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Recent IP Decisions – February 2010

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Today's Cases

Wyeth v. Kappos

- miscalculation of patent term adjustment

Therasense, Inc. (Abbott) v. Becton, Dickinson and Co.

- inequitable conduct based on contradictory statement to EPO

Boehringer Ingelheim Int'l v. Barr Laboratories, Inc.

- restriction requirements and double patenting

Ex parte Lansac

- intended use/functional limitations



Wyeth v. Kappos

1994: 17 years from issue → 20 year from filing

1999: Patent term adjustment codified under 35 U.S.C. 154(b)(1):

- (A) guarantee for prompt PTO responses
- (B) guarantee \leq 3-year application pendency
- (C) adjustment for delays due to interferences, secrecy orders & appeals

Overlap limitation under 35 U.S.C. 154(b)(2)(A):

- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.



Wyeth v. Kappos

2000: Under direction of 154(b)(3), PTO set forth 37 C.F.R. 1.703(f):

- To the extent that periods of adjustment attributable to the overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.
- The regulations defined “periods of adjustment” as “the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed” 37 C.F.R. § 1.703(b) (2000).



Wyeth v. Kappos

2004: PTO replaced “periods of adjustment” with “periods of delay” to clarify regulation...

- The language of former § 1.703(f) misled applicants into believing that [periods of A-delay] and [periods of B-delay] were overlapping only if the [period of A-delay] occurred more than three years after the actual filing date of the application. If an application is entitled to a [B-]adjustment . . . the entire period during which the application was pending before the [PTO] . . . , and not just the period beginning three years after the actual filing date of the application; is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).
- Under PTO definition, (B) guarantee starts with filing of application – (A) and (B) overlap can arise during pendency.



Wyeth v. Kappos

Procedural History:

- After petitioning PTO for reconsideration of adjustments to 7,179,892 and 7,189,819 patents, Wyeth filed action in Dist Ct (DC) seeking order directing PTO to grant adjustments
- On summary judgment, Dist Ct held Wyeth entitled to extended patent term adjustments under 35 U.S.C. 154(b)
- Fed Cir reviewed grant of summary judgment without deference

Issue:

- Are (A) and (B) guarantees correctly determined in view of overlap limitation?



Wyeth v. Kappos

'892 patent:

- 610 days of (A) delay with 51 days more than 3-years after filing
- 345 days of (B) delay
- 148 days of applicant delay

PTO calculation:

610 days (greater of A or B) – 148 days (applicant)
= 462 day adjustment

Wyeth calculation:

610 days (A) + 345 days (B) – 51 days (overlap) – 148 days
(applicant) = 756 day adjustment



Wyeth v. Kappos

Both Dist Ct and Fed Cir agreed with Wyeth statutory interpretation:

- This court detects no ambiguity in the terms “periods of delay” and “overlap.” Each term has an evident meaning within the context of section 154(b). The limitation in section 154(b) only arises when “periods of delay” resulting from violations of the three guarantees “overlap.” 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply. Thus, this court can easily detect any overlap by examining the delay periods covered by the A and B guarantees.

Language of statute should prevail:

- Regardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities, even if it could. In the end, the law has put a policy in effect that this court must enforce, not criticize or correct.



Wyeth v. Kappos

- Requires basic information and signature
- No requirement to indicate a belief that additional term is due
- Impacts patent if:
 - application filed on or after May 29, 2000
 - prosecution pendency greater than three years
 - a file history showing that the PTO delayed in examining the application during the first three years of pendency.

Doc Code: PETA.RCAL

Document Description: Request for Recalculation in view of Wyeth

PTO/SE/131 (01-10)

Approved for use through 02/28/11, OMB No. 1625-0112
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF WYETH*	
Attorney Docket Number:	Patent Number:
Filing Date (or 371 (b) or (f) Date):	Issue Date:
First Name of Inventor:	
Title:	
<p style="font-size: small;">PATENTEE HEREBY REQUESTS RECALCULATION OF THE PATENT TERM ADJUSTMENT (PTA) UNDER 35 USC 154(b) INDICATED ON THE ABOVE-IDENTIFIED PATENT. THE PATENTEE'S SOLE BASIS FOR REQUESTING THE RECALCULATION IS THE USPTO'S PRE-WYETH INTERPRETATION OF 35 U.S.C. 154(b)(2)(A).</p> <p style="font-size: small;">Note: This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A). See Instruction Sheet on page 2 for more information.</p> <p style="font-size: small;">Patentees are reminded that to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.</p> <p style="font-size: small;">*Wyeth v Kappos, No. 2009-1120 (Fed. Cir., Jan 7, 2010)</p>	
Signature	Date
Name (Print/Type)	Registration Number
<p style="font-size: x-small;"><i>Note: Signatures of all the inventors or assignees of record of the estate interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below.</i></p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>	

