#### (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

### (19) World Intellectual Property Organization

International Bureau





(10) International Publication Number WO 2013/078206 A1

(43) International Publication Date 30 May 2013 (30.05.2013)

(51) International Patent Classification:

 A61B 17/58 (2006.01)
 B22F 3/00 (2006.01)

 A61B 17/60 (2006.01)
 B22F 3/10 (2006.01)

 B22F 1/00 (2006.01)
 B22F 3/24 (2006.01)

(21) International Application Number:

PCT/US2012/066068

(22) International Filing Date:

20 November 2012 (20.11.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/562,006 21 November 2011 (21.11.2011)

US

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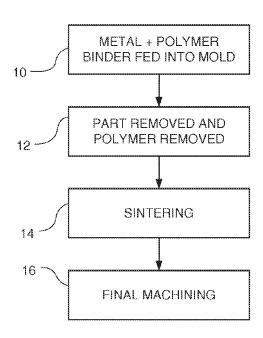
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,

[Continued on next page]

(54) Title: METHODS OF DESIGNING MOLDS FOR MACHINING COST REDUCTION

# FIG. 1 PRIOR ART



(57) Abstract: An orthopaedic knee cutting block prepared by a process comprising the steps of: creating a mold with a first core detail and a second core detail, each of the core details corresponding to a volume; filling the mold with a mixture of a binder and a metal; releasing a green part from the mold, the green part having a first void corresponding to the first core detail and a second void corresponding to the second core detail; removing the binder from the green part; heating the green part to create a sintered part; and machining the part by sawing a cutting slot such that the cutting slot overlaps with the first void and the second void. Alternatively, the orthopaedic knee cutting instrument may be made by a simple metal casting method.



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UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, Published: TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

with international search report (Art. 21(3))

#### METHODS OF DESIGNING MOLDS FOR MACHINING COST REDUCTION

#### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/562,006, filed November 21, 2011. The disclosure of this prior application is incorporated by reference in its entirety.

#### **BACKGROUND OF THE INVENTION**

[0002] The present invention relates generally to methods of designing molds. More specifically, the invention relates to methods of designing molds for orthopedic instruments and implants.

[0003] The traditional approaches to creating a shaped metal object include the lost wax and sand casting methods. Both casting methods rely on creating a mold of the object, either with a sand cavity or with a wax mold, then pouring in a liquefied metal. The metal fills the mold cavity and cools. Once the metal solidifies, the mold can be broken and the part removed. Alternatively, metal objects can be machined into shapes from a billet. For cast parts, secondary machining is usually necessary to meet tolerances and/or to achieve surface finishes and the like. However, machining operations require material removal and can be inefficient and costly.

[0004] Metal injection molding (MIM) allows net-shape or near net-shape metal components to be made in high volumes without expensive machining costs. Referring to FIG. 1, the MIM process starts in step 10 with mixing a metal powder and a polymeric binder to create a material that can be injected into a mold cavity. The binder provides the mixture with the appropriate rheological properties for handling, molding and later ease of removal from the die. The mixture is then heated in an injection mold barrel to an appropriate consistency and injected

into a mold cavity to take the shape of the mold. The injection molding machines can be the same ones as used for plastic injection molded parts. Once the mold has been formed, the green part is ejected from the mold in step 12. The binder is then removed from the green part, typically by introducing the part to a solvent or by burning out the polymer. The next step 14 is sintering the part in an oven to partially melt the metal particles. Temperatures typically reach about 1000 degrees Celsius during sintering. During this stage, the part may shrink 15-20 percent as the metal particles consolidate. After sintering, the part has a density very close to that of a traditionally formed part. Finally, in step 16, the sintered part is machined to its final shape.

[0005] One embodiment of the final machining steps of the prior art is shown in Figs 2 and 3. Fig. 2 illustrates a schematic partial sectional view of a cutting block 304 with slitting saw blade 306 inserted to its maximum depth Slitting saw blades may enter the face of cutting block 304 to form a precisely sized slot for the surgical saw blade. However, as can be seen in Fig. 2, the curvature of the blades results in incomplete removal of the metal in the slot, illustrated at 307. In an attempt to clean up the slot, blade 306 may be inserted from the other side of cutting block 304. This second machining step is illustrated in Fig. 3. As can be seem, a "dragon's tooth" 405 is still present that must be removed by another operation. Other operations include using a wire EDM to finish the part, filing the part, milling, etc. These operations all add extra cost and time to the final product.

