent due to be paid in Spain on .. 2002.

On 20 September 2002, X acknowledged receipt of these instructions, with a corresponding invoice to Z and the indication that the payment of the renewal fee would only be made upon the settlement of the invoice.

On 2 October 2002, Z ordered its bank to pay X's firm an amount settling i. a. the corresponding invoice.

The renewal fee concerned was however not paid in due time by X.

On 15 September 2003, Z sent to X „Annual fee payment instructions“ for the (n+1)th renewal fee of the concerned patent due to be paid in Spain on ... 2003.

On 29 September 2003, X acknowledged receipt of these instructions, with a corresponding invoice to Z and the indication that the payment of the renewal fee would only be made upon the settlement of the invoice.

It appears from a handwritten mention on said invoice that Z ordered on 6 October 2003 its bank to pay to X's firm an amount settling i. a. the corresponding invoice.

However, neither the still due (n)th nor the (n+1)th renewal fees were paid by X.

III. In view of this situation, the Complainant filed a complaint against X before the Disciplinary Committee on 14 September 2004.

The complaint also referred at that time to the alleged no-payment of renewal fees of the Spanish counterpart of the European patent published under Nr. ...96, but it appeared later that these fees had been finally paid with surcharge.

The complaint also enclosed and referred to a letter from Z dated 10 September 2004 alleging other malpractice and misconduct by X, but these were never enlarged upon or supported by further evidence.

The Complainant finally drew attention to the importance of the damage suffered by his client having lost the Spanish counterpart of his European patent published under Nr. ...85.

IV. In his reply sent on 14 February 2005 (with an English translation filed on 7 April 2005) to A, the Rapporteur of the Disciplinary Committee, X raised the following arguments:

a. the non-applicability of the Code of Conduct of the Institute of Professional representatives before the EPO to the situation concerned, on the basis that the services concerned were not offered as a European patent attorney but as a Spanish patent attorney acting before the Spanish Patent Office;

b. the non-admissibility of the complaint by the Complainant, in the absence of a direct relation between himself and the Complainant;

c. the delayed settlement by Z of different invoices sent to them regarding the payment of renewal fees in Spain, so that X's firm had to pay in advance corresponding amounts to the Spanish Patent Office.

V. In its decision of 17 June 2005, in view of the facts and arguments submitted and on the basis of Articles 4(1) and 6(2)b of the Regulation on discipline for professional representatives (RDR, OJ EPO 1978, 91) the Disciplinary Committee issued X with a reprimand.

VI. On 15 July 2005, X (the Appellant) filed an appeal before the Disciplinary Board of Appeal (the Board) against the above decision. The statement setting out the grounds of appeal was received on 16 August 2005.

VII. By letters from the Board of 29 September 2005, the Presidents of the European Patent Office and of the Council of the Institute of Professional representatives were given the opportunity to comment on this appeal, pursuant to Article 12 RDR. Neither President gave a comment.

VIII. On 6 April 2006, the Board issued a communication setting out its preliminary views on the merits of the appeal.

IX. The Appellant provided a reply to that communication on 23 June 2006 and further arguments on 21 August 2006.

The Appellant's arguments in the present appeal are summarised as follows:

The Appellant essentially maintained the arguments he had submitted before the Disciplinary Committee (above mentioned in Section IV).

The Appellant also requested, for the first time in his statement of grounds of appeal, the exclusion of A as a Member of the Disciplinary Committee. That request was based on the ground that A was a member of the Directorate of the Official Bar Association of Industrial Property Agents of Spain (COAPI), said Directorate having taken, on ... 2002, a decision applying a disciplinary sanction to him, which decision was appealed against and set aside by the Superior Tribunal of Justice by a judgement notified to the Appellant on 23 May 2005.

The Appellant finally elaborated on the argument of constant delays and irregularities in the payments made by Z to his firm, Z being therefore exclusively responsible for the non-payment of the renewal fees concerned.

X. During the appeal procedure, the Complainant provided the Board with several submissions and requests (10 October 2005, 18 May 2006, 1 June 2006, 26 June 2006, 12 July 2006, and 29 August 2006), including book-keeping and invoicing matters in dispute between Z and the Appellant, a non-supported and non-specified reference to a former national disciplinary decision in Austria and a request for an aggravated sanction to be taken by the Board against the Appellant.

XI. The Appellant requested the exclusion of A and the setting aside of the decision contested.

Reasons for the decision

1. The appeal meets the requirements of Article 22(1) RDR and Article 6 of the Additional rules of Procedure of the Disciplinary Board of Appeal dated 9 April 1980 (OJ EPO 1980, 188). It is therefore admissible.

2. Exclusion of A

Article 16 of the RDR provided that Article 24 EPC shall apply *mutatis mutandis* as regards the exclusion of and objection to members of any of the Disciplinary Bodies.

Article 24 EPC prevents Members of Boards from taking part in procedures if they have any personal interest therein (Art. 24(1) EPC) or are suspected of partiality (Art. 24(3) EPC).

Admissibility of the objection

Under Article 24(3) EPC, it is required, for an objection to be admissible, that it be raised by a party when said party is made aware of the reason for that objection, before the party takes any other procedural step.

In the present case, the Appellant raised his objection against A for the first time in his statement of grounds of appeal dated 16 August 2005.

Should a personal interest of partiality of A have existed, the Board considers it would have arisen from the decision taken in first instance by the Directorate of the COAPI, since that instance was the one to which A was possibly connected.

When the Appellant performed a procedural act in the procedure, i. e. when he sent to A his arguments in reply to the complaint in first instance, on 14 February 2005, he was aware of the possible reason for objection, i. e. the decision of the Directorate of the COAPI dated ... 2002 and the presence in the Disciplinary Committee of a member of COAPI (allegedly of its Directorate), since he had already appealed said decision of the Directorate of the COAPI.

The Board is consequently of the opinion that the Appellant was no longer entitled to raise his objection for the first time before the Board.

This opinion is not changed by the allegation of the Appellant that A has a „personal interest“ pursuant to Article 24 EPC, because the decision of the Directorate of the COAPI dated ... 2002 was vacated by a Spanish court, the decision of which was notified to the Appellant on 23 May 2005, i. e. after his first procedural step in the first instance of the present procedure. That Spanish procedure is unrelated to the present one and no facts whatsoever were presented why in this case A should have had a „personal interest“.

The Board therefore dismisses the request for exclusion of A as inadmissible under Article 16 RDR and Article 24 EPC.

3. Relevant facts

It appears from the above-mentioned facts that the basis for the complaint lies only in the non-payment by the Appellant of the (n)th and (n+1)th renewal fees in Spain for the national counterpart of the European patent published under Nr ...85.

The renewal fees in Spain for the national counterpart of the European patent published under Nr ...96 appear to have finally been paid with surcharge.

The question raised by the Complainant of the damages allegedly suffered by the patent proprietor, is obviously out of the competence of this Board, the purpose of disciplinary proceedings being not for individuals to pursue their interests *vis-à-vis* others, but rather to serve the public interest in the orderly and proper exercise of professional representation before the EPO. The claims by individuals arising from a representative's infringement of the rules of professional conduct are a matter for the competent courts under civil, criminal or administrative law (cf. D 24/99 of May 2001, unpublished, point 1 of the Reasons and D 15/95, OJ EPO 1998, 297, point 2 of the Reasons).

No other element has been established or even substantiated in the present case.

4. Competence

The Appellant challenges the competence of the European Disciplinary Bodies in the present case, on the basis that it only concerns the payment of national fees before the Spanish Intellectual Property Office, which requires the participation of a Spanish registered Industrial Property Agent and not of a European authorised representative.

The Code of Conduct of the Institute of Professional representatives before the EPO (Code of Conduct, as last amended on 8 May 2001, OJ EPO 2003, 523, Preamble) provides that „this Code is to govern the conduct and other activities of the members in so far as such activities are related to the Convention on the grant of European Patents“.

As decided by the Disciplinary Board of Appeal in case D 19/99 of 18 December 2001 (unpublished, Reasons 5.1 and 5.2), this, in conjunction with the principle of strict interpretation of disciplinary measures, excludes the application of the European disciplinary rules to acts performed by a European authorised representative referring only to national patents, without any connection with any European patent.

However, it was also decided by the Disciplinary Board of Appeal in case D 16/95 of 29 March 1998 (unpublished, Reasons, 3) that the filing of a translation and the payment of corresponding fees in the national phase for the national counterpart of a European patent, even if these activities are not in direct relation with the grant, opposition or appeal procedures, are in relation to a European patent and basically belong to the sphere of competence of a European authorised representative.

The Board confirms that the exercise of the profession of a European authorised representative under the obligations of the European disciplinary rules, although not encompassing acts without any connection with a European patent, cannot be solely restricted to the acts as a professional representative directly before the EPO.

It further notes that, even under the principle of strict interpretation of disciplinary measures, the activities governed by the Code of Conduct, under its Preamble,

are not restricted to activities due to be carried out under the EPC but more broadly encompasses all activities „related“ to the EPC.

The Board therefore considers, in the present case, that the acts for which the European authorised representative was responsible were related to the EPC, that the European disciplinary rules apply thereto and that consequently the European disciplinary rules apply thereto and that consequently the European Disciplinary Bodies are competent.

5. Admissibility of the complaint

The Appellant refers to the absence of a direct relation between himself and the Complainant to challenge the admissibility of the original complaint.

Although it is correct that there is no direct relation between the Appellant and the Complainant, it is clear that in the present case the Appellant acted through the intermediary of another firm for the Complainant.

The Board considers that, even with the existence of an intermediate firm, there is a clear relation between the Appellant and the Complainant, the Appellant having acted for the Complainant and being responsible among others to him, for the acts so accomplished or omitted.

6. The disciplinary measure

The Disciplinary Committee issued X a reprimand.

The Appellant requests the revocation of the decision, whereas the „Complainant“ „requests“ the deletion of the Appellant from the list of professional representatives.

Concerning the submissions provided by the Complainant, the Board observes that the Complainant is not a party to the disciplinary proceedings, as established under Articles 8(2) and 21(1) RDR and confirmed by the case law of the Disciplinary Board of Appeal (cf. D 16/95, D 1/98 of 21 July 1998 and D 24/99 of 14 May 2001, both unpublished). The Complainant is therefore not entitled to present any request in the present proceedings, in particular to request that the Appellant be issued with a heavier sanction.

The facts established consist of:

- non-payment of a renewal fee for which the Appellant had received instructions and payment;
- failure to notice and report to the client the non-payment, thus missing the possibility of later payment with surcharge;
- request for payment of the next renewal fee as though everything was in order, i. e. without having checked the status of payments and having noticed lack of payment of the previous renewal fee.

The only argument raised in substance by the Appellant as possible justification is that the delay in payment

by Z provoked the irregularities that caused the non-payment of the official fees, Z being therefore exclusively responsible for the situation that arose.

