

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Confirmation No.: 6375

Application No.: 10/722,102

Attorney Docket No: 780-A03-012C

Filed: November 25, 2003

Group Art Unit: 3733

For: KNEE ARTHROPLASTY METHOD

Examiner: P. Philogene

RESPONSE TO OFFICE ACTION

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In reply to the Office Action mailed July 9, 2007, please enter this Response into the file of the above-entitled application.

In accordance with USPTO practice, each section of this Response begins on a separate sheet. Applicant submits, these amendments and remarks serve to clarify the present invention, and are independent of patentability.

Amendments to the Claims

1. (Currently amended) A method of performing surgery on a patient's knee including a femur and a tibia, the method comprising the steps of:
making an incision in a knee portion of a leg of the patient;
expanding the incision from an unexpanded configuration to an expanded configuration by applying force against opposite edge portions of the incision;
positioning a cutting guide through the expanded incision and on a [[side]] surface of a distal end portion of the femur, the cutting guide sized to be received in the expanded configuration;
moving a cutting tool through the incision into engagement with a guide surface on the cutting guide;
cutting the femur by moving the cutting tool along the guide surface,
wherein the cutting guide is positioned free of an extramedullary or intramedullary alignment rod using navigation references derived from the surface of the bone to be cut, said navigation references derived independently from an intramedullary device.
2. (Currently amended) The method of claim 1 wherein the [[side]] surface is a medial or lateral side of the distal end portion of the femur.
3. (Canceled)
4. (Original) The method of claim 1 wherein a computer navigation system is used in the positioning step.
5. (Original) The method of claim 1 wherein the positioning step includes removably attaching the cutting guide to the side surface of the distal end portion of the femur.

6. (Original) The method of claim 5 wherein the cutting guide is removably attached with first and second pins extending through holes in the cutting guide and into the femur.

7. (Original) The method of claim 1 wherein the guide surface comprises a plurality of straight guide segments.

8. (Original) The method of claim 7 wherein the plurality of straight guide segments comprises:

a distal guide segment disposed in a plane which extends perpendicular to a longitudinal central axis of the femur and extends through lateral and medial condyles of the femur;

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

9. (Currently amended) The method of claim 1 further comprising the step of removing at least a portion of the [[side]] surface of the distal end portion of the femur prior to positioning the cutting guide such that a flattened section of the side surface is created and abuttingly engaged by a major side surface of the cutting guide when the cutting guide is positioned thereon.

10. (Original) The method of claim 1 wherein said step of cutting the femur includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an

initial portion of a cut in the femur, and completing the cut in the femur while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the femur.

11. (Currently amended) The method of claim 10 wherein the cutting guide is positioned on ~~[[the]]~~ a side surface of the distal end portion of the femur during completion of the cut.

12. (Currently amended) The method of claim 10 wherein the cutting guide is removed from ~~[[the]]~~ a side surface of the distal end portion of the femur after making the initial portion of the cut and before completion of the cut.

13. (Currently amended) A total knee replacement cutting guide for forming a cut surface on a bone in preparation to receive a total joint replacement component comprising:

a disposable cutting guide member fabricated from a polymeric material and designed for a single use, having a body ~~configured and~~ dimensioned for attachment to a ~~[[side]]~~ surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod; and

at least one guide surface ~~extending from one side of the guide member to an opposite side of the guide member, the at least one guide surface configured and~~ dimensioned for engagement with a cutting tool to thereby direct the cutting tool ~~in making only a portion of the cut surface;~~

wherein said cutting guide, being both polymeric and disposable, is readily modified in successive iterations for new or customized instrumentation.

14. (Original) The total knee replacement cutting guide of claim 13 wherein the guide member attaches to either a medial or lateral side surface of the end portion of the bone.

15. (Original) The total knee replacement cutting guide of claim 13 wherein the at least one guide surface includes a distal end surface having opposite ends spaced apart by a distance which is less than a distance that the total joint replacement component extends across the bone when implanted.

16. (Original) The total knee replacement cutting guide of claim 15 wherein the guide member has an aperture for receiving a pin to thereby secure the guide member to the bone.

