# UNITED STATES PATENT AND TRADEMARK OFFICE



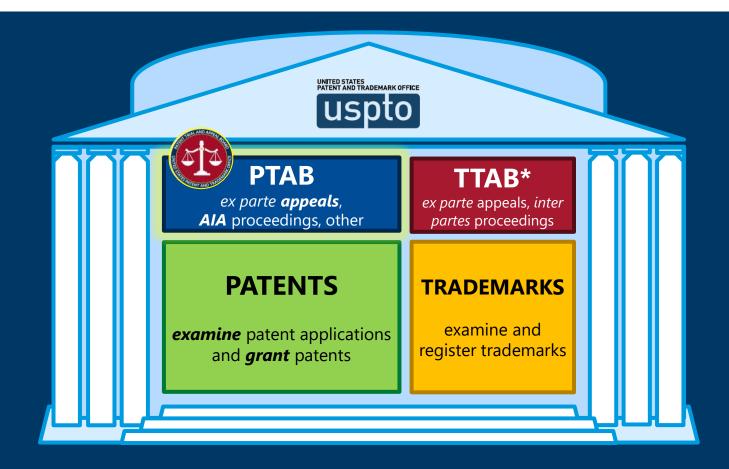
# Patent Trial and Appeal Board Inventor Hour: Episode 29

Jeffrey Fredman, Administrative Patent Judge
John Schneider, Administrative Patent Judge
Amee Shah, Administrative Patent Judge
Brandy Zukanovich, Office of the Chief Judge Patent Attorney
Ulrike Jenks, Administrative Patent Judge
Cynthia Hardman, Administrative Patent Judge

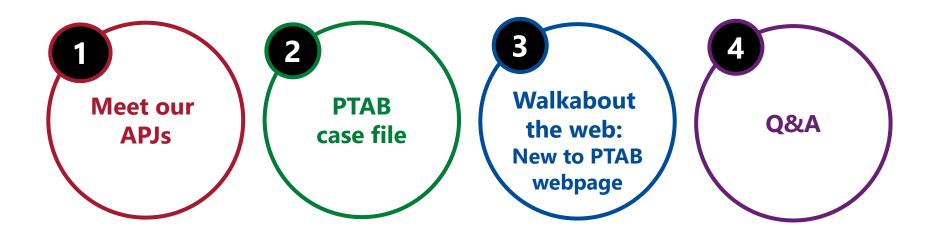
June 27, 2024



### What is the Patent Trial and Appeal Board?



# Today's agenda





# Question/comment submission

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Brandy Zukanovich, Office of the Chief Judge Patent Attorney





**Brandy Zukanovich**Office of the Chief Judge Patent Attorney



**Jeffrey Fredman** Administrative Patent Judge



**John Schneider** Administrative Patent Judge





# Question/comment submission

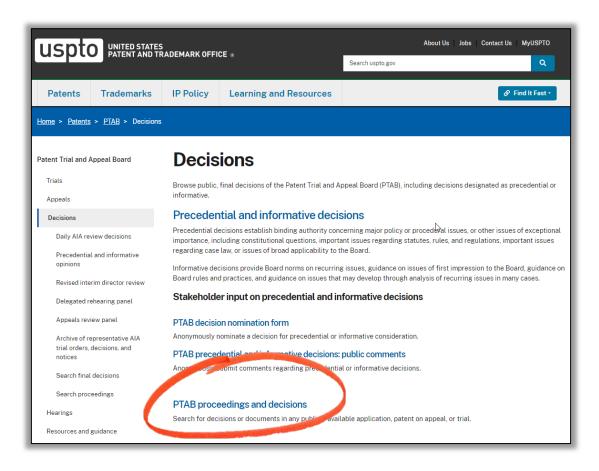
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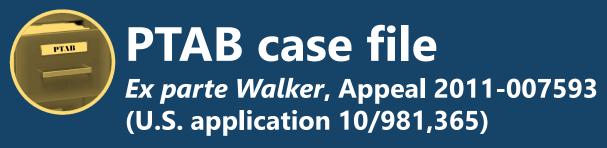
# Where to find PTAB decisions: www.uspto.gov/patents/ptab/decisions