The Board first notes, as already mentioned, that invoices related to the payment of the (n)th and (n+1)th renewal fees in Spain for the national counterpart of the European patent published under Nr ...85 were settled in due time by Z to the firm of the Appellant to allow him to pay said renewal fees to the Spanish Patent Office.

On the other hand, the alleged invoicing problems are for the most part subsequent to the established fact of the non-payment of renewal fees in Spain by the Appellant, and consequently do not justify these non-payments.

In any case, invoicing and book-keeping problems as alleged in the present case, could not have been balanced with the duties of the European authorised representative to execute payment of the renewal fees for which he had accepted the mandate and for which he had received pre-payment, moreover being aware that the consequence of default of payment of said renewal fees would be the loss of the patent in Spain.

Finally, contrary to his first argument that Z was solely responsible for the non-payment, the Appellant himself stated that the annuity due in 2002 was „invoiced but not paid by (his firm)“, „likely due to changes in our staff mainly affected to our Annuity Department“. He further acknowledged „that more errors than desired have taken place at the time of invoicing during year 2003“ and concludes „We apologize for our mistake and, at our cost, will appeal to the Spanish Patent Office to get the reinstatement of the patents“ (letter of 16.12.03 to Z).

The Board holds therefore that the situation did not justify the Appellant's lack of action and considers that the Appellant failed in these circumstances to comply with the Rules of professional conduct of the members of the Institute of Professional Representatives before the EPO, in particular that he has failed to fulfil his obligation to give at all times adequate care and attention and apply the necessary expertise to work entrusted to him by clients, as required by point 4(a) of the Code of Conduct.

In conclusion, the Board concurs with the impugned decision to issue X with a reprimand.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:	The Chairman:
P. Martorana	P. Messerli

epi Excess Liability Insurance 2007/2008

On 1 October 2007 the *epi* Excess Liability Insurance scheme will go into its nineteenth year of existence. It aims to give better insurance coverage at a reasonable price to *epi* members.

The indemnity of basic professional liability insurance schemes is often limited to EUR 1.022.584. Therefore, the *epi* Excess Liability Insurance scheme indemnifies losses as far as they exceed EUR 1.022.584/equivalent. Its limit of indemnity is a further EUR 1.533.876 per loss so that – together with basic insurance – a total loss of EUR 2.556.400 is covered.

There is a collective indemnity limit to EUR 15.338.756 p.a. for all participating *epi* members which according to insurance calculations will hardly be reached. The premium for the *epi* Excess Liability Insurance scheme for the insurance year 2007/2008 amounts to **EUR 402,64** plus legal insurance tax.

Persons wishing to join the *epi* insurance policy should directly contact the broker, Funk GmbH, for all policy matters, application forms etc., and payments. Please make your payments to the broker's account mentioned hereafter, free of bank charges, indicating the following reference „*epi* insurance 01 0047425000“ (this is the *epi* client number with the broker) as well as your name.

epi invites each member to carefully consider joining the *epi* Excess Liability Insurance scheme since clients'

claims may easily reach the sum of EUR 2.556.460 They may ruin your economic and professional situation if no adequate insurance cover is provided for. The *epi* Excess Liability Insurance scheme improves your insurance cover at a reasonable price and provides insurance cover for you as an *epi* member in all thirty-two EPC contractual countries regardless of where you exercise your profession.

For further information on the *epi* Excess Liability Insurance please contact:

Funk International GmbH

Petra Verwiebe
Postfach 30 17 60
D-20306 Hamburg
Phone: +49 40 3 59 14-378
Fax: +49 40 3 59 14-5 59
p.verwiebe@funk-gruppe.de

Bank connection of Funk International GmbH:

Account No. 9 131 310 00
Bank Code 200 800 00
Dresdner Bank AG, Hamburg, Germany

Symposium „Die Zukunft der Patentgerichtsbarkeit in Europa“ „The Future of the Patent Jurisdiction in Europe“ Munich, 25th and 26th June 2007

E. Lyndon-Stanford (GB)

The symposium was run by the Bundespatentgericht and had an impressive line-up of speakers, including the German Minister of Justice and judges from the Court of Appeal in France and the UK and a judge of the German Bundesgerichtshof, as well as a judge of the Japanese High Court, a judge of the US Court of Appeals and a judge of the Chinese Supreme Court, and also Dr. Margot Fröhlinger (a Director) and Mr. Nootboom for the Commission. The *epi* was represented by its President and the Chairman of the EPPC, and a Vice-President (Mr. Kim Finnilä) attended in another capacity. However, in spite of excellent organisation and the great and the good being in attendance, we did not learn a tremendous amount although we did learn a little.

The main topic was the EPLA. Almost everyone there declared in favour of the EPLA and we were told that the judges were uniformly in favour. The villains were seen as the politicians. Those who were against couched their opposition in terms of the EPLA not complying with European Community law and in one case (France) that it was not right to discriminate between member states and have one group in the EPLA and another group not. There was a sense that the real reasons had not been given though one delegate suggested that four or five languages should be used for the EPLA and another delegate suggested a five language solution. However, Mr. Rosenberg (British industry) saw no need for any European court and pointed out that parallel cases are

very rare, to which M. Sueur (French industry) replied that the parallel cases were only the tip of the iceberg, the investigation of patent rights in different countries being a burden on industry.

There was a strong consensus that the judges of a European Court of first instance (EPLA or CP) should be specialised, have access to technical expertise (with a number of speakers stating that one of the judges should have technical expertise), and divide their time between the European Court and their national Court. Mr. Messerli suggested that the EPO BA members could serve as European Court judges but others resisted this.

Two speakers questioned whether the EPLA was contrary to Community law, one querying why the Commission had not sought an opinion from the ECJ. The English judge of appeal said that he could not see why the EPLA was incompatible with Community law, but referred to a paper he had written with another which concludes that the EPLA is indeed contrary to Community law but suggests how it can be amended to be in accordance with the law – E.I.P.R. 209/2007. Some speakers referred to the Benelux Court and to the Baltic Patent Court. On the second day, M. Battistelli, the French Commissioner and Director General of the National Institute for IP (INPI), the French patent office, commented that exactly the same qualified majority was required in the Council of Ministers to authorise the Commission to negotiate the EPLA as was required to agree the French proposal.

There was a discussion of whether more than one court should have jurisdiction over a matter, some calling it forum shopping and seeing it leading to great harm and others calling it beneficial competition.

Two interesting suggestions were made. One, by Prof. Mario Franzosi, a Milan lawyer, that nothing need be changed except to have a common appeal court for appeals from the first instance courts. Another, by Dr. Eugen Popp, a Munich patent attorney, that nothing need be changed except that all first instance courts should be empowered to grant cross-border injunctions. Prof. Franzosi also suggested that the member states

should pay for the translations and that only the main claims (presumably the independent claims) need be translated.

Dr. Fröhlinger on behalf of the Commission noted that there was a clear blocking minority against the EPLA and against the Commission proposals in the Council of Ministers, and thus a compromise was necessary while retaining the most important aspects of the EPLA. She saw the compromise being along the lines of the TM Regulation, with a common court of appeal, but with only a limited number of first instance courts, each having the same rules of procedure, and a central registrar. She suggested that in those countries where the judges had no technical expertise, there could be assistant technical rapporteurs with no right to vote. Mr. Grossenbacher, the EPO Administrative Council Chairman, said that there should be technical members as judges. To this, Mr. Nooteboom added that the only way forward was the hybrid solution, and that the „architecture would follow“, whatever this means, maybe a full Community Patent along Commission lines.

Mr. Rosenberg (GB) noted that the most important step was the introduction of the London Agreement on translations and Mr. Grossenbacher (EPO) said that the London Agreement would reduce costs by 75 % (I assume compared to the present translation costs). Mr. Battistelli commented that the ratification of the London Agreement was in M. Sarkozy's election manifesto and that he will ratify.

Mr. Grossenbacher saw the EPLA as an essential precursor to the Community courts in the same way as the EPC was an essential precursor to the Community Patent.

Mr. Grossenbacher emphasised that ratification was optional.

On the second day, in the panel discussion, the President of the Administrative Council of the Portuguese Institute of IP said that we should concentrate on a balanced compromise, from which we can assume that the Portuguese presidency will work along those lines. He also commented that the EPLA provided a good basis.

Report on EPLA – Litigation Working Party Meeting, 27th June 2007

E. Lyndon-Stanford (GB)

Discussion in the Council of Ministers

The Commission representative gave a report of the discussion in the recent Council of Ministers. They discussed the three alternatives proposed:

- a) the EPLA;
- b) the French proposal;

- c) a compromise between (a) and (b) – decentralisation of the courts of first instance, centralisation of the court of appeal and a technical qualification in the courts.

It was noted that (a) was the most developed, that (b) was better suited for a uniform patent jurisdiction but needed more work, and that there were no details of (c).

The legal position was discussed, whether the national jurisdictions could be transferred to the ECJ and whether the EPLA was admissible according to Community law, and more generally whether member states could act independently of the EC. It seems that the Commission legal services have said „no“. The intention is that these questions will be resolved during the Portuguese presidency (July to December 2007) and the work will in any case be continued.

The results of two conferences had been noted, a first in Berlin in March and a second in Munich on the previous two days, which showed great interest on the part of industry.

The Finnish delegate commented that under (c), the court procedures must be harmonised.

The EU Commission representative commented that technical expertise was guaranteed but that it had to be discussed whether it was through technically-qualified judges or having technical assistance with no vote. The Portuguese presidency would discuss the details of the technical aspect as well as of procedural questions, it being noted that there was support for the details in the EPLA. The Chairman commented that the Working Party would support the work of the Commission.

The Portuguese delegation said that there would be four meetings of a working party, on 20th July, 14th

September, 17th October and 7th November, and that more information would be available before 20th July, the date of the first meeting. They expected to move forward in a pragmatic way and would be considering, for both the first and second instance courts, the degree of specialisation (presumably of the judges), the languages and funding.

In the context of the EU Council Presidency questionnaire of 23rd April 2007, there was a discussion of „internal coordination“ and I was not the only person who did not understand it. It related to which legal services would be advising the working party, those of the Council or those of the Commission. It seemed that it was the legal services of the Council but the Commission representative commented that the legal services of the Commission had not given the answer.

The Italian representative commented that his country preferred the French proposal. If there was decentralisation of the first instance courts, to cover all technologies, a huge number of technical judges would be required to cover every field of technology, expensive and not possible. The chairman terminated the discussion of the point.

Next meeting of the WG: will be 11:30 on 12th December 2007.

Les troisièmes Rencontres européennes du CEIPI

L. Nuss (FR)

Ce n'est plus un secret pour personne et l'information a été largement diffusée, la CBE 2000 entrera en vigueur le 13 décembre 2007. Des formations spécifiques ont donc fleuri, leur nombre croissant aussi vite que la prise de conscience de l'ampleur des modifications qui ont été apportées dans la Convention et dans le règlement d'exécution.