17. (Original) The total knee replacement cutting guide of claim 16 wherein the at least one guide surface includes:

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the femur; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

18. (Original) The total knee replacement cutting guide of claim 16 wherein the cutting guide is a non-captured cutting guide.

19. (Currently amended) A method of performing surgery on a joint in a patient including a first bone and a second bone, the method comprising the steps of:

fabricating a disposable cutting guide, designed for a single use from a polymeric material, and modified for updated or customized instrumentation;

making an incision proximal to the joint in the patient;

positioning ~~the~~ cutting guide through the incision and on a side surface of an end portion of the first bone before the anterior surface of said first bone is resected;

moving a cutting tool through the incision into engagement with a guide surface on the

cutting guide;

cutting the first bone by moving the cutting tool along the guide surface,
wherein the cutting guide is positioned ~~free of an extramedullary or intramedullary~~
~~alignment rod~~ using navigation references derived from the surface of the bone to be cut, said
navigation references derived independently from an intramedullary device.

20. (Currently amended) The method of claim 19 wherein the side surface is a medial or
lateral side of the end portion of the first bone.

21. (Canceled)

22. (Original) The method of claim 19 wherein a computer navigation system is used in the
positioning step.

23. (Original) The method of claim 19 wherein the positioning step includes removably
attaching the cutting guide to the side surface of the end portion of the first bone.

24. (Original) The method of claim 23 wherein the cutting guide is removably attached
with first and second pins extending through holes in the cutting guide and into the first bone.

25. (Original) The method of claim 19 wherein the guide surface comprises a plurality of
straight guide segments.

26. (Original) The method of claim 25 wherein the plurality of straight guide segments
comprises:

a distal guide segment disposed in a plane which extends perpendicular to a longitudinal
central axis of the first bone;

an anterior chamfer guide segment disposed in a plane which extends at an acute angle to a

plane containing the distal guide surface;

a posterior chamfer guide segment disposed in a plane which extends at an acute angle to a plane containing the distal guide surface, the plane containing the posterior chamfer guide surface extending perpendicular to the plane containing the anterior chamfer guide surface;

an anterior guide segment disposed in a plane which extends perpendicular to a plane containing the distal guide surface and extends generally parallel to a longitudinal central axis of the first bone; and

a posterior guide surface disposed in a plane which extends parallel to a plane containing the anterior guide surface and perpendicular to a plane containing the distal guide surface.

27. (Original) The method of claim 19 further comprising the step of removing at least a portion of the side surface prior to positioning the cutting guide such that a flattened section of the side surface is created and abuttingly engaged by a major side surface of the cutting guide when the cutting guide is positioned thereon.

28. (Original) The method of claim 19 wherein said step of cutting the first bone includes utilizing the guide surface on the cutting guide to guide the cutting tool during making of an initial portion of a cut in the first bone, and completing the cut in the first bone while guiding the cutting tool with a surface formed during making of the initial portion of the cut in the first bone.

29. (Original) The method of claim 28 wherein the cutting guide is positioned on the side surface of the end portion of the first bone during completion of the cut.

30. (Original) The method of claim 29 wherein the cutting guide is removed from the side surface of the end portion of the first bone after making the initial portion of the cut and before completion of the cut.

31. (Previously presented) The method of claim 1, wherein said incision is between about

seven and about thirteen centimeters.

32. (Previously presented) The method of claim 1, where said positioning step further includes the step of using light beams.

33. (Previously presented) The method of claim 1, wherein in said step of making an incision, said incision is offset from the center of said knee area.

34. (Previously presented) The method of claim 13, wherein said at least one guide surface includes a guide surface corresponding to each guide surface required by said joint replacement component.

35. (Previously presented) The method of claim 19, wherein after said step of cutting, further including the steps of:

removing said cutting guide; and,

guiding said cutting tool using cuts formed in said cutting step to complete said cuts.

36. (Previously presented) The method of claim 19, wherein in said step of positioning, said cutting guide is sized smaller than said side surface.

37. (Previously presented) The method of claim 19, wherein after said step of positioning, further including the step of:

aligning said cutting guide using markings on said side surface.