[0006] Among the advantages of metal injection molding are the greater design flexibility and lower machining costs. Whereas traditional machining methods rely on the removal of material from a part, MIM parts can be built to near net shape and later machining costs can be lowered or eliminated. All the benefits and design constraints of plastic metal injection molding essentially carry over to MIM.

[0007] Depending on the tolerances required for the final part, further machining may be necessary. In general, larger objects produced with MIM need much more subsequent machining than smaller parts, limiting MIM's applicability to smaller objects. For example, a typical tolerance for an unfinished MIM'ed part is  $\pm$  5/1000" per inch, but a cutting slot tolerance for an orthopedic cutting block may be  $\pm$ 1/1000" per inch, so the finished MIM part must sometimes be machined to meet tolerances. Similar tolerances may be needed for implant components such as femoral stems, tibial baseplates, knee arthroplasty femoral components and other orthopedic implants.

[0008] Although MIM is becoming widely used, many products still need additional machining operations due to an inability to meet the fine tolerances needed for some applications. This is especially true for orthopedic cutting blocks and implants. Therefore, there is a continuing need to improve the design of molds used in a MIM or casting process.

#### SUMMARY OF THE INVENTION

[0009] The various embodiments of the present invention described below and shown in the Figures describe methods of mold design that increase the efficiency of later machining operations.

[0010] One aspect of the disclosure discloses an orthopaedic knee cutting block prepared by a process comprising the steps of: creating a mold with a first core detail and a second core detail, each of the core details corresponding to a volume; filling the mold with a mixture of a binder and a metal; releasing a green part from the mold, the green part having a first void corresponding to the first core detail and a second void corresponding to the second core detail; removing the binder from the green part; heating the green part to create a sintered part; and

machining the sintered part by sawing a cutting slot such that the cutting slot overlaps with the first void and the second void.

- [0011] In some embodiments, the first and second core details are located on a proximal portion.
  - [0012] In some embodiments, the cutting slot is an anterior cutting slot.
- [0013] In some embodiments, the orthopaedic knee cutting block may include a posterior cutting slot.
- [0014] In some embodiments, the orthopaedic knee cutting block may include at least one chamfer cut slot.
- [0015] In some embodiments, the orthopaedic knee cutting block may include a countersink.
- [0016] One aspect of the disclosure discloses a method of designing a mold for an orthopedic instrument or implant, comprising creating a mold with core details corresponding to a volume that a single machining operation cannot remove; filling the mold with a mixture of a binder and a metal; releasing a green part from the mold; removing the binder from the green part; heating the green part to create a sintered part; and machining the sintered part.
- [0017] Another aspect of the disclosure discloses a method of designing a mold for an orthopedic instrument or implant, comprising creating a mold with core details corresponding to a volume that simplifies a later machining operation; filling the mold with a mixture of a binder and a metal; releasing a green part from the mold; removing the binder from the green part; heating the green part to create a sintered part; and machining the sintered part.
- [0018] Still further aspects of the disclosure include a method of designing a mold for an orthopedic instrument or implant, comprising creating a mold with core details corresponding to

a volume that a single machining operation will not be able to remove; filling the mold with a molten metal; allowing the molten metal to solidify; releasing a part from the mold; and machining the part.

[0019] Yet further aspects of the disclosure include a method of designing a mold for an orthopedic instrument or implant, comprising creating a mold with core details corresponding to a volume that simplifies a later machining operation; filling the mold with a molten metal; allowing the molten metal to solidify; releasing a part from the mold; and machining the part.

[0020] Other aspects of the disclosure include wherein the orthopedic instrument is a cutting block. Still further aspects include wherein the machining operation uses a slitting saw on a milling machine and wherein the volume is tooth-shaped or torus-shaped.

[0021] Further areas of applicability of the invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the particular embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0022] The accompanying drawings illustrate the embodiments of the invention and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:
  - [0023] FIG. 1 is a block diagram of a metal-injection-molding (MIM) process.
- [0024] FIG. 2 shows a schematic partial sectional view of a prior art unfinished cutting block being machined.
- [0025] FIG. 3 a schematic partial sectional view of a prior art unfinished cutting block being machined subsequent to the step shown in FIG. 2.