Mais le mérite du CEIPI a été d'être le premier à organiser une manifestation de grande envergure sur ce thème puisque c'est dès la rentrée 2006 qu'a été mise sur pied l'organisation des troisièmes Rencontres européennes qui se sont tenues à Strasbourg les 20 et 21 avril 2007. Certes, il y a un an, l'on savait, sans être devin, que la nouvelle CBE entrerait en vigueur au plus tard fin 2007. Mais il fallait être, sinon visionnaire, du moins audacieux, pour soutenir la gageure d'organiser un colloque de deux jours sur un thème qui, à l'époque, paraissait peu porteur.

Et non seulement l'histoire est en train de donner raison à ceux qui, dès le début, avaient compris l'importance et l'intérêt d'organiser une manifestation sur ce

sujet, mais de plus, le contenu lui-même de ces troisièmes Rencontres fut d'un niveau particulièrement élevé.

Les professionnels ne s'y sont d'ailleurs pas trompés, puisqu'ils se sont rendus en masse à cet événement : plus de 320 participants venus des quatre coins de l'Europe, tous praticiens du droit des brevets, qu'ils soient mandataires européens, avocats, magistrats, juristes d'entreprises ou encore universitaires.

Et comme à son habitude, le CEIPI sut parfaitement allier travail et convivialité, débats passionnés et discussions détendues autour d'un verre, bref, l'utile à l'agréable.

Le colloque avait été articulé autour des trois catégories essentielles des changements intervenus dans la nouvelle CBE, à savoir, d'une part, les modifications relatives à la procédure, d'autre part, les changements de fond relatifs à la loi elle-même et, enfin, les nouvelles procédures.

La première partie fut présidée par Fabrice Claireau, Directeur Juridique de l'INPI, la seconde par Kim Finnilä, Vice-Président de l'epi, et la troisième par Walter Holzer, Directeur du Diplôme du CEIPI „Contentieux des brevets

en Europe” et, comme chacun le sait, ancien Président de *l'epi*.

Compte tenu de la technicité de la matière et de l'ampleur des modifications, les organisateurs avaient eu la clairvoyance de faire appel aux architectes de la révision de la CBE, c'est-à-dire ceux qui, au sein de l'OEB, avaient eux-mêmes légiféré les nouveaux textes.

C'est ainsi que les différents spécialistes de l'OEB que sont notamment Robert Cramer, Ulrich Joos, Ingwer Koch, Gert Kolle, Eugen Stohr et Eskil Waage se sont succédés à la tribune pour transmettre leur savoir à l'auditoire. La qualité de ces interventions n'eut d'égale que la richesse des débats qui s'en sont suivis et ce n'est qu'avec beaucoup de difficulté que nos amis Yves Rebol et Dieter Stauder purent finalement convaincre

l'assistance de se transporter à quelques kilomètres de Strasbourg, pour poursuivre ces échanges dans une auberge alsacienne.

Nous garderons tous un excellent souvenir de cette manifestation, également marquée par la présence de Manuel Desantes, Vice-Président de la DG5 de l'OEB, de Fabienne Keller, Maire de Strasbourg et Sénateur du Bas-Rhin, ainsi que de Florence Benoît-Rohmer, Présidente de l'Université Robert Schuman. Mais surtout, nous en sommes sortis avec la sensation toujours agréable et motivante d'avoir progressé dans le domaine de la connaissance et de s'être enrichis aussi bien sur le plan du savoir que sur le plan humain.

Vivement les quatrièmes Rencontres et sans attendre une nouvelle révision de la CBE !

CEIPI study course „Master of IP Law and Management“

Dear epi Members,

In the beginning of this year CEIPI at Strasbourg started the first course of their new Master study, the *Master of IP Law and Management* (MIPLM). The study group of 12 participants with different professional background from all across Europe is successfully finishing their studies in these days.

I would like to highly recommend this program to your attention.

It combines legal, economic and management sciences and includes lectures from leading scholars in the field of IP Law and Management. Its ultimate objective is to qualify experienced IP professionals for acting as practically skilled IP managers with sound knowledge on wealth creation in our knowledge-based economy.

CEIPI will realize the second course already this year. It is scheduled to start October 22th. The entire part-time training comprises a period of six months with monthly lecture weeks. The academic degree *Master of Intellectual Property Law and Management* (MIPLM) will be awarded by the President of the Robert Schuman University.

The CEIPI's brochure with detailed information regarding content, timetable and admission standards as well as additional information and on-line application are provided at www.ceipi.edu

We would be pleased, if the course arouses your interest. Please feel free to contact CEIPI for further information.

Chris Mercer, President

CEIPI
11, Rue du Maréchal Juin
BP 68
67046 STRASBOURG Cedex
Tel. 03 88 14 45 86/87
Fax 03 88 14 45 94
Email : ceipi@urs.u-strasbg.fr
www.ceipi.edu

Contact for questions regarding the Master of IP Law and Management :

Dr. Michael Beyer, Michael.Beyer@sti-ipm.de,
Tel. +49 (0)162/290 1809,
Steinbeis-Transfer-Institute
Intellectual Property Management,
Kistlerhofstraße 168,
81379 Munich, Germany

Please visit our website for news !

www.patentepi.com

Report on the 1st IP-Management and Law Master-Diploma Course of CEIPI

Paul Rosenich (LI)

The following is a report about the newly launched IP-Management and Law Master-Diploma Course of CEIPI at the Legal Faculty of The University Robert Schuman in Strasbourg, France.

Lifetime-long-learning is also in our Patent Attorneys' World the crucial means for providing proper and accurate service to our clients. CEIPI is the Europe wide leading provider of training for European Patent Attorneys. Recently it launched together with the Steinbeis University of Berlin a practice oriented Master Diploma Course IP Management and Law. The Study Program is academically lead by Prof. Yves Reboul (CEIPI) and Prof. Alexander Wurzer (Steinbeis).

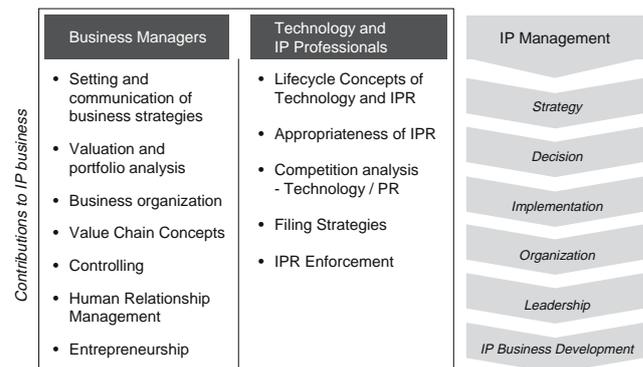
On July 7th 2007 the first Course of this kind finished successfully and released – under the patronage of the President of University Robert Schuman – twelve new and well trained IP-Managers as LLM's into their continued career.

IP-management differs fundamentally from IP administration. IP-management comprises all the activities necessary to lead and guide an Organization or a Company respectively, whereas IP-administration is more concerned with operational issues and the smooth functioning of application processes. IP-management is responsible for an organization's IP policy, it's IP strategy, the coordination of work related to IP within the company and the elimination of disturbing factors through third parties. As IP-manager the Practitioners have been trained from a management point of view and have been provided with training in strategy, decision making, planning and controlling as well as a variety of different legal and business aspects related to IP.

The high quality content of academic training was structured according to the following principles:

- Meet the challenge of high level IP management
- Build up IP professionals who can operate at the firm level and as independent experts
- Rely on the principle of continuously updating teaching materials
- Communicate empiric findings and is as practice oriented as possible
- Teach best practice IP management across various industries
- Assume a practical definition of IP management
- Emphasize on the following topics: Strategy, Decision, Implementation, Organization, Leadership, Controlling and IP-Business Development
- Provide and build an international network of IP-Managing Specialists

Figure1: IP Business Players



Strategy Module

Strategy as seen by Sun Tzu in the „Art of War“ some 2500 years ago is the art of maximizing one's own interests while keeping one's efforts as minimal as possible. Strategy comprises the know-how and know-why of sustainable value creation. Most important, in the context of IP management is to align a company's IP portfolio to its overall business targets.

In this module participants were taught to ask how a firm's IP portfolio helps it to create value. The essential question is: „How does the firm make money and how does the firm's IP help the company in getting there?“

Decision Making Module

Decisions are made by humans on the basis of available information. The human mind processes and selects information according to an individual's training and cultural background. What may seem of relevance to a technician may appear irrelevant to a lawyer or a business administrator.

This module trains participants to gather company internal and market based external information related to IP while using frameworks such as those developed by Michael Porter:

How does the competitive landscape look like in the IP field? Is the legislator planning any amendments relating to IP that may impact business? How does customer demand relate to IP protected business segments? What's the value of the IP portfolio? What's the life cycle of the IP portfolio and how likely is it that competitors will succeed in inventing (patents) or marketing (trade marks) around the IP owned by the firm?

Issues such as risk assessment and grasping new opportunities through joint ventures patent pool or licensing agreements also came into play.

Implementation Module

Implementation is driven by the identification of the most effective and efficient paths in a particular business context. This module trained participants to develop value chains that help put theory into practice and examine the interplay between various value chains. In terms of skills this module teaches project management, the ability to align different value added processes and attract funding.

Content-wise it equipped participants with practical information on an investor's perspective on a company's IP portfolio, accounting and taxation rules related to IP as well as basic financial instruments such as the securitization of an IP portfolio. IP related legal knowledge is required when technology transfer or inter-company co-operations are involved.

Organization Module

This module taught participants to design organizational structures that help companies to achieve their goals. This implies building a culture based on knowledge sharing, but also structuring the company, its various departments and business units in the most beneficial way. Participants are trained to ask, „how can the IP department be aligned to other business units, so to assure co-operation rather than isolation?“

The „act- in- isolation- syndrome“ is often responsible for underleveraged IP portfolios. A company's business strategy must matter as early as it's filing decision. Future IP managers are thus equipped with competencies in IP portfolio analysis, portfolio exploitation, litigation, licensing and valuation. Basic controlling techniques are taught from the IP angle.

Leadership Module

This module taught human relationship management and reporting. While human relationship management

requires skills such as cultural sensibility, recruiting and retaining superior talent as well as motivating staff to outperform targets set, reporting provides an important tool to achieve these targets. Again, we were confronted with the dilemma that decisions –this time on people– are based on available information.

Thus, this module explored how to spur motivation, innovation and creativity. It further explored what information is needed on IP and other business fields to manage people and turn an administrative unit into a profit center.