38. (New) The method of claim 1, where said cutting guide is disposable in that it is fabricated of a polymeric material at a lower cost than a reusable metallic cutting guide, and by being designed to be used in a single procedure and thereafter discarded.

39. (New) The cutting guide of claim 13, wherein alignment of said cutting guide is performed by means selected from the group consisting of: computer navigation, preoperative imaging, and extramedullary alignment.

Remarks

Claims 1-39 are presented for the Examiner's review and consideration. Herein, claims 1-2, 9, 11-13, and 19-20 have been amended; claims 38-39 have been added; and claims 3 and 21 have been canceled. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §102(e) Rejection - Coates

Claims 1-37 were rejected under 35 U.S.C. §102(e) as being anticipated by Coates (5,035,699) ("Coates"). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Coates discloses a surgical device for accurately positioning and cutting a patellar groove in a resected distal femur to receive a patellar track portion of a prosthesis, including a guide element adapted to fit over the distal end of a resected femur... (Abstract). With reference to Fig. 1 of Coates, end 14 is adapted to fit on the posterior side of the resected femur and consists of 2 arms adapted to fit over the medial and lateral condyles of the femur. (Col. 2, lns. 31-33). The central portion of the cutting guide 10 consists of an elongated opening 23 which exposes at least the distal and anterior aspects of the resected femur so that a patellar groove may be cut therein. (Id).

Thus Coates is directed to a cutting guide which is aligned by being positioned on a resected femur. Coates does not address how the femur is resected, however at the time of Coates, the commonly accepted method was through the use of an intramedullary rod. There is no suggestion in Coates of an alternative method.

In contrast, the present invention discloses method[s] of performing surgery, and instruments, implants, and other surgical implements that can be used in surgery. The surgery may be of any desired type. (§[0002]). The surgery may be performed on any desired joint in a patient's body. Id.

When the femoral cuts are to be made on the distal end portion 124 of the femur 126, the femoral cutting guide 750 is connected to the distal end of the femur. (§[0490]).

...extramedullary instrument could be employed. If desired, the base 1376 could be pinned directly to the femur in a manner analogous to the cutting guide 800 (Fig. 54). (Id). Alternatively, the base 1376 could be positioned on the femur using a computer navigation system. (Id).

It is contemplated that emitters, receivers, and/or reflectors of computer navigation systems could be pinned or otherwise attached onto the femur 126 and tibia 214 to provide cutting positions and to facilitate ligament balancing through relatively small incisions. (§[0288]). The computer navigation system may utilize three or four separate registers which have optical feedback to a central unit. (Id). The computer navigation system may utilize electromagnetic or photo-optical feedback.

It is contemplated that the imaging of the knee portion 76 of the patient's leg 70 may be done preoperatively, on an out-patient basis. (§[0556]). The implant 950, which has been shaped to conform to the space between the surfaces 958 and 960, may then be moved to an operating room for insertion into a patient during the surgical procedure. (Id).

...Discussed throughout this specification, the present invention includes disposable surgical implants and instruments. (§[0706]). One advantage of the disposable system is that the disposable cutting blocks could easily be modified for new or updated instrumentation or for customized instrumentation. (§[0712]).

Thus, the present invention provides for attachment of a cutting guide to a femur without first resecting the femur, and without connection to an EM or IM rod. Moreover, the present invention provides for disposable cutting blocks, which, because they are made from a low cost, easy to manufacture polymer, may be modified for each use to accommodate custom requirements.

As discussed above, Coates does not provide a means for connecting or aligning a cutting guide without first resecting the knee for a total knee replacement. Of course, alignment must be performed for the resection, and no means are disclosed for such. Notwithstanding this, it is clear that the cutting guide of Coates is not aligned with respect to knee, generally, but to the resection, only. Thus, Coates does not provide a means of positioning a cutting guide without a prior resection of the femur, and the anterior section, in particular. In addition, the use of intramedullary alignment is implicit in Coates. Further, there is no discussion of disposable instrumentation in Coates, nor of the attendant benefits of same.

Claim 1 recites, *inter alia*, positioning a cutting guide on a surface of a distal end portion of the femur, positioned free of an extramedullary or intramedullary rod, and positioned using navigation references derived from the surface of the bone to be cut, and not derived from an intramedullary device.

