

Regional Workshop on the Use of PCT Products

Session 1 Use of PCT Products and Other Offices' Work Products

Tokyo, Japan September 13-14, 2016

Mr. Kenichiro NATSUME
Director
PCT International Cooperation Division
Patents and Technology Sector

Goal of This Workshop

- Obtain (Learn) skills to
 - Access to PCT Products
 - Access to work products by other offices
- Enhance ability to
 - ■Analyze work products (e.g. prior art, office action)
 - ■Apply to actual examination
- Share experiences



Patent Examination and PCT Products

- Patent Examination (Substantive Examination)
 - Prior Art Search
 - □ Examination (novelty, inventive step ...)
- PCT Products
 - **□**ISR
 - **□**WO
 - ■IPRP Chapter II
- Work Products by Other Offices

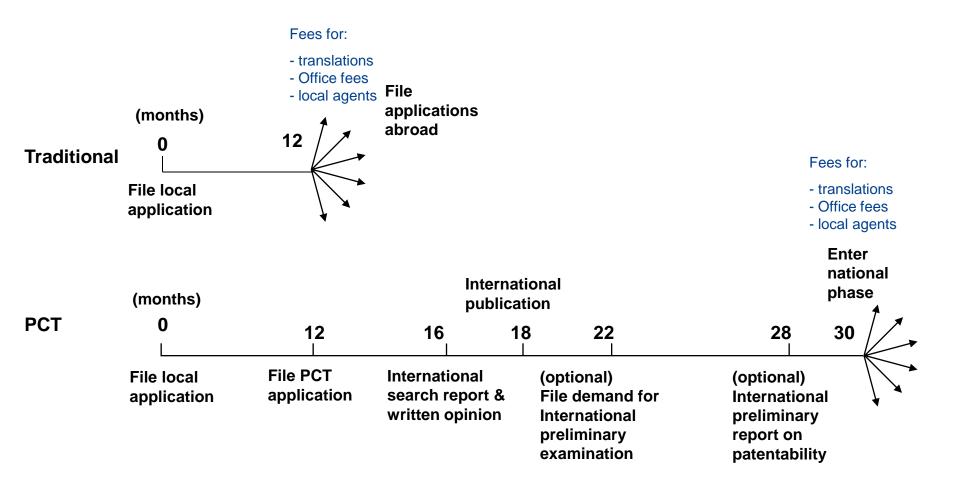


Outline of the Workshop

- Background Information
 - Review of the PCT system
- Access to the information
 - ☐ Patentscope, WIPO-CASE, AIPN ...
- Work on Cases

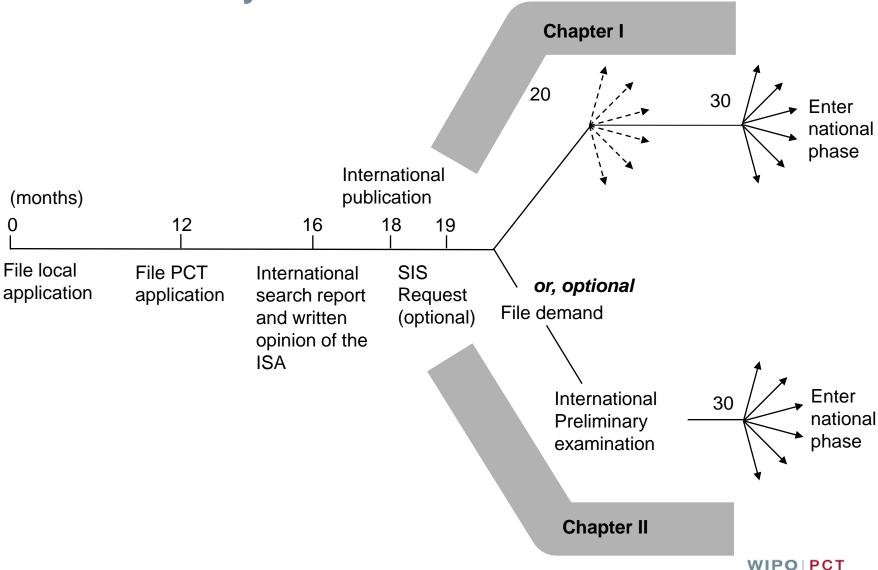


Traditional patent system vs. PCT system





The PCT system



The International Patent System



International Search and Written Opinion of the ISA

The International Searching Authority (1)