The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1460, Alexandria, VA 22313-1460. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1460.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Therasense (Abbott) v. Becton (BD)

Procedural History:

- BD sought declaratory judgment against Abbott for noninfringement of US 6,143,164 and 6,592,745 in Dist Ct (MA)
- Abbott countersued for infringement of '164, '745, and US 5,820,551 in Dist Ct (NDCA)
- Dist Ct issued summary judgment finding DB did not infringe '164 or '745 patents
- After bench trial, claims 1-4 of '551 patent invalid due to obviousness and entire '551 patent unenforceable due to inequitable conduct
- Appealed to Fed Cir – review for clear error

Issue:

- Whether claims 1-4 of '551 patent are obvious - Fed Cir affirmed
- Is '551 patent unenforceable due to inequitable conduct?



Therasense (Abbott) v. Becton (BD)

Standard:

- “[I]nequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.” Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed. Cir. 2008) (quoting Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005)) (quotation marks omitted).
- Rule 56 requires the submission of any known information that contradicts information submitted to the PTO.
- “if a misstatement or omission is material under the . . . Rule 56 standard, it is material [for purposes of inequitable conduct].” Digital Control, 437 F.3d at 1316; see also Pharmacia, 417 F.3d at 1373 (affirming a finding of inequitable conduct where a prior article by a declarant contradicted his declaration to the PTO).



Therasense (Abbott) v. Becton (BD)

PTO representations:

- '551 rejected as obvious over US 4,545,382 (another patent family owned by Abbott)
- During an Examiner's Interview, Abbott's attorney presented new claims directed to a glucose sensor that did not require a protective membrane when testing whole blood and pointed out that the '382 patent teaches that active electrodes used with whole blood require a protective membrane.
- The examiner then agreed that if Abbott produced "an affidavit or other evidentiary showing that at the time of the invention such a membrane was considered essential [for whole blood, it] would overcome [the '382 patent's] teaching."



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Declaration of Abbott's Director of Research and Development provided:

- [B]ased on his historical knowledge he is confiednt [sic] that on the filing date of the earlist [sic] application leading to the present application on June 6, 1983 and for a considerable time thereafter one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. Therefore, he is sure that one skilled in the art would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.



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Abbott's Attorney further represented:

- The art continued to believe [following the '382 patent] that a barrier layer for whole blood sample was necessary for a considerable period. . . .

One skilled in the art would not have read the disclosure of the Higgins patent (U.S. 4,545,382) as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the "optionally, but preferably" language at line 63 of column [4] as a technical teaching but rather mere patent phraseology. This is supported by the Declaration under 37 C.F.R. 1.132 of Gordon Sanghera which accompanies the present amendment.

. . . . The applicants have established that a new claim limitation supported by the present application provides a patentable distinction over U.S. Patent No. 4,545,382, the key reference in the prosecution of the present application and its predecessors. There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in this patent or the other prior art of record in this application.



Therasense (Abbott) v. Becton (BD)

EPO representations:

- EP 0 078 636 - a counterpart to the '382 patent with virtually identical specifications – was rejected as obvious over a German reference

To distinguish over the cited reference, Abbott's Attorney submitted a brief stating:

- Contrary to the semipermeable membrane of D1, the protective membrane optionally utilized with the glucose sensor of the patent is [sic] suit is not controlling the permeability of the substrate (as set forth above under IV.2., in the membrane of D1 the permeability for the substrate must be kept on a low value to achieve a linear relationship between the measures [sic] currency and the substrate concentration in the test solution). Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:



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- “Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”
- See also claim 10 of the patent in suit as granted according to which the sensor electrode has an outermost protective membrane (11) permeable to water and glucose molecules. Finally, see Example 7 in column 10, lines 19 to 26 reporting that by using such a protective membrane the response time did not increase but from 24 to 60 sec. (without membrane) to 36 - 76 sec. (with membrane). Accordingly, the purpose of the protective membrane of the patent in suit, preferably to be used with in vivo measurements, is a safety measurement to prevent any course [sic] particles coming off during use but not a permeability control for the substrate.