[0026] FIG. 4 shows a front view of a finished orthopedic cutting block.

[0027] FIG. 5 shows a partial view of an unfinished orthopedic cutting block.

[0028] FIG. 6 shows a side view of a cutting block with a cavity detail.

[0029] FIG. 7 shows a partial view of a finished orthopaedic cutting block.

[0030] FIG. 8 shows a detailed view of a countersink around a spike.

#### DETAILED DESCRIPTION OF THE EMBODIMENTS

[0031] The following description of the depicted embodiment(s) is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses.

[0032] Embodiments of the present disclosure provide orthopedic cutting blocks and methods of manufacture that reduce secondary machining operations and/or make machining operations easier to perform.

[0033] "Core details" refers to the features on the inside of a mold that defines the shape of the space within a mold and the external surface of an object produced in the mold. These features can take any three-dimensional shape.

[0034] Fig. 4 illustrates a finished cutting block 104. The cutting block 104 has a proximal portion 120 and a distal portion 130. The cutting block includes a captive 102, or close-ended cutting slot. In use, the cutting block 104 is typically connected to a patient's bone using pins that are inserted into holes 105. After the cutting block is placed on the patient's bone, a surgical saw blade is inserted into the captive 102 and is used to make a cut in the patient's bone. The cutting block 104 may include other cutting slots, such as slots 108, 109, and 110. One of ordinary skill in the art would understand that these cutting slots 102, 108, 109, 110 must be placed at the right locations and orientations to ensure the bone cuts are made in the desired locations. Cutting blocks like the one shown in FIG. 4 have traditionally been made from a piece

of bar stock that is subsequently machined into shape. In current designs, the edges of captive 102 as shown in FIG. 4 may have been formed by a wire electrical discharge machine ("EDM") or by a slitting saw blade or other milling operation.

[0035] Fig. 5 illustrates one embodiment of the invention. Fig. 5 is a frontal view of an unfinished orthopedic cutting block 501, such as a "green" part or "as cast" part. The unfinished block is shown just before machining. The orthopaedic cutting block 501 may include one or more voids 502 in a proximal portion 520. The voids 502 also may be called cavities in the cutting block 501. The void 502 is present because of a corresponding volume in a core detail in the material mold. The cutting block mold is designed so that the free space occupied by void 502 corresponds to the volume that cannot be removed by a single slitting saw operation. Therefore, the final machining operation is quicker and cheaper because the part only needs to be plunged with a slitting saw and does not need any other machining operations, such as wire EDM. One of ordinary skill in the art can readily envision incorporating these types of core details into other types of fabrication methods, such as sand casting, lost wax casting, or selective laser sintering.

[0036] Fig. 6 illustrates a partial sectional side view of the void 502. The sides of the void 502 may be tapered for mold release.

[0037] Fig. 7 is a frontal view of a finished orthopedic cutting block 510 with a machined slot 512. The machined slot 512 overlaps or engages the voids 502.

[0038] Another embodiment of the present disclosure is shown in Fig. 8, an end-view of cutting block 601. Cutting block 601 may have one or more spikes 602 that are used to secure the cutting block to the bone. It is advantageous to provide a countersink 610 at the base of the spikes. Alternatively, the countersink 610 may be called an undercut area. The countersink can

be incorporated in the mold as a core detail. Because the primary datum on the cutting block is created during the machining of the near net shape MIM body, the countersink allows for reduced machining time, as the full geometry of the metal spike can be created during the molding process, and creation of the primary datum (through milling or grinding) can be done without having to "walk" around the metal spikes while avoiding the challenge of "matching" surfaces. If the countersink were not present the mill bit could nick the metal bone spike and create a mismatched surface. Instead of trying to mill right up against the spikes in order to create the primary datum surface, the tool can maintain clearance and create the full datum surface with no risk of contacting the spikes. In the depicted embodiment, the countersink 610 is shown as a circular depression but other shapes may be used. As examples, the countersink 610 may be square, rectangular, triangular, or elliptical.

[0039] The design methods of the present disclosure may be applied to any situation where a MIM part needs post-machining. In general, it may be said that it is more applicable to larger parts, where the inherent tolerances of MIM design become limiting.