- Checks unity of invention (Rules 13 and 40)
- Checks title (Rule 37); checks abstract (Rule 38)
- Searches claimed invention (Article 15(3), Rule 33.3)
- Authorizes rectification of obvious mistakes if the mistake is:
 - in any part of the international application other than the request, (Rule 91.1(b)(ii)) or
 - in any paper submitted to that Authority (Rule 91.1(b)(iv))



The International Searching Authority (2)

- Establishes international search report (ISR) (Rules 42 and 43) and/or declaration that no international search report will be established (Article 17(2))
- Establishes written opinion of the ISA (Rule 43*bis*): non-binding first opinion on novelty, inventive step (non-obviousness) and industrial applicability of claimed invention



International Searching Authorities (21 in total)

- AT Austria
- AU Australia
- BR Brazil
- CA Canada
- CL Chile
- CN China
- EG Egypt
- ES Spain
- FI Finland
- IL Israel
- IN India
- JP Japan

- KR Republic of Korea
- RU Russian Federation
- SE Sweden
- SG Singapore
- UA Ukraine
- US United States of America
- EP European Patent Office
- XN Nordic Patent Institute (Denmark, Iceland, Norway)
- XV Visegrad Patent Institute (VPI) (Czech Republic, Hungary, Poland, Slovakia)



Prior art for international search (Article 15(2) and Rule 33)

- Prior art:
 - everything which has been made available to the public,
 - Where??
 - What kind of disclosure??
 - which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step,
 - provided the making available to the public occurred prior to the what date? (priority/international filing date).
- PCT Minimum Documentation (Rule 34)



Written opinion of the ISA (Rule 43bis) (1)

- Initial preliminary non-binding opinion on:
 - novelty (not anticipated)
 - inventive step (not obvious)
 - industrial applicability
- A written opinion will be established for all international applications at the same time as the ISR
- The written opinion is sent to applicant and the International Bureau together with the ISR



Written opinion of the ISA (Rule 43*bis*) (2)

- The written opinion is made publicly available on PATENTSCOPE in its original language as of the date of publication of the international application
- No formal procedure for applicants to respond to written opinion of the ISA
- Possibility to submit informal comments to the International Bureau
 - They are made publicly available together with the written opinion in their original language
 - They are communicated to the DOs together with the IPRP (Chapter I) if and when it is sent
- Note: The IPRP Chapter I and its translation are established at 30 months from the priority date The International

Patent System

Prior art for written opinion of the ISA (Rules 43*bis*.1(b) and 64.1)

- Prior art:
 - same as for international search purposes; BUT:
 - □ relevant date: everything made available to the public prior to what date??
- The ISA may request a copy of a priority document from the International Bureau (Rule 66.7(a)); however, even if, at the time of establishment of the written opinion of the ISA, a copy cannot be made available to the ISA, the written opinion will nevertheless be established on the assumption that the priority date is the relevant prior art date, except if the applicant had failed to comply with his obligations under Rule 17.1

The International Patent System

International preliminary report on patentability (IPRP) (Chapter I of the PCT) (Rule 44bis)

- If applicant does <u>not</u> file a demand for international preliminary examination:
 - □ IB establishes the IPRP (Chapter I) on the basis of the written opinion of the ISA
 - IPRP (Chapter I) and its translation
 - are sent to designated Offices
 - are made publicly available on PATENTSCOPE (but not "published" like the international application and ISR) at the expiry of 30 months from the priority date



Use of the written opinion of the ISA for the purposes of the Chapter II procedure (Rule 66.1*bis*)