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Abbott's Attorney submitted a later brief stating:

- “Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”
- It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is “permeable” to glucose molecules.



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Dist Ct found EPO statements contradicted PTO representations in two significant ways:

- by describing the “[o]ptionally, but preferably” language as “unequivocally clear,” Abbott’s EPO representations contradicted Abbott’s representations to the PTO that a person having ordinary skill in the art would have understood the phrase as mere “patent phraseology” that did not convey a clear meaning.
- the EPO documents clearly explained that membranes were merely preferred for live blood.

Fed Cir:

“These findings are not clearly erroneous, and indeed are manifestly correct.”



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Abbott contended that:

- in the EPO, the focus was on distinguishing the semipermeable membrane of the German reference for the protective, permeable membrane of the EPO application
- Fed Cir acknowledged that this distinction was made BUT the Dist Ct found that Abbott also argued that the protective membrane was optional – which is not irrelevant to the distinction of the German reference – and that this is “unequivocally clear” from the patent language



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Abbott also argued that lawyer argument about prior art is not information material to patentability and that since both the EPO and the PTO representations were merely argument, any inconsistency between the two could not be material. (Citing *Innogenetics* and others.)

The Fed Cir distinguished these cases:

“None of these cases involved a situation in which contradictory arguments made in another forum were withheld from the PTO. They do not speak to the applicant’s obligation to advise the PTO of contrary representations made in another forum... An applicant’s earlier statements about prior art, especially one’s own prior art, are material to the PTO when those statements directly contradict the applicant’s position regarding that prior art in the PTO. See 37 C.F.R. § 1.56(b)(2). In any event, the representations to the PTO were not merely lawyer argument; they were factual assertions as to the views of those skilled in the art, provided in affidavit form.”



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Dist Ct established intent based on five findings:

- the statements made to the PTO concerning the prior art '382 patent were absolutely critical in overcoming the examiner's earlier rejections of the claims of the '551 patent – undisputed
- the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO – not clearly erroneous
- Attorney and Director both knew of the EPO statements and consciously withheld them from the PTO – undisputed
- neither Attorney nor Director provided a credible explanation for failing to submit the EPO documents to the PTO – based on testimony
- Attorney's and Director's explanations for withholding the EPO documents were so incredible that they suggested intent to deceive – based on testimony



US 7,651,688

- over 900 references submitted in 6 IDS – most after NOA
- Examiner added 9 references based on search
- Ken Burchfiel of Sughrue (prosecuting firm):
 - “In view of... *Dayco...* and *McKesson ...* it is prudent to provide an examiner with citations to office actions in copending applications.”
 - “It may also be prudent to identify relevant foreign applications and office actions in an IDS, in view of *Therasense...* Although the prosecution history of a foreign application cannot be used to construe patent claims, it may now render them unenforceable.”