Business Development Module

Intellectual Property as a knowledge based good has different characteristics than tangible goods. Knowledge is a pure public good satisfying the criteria of non-excludability and non-rivalry. This means that the consumption of the good by one individual does not reduce the amount of the good available for consumption by others (non-rivalry) and that it is not possible to exclude others from the good's consumption (non-excludability). Patents transform a pure public good temporarily into a private good and empower the right's holder to manage knowledge as if it were a private good. IP based business models must take these aspects of IP on board if sustained competitive advantage is to be achieved.

For that reason this module trained participants to look at business development as a cross cutting issue and take issues such as monopoly design or cost versus quality based market differentiation into consideration when designing a business plan.

It is believed that these additional skills will help Patent Attorneys in Industry and Private Practice, to even better assist their clients in reaching their business goals. Together with skilled legal knowledge and practice the new specialists may be of additional leveraging benefit for IP related business.

This Master Course is recommended for those European Patent Attorneys who are in or want to step into an environment with more emphasis on IP related business.

Selection of PCT Receiving Office

L. Steenbeek (NL)

Many PCT applicants in Europe file their PCT applications with their national patent office or with the European Patent Office. However, maybe this practice should be reconsidered in view of the following considerations. After all, once electronic filing software is used, it does

not really matter anymore whether a PCT application is filed directly with EPO, with WIPO or with a patent office across the street. While some national laws require that priority applications are filed with the local national patent office, once the priority application has passed

the security clearance, the applicant is free to file corresponding applications.

An important consideration is formed by the so-called Notices of incompatibility, i. e. statements filed by offices that they will not apply certain PCT Rules because they deviate from their local law. For a full overview of these notices see http://www.wipo.int/pct/en/texts/reservations/res_incomp.pdf.

From this overview it follows that as per July 5, 2007, the PCT Rules (for the April 2007 version, see http://www.wipo.int/pct/en/texts/pdf/pct_regs.pdf) are not (yet) fully applied by the following PCT Receiving Offices in the EPC Contracting States:

- Rule 20.8(a): reference to earlier application to repair missing parts or instead of certain parts: EP, BE, CZ, DE, ES, HU, IT.
- Rule 26bis.3(j): restoration of priority term: EP, BE, CZ, DE, ES, FR, GR, HU, IT, PT.

In the above cases, using WIPO as PCT Receiving Office does not cause problems in the international phase. Of course, applicants who can file PCT applications with Receiving Offices that have not filed a notice of incompatibility (such as the NL patent office) may continue using that office.

It is possible that if a certain Receiving Office encounters an issue covered by a Notice of incompatibility submitted by it, this Receiving Office decides to transfer responsibility for the application to WIPO under Rule 19.4(a)(iii) PCT. However, the policies of offices in this respect are not well-described, and there is no generic rule or guideline prescribing that a Receiving Office should transfer responsibility to WIPO.

It should be noted that while the PCT Receiving Office may accept something, after the international phase, in the national phase, a Designated Office may still not accept it. So, the Notices of incompatibility filed by

Designated Offices should also be considered. However, where the choice is between a worldwide problem caused by a PCT Receiving Office's non-application of certain PCT Rules, and a local problem because some Designated Offices' non-application of certain PCT Rules, in many circumstances it is preferred to keep at least a right for some states rather than no right at all.

With regard to the above-mentioned subjects (missing parts and restoration of priority year), the following Notices of incompatibility have been submitted by Designated Offices:

- Rule 20.8(b): reference to earlier application to repair missing parts or instead of certain parts: EP, CZ, DE, ES, HU, LT, TR + CN, CU, ID, JP, KR, MX, PH. So, no problems in most PCT Contracting States including e.g. GB, IN, PL, RU and US.
- Rule 49ter(1)(g): restoration of priority term: EP, CZ, DE, ES, HU, LT, PT, TR + BR, CA, CN, CO, CU, DZ, ID, IN, JP, KR, MX, NO, PH, US. In this respect, many interesting countries have filed a notice of incompatibility. However, the PCT Rule still makes sense for the vast majority of 137 PCT Contracting States, including e.g. GB, PL and RU.

It may be assumed that the EPO will drop its Notices of incompatibility after the entry into force of the EPC2000, and that the same holds for other offices when they join the Patent Law Treaty.

One could doubt whether any Notice of incompatibility filed by the EPO is lawful in view of Art. 150(2) EPC, saying that in case of conflict between the EPC and the PCT, the PCT prevails, from which it seems to follow that European patent law simply cannot be incompatible with the PCT, so that there cannot be any basis for a Notice of incompatibility by the EPO. However, as long as the Boards of Appeal have not produced case-law in this respect, one had better not rely on this doubt.

Notice from the European Patent Office dated 18 June 2007 following up on the Notice dated 8 March 2007 (see OJ EPO 2007, 258¹) concerning the issue of the direct applicability of Article 70(7) of the TRIPS Agreement in Spain to European patent applications filed prior to the expiry of the reservation entered by Spain under Article 167(2)(a) EPC

1. Reservation entered by Spain

Upon joining the European Patent Organisation, the Kingdom of Spain entered a reservation under Article 167(2)(a) EPC, providing that European patents were ineffective in Spain in so far as they conferred protection on chemical or pharmaceutical products as such. *At no time has the European Patent Office been*

notified that the reservation entered by Spain has been withdrawn.

2. Administration of the European granting procedure

The European Patent Office is solely responsible for the administration of the European patent granting procedure, which it conducts with impartiality, balancing the interests

¹ http://www.european-patent-office.org/epo/pubs/oj007/04_07/04_2587.pdf

of applicants and third parties whilst bearing in mind the general public interest which it was created to serve.

The issue of whether the transitional provisions of the TRIPS Agreement are directly applicable in Spain is a *national matter* which must be resolved by the appropriate instances in that jurisdiction. It is not the intent of the European Patent Office to interfere in this matter. Neither the present Notice nor the Notice from the European Patent Office dated 8 March 2007 can be interpreted as espousing a position or emitting an opinion concerning the direct applicability of the TRIPS Agreement in Spain.

3. Withdrawal of the recommendation contained in the Notice of the President of the European Patent Office dated 13 May 1992 as far as Spain is concerned

The attention of the European Patent Office was drawn to the necessity for the Office to examine the substance of the transitional provisions of Article 70 of the TRIPS Agreement of its own volition and strictly for the purposes of determining whether adjustments to the European Patent Office's practice of granting European patents are necessary, given the possibility that the TRIPS Agreement might ultimately be deemed to be directly applicable in Spain.

In light of this analysis, with regard to European patent applications still pending, the European Patent Office decided to withdraw the recommendation to applicants to file a separate set of claims in view of the reservation entered by Spain, which was contained in the Notice of the President of the European Patent Office dated 13 May 1992.

4. Effect of the withdrawal of the recommendation contained in the 1992 Notice

The following is the opinion of the European Patent Office as to the impact of the withdrawal of the recom-

mendation contained in the Notice of the President of the European Patent Office dated 13 May 1992 as far as Spain is concerned *with regard to the European patent granting procedure*.

The sole effect of this withdrawal is that the European Patent Office is no longer able to recommend maintaining a separate set of claims for European patent applications designating Spain, filed before 8 October 1992, containing claims covered by the reservation entered by Spain and still pending.

Should the applicant, for whatever reason, choose not to withdraw this separate set of claims, the European patent application would then accordingly proceed to grant with a separate set of claims for Spain, and there would be no protection for the chemical or pharmaceutical products as such in Spain, regardless of whether the transitional provisions of the TRIPS Agreement were ultimately found to be directly applicable in Spain or not.

Finally, it is emphasised that the Notice from the European Patent Office dated 8 March 2007 is applicable only to *European patent applications* filed prior to 8 October 1992, the date of the expiry of the reservation entered by Spain, and *still pending before the Office*.

In the event of the TRIPS Agreement being found to be directly applicable in Spain, with regard to any patents already granted by the EPO, the Office has concluded that *with regard to its opposition procedure*, it does not need to review any of its existing practices. TRIPS Article 70(7) by definition only applies to pending applications and TRIPS Article 70(1) and (3) makes clear that there is no intention for the Agreement to have retroactive effect. In any event, any attempt post-grant to obtain enhanced protection provided for under the TRIPS Agreement in opposition proceedings would be prohibited by Article 123(3) EPC.

Draft European Patent Litigation Agreement (EPLA): Jurisdiction of the European Patent Court and effects of decisions

S. Luginbuehl and E. Waage¹

A. Introduction

Legal theory traditionally distinguishes between

- a court's *international jurisdiction*,
- a court's *territorial jurisdiction* and
- a court's *jurisdiction as regards the subject-matter*.

The rules on *international jurisdiction* determine which state is competent to settle a dispute with an international dimension, whereas those on *territorial jurisdiction* are concerned with the geographical assignment of disputes to particular courts.

Territorial jurisdiction can itself be subdivided into different categories. For example, a distinction is drawn between *exclusive* and *non-exclusive* jurisdiction. A

¹ Lawyers at the European Patent Office, Directorate 522 International Legal Affairs (international_legal_affairs@epo.org). All the opinions expressed are our own and do not necessarily reflect those of the European Patent Office.

court has *exclusive* jurisdiction where the case in question cannot be heard by any other court.

The rules on *jurisdiction as regards the subject-matter* determine which court may rule on what legal matters. Thus, if *only one* court within a particular territory has jurisdiction as regards the subject-matter to hear a case, that court has territorial jurisdiction by virtue of its jurisdiction as regards the subject-matter.

B. The European Patent Court's jurisdiction as regards the subject-matter

1. General rules

Under Article 3 Draft EPLA,² a European Patent Court would be established for the EPC contracting states acceding to the EPLA³.

The jurisdiction as regards the subject-matter of the European Patent Court is governed by Part III of the Draft EPLA.

Under Article 41(1) Draft EPLA, the European Patent Court would have exclusive jurisdiction for the EPLA contracting states in respect of actions relating to actual or threatened infringement of a European patent,

- actions for a declaration of non-infringement of a European patent,
- actions or counterclaims for revocation of a European patent and
- actions for damages or compensation derived from the provisional protection conferred by a published European patent application.

Infringement and validity are thus to be decided in the *same* proceedings before the *same* court, which is usual practice in the majority of European states, Germany being one notable exception.

It goes without saying that the European Patent Court would have no jurisdiction for the EPC contracting states that do not accede to the EPLA. For these states nothing would change with regard to the jurisdiction of their courts concerning European patent litigation.

2. Shared jurisdiction during a transitional period

To ease transition to the new European court system, a seven-year *transitional period* has been provided for in Article 85(1) Draft EPLA. During the transitional period, parties will be free to decide whether to bring their case before a competent *national* court or the European Patent Court. In other words, the European Patent Court will *share* jurisdiction with the competent national courts of the EPLA contracting states during this initial phase.