[0040] The orthopaedic knee cutting block instrument can be manufactured in several different ways. As a first example, the orthopaedic knee cutting block can be prepared by a process having the steps of: creating a mold with a first core detail and a second core detail, each of the core details corresponding to a volume; filling the mold with a mixture of a binder and a metal; releasing a green part from the mold, the green part having a first void corresponding to the first core detail and a second void corresponding to the second core detail; removing the binder from the green part; heating the green part to create a sintered part; and machining the sintered part by sawing a cutting slot such that the cutting slot overlaps with the first void and the second void. As a second example, the orthopedic knee cutting block instrument is manufactured

by: creating a mold with a core detail corresponding to a volume; filling the mold with a molten metal; allowing the molten metal to solidify to produce a part; releasing the part from the mold, the part having a void corresponding to the core detail; and machining a slot in the part, wherein the slot intersects the void.

[0041] As various modifications could be made to the exemplary embodiments, as described above with reference to the corresponding illustrations, without departing from the scope of the invention, it is intended that all matter contained in the foregoing description and shown in the accompanying drawings shall be interpreted as illustrative rather than limiting. Thus, the breadth and scope of the invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the claims and their equivalents.

#### **CLAIMS**

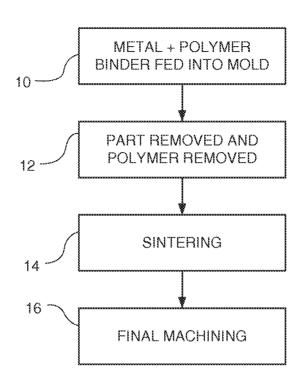
#### What is claimed is:

- 1. An orthopaedic knee cutting block prepared by a process comprising the steps of:
  - a. creating a mold with a first core detail and a second core detail, each of the core details corresponding to a volume;
  - b. filling the mold with a mixture of a binder and a metal;
  - c. releasing a green part from the mold, the green part having a first void corresponding to the first core detail and a second void corresponding to the second core detail;
  - d. removing the binder from the green part;
  - e. heating the green part to create a sintered part; and
  - f. machining the sintered part by sawing a cutting slot such that the cutting slot overlaps with the first void and the second void.
- 2. The orthopaedic knee cutting block of claim 1, wherein the first and second core details are located on a proximal portion.
- 3. The orthopaedic knee cutting block of claim 1, wherein the cutting slot is an anterior cutting slot.
- 4. The orthopaedic knee cutting block of claim 1, further comprising a posterior cutting slot.
- 5. The orthopaedic knee cutting block of claim 1, further comprising at least one chamfer cut slot.
- 6. The orthopaedic knee cutting block of claim 1, further comprising a countersink.
- 7. A method of manufacturing an orthopedic knee cutting block instrument comprising:
  - a. creating a mold with a core detail corresponding to a volume;

- b. filling the mold with a mixture of a binder and a metal;
- c. releasing a green part from the mold, the green part having a void created by the core detail;
- d. removing the binder from the green part;
- e. heating the green part to create a sintered part; and
- f. machining a slot in the sintered part, wherein the slot intersects the void.
- 8. The method of claim 7, wherein the core detail is located on a proximal portion.
- 9. The method of claim 7, wherein the slot is an anterior cutting slot.
- 10. A method of manufacturing an orthopedic knee cutting block instrument comprising:
  - a. creating a mold with a core detail corresponding to a volume;
  - b. filling the mold with a molten metal;
  - c. allowing the molten metal to solidify to produce a part;
  - d. releasing the part from the mold, the part having a void corresponding to the core detail; and
  - e. machining a slot in the part, wherein the slot intersects the void.
- 11. The method of claim 10, wherein the core detail is located on a proximal portion.
- 12. The method of claim 10, wherein the slot is an anterior cutting slot.