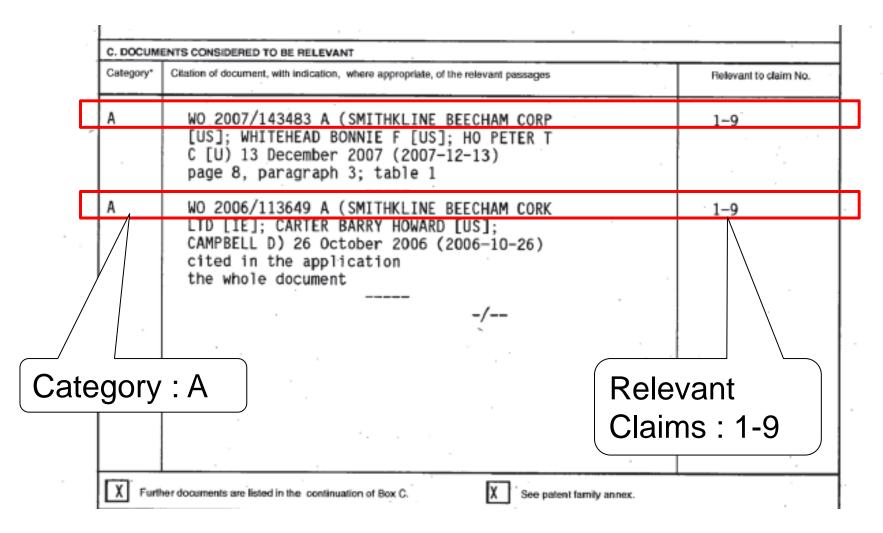
- If applicant files a demand for international preliminary examination:
 - written opinion of the ISA becomes written opinion of the IPEA (exception: IPEA decides not to accept written opinions by certain ISAs)
 - informal comments by applicant on written opinion of ISA will not be sent to IPEA (Article 34 amendments/arguments only)
 - if an international preliminary examination report is established, any informal comments submitted to the IB will not be sent to

 DOs or EOs

 If an international preliminary examination report is established, any informal comments submitted to the IB will not be sent to

	PCT	
	NTERNATIONAL SEARCH I	REPORT
	(PCT Article 18 and Rules 43 and 4	44)
Applicant's or agent's file reference		
P08017	FOR FURTHER ACTION a	see Form PCT/ISA/220 s well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year	r) (Earliest) Priority Date (day/month/year)
PCT/EP2009/060890	24/08/2009	25/08/2008
Applicant	, 00, 2,003	
RATIOPHARM GMBH		
This international search report has been p according to Article 18. A copy is being trai	prepared by this International Searching	Authority and is transmitted to the applicant
This international search report consists of X It is also accompanied by a		
[A] It is also accompanied by a	a copy of each prior art document cited in	in enis report.
a translation of the of a translation fun b. This international search re authorized by or notified to	this Authority under Rule 91 (Rule 43.6)	, which is the language search (Rules 12.3(a) and 23.1(b))
2. Certain claims were foun	d unsearchable (See Box No. II)	
3. Unity of invention is lack	ing (see Box No III)	
With regard to the title,		
X the text is approved as sub	mitted by the applicant	
	ned by this Authority to read as follows:	
the text has been establish 5. With regard to the abstract,	ed by this Authority to read as follows:	
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		TIONAL SEAR(l	application No 009/060890
Patent document cited in search report		Publication date	Patent family member(s)	·	Publication date
WO 2007143483	Α.	13-12-2007	NONE		
WO 2006113649	A	26-10-2006	AR 05425 AU 200623642 CA 260620	23 A1 07 A1	13-06-2007 26-10-2006 26-10-2006
			CN 10120321 EA 20070225 EP 187134	3 A1 17 A1	18-06-2008 28-04-2008 02-01-2008
			JP 200853693 KR 2008000555 US 200820633	7 A	11-09-2008 14-01-2008 28-08-2008
 W0 2008067144	Α -	05-06-2008	EP 208886	2 A2	19-08-2009