3. Provisional and protective measures: jurisdiction of national courts

Under Article 45(1) Draft EPLA, the national courts of the EPLA contracting states are to retain jurisdiction to order

provisional or protective measures provided for under the applicable national law. This is designed to enable claimants to file at short notice a request with the nearest court so that they can immediately prevent any further infringement of their rights. Nevertheless, they must bring an action relating to the merits before the European Patent Court within 31 days or, if such an action is already pending before the European Patent Court, notify it within 31 days of the filing of a request for provisional or protective measures with the national court. If they fail to do so, the order will cease to have effect (Article 45(2) and (3) Draft EPLA).

Moreover, the national courts of the EPLA contracting states will retain jurisdiction in respect of the provisional seizure of goods as security for any damages, compensation, costs or any other payment resulting from proceedings before the European Patent Court (Article 46 Draft EPLA).

4. Appeals

The Court of Appeal of the European Patent Court will have exclusive jurisdiction to decide on appeals against decisions of the Court of First Instance and on petitions for review (Article 44 Draft EPLA).

5. Relationship between the European Patent Court and the Court of Justice of the European Communities (ECJ)

The drafters of the EPLA in the Working Party on Litigation⁴ have also been at pains to ensure that the EPLA will not affect the powers of the ECJ to interpret Community law.

Under Article 40(1) Draft EPLA, those EPLA contracting states that are also EU member states will designate the European Patent Court as their national court for the purposes of the preliminary ruling procedure under Article 234 EC Treaty.

The European Patent Court of First Instance will thus be entitled to request the ECJ to give a preliminary ruling on questions relating to Community law⁵, under the conditions laid down in Article 234 EC Treaty („if it considers ...“, „necessary to enable it to give a judgment“). As for the European Patent Court of Appeal, it will be obliged to bring the matter before the ECJ where such questions are raised.

This means that, like any other court of an EU member state, the European Patent Court will be bound by past

² For the most recent draft, see WPL/10/05 published at <http://www.epo.org/patents/law/legislative-initiatives/eplalatestdrafts.html>

³ See Luginbuehl, „A Stone's Throw Away from a European Patent Court: The European Patent Litigation Agreement“, [2003] EIPR, 256; Kollé/Waage, „A Patent Court for Europe – the European Patent Litigation Agreement (EPLA)“, Special edition of the OJ EPO 2005, 44.

⁴ The Working Party on Litigation was mandated by the Paris Intergovernmental Conference to present „a draft text for an optional protocol to the EPC which ... would commit its signatory states to an integrated judicial system, including uniform rules of procedure and a common appeal court“, see OJ EPO 1999, 545. See also Boval, „Le contentieux d'un juge français sur les projets d'avenir concernant le contentieux des brevets en Europe, Quel droit de la propriété industrielle pour le 3^e millénaire?“, Editions Litec, 2001, 153-168, 158.

⁵ This includes, in particular, questions relating to

- Directive 98/44/EC on the legal protection of biotechnological inventions,
- Directive 2004/48/EC on the enforcement of intellectual property rights,
- Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters as well as
- other measures adopted as part of the judicial co-operation in civil matters within the EU, e.g. Regulation 2000/1348/EC on the service of judicial and extrajudicial documents in civil or commercial matters.

and future case law of the ECJ, as soon as questions relating to Community law are raised before the European Patent Court.

A precedent for this competence, conferred on a supranational court (here the European Patent Court), to refer questions for a preliminary ruling to the ECJ is provided by the ECJ's case law concerning the Benelux Court of Justice.⁶

By virtue of Article 40(2) Draft EPLA, the ECJ's rulings on preliminary questions will be *binding* on the European Patent Court where the latter's decisions affect EU member states.

De lege ferenda, it could be contemplated for the sake of clarity to insert another provision into the Draft EPLA to make clear that the ECJ's case law is binding on the European Patent Court *generally* whenever the latter is required to apply Community law.

C. The international and territorial jurisdiction of the European Patent Court

Under Article 39(1) Draft EPLA, contracting states to the EPLA which are also EU member states and to which the Regulation 44/2001 is applicable⁷ will designate the European Patent Court as their national court within the meaning of that regulation. The same applies to the contracting states to the Brussels⁸ or Lugano⁹ Conventions (Article 38(1) Draft EPLA).

The Working Party on Litigation inserted the above provisions in order to guarantee that the EPLA does not interfere with existing European instruments concerning jurisdiction and recognition. The rules on *international* (and, where it is determined at the same time, *territorial*¹⁰) jurisdiction laid down in those instruments are therefore also applicable when determining the jurisdiction of the European Patent Court.

Crucial to the concept of the Draft EPLA is the tenet that the European Patent Court will act as a *unitary* court for the territory of the EPLA contracting states.

The European Patent Court would comprise the Court of First Instance, the Court of Appeal and a Registry (Article 3(2)(a) Draft EPLA).

The Court of First Instance would be composed of one Central Division and of a number of Regional Divisions located in the EPLA contracting states (Article 10(1) Draft EPLA and Article 19(1) Draft Statute¹¹).

However, the Divisions would *merely have an organisational function*, comparable to that of senates or chambers in national courts, the only difference being that they would be spread out geographically throughout the EPLA contracting states.

This would in no way affect the unity of the Court. Contrary to a widespread misconception, the different Divisions would *not* be independent courts. The international composition of the Divisions of the European Patent Court (the judges on a panel must be of „at least two different nationalities“, Article 26(1) Draft Statute) also shows that a Regional Division located e.g. in Germany will *not* be a German court bound by German law, but a *unit* of the European Patent Court *solely bound by the EPLA*.

In practice, the claimant would be required to file the action, in accordance with the Rules of Procedure of the European Patent Court, before the Central Division or the competent Regional Division (Article 41(2) Draft EPLA), which would then decide whether it had jurisdiction to hear the case (see Article 76(2)(c) Draft EPLA).¹² The Rules of Procedure will therefore also have to establish which Division *within the Court is responsible for which territory. This rule was introduced to guarantee the „local presence“ of the Court and ensure that cases are distributed as efficiently as possible within the European Patent Court.*

There appears to be some concern that the rules on jurisdiction laid down in Regulation 44/2001 and in the Brussels and Lugano Conventions could be infringed if a European Patent Court consisting of Regional Divisions were to rule on disputes.¹³

However, these concerns are unfounded, as will be shown by some examples.

Example 1: Let us assume that a claimant resident in the UK wishes to bring an action relating to infringement of his European patent against a person resident in Sweden. The claimant believes that his European patent is being infringed in Poland. Unlike Poland, the UK and Sweden have acceded to the EPLA. There is a Regional Division of the European Patent Court in the UK, whereas Sweden has waived its right to such a Division.

6 See ECJ judgment in Case C-337/95: „As a court common to more than one Member State which has the task of ensuring that the legal rules common to the three Benelux States are applied uniformly and reference to which is a step in the proceedings before the national courts leading to definitive interpretations of the common Benelux rules, the Benelux Court of Justice must be regarded as entitled to refer questions to the Court of Justice for a preliminary ruling. To allow such a court, faced with the task of interpreting Community rules in the performance of its function, to follow the procedure provided for by Article 177 [now 234] of the Treaty serves the purpose of that provision, which is to ensure the uniform interpretation of Community law.“

7 Regulation 44/2001 applies to all EU member states except Denmark.

8 EEC Convention of 27 September 1968 on jurisdiction and the enforcement of judgments in civil and commercial matters; the Brussels Convention now applies only to Denmark and is to be replaced shortly by a new agreement, see Council Decision of 20 September 2005 on the signing of the Agreement between the European Community and the Kingdom of Denmark on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters and the agreement referred to (OJ EU 2005 L 299, 61) and Council Decision of 27 April 2006 concerning the conclusion of the Agreement between the European Community and the Kingdom of Denmark on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ EU 2006 L 120, 22).

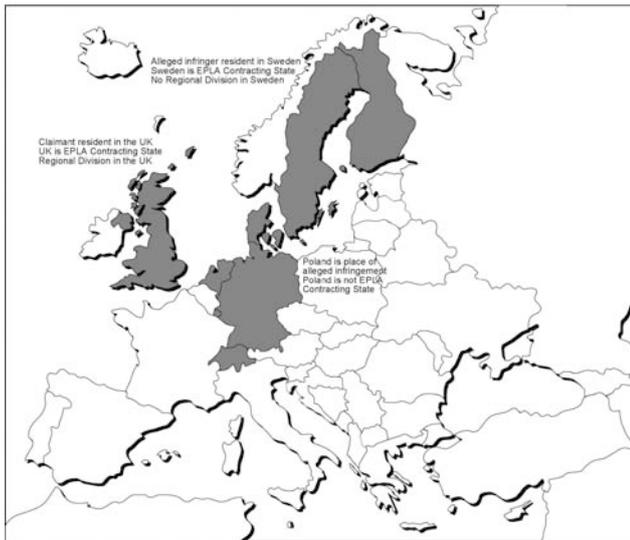
9 EC – EEA Convention of 16 September 1988 on jurisdiction and the enforcement of judgments in civil and commercial matters.

10 See e.g. Article 5(3) of Regulation 44/2001 and the Brussels and Lugano Conventions.

11 The most recent draft of the Statute of the European Patent Court is published at <http://www.epo.org/patents/law/legislative-initiatives/eplalatestdrafts.html>

12 See also Casalonga, „Le contentieux futur du brevet européen, Enfin une solution“, *Pi*, July 2006, 253269, 258.

13 See Scordamaglia, „Les contraintes du droit communautaire qui pèsent sur la création d'une Cour européenne chargée de connaître des litiges concernant les brevets européens“, *Propriété industrielle*, 2007, 9-14, 11.



For the purposes of example 1, EPLA contracting states are marked in red

- this is obviously without prejudice to a country's eventual position.

When examining which court has international or territorial jurisdiction, the complainant will soon come across Regulation 44/2001. He will then discover that, in such a case, he may sue either

- in the competent courts in the defendant's state of domicile (Art. 2 Regulation 44/2001), that is, Sweden or
- in the courts in the place where the harmful event occurred (Article 5(3) Regulation 44/2001), that is, Poland.

This means that he can bring an action either before the European Patent Court, because the defendant is domiciled in Sweden, or before the national courts in Poland.

Neither Regulation 44/2001 nor the Brussels and Lugano Conventions prescribe precisely which court in a particular country must hear the case. It is therefore a matter for each state to decide itself on which courts to confer jurisdiction as regards the subject-matter to hear such cases within its territory.¹⁴

For Sweden, it would be the European Patent Court. It would be irrelevant in that connection that there is no Regional Division in Sweden because it had designated the European Patent Court (but *not* a particular organisational division of the European Patent Court) as the court having jurisdiction in this case. Which Division is competent for the Swedish territory will be defined in the Rules of Procedures. This could be the Central Division or a Regional Division located in another EPLA contracting state.