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### **PRIOR ART**



PRIOR ART

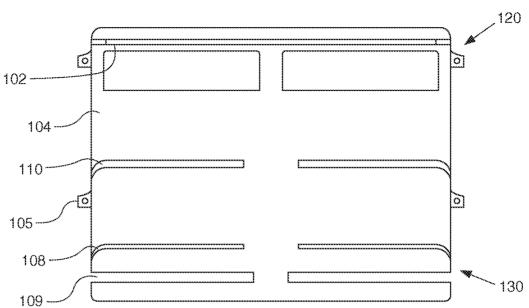
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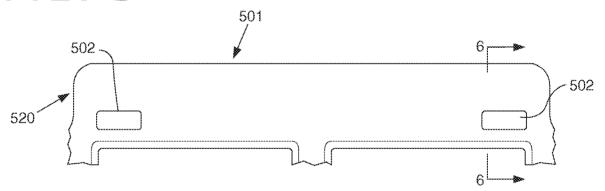
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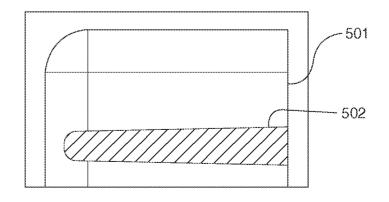
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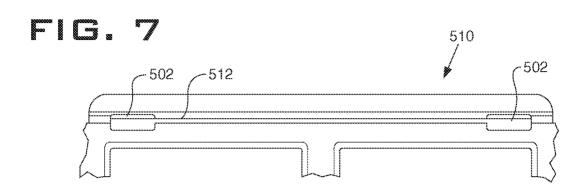
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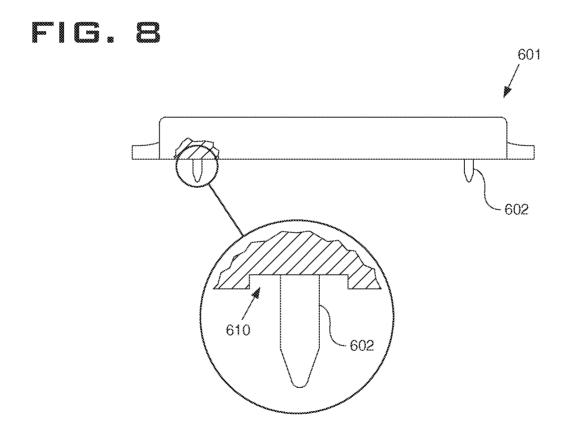






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#### INTERNATIONAL SEARCH REPORT

International application No. PCT/US12/66068

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

Δ	CLASSIFICATION	ON OF	SUBJECT	MATTER

IPC(8) - A61B 17/58, 17/60; B22F 1/00, 3/00, 3/10, 3/24 (2013.01)

USPC - 419/26, 28, 44; 606/88, 87, 86R, 96, 79, 89, 53, 1

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8): A61B 17/58, 17/60; B22F 1/00, 3/00, 3/10, 3/24 (2013.01)

USPC: 419/26, 28, 44; 606/88, 87, 86R, 96, 79, 89, 53, 1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); DialogPro (Derwent, INSPEC, NTIS, PASCAL, Current Contents Search, Dissertation Abstracts Online, Inside Conferences); IP.com; Google Scholar; orthope\*, arthroplas\*, knee\*, bone\*, joint\*, cutting\* near5 block\* or guid\* or templat\*, casting\*, molding\*

#### C. DOCUMENTS CONSIDERED TO BE RELEVANT

Further documents are listed in the continuation of Box C.

document defining the general state of the art which is not considered

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0262149 A1 (CHARLES, D et al.) October 14, 2010; figure 14; paragraphs [0019], [0024], [0028], [0029], [0031], [0033], [0034], [0037], [0080]	1-12
Y	US 2011/0238073 A1 (LANG, P et al.) September 29, 2011; figures 32, 33; 37A-37D; paragraphs [0151]-[0154], [0475], [0476], [0494]-[0496]	1-12
Υ	US 2007/0073305 A1 (LIONBERGER, DR et al.) March 29, 2007; paragraphs [0035], [0036]	6
Υ	US 2011/0082494 A1 (KERR, DE et al.) April 7, 2011; paragraph [0043]	10-12
Α	WO 2001/014602 A2 (LONG, M et al.) March 1, 2001; entire document	1-12
Α	US 2007/0282347 A9 (GRIMM, JE et al.) December 6, 2007; entire document	1-12

1	"E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is			document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
		cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is	
	"O" document referring to an oral disclosure, use, exhibition or other means			combined with one or more other such documents, such combination being obvious to a person skilled in the art	
	"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family	
ſ	Date of the actual completion of the international search		Date of mailing of the international search report		
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r	Name and mailing address of the ISA/US		Authorized officer:		
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents			Shane Thomas		
	P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		РСТ Н	PCT Helpdesk: 571-272-4300	
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Special categories of cited documents:

to be of particular relevance

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