Category: X, Y

•		JOIY . 73, 1	
	C. DOCUME	ENTS CONSIDERED TO BE RELEVANT	
	Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
\[Х	US 2004/189715 A1 (MATTHEWS JOSEPH H [US] ET AL MATTHEWS III JOSEPH H [US] ET AL)	1-3,5-12
	Υ	30 September 2004 (2004-09-30) paragraphs [0011], [0019], [0021], [0022], [0044], [0060] - [0062], [0068], [0074], [0076], [0077]; figures 1,9,13-16	4
	Υ	EP 2 053 850 A1 (VESTEL ELEKT SANAYI VE TICARET [TR]) 29 April 2009 (2009-04-29) column 9, line 51 - column 10, line 6; figures 4,5,9	4
	Υ	US 6 552 738 B1 (LIN WALTER C [US] ET AL) 22 April 2003 (2003-04-22) column 1, line 22 - line 39; figures 1-4 column 1, line 67 - line 15 column 3, line 66 - column 5, line 59	5,12
	X Furth	are documents are listed in the continuation of Box C. X See patent family annex.	Relevant Claims

WIPO | PCT
The International
Patent System

From the				
From the INTERNATIONAL SEARCHING AUTHORI	TY			
To:			DCT	
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		WD	ITTEN OPINION OF THE	
see form PCT/ISA/220			ONAL SEARCHING AUTHORIT	
			(PCT Rule 43bis.1)	
		ate of mailing		
		layimonthiyear)	see form PCT/ISA210 (second sheet)	
Applicant's or agent's file reference		FOR FURTHER ACTION		
see form PCT/ISA/220		See paragraph 2 below		
International application No. Int	emational filing date (day.f	nonth/year)	Priority date (day/month/year)	
	1.08.2009		25.08.2008	
International Patent Classification (IPC) or both	national classification and	IPC		
INV. A61K31/517				
			<u> </u>	
Applicant				
RATIOPHARM GMBH				
1. This opinion contains indications	relating to the following	na items:		
Box No. I Basis of the opinio	n .			
☐ Box No. II Priority				
☐ Box No. III Non-establishment	of opinion with regard t	o novelty, inve	ntive step and industrial applicability	
☐ Box No. IV Lack of unity of inv		,,	mire stop and modernal approaching	
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 Box No. V Reasoned stateme applicability; citation 	ent under Rule 43 <i>bis</i> .1(a)(i) with regard	to novelty, inventive step or industrial statement	
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/EP2009/060890

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement

Novelty (N)

Yes: Claims

1-9

: Claims

Inventive step (IS)

Yes: Claims

No: Claims

Industrial applicability (IA)

Yes: Claims No: Claims

1-3

Citations and explanations see separate sheet

2. Novelty

Prior art document D1 discloses unit dosage forms comprising 0.5mg to 1000mg of lapatinib, which is below the amount claimed in the present application (p. 8, para. 3). Furthermore, a daily dose of 1250mg or 1500mg lapatinib is disclosed in D1 without, however, further specifying the amounts of active agent per unit dose (Table 1). Tablets comprising 250mg lapatinib are further known from D2 (ex. 1) and D3 is the package leaflet of Tyverb® 250mg, of which 5 tablets have to be administered per day.

Thus, in view of the cited prior art, the subject-matter of claims 1-9 seems to be novel (Art. 33(2) PCT).

Inventive Step

D3, which is regarded as closest prior art, differs from the subject-matter of the present application in the amount of active agent per unit dose. In view of the cited prior art, the technical problem of the present application seems to be the provision of an alternative dosage form of lapatinib, which is convenient to administer and which contains the whole daily lapatinib medication in a unit dose.

The provision of a unit dose comprising between 1200 and 1300mg lapatinib is not obvious in view of the cited prior art. As shown in the examples, the lapatinib formulations of the present application are even superior compared to the reference with regard to in-vitro parameters (fig. 1).

As a result, the subject-matter of claims 1-9 of the present application seems to involve an inventive step (Art. 33(3) PCT).

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims <u>4, 5, 9, 11, 12</u>

No: Claims <u>1-3, 6-8, 10</u>

Inventive step (IS) Yes: Claims

No: Claims 1-12

Industrial applicability (IA) Yes: Claims <u>1-12</u>

No: Claims

2. Citations and explanations

see separate sheet



3 Novelty

Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of independent claims 1, 6 and 7 and dependent claims 2, 3, 8 and 10 is not new in the sense of Article 33(2) PCT, and the criteria of Article 33(1) PCT are therefore not met.