Example 2: Now let us assume that Poland has also acceded to the EPLA and that the Central Division of the European Patent Court of First Instance has competence for the territory of Sweden and Poland. Once again, the claimant resident in the UK will have to consult Regulation 44/2001 to determine what court has inter-

national or territorial jurisdiction to hear his case. Since the European Patent Court has jurisdiction for Sweden and Poland, the claimant will have to sue before it, regardless of whether he acts on the basis of Article 2 or Article 5(3) of Regulation 44/2001. The fact that the Central Division will hear the case as a Regional Division is a purely organisational matter, decided in accordance with the Rules of Procedure of the European Patent Court.

It is plain that the provisions on jurisdiction in the Draft EPLA may pose a dogmatic challenge for many experts on private international law since neither Regulation 44/2001 nor the Brussels and Lugano Conventions are designed to cater for the (very unlikely) event that, for example, a member state designates a national court of another member state or, as in this case, a new European Court as the „national“ civil court having international and territorial jurisdiction for its territory. However, it can scarcely be argued that the above instruments prevent a member state from designating a particular court (which has jurisdiction as regards the subject-matter) as likewise having international or territorial jurisdiction, or that such a decision requires the consent of the other member states.

The situation would presumably be different if a member state conferred jurisdiction on a national court not situated in an EU member state or not situated in a state party to the Lugano Convention. The same would apply to any designation of an international court not bound in its decision by the European legal tradition. In those cases, it could be argued – not least on the basis of the general duty of mutual recognition of decisions enshrined in the above instruments – that such designation would not be covered by the original terms of the agreement, so that the instrument would have to be amended accordingly.¹⁵

D. The effects of decisions

Decisions on an action for revocation should have effect *erga omnes*, whilst those on infringement of a European patent should only have effect *inter partes*.

Still open for discussion is the issue dealt with in Article 43(2) Draft EPLA: should decisions of the European Patent Court revoking a European patent or maintaining it in amended form

- have effect only in those EPLA contracting states for which revocation was requested (and granted by the Court)

or

- have effect in all the contracting states, even where the patent proprietor did not request that it be extended to all of them?

The option of extending a revocation decision to all states in which the European patent has effect allows the patent proprietor to avoid a situation whereby, in the event of a refusal of the request for revocation in relation

¹⁴ See Schlosser, Report on the Brussels Convention, OJ EC 1979 C 59, 71, N 81; Kropholler, *Europäisches Zivilprozessrecht*, 8th edition, vor Art. 2 N 4.

¹⁵ See also Article 39 et seq of the Vienna Convention on the Law of Treaties of 23 May 1969.

to a certain part of the territory covered by the European patent (e.g. the European patent for the UK), the claimant adapts his request in the light of the reasons for the decision and resubmits it for a different part (e.g. the European patent for the Netherlands). On the other hand, in case of revocation, the patent proprietor will not be able to retain any part of the European patent.

A number of delegations in the Working Party on Litigation have declared that they would prefer an approach whereby decisions to revoke a European patent would have effect in all EPLA contracting states, unless the patent proprietor was able to produce evidence convincing the European Patent Court that the grounds for revocation did not apply in one particular state (the revocation decision would then not have effect in the state where the grounds did not apply). Such an approach whereby, in principle, decisions have effect, *eo ipso*, in all the contracting states would indeed be more appropriate to the idea of a unitary territorial court.

Yet this approach would basically lead to a unitary patent in the EPLA contracting states. Not least with a view to the future Community patent, some delegations in the Working Party on Litigation expressed reservations in this regard. In addition, given the aim of establishing uniform case law, an approach allowing the patent proprietor to convince the Court that certain grounds for revocation do not apply in particular EPLA states would be undesirable. Although there is no obligation to incorporate the grounds for revocation set out in Article

138 EPC into national law, effective harmonisation in Europe requires that the Court be able, of its own motion, to examine all the grounds for revocation of European patents.

The revocation of a European patent by the European Patent Court would render the patent invalid *ex tunc* (Article 43(3) Draft EPLA), i.e. it would be deemed to have had no effects from the outset. Nevertheless, the retroactive effect of the revocation would not, in principle, affect any final decision on infringement enforced prior to the revocation of the patent (Article 43(5) Draft EPLA). That rule corresponds to Article 33(2) of the Community Patent Convention, as amended in 1989,¹⁶ and to Article 29(2) of the proposal for a Regulation on the Community patent.¹⁷

If the validity of a European patent were contested in proceedings initiated by the holder of an exclusive licence under that patent in which the proprietor of the patent did not take part, the European Patent Court's decision would have effect only on the parties to those proceedings (Article 43(4) Draft EPLA). In this context, „contested“ could only mean that the defendant (i.e. the alleged infringer) has raised a defence of invalidity and not a counterclaim. This is intended to ensure that the patent proprietor is as far as possible protected from any unpleasant surprises where he has not, from the outset, denied the exclusive licence holder the right to initiate litigation (see Article 51(2) Draft EPLA).

Orphan Drug Legislation Delivering incentives to develop drugs for rare diseases

M. Gibson (GB)

Introduction

A pharmaceutical company is likely to have spent in excess of £500 million to bring a medicinal product to the market (Tufts Center for the Study of Drug Development May/June 2003 Impact Report). A pharmaceutical company must therefore achieve some degree of market exclusivity to recover these costs and ideally make a profit to sustain further research and development.

Marketing exclusivity is often provided by patent protection, however, even with patent term extension provisions for pharmaceutical products (Supplementary Protection Certificates or SPCs) the duration of such protection cannot extend beyond 25 years from the filing date of the patent application. In some circum-

stances, patent applications are filed on potential drug candidates around 5 years before commencing the regulatory approval process which may typically take a further 10 years. Therefore, the remaining patent term for a pharmaceutical product upon reaching the market may be as low as 5 years or sometimes lower, resulting in required sales of £100 million per annum to simply break even.

According to the World Health Organisation, there are around 5000 rare diseases. They affect a small part of the population, yet they constitute a real public health issue since patients are suffering from the lack of treatment

¹⁶ Convention for the European Patent for the Common Market, OJ EC 1989 L 401, 9ff.

¹⁷ Proposal for a Council Regulation on the Community patent, COM(2000) 412 final.

for their particular disease. Tropical diseases are also missing efficacious and safe treatments.

It is generally accepted that pharmaceutical companies have previously had no incentive to develop medicinal products for rare diseases under normal market conditions because the cost of bringing them to the market would not be recovered by the expected sales of the medicinal products.

However, legislation, first adopted in the United States in 1983, has provided an incentive for companies to develop drugs for rare diseases (known as „orphan drugs“) by providing a generous period of marketing exclusivity of 7 years in the United States and 10 years in the European Union, thereby reducing the annual sales required to recover the cost of bringing them to the market. Additional incentives are also available to reduce the costs of the approval process and the actual procedure for applying for orphan drug designation attracts no fees.

The term „orphan drug“ typically relates to a product which treats a rare disease affecting less than 10 patients per 10,000 inhabitants of a country. The drug may be previously unapproved or a new orphan indication for an already marketed drug. In addition, orphan drug status may be granted for a further drug for the same rare disease or condition if the further drug is clinically superior to the first drug.

Orphan drug protection is currently provided in the United States (Orphan Drug Act 1983), European Union (Orphan Drug Legislation 2000), Japan (Orphan Drug Legislation 1993), Australia (Orphan Drug Program 1998) and a more limited form of protection in Singapore. The key features of each legislation are discussed below:

United States

The Office of Orphan Products Development (OOPD) is part of the US Food and Drug Administration (FDA) and is dedicated to promoting development of products that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions.

A rare disease is defined in the US Orphan Drug Act 1983 in two ways:

- (1) any disease or condition which affects less than 200,000 patients per year, which corresponds to 7.5 incidences per 10,000 inhabitants; or
- (2) any disease or condition which affects more than 200,000 patients per year, but for which there is no expectation that the cost of developing the drug will be recovered by sales of the drug in the US¹.

An application for US orphan drug designation must contain (in duplicate):

- (a) a description of the rare disease or condition and the reasons why such therapy is needed;
- (b) a description of the drug and scientific rationale for the use of the drug for the rare disease or condition,

including all data from non-clinical laboratory studies and clinical investigations;

- (c) a summary of the regulatory status and marketing history of the drug in the United States and in foreign countries; and
- (d) documentation to demonstrate that the drug meets the above criteria.

Once orphan drug status has been designated, sponsors are granted 7 years of marketing exclusivity after approval of the orphan drug².

Added tax incentives are provided by the US Act for clinical research undertaken, research study design assistance and funding assistance via orphan grants³.

Such tax incentives are available for any indication that meets the criteria set out above, even if the product itself is used for other indications that have not qualified for orphan drug status. For example, Taxol has qualified for orphan drug status for use in the rare AIDS-related Kaposi's sarcoma, even though the largest market for Taxol is for breast cancer.

Tax credit is normally provided for 50 % of the costs of clinical testing expenses. The full 50 % applies to contract research expenses as well as in-house research expenses. Both successful and unsuccessful products qualify for the tax credit. Normally the credit is limited to clinical testing that takes place in the United States, although it is also available for foreign trials when there is an insufficient testing population in the US.

European Union

The orphan drug designation process is decided by the European Agency for the Evaluation of Medicinal Products (EMA), through the Committee for Orphan Medicinal Products (COMP).

Orphan drug status will be granted if the product is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition that is either:

- (a) a condition that affects less than 5 in 10,000 persons in the European Community; or
- (b) a condition for which it is unlikely that the marketing of the medicinal product in the European Community will generate sufficient return to justify the necessary investment⁴.

The calculation of the incidence threshold will depend on the type of drug. For example, the incidence threshold for prevention (i. e. prophylaxis) of a disease is calculated based on the average number of patients who would catch the disease in the absence of the treatment, whereas the incidence threshold for the treatment of a disease is calculated based on the cumulative number of people with that disease (i. e. taking into account new incidences and deaths per year).

2 SEC. 526 [360cc]. (a)(3), Orphan Drug Act (as amended)

3 SEC. 5 [360ee]. (a), Orphan Drug Act (as amended)

4 Article 3(1)(a) Regulation (EC) No 141/2000

1 SEC. 526 [360bb]. (a)(1), Orphan Drug Act (as amended)

As well as the above criteria, the product must additionally meet the test that there must be no satisfactory method of diagnosis, prevention or treatment of the condition already authorized in the European Community. However, if a satisfactory method does exist, then this hurdle can alternatively be overcome by demonstrating that the product will be of significant benefit to those affected by that condition⁵.

Therefore, it seems that diseases prevalent in developing countries, but rare in Europe, can technically meet the legal requirements if there are only a few documented cases of the disease occurring „...in the Community.“

The request for orphan medicinal product designation can be made at any stage of drug development as soon as sufficient scientific evidence can be presented⁶. The research may therefore be pre-clinical (not yet tested on human subjects) or may have reached the human clinical trial phase. The application should be accompanied by the following⁷:

- (a) name or corporate name and permanent address of the sponsor;
- (b) active ingredients;
- (c) proposed therapeutic indication;
- (d) justification that the above mentioned criteria have been met; and
- (e) description of the stage of development.