Claim 13 recites, *inter alia*, a disposable cutting guide member fabricated from a polymeric material and designed for a single use, having a body dimensioned for attachment to a surface of an end portion of the bone free of an extramedullary or intramedullary alignment rod, and wherein said cutting guide, being both polymeric and disposable, is readily modified in successive iterations for new or customized instrumentation.

Claim 19 recites, *inter alia*, fabricating a disposable cutting guide, designed for a single use from a polymeric material, and modified for updated or customized instrumentation, and positioning the cutting guide through the incision and on a side surface of an end portion of the first bone before the anterior surface of said first bone is resected, using navigation references derived from the surface of the bone to be cut, and not derived from an intramedullary device.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Coates. Claims 3 and 21 are canceled. As claims 2 and 4-12 depend from claim 1; claims 14-18 depend from claim 13; and claims 20 and 22-29 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the remaining dependent claims are allowable over Coates at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 102 rejection.

35 U.S.C. §102(e) Rejection - Haines

Claims 1-37 were rejected under 35 U.S.C. §102(e) as being anticipated by Haines et al. (6,056,754) (“Haines”). For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

In Haines, a femur is resected by means of pattern plates having a cutting path with at least two continuous, non-coplanar guide surfaces. (Abstract). The cutting path has a similar profile to the interior profile of a femoral prosthesis. (Id). The cutting path guides a reciprocating, oscillating, or rotating cutting tool along a path for removing material from some or all of the distal femur to accept a distal femoral prosthesis. (Id).

The apparatus of [Haines] comprises a number of components including a positioning apparatus, a pattern apparatus and a cutting apparatus. (Col. 6, lns. 35-37). Pattern plates 32 include fixation apertures 34 extending therethrough for accepting fixation means, as will hereinafter be described, for affixing the pattern plates 32 to a bone. (Col. 8, lns. 59-61).

The positioning body 120 comprises a frame 122 having sides 124, bottom 126 and top 128 arranged to form a frame having a rectangular aperture defined therewithin. (Col. 10, lns. 19-22).

The alignment apparatus 180 interconnects with the positioning body 120 by means of alignment guide body 182 which is a U-shaped member having sides 184 and a bottom 186. (Col. 11, lns. 2-5). The alignment guide body 182 is sized to fit within the rectangular aperture formed within the positioning body 120. (Id). The alignment plate 192 further includes rod guide aperture 197 which receives rod guide bolt 196 therethrough to interconnect the alignment plate 192 with the IM rod guide 210... (Col. 11, lns. 26-29).

The IM rod guide 210 includes IM rod aperture 212 for receiving an IM rod therethrough. (Col. 11, lns. 33-34). The IM rod guide 210 is interconnected at a forward end with the alignment plate 192 by means of plate attachment aperture 214 on the rod guide 210 which receives rod guide bolt 196 therein after such bolt 196 passes through the alignment plate 192 to secure the

rod guide 210 in a pivoting relationship with respect the alignment plate 192 at forward ends of the rod guide 210 and the alignment plate 192. (Id).

The alignment plate 192 further includes a printed angular rotation scale which indicates the degree of angular rotation between the rod guide 220 and the alignment apparatus, and hence the angular rotation between the IM rod and the positioning body 120. (Col. 11, lns. 51-55). After such alignment is determined, it can be locked into place by tightening down rod guide lock bolt 200. (Id). Thereafter, with such angular rotation fixed, the pattern apparatus 30 can be positioned with respect to the bone to cut, and the positioning apparatus 110 can be removed from interconnection with the IM rod and the pattern apparatus 30, the IM rod removed from the bone, and bone cutting can be initiated. (Id).

Various fixation means, including those known in the art, can be used to fix the pattern plate or plates to the femur or other bone to be cut. FIG. 11 shows a preferred fixation means, generally indicated at 260. (Col. 12, lns. 23-25). The fixation means 260 includes a spike plate 264 carrying on one side thereof a spike or spikes 262 for contacting, and even extending into, bone 261. (Id).