3.1 Claim 1: Document D1 discloses:

A method for displaying an on-screen display (Fig. 13-15) comprising the steps of:

determining at least one display parameter (paragraph [0022]: "...the various applications present a GUI tailored for control via a limited input device from a distance) of an on-screen display (paragraph [0022]: GUI; Fig. 13-15: 1302, 1402, 1502) based upon the type (paragraph [0021]: "...to switch between the first and second graphical user interface modes based on the input device used to control the operating system"; paragraph [0076]; Fig. 16) of user interface device (Fig. 1: 40, 42, 55; paragraph [0044]) used;

displaying said on-screen display according to said determined at least one display parameter (paragraphs [0022], [0062], [0077]).

3.2 <u>Claim 6</u> is directed to a computer program product for carrying out the method

4 Inventive Step

Session 1 -25

Furthermore, the subject-matter of dependent claims 4, 5, 9, 11 and 12 does not involve an inventive step in the sense of Article 33(3) PCT, and the criteria of Article 33(1) PCT are therefore not met. Document D1 is considered to represent the closest prior art to the subject-matter of these claims.

- 4.1 Claim 4: Document D1 does not disclose determining the dimension of the on-screen display based on the distance between the remote control device and display of said on-screen display. Nevertheless, this practice is known from e.g. document D2, and the skilled person would simply adopt such known practice with corresponding effect starting from D1 in order to achieve constantly good readability of the OSD when the distance of the user from the display device is variable.
- 4.2 <u>Claims 5, 9, 12</u>: Document D1 is not specific about the location of the "local control device". Nevertheless, the skilled person would choose as Monitor 47 in Fig. 1 of D1 among any known display devices, among which are display devices with built-in USB ports as well as touch-screens. Therefore displays with built-in touch-screens or with a mouse/keyboard connected to the display USB ports fully fall within the sope of the "local control device located on said."



International Preliminary Examination

International preliminary examination (1)

- Results in the establishment by the IPEA of a nonbinding opinion on
 - □ novelty (not anticipated) (Article 33(2) and Rule 64)
 - □ inventive step (not obvious) (Article 33(3) and Rule 65)
 - □ industrial applicability (Article 33(4))
- International preliminary examination provides an opportunity to make amendments and to address patentability issues raised by the ISA



International Preliminary Examination (2)

■ Only claims relating to the invention(s) searched by the ISA will be examined by the IPEA (Rules 66.1(e) and 66.2(a)(vi))



Prior art for IPE (Rule 64.1) (1)

■ What is considered prior art?

Everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) provided that such making available occurred prior to <a href="https://www.what.edu/what.e



Prior art for IPE (Rule 64.1) (2)

- What is the relevant date?
 - □ the date of the earlier application of which priority is claimed unless the IPEA considers that the priority claim is not valid for reasons other than the fact that the international filing date is later than the date on which the priority period expired, but is within two months from that date; or
 - □ the international filing date of the international application in all other cases



Mandatory top-up search (Rule 66.1 ter)

Aims at uncovering any prior art not available at the time when the ISR was established, in particular "secret" prior art (patent applications published on or after the date of establishment of the ISR but which have an earlier priority date)

Exceptions:

- Only in respect of claims for which the IPEA establishes an IPRP Chapter II
- Where a search would serve no useful purpose, e.g. where the IPEA considers that the documents cited in the ISR are sufficient to demonstrate lack of novelty of the entire subject matter



Written opinion of IPEA (Rules 66.2 and 66.6)

- The written opinion of the ISA is considered to be the written opinion of the IPEA (exception: IPEA decides not to accept written opinions by certain other ISAs)
- Where the written opinion of the ISA is taken as the written opinion of the IPEA, no second written opinion has to be issued
- If a second written opinion is issued, the applicant may respond within the time limit fixed in that second written opinion
- Possibility to request an interview with the examiner at the IPEA (Rule 66.6)

Patent System

- Must be established by the IPEA within:
 - 28 months from the priority date
 - □ 6 months from the time provided under Rule 69.1 for the start of the international preliminary examination
 - □ 6 months from date of receipt by IPEA of translation under Rule 55.2,

whichever expires last (Rule 69.2)