(12) United States Patent Hanai et al.	(10) Patent No.: (45) Date of Patent:	US 7,651,688 B2 *Jan. 26, 2010
(54) METHOD OF MODULATING THE ACTIVITY OF FUNCTIONAL IMMUNE MOLECULES TO CDS2	5,858,983 A 1/1999 Seed et al. 5,880,268 A 3/1999 Gallatin 5,851,996 A 4/1999 Mateo 5,922,845 A 7/1999 Deo 5,932,703 A 8/1999 Godiska 5,935,821 A 8/1999 Chatterjee 5,977,316 A 11/1999 Chatterjee 6,018,037 A 1/2000 Koike 6,054,304 A 4/2000 Taniguchi et al. 6,129,913 A 10/2000 Ames 6,150,132 A 11/2000 Wells 6,169,070 B1 1/2001 Chen 6,238,894 B1 5/2001 Taylor 6,245,332 B1 6/2001 Butcher 6,251,219 B1 9/2001 Taniguchi 6,350,868 B1 2/2002 Weston 6,437,098 B1 8/2002 Shitara 6,455,043 B1 9/2002 Grillo-Lopez 6,488,930 B1 12/2002 Wu 6,488,015 B1 12/2002 Godiska 6,602,684 B1 8/2003 Umami et al. 6,737,006 B1 3/2004 Presta 6,762,174 B1 7/2004 Taub 6,946,292 B2 9/2005 Kanda et al. 6,986,890 B1 1/2006 Shitara 6,989,145 B2 1/2006 Shitara 7,033,589 B1 4/2006 Reff et al. 7,138,117 B1 11/2006 Wu 7,234,775 B2 * 5/2007 Hanai et al. 530/387.1 7,257,775 B2 11/2007 Idusogie 2002/0019341 A1 2/2002 Butcher 2002/0098527 A1 7/2002 Shitara 2002/0130015 A1 10/2002 Wells 2002/0187930 A1 12/2002 Wells 2003/0115614 A1 6/2003 Kanda 2003/0157108 A1 8/2003 Presta 2003/0158389 A1 8/2003 Idusogie 2003/0170813 A1 9/2003 Suga 2003/0175273 A1 9/2003 Shitara	
(75) Inventors: Nobuo Hanai, Machida (JP); Kazuyasu Nakamura, Machida (JP); Emi Hosaka, Machida (JP); Motoo Yamasaki, Machida (JP); Kazuhisa Uchida, Machida (JP); Toyohide Shinkawa, Machida (JP); Susumu Imabeppu, Ube (JP); Yutaka Kanda, Machida (JP); Naoko Yamane, Machida (JP); Hideharu Anazawa, Tokyo (JP)		
(73) Assignee: Kyowa Hakko Kirin Co., Ltd. Tokyo (JP)		
(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 59 days. This patent is subject to a terminal disclaimer.		
(21) Appl. No.: 11/686,915		
(22) Filed: Mar. 15, 2007		
(65) Prior Publication Data US 2007/0166304 A1 Jul. 19, 2007		
Related U.S. Application Data		
(62) Division of application No. 11/126,176, filed on May 11, 2005, now Pat. No. 7,214,775, which is a division of application No. 09/958,307, filed as application No. PCT/JP00/02260 on Apr. 7, 2000, now abandoned.		
(30) Foreign Application Priority Data Apr. 9, 1999 (JP) P. 11-103158		
(51) Int. Cl. A61K 39/00 (2006.01) A61K 39/395 (2006.01)		
(52) U.S. Cl. 424/133.1; 424/138.1		
(58) Field of Classification Search None See application file for complete search history.		
(56) References Cited U.S. PATENT DOCUMENTS 4,350,683 A 9/1982 Galfre 4,721,777 A 1/1988 Uemura 4,757,618 A 7/1988 Brown 4,816,567 A 3/1989 Casilly 4,849,509 A 7/1989 Thurin 5,272,070 A 12/1993 Lehrman 5,453,563 A 9/1995 Rsdolph 5,464,764 A 11/1995 Capecci 5,614,585 A 3/1997 Oppermann 5,658,789 A 8/1997 Ouarania 5,665,569 A 9/1997 Ohno 5,672,502 A 9/1997 Birch 5,728,568 A 3/1998 Sullivan 5,830,470 A 11/1998 Nakamura		
		(Continued)
		FOREIGN PATENT DOCUMENTS CA 2424602 4/2002
		(Continued)
		OTHER PUBLICATIONS Hale (J of Biological Regulators and Homeostatic Agents, 2001, 15:386-351).*
		(Continued)
		Primary Examiner—Laura B Goddard (74) Attorney, Agent, or Firm—Sughrue Mion, PLLC
		(57) ABSTRACT The invention relates to a method for controlling the activity of an immunologically functional molecule, such as an antibody, a protein, a peptide or the like, an agent of promoting the activity of an immunologically functional molecule, and an immunologically functional molecule having the promoted activity.
		3 Claims, 12 Drawing Sheets



Boehringer Ingelheim v. Barr Labs

Procedural History:

- Appeal from Dist Ct (Del) judgment of invalidity of US 4,886,812 for obviousness-type double patenting

Issue:

- Whether retroactive terminal disclaimer effective to overcome invalidity based on obviousness-type double patenting?
- Whether safe-harbor provision of 35 U.S.C. 121 precluded finding of obvious-type double patenting?