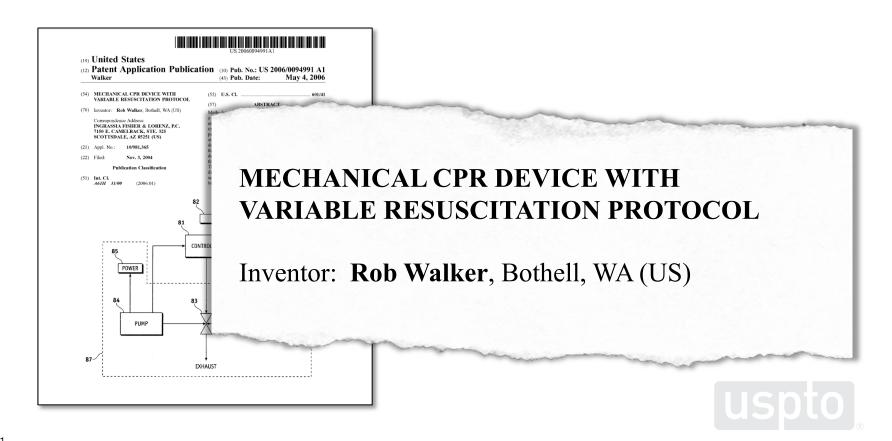


Ulrike Jenks, Administrative Patent Judge

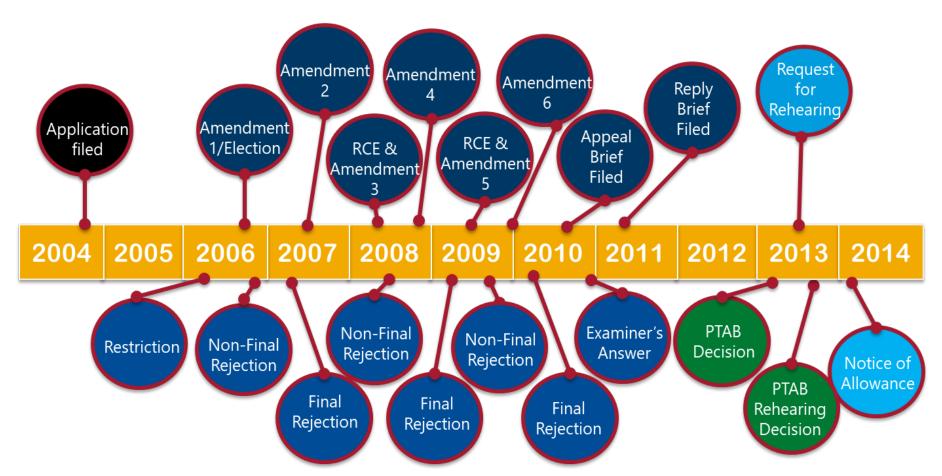


### U.S. application 10/981,365

(Appeal No. 2011-007593)



### **Prosecution timeline**



### U.S. application 10/981,365

(Appeal No. 2011-007593)

Claim 19 (Currently Amended): A method of controlling the administration of cardiopulmonary resuscitation (CPR) to a patient through a mechanical CPR device during a CPR delivery period according to a CPR protocol programmed in a controller of the mechanical CPR device, the CPR protocol comprising:

alternating between a period of delivery of chest compressions to the patient with the mechanical CPR device and a period of non-delivery of chest compressions to the patient for an initial portion of the CPR delivery period; and

after the step of alternating between the period of delivery of chest compressions and the period of non-delivery of chest compressions, delivering an uninterrupted series of chest compressions to the patient with the mechanical CPR device for the remainder of the CPR delivery period, wherein the remainder of the CPR delivery period is longer than the period of delivery of chest compressions during the initial portion of the CPR delivery period.

### **Examiner's final rejection**



APPLICATION NO.

Jason D. Kelly Shumaker & Sieffert 1625 Radio Drive Suite 300 St. Paul, MN 55125

#### Please find below and/o

The time period for repl

Notice of the Office of following e-mail addres pairdocketing@ssiplaw.com Claims 19-22, 26-30, 69-72, 76-79, 88-92, 96-105 and 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over the American Heart Association guidelines for administration of CPR as admitted by applicant in view of Kern et al. (NPL cited on 892 08/01/2008) and Weisfeldt et al.

Claims 31-34, 73, 74, 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 22, 69, 83 and 88 above, and further in view of Sherman.

PTOL-90A (Rev. 04/07)

### **Prior art**

### American Heart Assoc. Guidelines

#### Part 3: Adult Basic Life Support

#### Major Guidelines Changes

Following are the major guidelines changes related to adult basic life support, with the rationale for the change.

#### BLS Role in Stroke and ACS Management

- 1. Rescuers should "phone first" for unresponsive adults. Exceptions: "phone fast" (provide CPR first) for adult victims of submersion, trauma, and drug intoxication (Class Indeterminate).
- Prehospital BLS providers should identify possible stroke victims (through use of stroke scales or screens) and provide rapid transport and prearrival notification to the receiving hospital to increase the likelihood of their eligibility for intravenous fibrinolytic therapy (Class I).
- 3. Patients with suspected stroke merit the same prio for dispatch as patients with acute myocardial infarction
- (AMI) or major trauma (Class IIb).