- May contain "annexes" (Rule 70.16):
 - replacement sheets containing amendments under Art. 19 or Art. 34 and any letter indicating the basis for the amendments
 - replacement sheets containing rectifications of obvious mistakes authorized under Rule 91 by the IPEA and accompanying letter
 - when referred to in the report, any sheet and letter concerning the rectification of an obvious mistake which has not been taken into account because it was not available in time (Rule 66.4bis)

- May contain "annexes" (Rule 70.16):
 - earlier amendments when later amendments are not used as a basis for the report because they are
 - considered to go beyond the disclosure in the international application or
 - not accompanied by a letter indicating the basis for the amendments
- Not annexed to the report: any other correspondence or copies of amendments superseded by later amendments



- No provisions for appeal or further proceedings during the international phase before the International Authorities
- Sent to the applicant and the IB (Rule 71.1)
- IB forwards copies of the report, and any required translation of the report into English (prepared by the IB), to the elected Offices (Article 36(3)(a) and Rule 72.1)
- The annexes are not translated by the IB (Article 36(3)(b))



- Calls attention to:
 - □ non-written disclosures (see Rules 64.2 and 70.9)
 - certain published documents (see Rules 64.3 and 70.10)
- Shall cite (Rule 70.7):
 - □ all documents considered to be relevant for supporting statements made concerning claims
 - documents whether or not they are cited in the ISR
 - documents cited in the ISR when the IPEA considers them relevant

Patent System

PATENT COOPERATION TREATY			
	PCT		
	NAL PRELIMINARY REP Chapter II of the Patent Coop		
	(PCT Article 36 and R	Rule 70)	
Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PC	T/IPEA/416
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 This report is the international pr Authority under Article 35 and t 	eliminary examination report, estat ransmitted to the applicant accordi	ing to Article 3	International Preliminary Examining 5.
	of 5 sheets, includ		
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sheets of the	description, claims and/or drawing	gs which have	peen amended and are the basis of this repo
and/or sheet	s containing rectifications authorizative Instructions).	ed by this Auti	ority (see Rule 70.16 and Section 607 of the
cheets which	supersede earlier sheets, but which	h this Authorit	y considers contain an amendment that goo
beyond the	fisclosure in the international appli	ication as filed,	as indicated in item 4 of Box No. I and the
Supplement			
b (sent to the Internat	ional Bureau only) a total of (indic	cate type and m	mber of electronic carrier(s))
	, containing a seq	quence listing a	nd/or tables related thereto, in electronic
form only, as indica Administrative Inst	ted in the Supplemental Box Relati	ing to Sequenc	e Listing (see Section 802 of the
 This report contains indications Box No. I Basis 	relating to the following items: of the report		
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Box No. II Priori			westive step and industrial applicability
		ra to noverty, i	ventive step and industrial applicability
	of unity of invention		
Box No. V Reason	ned statement under Article 35(2)	with regard to	novelty, inventive step or industrial
	ability; citations and explanations in documents cited	supporting suc	ii otatement
	in defects in the international appli	iestion	
Box No. VIII Certa	in observations on the international	u application	
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		the elements of the international application, this			
receivii this rep		re in response to an invitation under Article 14 ar	e referred to in this report as "o	riginally ,	filed" and are not annexed to
		national application as originally filed/furnished			
⊠ tł	he descr	iption:			
pa	ages	1-4,6-14			as originally filed/furnished
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	nations supporting such stat	egard to novelty, inventive step or industrial ap tement	• • • • • • • • • • • • • • • • • • • •
Statement			
Novelty (N)	Claims	1-5	Y
	Claims		N
Inventive step (IS)	Claims	1-5	Y
	Claims		N
Industrial applicability (IA)	Claims	1-5	Y
	Claims		N



Claims 1-5

"A means for selecting a device to be operated, which selects an external device corresponding to a physical address designated in a first CEC message when a device not compatible with CEC is included in the input path via which a second CEC message is transmitted," described in claim 1, is not mentioned in the above document, nor would a person skilled in the art having reference to the above document easily conceive of said means.

Accordingly, the novelty and inventive step of the invention as set forth in claims 1-5 are not denied by the above document.