Boehringer Ingelheim v. Barr Labs

First application (06/810,947)

- Restriction requirement – 15 claims in 10 groups
- Elected Group II (compound) and IX (use of compound)

Divisional of '947 (07/124,197)

- Method of use claims encompass Groups VIII and X of restriction and Group XI (other than Group II)
- Allowed as US 4,843,086 (expired June 27, 2006)
- Term extended 1,564 days for FDA approval delay

Divisional of '197 (07/256,671)

- Claims encompass Groups I, III, IV and V of restriction and do not cross claims of '947 and '197 applications
- Allowed as US 4,886,812 (expired June 27, 2006)



Boehringer Ingelheim v. Barr Labs

- On the last day of infringement trial (March 2008), Boehringer sought to overcome the obviousness-type double patenting defense based on the then-expired '086 patent by filing a terminal disclaimer of the '812 patent with the PTO.
- Terminal disclaimer purported to disclaim “only the terminal part of the statutory term of the '812 patent which would extend beyond 1,564 days after the full statutory term of the '086 patent as that term is defined in 35 U.S.C. [§] 154, so that, by virtue of this disclaimer, the [']812 patent will expire on October 8, 2010.”
- Dist Ct concluded that Boehringer’s terminal disclaimer was ineffective to overcome the obviousness-type double patenting rejection, because the disclaimer was filed after the '086 patent had expired.



Boehringer Ingelheim v. Barr Labs

- Dist Ct also rejected Boehringer's argument that the safe-harbor provision of 35 U.S.C. § 121 precluded the use of the '086 patent as an invalidating reference.
- Dist Ct concluded that compound claims of the '812 patent were obvious in view of the method-of-use claims of the '086 patent and held that the '812 patent was invalid for obviousness-type double patenting.



Boehringer Ingelheim v. Barr Labs

- The question here is whether a retroactive terminal disclaimer—i.e., a terminal disclaimer that is filed after the expiration date of an earlier commonly owned patent—is effective to overcome obviousness-type double patenting.
- “The fundamental reason for the rule [of obviousness-type double patenting] is to prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about.” In re Van Ornum, 686 F.2d 937, 943-44 (CCPA 1982) (quoting In re Schneller, 397 F.2d 350, 354 (CCPA 1968)); see also Lonardo, 119 F.3d at 965 (emphasizing purpose of doctrine of double patenting of precluding “patentee from obtaining a time-wise extension of patent [rights] for the same invention or an obvious modification thereof”).



Boehringer Ingelheim v. Barr Labs

- When a patentee does not terminally disclaim the later patent before the expiration of the earlier related patent, the later patent purports to remain in force even after the date on which the patentee no longer has any right to exclude others from practicing the claimed subject matter.
- By permitting the later patent to remain in force beyond the date of the earlier patent's expiration, the patentee wrongly purports to inform the public that it is precluded from making, using, selling, offering for sale, or importing the claimed invention during a period after the expiration of the earlier patent.
- Paragon Solutions, LLC v. Timex Corp., 566 F.3d 1075, 1091 (Fed. Cir. 2009) (discussing importance of ability of “potential infringers to ascertain the propriety of particular activities” and “the notice function central to the patent system”); PSC Computer Prods., Inc. v. Foxconn Int'l, Inc., 355 F.3d 1353, 1361 (Fed. Cir. 2004) (emphasizing “the important public notice function of patents—the mechanism whereby the public learns which innovations are the subjects of the claimed invention, and which are in the public domain”).



Boehringer Ingelheim v. Barr Labs

- Permitting a retroactive terminal disclaimer would be inconsistent with “[t]he fundamental reason” for obviousness-type double patenting, namely, “to prevent unjustified timewise extension of the right to exclude.” Van Ornum, 686 F.2d at 943-44 (emphasis removed).
- HELD: a terminal disclaimer filed after the expiration of the earlier patent over which claims have been found obvious cannot cure obviousness-type double patenting.



Boehringer Ingelheim v. Barr Labs

- Boehringer argued that it did not enjoy any unjustified advantage because it had properly obtained a term extension of the '086 patent under 35 U.S.C. § 156.
- Fed Cir rejected argument pointing out the rights enjoyed during term are not the same as rights enjoyed during extension
 - if Boehringer had disclaimed the terminal portion of the '812 patent prior to the expiration of the '086 patent, then a competitor would have been placed on notice that, during the § 156 extension period following June 27, 2006, Boehringer only had the right to exclude the “use then under regulatory review”



Boehringer Ingelheim v. Barr Labs

- Boehringer alternatively argued that the safe-harbor provision of 35 U.S.C. § 121 shields the '812 patent from invalidity on the basis of double patenting in view of the '086 patent.
- Section 121 provides in relevant part:
 - A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them...
- “When the PTO requires an applicant to withdraw claims to a patentably distinct invention (a restriction requirement), § 121 shields those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application.” Geneva Pharms.