The application procedure attracts no fees and commences with free pre-submission meetings with the EMEA where assistance is provided to prepare orphan designation applications. The application is then submitted for validation by the EMEA (Day 1) and is assessed by COMP, who will provide an opinion within 90 days of a valid application⁸. The opinion is then sent to the European Commission who will adopt a decision within 30 days⁹. The decision shall be notified to the sponsor and communicated to the competent authorities. If the COMP rejects the application, the EMEA will inform the sponsor, who will have a further 90 days to appeal¹⁰.

Once a drug has been designated orphan status, the person or company who applied for designation (the „sponsor“) is granted a 100% fee reduction for all advice on the development of orphan medicinal products after designation and a 50% fee reduction for all steps of obtaining marketing authorisation via the centralised procedure¹¹. It is important to note that designation as an orphan medicinal product is not an endorsement for the use of the product in the designated condition. This can only be done once efficacy, safety and quality data has been submitted to the marketing authority for authorisation.

It is possible for the sponsor to assign their rights of orphan drug status to a third party prior to marketing

authorisation or set up a joint venture to assist with development of the drug, however, the sponsor must update the EMEA annually of any such changes.

Once marketing authorisation has been granted, the legislation provides a 10 year period of market exclusivity to prevent the marketing of directly competitive similar products¹². This exclusivity is a substantial competitive advantage and provides orphan drugs with substantial protection not afforded to mainstream pharmaceutical products. However, this period of exclusivity may be reduced to 6 years if at the end of the fifth year, it is established that the medical product no longer meets the criteria set out above¹³. On 7 March 2007, the European Commission published guidance notes for the review process of the designation criteria for a particular orphan drug¹⁴.

Generally, EU orphan drug designation provides no protection against a third party applying for orphan drug designation for the same medicinal product and the same rare disease in an alternative country. Furthermore, it is possible in the EU for more than one sponsor to be granted orphan drug status for the same drug and the same rare disease. In such an instance, the first sponsor to receive marketing authorisation would be able to prevent marketing by any other sponsor(s).

Japan

Japan established its orphan drug program in 1993, when it passed the Partial Amendments of the Pharmaceutical Affairs Law and the Law Concerning the Drug

Fund for ADR relief and R&D Promotion. According to this legislation, orphan drug status can be granted to a drug, provided it fulfils the following three criteria:

- (a) The disease for which use of the drug is claimed must be incurable. There must be no possible alternative treatment, or the efficacy and expected safety of the drug must be excellent in comparison with other available drugs;
- (b) The number of patients affected by this disease in Japan must be less than 50,000 on the Japanese territory, which corresponds to a maximum incidence of four per ten thousand; and
- (c) The drug has a high probability for successful development, at least on a theoretical basis; i.e. it must appear feasible that the development plan, if followed, can lead to an approved drug product.

The Ministry of Health, Labour and Welfare (MHLW) are responsible for granting orphan drug status and in order to receive orphan designation, the sponsors must submit the following data to the authorities:

- (a) Estimated size of patient population;
- (b) Non-clinical and early phase clinical study; and
- (c) Development protocol.

5 Article 3(1)(b) Regulation (EC) No 141/2000

6 Article 5(1) Regulation (EC) No 141/2000

7 Article 5(2) Regulation (EC) No 141/2000

8 Article 5(5) Regulation (EC) No 141/2000

9 Article 5(8) Regulation (EC) No 141/2000

10 Article 5(7) Regulation (EC) No 141/2000

11 Article 7(2) Regulation (EC) No 141/2000

12 Article 8(1) Regulation (EC) No 141/2000

13 Article 8(2) Regulation (EC) No 141/2000

14 http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2007/2007_03/draft_guideline_art8-2_200702.pdf

The application is then examined by the Medicinal products subcommittee and their conclusions are sent to a special committee.

Orphan drugs benefit from a fast-track Marketing Authorization procedure. In particular, the law requires priority of evaluation of applications made for indications concerning rare diseases. In addition to this measure, the Organization for Pharmaceutical Safety and Research provides pharmaceutical companies launching orphan drugs with a consultation on development protocols and some advice concerning the preparation of approval applications. The registration validity period, which varies from four to six years for traditional drugs, is extended to 10 years for orphan products.

Some government funds, such as the Drug Fund for Side-Effects Relief and Research Promotion, are available. These funds guarantee financial assistance in covering a proportion of the expenditure devoted to research and development of orphan drugs.

Funding also covers scientific activities and the provision of advice in terms of development, notably concerning clinical trials.

The Japanese authorities reimburse the development costs up to 50%. In addition, a 6% tax reduction for Research and Development expenses is granted, other than those coming from funding grants and within the limit of 10% of company tax. Although this is a lower percentage than the credit available under the US Orphan Drug program, the credit applies to non-clinical studies as well as clinical studies, unlike the US program. Companies making profits on sales of orphan drugs must return a proportion of the subsidy granted as a contribution to these funds.

Australia

The Australian Orphan Drug Program 1998 aims to ensure the availability of a greater range of treatments for rare diseases and allows the Australian Therapeutic Goods Administration (TGA) to use information from the US Food and Drug

Administration (FDA) Orphan Drugs Program as part of the Australian evaluation process.

Orphan drug status will be granted if the drug is:

- (1) intended to treat, prevent or diagnose a rare disease, which is defined as one with a prevalence of 2000 patients/subjects or fewer in the Australian population, which corresponds to 1.1 incidences per 10,000 inhabitants¹⁵; or
- (2) not commercially viable to supply, treat prevent or diagnose another disease¹⁶.

Once orphan designation is granted, the TGA waives the evaluation fees, thus removing a major impediment to making orphan drugs available. A distinct evaluation pathway for processing orphan drugs is also set up.

One of the programme's important purposes is the possibility to make drugs available to treat leprosy and trachoma, which affect the aboriginals.

The main characteristic of the Australian Program is that it is based upon a close collaboration of the TGA with the US FDA. The Australian programme takes into account the FDA's orphan drugs evaluations. Additional criteria are also established for identifying and evaluating orphan drugs in Australia, which have not been evaluated in the USA or do not meet the US criteria.

The main characteristics of the orphan drug policy in Australia are:

- (a) a legal framework for orphan drug designation;
- (b) waiver of application and evaluation and no annual registration fees¹⁷; and
- (c) a five-year exclusivity (under consideration by the Australian jurisdiction).

Regarding the funding of orphan drugs, TGA covers all costs of the orphan drug designation process, and then balances its expenditures with other components of the health care system overall budget.

The health-care financing system in Australia may be an issue in the delivery of orphan drugs to patients. In fact, the cost of orphan drugs may prevent some patients using them. Australia has a Pharmaceutical Benefits Scheme, which provides subsidies to make some drugs affordable. The place of orphan drugs in such a scheme is under discussion between the Australian Health-care Authorities decision-makers.

In Australia, research and development is not supported by grants or tax incentives. There is no specific law concerning intellectual property for orphan drugs. The legal status is applied to orphan drugs as for any other drug registered for supply in Australia. On the other hand, registration fees are covered by the Therapeutic Goods Administration.

Singapore

Singapore was the first country outside the US to have official orphan drug legislation, which was introduced through the Orphan Drug Exemption to the Medicines Act. The legislation, which came into force at the end of 1991, gave a definition of orphan drugs and of the legal framework for imports into Singapore.

A rare disease is defined as a life threatening and severely debilitating illness.

An orphan drug is considered a medicinal product, which has been identified by any doctor or dentist as an appropriate and essential remedy with no effective substitute for the treatment of a rare disease.

The product should not hold a previous product license under the Medicine Act and should be approved by the competent Health Authorities either from the country of origin or from any other country where the orphan drug has been used.

15 Regulation 2, Therapeutic Goods Regulations 1990

16 Regulation 16H(2), Therapeutic Goods Regulations 1990

17 Regulation 45(12)(c), Therapeutic Goods Regulations 1990

Orphan drug importers must maintain proper records, including:

- The quantity imported or supplied;
- The date of reception or supply; and
- The name and address of the person for whom the orphan drug is provided.

In addition, any other drug imported shall be kept in a hospital and be under the charge and control of a „custodian“ who must be a physician, dentist or pharmacist appointed by the hospital.

Any doctor or dentist who requires an orphan drug for the treatment of his/her patient who is suffering from a rare disease may request the custodian to provide him with the drug.

So far, there has been no other incentive, such as marketing exclusivity or subsidies in the orphan drug policy.

Criticism

The main criticism of orphan drug legislation has been that the lack of competition has driven up orphan drug prices which has important economic implications for healthcare providers. For example, nitric oxide was available for years and cost very little (£2000 to supply a neo-natal unit with nitric oxide for one year; Subhedar, N. V. *et al.*, (2002) *The Lancet* **359**, 1781), however, since receiving orphan status, the cost has risen to over £63,000 per year.

There is also some criticism relating to the lack of research input and the quality of clinical trials has been questioned. This is mainly due to the fact that if less than

10 people per 100,000 are afflicted with the disease then it becomes much harder to recruit patients for clinical trials, which can be challenging even for more common diseases.

Summary

The criticism levelled at orphan drug legislation must be seen to be unfair. The pharmaceutical industry has previously been condemned for not developing medicinal products for rare diseases based on the risks of not recovering their substantial research and development costs. For example, in the decade leading up to the US Orphan Drug Act 1983 only 10 orphan drugs entered the market compared with the 269 orphan drugs put on the market since the act was introduced.

The legislation therefore provides pharmaceutical companies with unique incentives, such as those discussed above, to market products for the treatment of rare diseases. The patients of these rare, yet debilitating, diseases will benefit enormously from orphan drug provisions in the long term. Healthcare insurers will be impacted by the high price of orphan drugs which is inevitable based on the lack of competition and the desire to recover substantial costs but they are comfortable with this arrangement because the number of claims is comparatively low.

Patient benefit must be the over-riding objective of the legislation, therefore, the success of orphan drug legislation should be judged by the benefits observed in patients suffering from these previously untreated rare diseases.