Thus Haines discloses an intramedullary rod (IM rod) which serves to reference the positioning body, whereupon the latter orients the alignment guide. The alignment guide is used to position the pattern plates, which are in turn affixed to bone using conventional means. Once the pattern plates are affixed, the IM rod is removed and the bone cuts are carried out.

Accordingly, while Haines does not appear to require a resection of the anterior surface of the bone prior to positioning a cutting guide, as in Coates, Haines none the less requires an intramedullary rod, with its attendant drawbacks, including trauma to bone tissue, increased bleeding, and an increased potential for fat emboli. Further, as in Coates, Haines does not disclose a customized disposable cutting guide.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Haines. Claims 3 and 21 are canceled. As claims 2 and 4-12 depend from claim 1; claims 14-18 depend from claim 13; and claims 20 and 22-29 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant

respectfully submits that the remaining dependent claims are allowable over Haines at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 102 rejection.

New Claims

Claim 38 has been added to specify, *inter alia*, that the cutting guide of claim 1 is disposable. Claim 39 has been added to specify, *inter alia*, means of aligning the cutting guide of claim 13. Support for these claims may be found in the discussion of the present invention, in support of arguments pertaining to Coates, above.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "P. Bianco", with a large, sweeping flourish above the name.

Paul Bianco, Reg. #43,500

Customer Number: 33771
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO, P.L.
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: P. Bonutti

Confirmation No.: 6375

Application No.: 10/722,102

Group Art Unit: 3733

Filed: November 25, 2003

Attorney Docket No.: 780-A03-012C

For: KNEE ARTHROPLASTY METHOD

Examiner: P. Philogene

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. § 1.56**

Commissioner for Patents
Alexandria, VA 22313

Sir:

In accordance with the duty of disclosure provisions of C.F.R. § 1.56, there is hereby provided certain information, which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

A revised Form PTO/SB/08 listing all patents, publications, applications, or other information submitted for consideration is enclosed. Copies of the listed U.S. Patents and Published U.S. Patent Applications, are not being submitted pursuant to the USPTO's waiver of the requirement of 37 C.F.R. § 1.98(a)(2)(i).

Enclosures accompanying this Information Disclosure Statement are: (a) copy of the cited foreign patent applications.

No admission is made that the information cited in this Statement is, or is considered to be prior art, material to patentability nor a representation that a search has been made.

The \$180.00 fee set forth in 37 C.F.R. §1.17 (p) in accordance with 37 C.F.R. §1.97 (c). The required fee was paid via Credit Card along with the Electronic Submission. The commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement to Deposit Account No. 503410 (Attorney Docket No. 780-A03-012C).

Respectfully submitted,

Dated: _____

9 OCT 2007



Paul D. Bianco (Reg. No. 43,500)

Attorney for Applicant

Fleit, Kain, Gibbons, Gutman, Bongini & Bianco P.L.

21355 East Dixie Highway

Suite 115

Miami, Florida 33180

305-830-2600 (telephone)

Electronic Patent Application Fee Transmittal				
Application Number:		10722102		
Filing Date:		25-Nov-2003		
Title of Invention:		Knee arthroplasty method		
First Named Inventor/Applicant Name:		Peter M. Bonutti		
Filer:		Paul David Bianco/Dinah Fuentes		
Attorney Docket Number:		780-A03-012C		
Filed as Small Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt

EFS ID:	2293002
Application Number:	10722102
International Application Number:	
Confirmation Number:	6375
Title of Invention:	Knee arthroplasty method
First Named Inventor/Applicant Name:	Peter M. Bonutti
Customer Number:	33771
Filer:	Paul David Bianco/Dinah Fuentes
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Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
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	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment - After Non-Final Rejection		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	15	
	Information Disclosure Statement (IDS) Filed		16	18	
Warnings:					
Information:					
2	Foreign Reference	WO93025157.pdf	2424384 33e48d588413e1218569580f02ca35029c5b7649	no	78
Warnings:					
Information:					
3	Fee Worksheet (PTO-06)	fee-info.pdf	8157 6224382068314de74f7b4122fbc2464b09a249a7	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			2916456		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					