Boehringer Ingelheim v. Barr Labs

- Whether § 121 can ever apply to a divisional of a divisional of the application in which a restriction requirement was entered:
 - The most straightforward reading of the statutory text is that the safe harbor of § 121 applies even when the PTO issues a restriction requirement that leads to more than two separate applications.
 - Moreover, § 121 refers broadly to “a divisional application,” and does not state that the divisional must be a direct divisional of the original application.
 - Assuming all other requirements of § 121 are met, the safe-harbor provision may apply to a divisional of a divisional of the application in which a restriction requirement was entered.



Boehringer Ingelheim v. Barr Labs

- Whether the “as a result of” requirement of § 121 applies to the '812 patent and is satisfied here:
 - must be satisfied by both the '086 and '812 patents.
 - The restriction requirement had the effect of obligating Boehringer to file one or more divisional applications if it wanted patent protection for the non-elected subject matter. Boehringer did so not by filing separate divisional applications but by filing two successive divisionals to different combinations of the inventions identified in the restriction requirement. In doing so, Boehringer neither violated the examiner’s restriction requirement nor risked loss of the safe harbor of § 121.
 - Safe-harbor would have been lost if '812 violated claim groupings of restriction requirement.
 - Because of safe-harbor, terminal disclaimer not needed



In re Lansac

Appeal from final rejection of claims under 102(b)

- Whether Examiner erred in finding that cited reference inherently describes the invention recited in the claims?
- Affirmed-in-part
- Claimed invention directed to medical device for surgically repairing an aortic valve. The device includes an aortic ring that forms a closed-perimeter structure around an external segment of an aortic root of a patient.

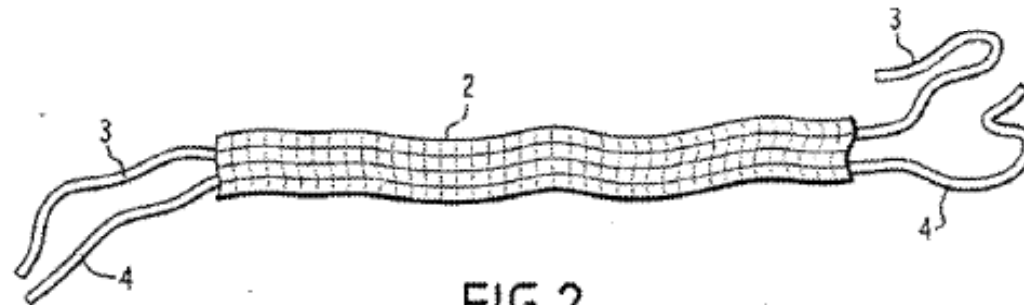


FIG. 2



In re Lansac

Cited 102 reference discloses:

- Chevillon describes a medical device for treating an aneurysm of the aorta. The device includes an implant 100 placed within an aorta *V*, and a collar 140a, 140b placed around the outside of the aorta to secure the two free ends 100a and 100b of the implant.

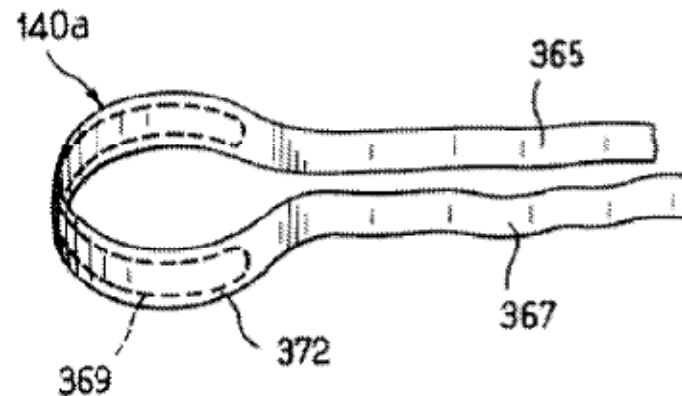


FIG. 11



In re Lansac

- The Examiner rejects claims 17-36 as anticipated by Chevillon, finding that Chevillon describes all of the claimed structural elements thereof, and that the device of Chevillon is “inherently capable for use as claimed.”