Next Board and Council Meetings

Board Meetings

75th Board Meeting, 1st December 2007, Munich
76th Board Meeting, 29th March 2008, Rome

Council Meetings

63rd Council Meeting, 22nd-23rd October 2007, Nuremberg,
64th Council Meeting, 26th-27th May 2008, Vilnius,
65th Council Meeting, 24th-25th November 2008, Munich

Disziplinarorgane und Ausschüsse
Disciplinary bodies and Committees · Organes de discipline et Commissions

Disziplinarrat (epi)	Disciplinary Committee (epi)	Commission de discipline (epi)
AT – W. Katschinka BE – T. Debled BG – E. Benatov CH – K. Schmauder CZ – V. Žak DE – W. Fröhling DK – U. Nørgaard EE – J. Toome ES – V. Gil Vega FI – P. C. Sundman	FR – P. Monain GB – S. Wright** GR – T. Kilimiris HU – J. Markó IE – G. Kinsella IS – A. Vilhjálmsson IT – B. Muraca LI – P. Rosenich* LT – R. Zabolienne	LU – B. Dearling LV – L. Kuzjukevica NL – L. Van Wezenbeek PL – A. Rogozinska PT – A. J. Pissara Dias Machado RO – C. Pop SE – H. Larfeldt SI – J. Kraljic SK – T. Hörmann TR – T. Yurtseven
Disziplinarausschuss (EPA/epi) epi-Mitglieder	Disciplinary Board (EPO/epi) epi Members	Conseil de discipline (OEB/epi) Membres de l'epi
DE – W. Dabringhaus DK – B. Hammer-Jensen	FR – M. Santarelli	GB – J. Boff
Beschwerdekammer in Disziplinarangelegenheiten (EPA/epi) epi-Mitglieder	Disciplinary Board of Appeal (EPO/epi) epi Members	Chambre de recours en matière disciplinaire (OEB/epi) Membres de l'epi
AT – W. Kovac DE – N. M. Lenz FR – P. Gendraud	GB – T.L. Johnson GR – C. Kalonarov	NL – A. V. Huygens SE – C. Onn
epi-Finanzen	epi Finances	Finances de l'epi
AT – P. Pawloy CH – T. Ritscher DE – M. Maikowski	FR – S. Le Vaguerèse GB – T. Powell** IE – P. Kelly IT – S. Bordonaro	LT – M. Jason LU – J. P. Weyland* SE – K. Norin
Geschäftsordnung	By-Laws	Règlement intérieur
CH – C. E. Eder* DE – D. Speiser	FR – T. Schuffenecker	GB – T. L. Johnson
Standesregeln Ordentliche Mitglieder	Professional Conduct Full Members	Conduite professionnelle Membres titulaires
AT – F. Schweinzer BE – P. Overath BG – N. Neykov CH – U. Blum CY – C.A. Theodoulou DE – H. Geitz DK – L. Roerboel	ES – C. Polo Flores FI – J. Kupiainen FR – J.R. Callon de Lamarck GB – T. Powell* GR – A. Patrinos-Kilimiris HU – M. Lantos IE – M. Walsh IS – A. Vilhjálmsson	LI – R. Wildi LT – R. Zabolienne LU – J. Bleyer NL – F. Dietz PT – N. Cruz RO – L. Enescu SE – M. Linderoth TR – K. Dündar
Stellvertreter	Substitutes	Suppléants
AT – E. Piso CH – P.G. Maué DE – G. Ahrens	FR – J. Bauvir GB – S.M. Wright IS – G.Ö. Hardarson IT – G. Colucci	NL – J.J. Bottema RO – C. Pop SE – H. Larfeldt TR – K. Dericiglu

*Chairman/**Secretary

Europäische Patentpraxis	European Patent Practice	Pratique du brevet européen
AT – H. Nemeč	FI – T. Langenskiöld	LU – J. Beissel
AT – A. Peham	FI – A. Weckman	LU – B. Kutsch
BE – F. Leyder	FR – H. Dupont	MC – T. Schuffenecker
BE – P. Vandersteen	FR – L. Nuss	NL – M.J. Hatzmann
BG – T. Lekova	GB – P. Denerley	NL – L.J. Steenbeek
CH – E. Irniger	GB – E. Lyndon-Stanford*	PL – E. Malewska
CH – G. Surmely	HU – A. Mák	PL – A. Szafruga
CY – C.A. Theodoulou	HU – F. Török	PT – P. Alves Moreira
DE – M. Hössle	IE – L.J. Casey	PT – N. Cruz
DE – G. Leißler-Gerstl	IE – C. Lane	RO – D. Nicolaescu
DK – P. Indahl	IS – E.K. Fridriksson	RO – M. Oproiu
DK – A. Hegner	IS – G.Ö. Hardarson	SE – J.O. Hyltner
EE – J. Ostrat	IT – E. de Carli	SE – A. Skeppstedt**
EE – M. Sarap	IT – M. Modiano	SK – M. Majlingová
ES – E. Armijo	LI – B.G. Harmann	TR – H. Cayli
ES – L.A. Duran	LT – O. Klimaitiene	TR – A. Deris
Berufliche Qualifikation Ordentliche Mitglieder	Professional Qualification Full Members	Qualification professionnelle Membres titulaires
AT – F. Schweinzer	ES – A. Morgades	LU – C. Schroeder
BE – M. J. Luys**	FI – P. Valkonen	LT – L. Kucinkas
BG – V. Germanova	FR – F. Fernandez	LV – E. Lavrinovics
CH – W. Bernhardt	GB – A. Tombling	NL – F. Smit
CY – C. Theodoulou	GR – M. Zacharatou	PL – A. Slominska-Dziubek
CZ – J. Andera	HU – T. Marmarosi	PT – J. De Sampaio
DE – G. Leissler-Gerstl	IE – C. Boyce	RO – M. Teodorescu
DK – E. Christiansen	IS – A. Viljählmsson	SE – M. Linderöth
EE – E. Urgas	IT – F. Macchetta	SI – A. Primozic
	LI – S. Kaminski*	SK – V. Neuschl
		TR – S. Arkan
	Stellvertreter	Suppléants
AT – P. Kliment	FR – D. David	NL – A. Land
CH – M. Liebetanz	GB – J. Vleck	PT – I. Franco
CY – P. Poetis	IS – G. Hardarson	RO – C. Fierascu
DE – G. Ahrens	IT – P. Rambelli	SE – M. Holmberg
DK – A. Hegner	LT – O. Klimaitiene	SI – Z. Ros
EE – R. Pikkor	LU – A. Schmitt	TR – B. Kalenderli
FI – C. Westerholm		
	(Examination Board Members on behalf of the epi)	
CH – M. Seehof		IT – G. Checcacci
FR – M. Névant		NL – M. Hatzmann
Biotechnologische Erfindungen	Biotechnological Inventions	Inventions en biotechnologie
AT – A. Schwarz	FI – M. Lax	LU – P. Kihn
BE – A. De Clercq*	FR – A. Desaix	NL – B. Swinkels
BG – S. Stefanova	GB – S. Wright**	PT – J. E. Dinis de Carvalho
CH – D. Wächter	HU – A. Pethö	SE – L. Höglund
DE – G. Keller	IE – C. Gates	SK – J. Gunis
DK – B. Hammer Jensen	IT – G. Staub	TR – O. Mutlu
ES – F. Bernardo Noriega	LI – B. Bogensberger	

*Chairman/**Secretary

EPA-Finzen Ordentliche Mitglieder	EPO Finances Full Members	Finances OEB Membres titulaires
DE – W. Dabringhaus ES – I. Elosegui de la Pena	FR – S. Le Vaguerèse	GB – J. Boff*
Stellvertreter	Substitutes	Suppléants
	IT – A. Longoni	
Harmonisierung Ordentliche Mitglieder	Harmonization Full Members	Harmonisation Membres titulaires
BE – F. Leyder* CH – A. Braun	FR – S. Le Vaguerèse GB – J. D. Brown** NL – L. Steenbeek	IT – F. Macchetta SE – K. Norin
Stellvertreter	Substitutes	Suppléants
DE – O. Söllner ES – J. Botella Reyna FI – V.-M. Kärkkäinen	FR – E. Srour IT – G. Mazzini	LT – L. Kucinkas SI – P. Skulj
Editorial Committee		
AT – W. Holzer DE – E. Liesegang	FR – T. Schuffenecker	GB – T. Johnson
Online Communications Committee (OCC)		
DK – P. Indahl CH – K. Stocker	FI – J. Virkkala FR – J-R. Callon de Lamarck IT – L. Bosotti	GB – R. Burt GB – D. Smith NL – J. Van der Veer
Wahlausschuss	Electoral Committee	Commission pour les élections
CH – H. Breiter	DE – K.P. Raunecker	HU – T. Palágyi
Standing Advisory Committee before the EPO (SACEPO)		
epi-Delegierte	epi Delegates	Délégués de l'epi
ES – E. Armijo FI – K. Finnilä DE – M. Hössle NL – A.V. Huygens	BE – F. Leyder GB – E. Lyndon-Stanford GB – C. Mercer	FR – L. Nuss GR – H. Papaconstantinou HU – F. Török
Interne Rechnungsprüfer Ordentliche Mitglieder	Internal Auditors Full Members	Commissaires aux Comptes internes Membres titulaires
CH – A. Braun	DE – R. Zellentin	
Stellvertreter	Substitutes	Suppléants
DE – D. Laufhütte	DE – R. Keil	

*Chairman/**Secretary

VORSTAND

BOARD

BUREAU

Präsident

• *President* •
Chris P. MERCER (GB)

Président

Vize-Präsidenten

• *Vice-Presidents* •
Laurent NUSS (FR)
Kim FINNILÄ (FI)

Vice-Présidents

Generalsekretär

• *Secretary General* •
Wolfgang BAUM (DE)

Secrétaire Général

Stellvertr. Sekretär

• *Deputy Secretary* •
Frank L. ZACHARIAS (DE)

Secrétaire Adjoint

Schatzmeister

• *Treasurer* •
Claude QUINTELIER (BE)

Trésorier

Stellvertr. Schatzmeister

• *Deputy Treasurer* •
František KANIA (CZ)

Trésorier Adjoint

Mitglieder

• *Members* •

Membres

Selda ARKAN (TR) • *Enrique ARMIJO (ES)* • *Jacques BAUVIR (FR)*

Dagmar CECHVALOVÁ (SK) • *Ejvind CHRISTIANSEN (DK)* • *Paul DENERLEY (GB)*

Gunnar Örn HARDARSON (IS) • *Ruurd JORRITSMA (NL)* • *Susanne KAMINSKI (LI)*

Heinu KOITEL (EE) • *Leonas KUCINSKAS (LT)* • *Sigmar LAMPE (LU)*

Edvards LAVRINOVICS (LV) • *Gregor MACEK (SI)* • *Paul Georg MAUÉ (CH)*

Denis McCARTHY (IE) • *Enrico MITTLER (IT)* • *Klas NORIN (SE)* • *Margareta OPROIU (RO)*

Helen PAPAConstantinou (GR) • *João PEREIRA DA CRUZ (PT)* • *Thierry SCHUFFENECKER (MC)*

Friedrich SCHWEINZER (AT) • *Ádám SZENTPÉTERI (HU)* • *Milena TABAKOVA (BG)*

Christos A. THEODOULOU (CY) • *Elzbieta WILAMOWSKA-MARACEWICZ (PL)*