- FOA rejection:
 4. Claims 17-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chevillon et al. (U.S. Patent Number 6,248,116) as disclosed by Applicant within the Information Disclosure Statement.
 5. Chevillon et al. discloses a vascular ring (140) comprised of a flexible, suturable, biocompatible material wherein the ring has a height greater than 1 mm. (col. 4, lines 45-50; col. 6, lines 6-19 and 66-67; col. 7, lines 1-8; Figure 10).



In re Lansac

17. A device for implantation in proximity to an aortic valve of a patient, comprising:

an aortic ring having a flexible construction and being configured and sized for placement externally around an aortic root of the patient, the aortic root being generally tubular and containing therewithin the aortic valve having a plurality of valve leaflets, the leaflets cooperating with one another to control blood flow through the aortic root, *said aortic ring being elastically expandable in annular perimeter between a first ring configuration in which the aortic root is exposed to a diastolic phase of a cardiac cycle and a second ring configuration of larger annular perimeter than said first ring configuration in which the aortic root is exposed to a systolic phase of the cardiac cycle*, in said first ring configuration the aortic ring having an appropriately sized first perimeter length so as to urge the valve leaflets to coapt under the constraining effect of the aortic ring and restrict blood flow through the aortic valve, *and in said second ring configuration the aortic ring expands to a second perimeter length greater than said first perimeter length* whereby said aortic ring allows the aortic root to expand a controlled predetermined amount allowing the valve leaflets to open and allow blood flow therethrough.



In re Lansac

- The Examiner additionally finds that “[i]ndependent claims 17, 20, and 23 each recite a multitude of intended use or functional recitations” and “the anatomical structure of the aortic root does not structurally define the invention.”
- Appellant argues that Chevillon “fails to teach or suggest an aortic annuloplasty ring or device at all, let alone one that is specifically configured and sized to be placed around the aortic root to restore leaflet coaptation.”
- The Appellant also asserts that “[t]here is no evidence provided in the Chevillon reference indicating, expressly or implicitly, that vascular ring (140) would properly or effectively operate as claimed . . .,” or that collar 140a can perform the specific functions recited in the rejected claims.



In re Lansac

Regarding intended use:

“It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted).

- BPAI noted that all of the rejected claims are device claims, not method claims. As such, statements directed to the manner in which the device is used are mere statements of intended use and are not given patentable weight. *In re Schreiber*, 128 F.3d at 1477. Hence, statements of intended use present in all of the rejected claims which are directed to specific placement of the device, structure and operation of the aortic root, and effect on the valve leaflets and blood flow, are not given patentable weight.



In re Lansac

Regarding functional language:

With respect to functional limitations, “[a] patent applicant is free to recite features of an apparatus either structurally or functionally.” *Id.* at 1478 (citing *In re Swinehart*, 439 F.2d 210, 212 (CCPA 1971) (“[T]here is nothing intrinsically wrong with [defining something by what it does rather than what it is] in drafting patent claims.”). “Yet, choosing to define an element functionally, *i.e.*, by what it does, carries with it a risk.” *Id.*

- With regard to claim 23, BPAI found that the functional recitation “whereby the closed-perimeter structure serves to constrain....” does not distinguish over the art.



In re Lansac

With regard to claims 17 and 20:

- Claim 17 includes the functional recitation that “the aortic ring expands to a second perimeter length greater than said first perimeter length,” the second ring configuration being the configuration in which the aortic ring is subject to a systolic phase of the cardiac cycle.
- Claim 20 includes the functional recitation that “the aortic ring elastically expands a predetermined amount under the influence of the systolic phase” of the cardiac cycle.



In re Lansac

- Appellant argued that “Chevillon fails to teach an elastically expandable ring which can increase its annular perimeter, or equivalent diameter, in the transition between the diastolic and systolic phases of a cardiac cycle to achieve the claimed function.”
- “the Chevillon reference does not express any ability to perform this function and one of ordinary skill in the art would not view the [cited] passage... of the Chevillon reference as evidencing such an ability.” *Id.*



In re Lansac

BPAI agreed with Appellant

- The Examiner fails to establish how the disclosure that the collar 140a is elastically expandable inherently describes elastically expanding to a second ring configuration in response to the systolic phase of the cardiac cycle. It is speculative as to whether the collar 140a is *sufficiently elastic* to expand to a second ring configuration based on the systolic phase of the cardiac cycle, especially in view of the presence of the reinforcing core 369 (FF 2), and the fact that elasticity does not only depend on the material used, but also on the dimension thereof (e.g., thickness of the material).