  4. Victims of suspected ischemic stroke (with prearrival notification) should be transported to a facility capable of initiating fibrinolytic therapy within I hour of arrival unless that facility is >30 minutes away by ground

#### BLS Sequence

#### Rescue Breathing and Bag-Mask Ventilation

- Change ventilation volumes and inspiratory times for mouth-to-mask or bag-mask ventilation as follows: a. Without oxygen supplement: tidal volume approxi mately 10 mL/kg (700 to 1000 mL) over 2 seconds
- b. With oxygen supplement (≥40%): a smaller tidal volume of 6 to 7 mL/kg (approximately 400 to 600 mL) may be delivered over 1 to 2 seconds (Class
- 6. Alternative airway devices (ie, laryngeal mask airway and the esophageal-tracheal Combitube) may be accepable when rescuers are trained in their use (Class IIb).

7. Lay rescuers will no longer be taught or expected to perform a pulse check. The signal for lay rescuers to begin chest compressions (and attach an AED) is the absence of signs of circulation (normal breathing, coughing, or movement). Healthcare providers should continue to perform a pulse check with assessment of signs of circulation (breathing, coughing, or

#### Chest Compressions

- 9. The compression-ventilation ratio for 1- and 2-rescuer CPR is 15 compressions to 2 ventilations when the
- The compression rate for adult CPR is approximately 100 per minute (Class IIb).

Circulation, 2000;102(suppl 1):I-22-I-59.

Circulation is available at http://www.circulationaha.org

victim's airway is unprotected (not intubated) (Class

- 10. Chest compression-only CPR is recommended for use in dispatch-assisted CPR or when the rescuer is unwilling or unable to perform mouth-to-mouth rescue breathing (Class IIa).
- Audio prompts that guide action sequences and the timing of chest compressions and ventilations increase learning and retention of CPR skills and improve CPR performance (Class IIb).

#### Relief of Foreign-Rody Airway Obstruction

12. Lay rescuers will no longer be taught the sequence for management of foreign-body airway obstruction (FBAO) for unresponsive adults (Class IIb). If FBAO is suspected in the victim who has become unresponsive or who is found unresponsive, lay rescuers should perform the sequence of CPR. When rescue breathing is performed, the lay rescuer should look for a foreign body in the mouth and if one is seen, remove it. Healthcare providers should still perform the sequence for relief of FBAO in the unresponsive victim.

#### Introduction

The actions taken during the first few minutes of an emergency are critical to victim survival. BLS defines this sequence of actions and saves lives RLS includes

- Prompt recognition and action for myocardial infarction and stroke to prevent respiratory and cardiac arrest
- Rescue breathing for victims of respiratory arrest · Chest compressions and rescue breathing for victims of
- Attempted defibrillation of patients with ventricular fibril.
- lation (VF) or ventricular tachycardia (VT) with an automated external defibrillator (AED)
- · Recognition and relief of FBAO

With the inclusion of AED use in BLS skills, BLS is now defined by the first 3 links in the Chain of Survival: early access, early CPR, and early defibrillation (Figure 1).1 Each link must be strong throughout the community; this approach is consistent with the concept that the community is the "ultimate coronary care unit."2

Early access requires prompt recognition of emergencies that require time-critical BLS interventions, such as heart attack, stroke, FBAO, and respiratory and cardiac arrest. Early access of the EMS system quickly alerts EMS providers, who can respond with a defibrillator.3-5 Emergency Medical Dispatchers (EMDs) can lead callers through the steps of CPR until EMS personnel arrive.

#### Kern



Permetitation 39 (1998) 179-188



Efficacy of chest compression-only BLS CPR in the presence of an occluded airway

Karl B. Kern a.b.\*, RonaldW. Hilwig a, Robert A. Berg a.c., Gordon A. Ewy a.b

a University of Arizona Sarner Heart Center, University of Arizona College of Medicine, Tucson, AZ, USA b Section of Cardiology, Department of Medicine, University Medical Conter, University of Arizona College of Medicine, 1501 North Campbell Avenue, Tucson, AZ 85724-5037, USA Oppartment of Pediatrics, University of Arizona College of Medicine, Tucson, AZ, USA

Reluctance of the lay public to perform bystander CPR is becoming an increasingly worrisome problem in the USA. Most bystanders who admit such reluctance concede that fear of contagious disease from mouth-to-mouth contact is what keeps them from performing basic life support. Animal models of prehospital cardiac arrest indicates that 24-h survival is essentially as good with chest compression-only CPR as with chest compressions and assisted ventilation. This simpler technique is an attractive alternative strategy for encouraging more bystander participation. Such experimental studies have been criticized as irrelevant however secondary to differences between human and porcine airway mechanics. This study examined the effect of chest compression-only CPR under the worst possible circumstances where the airway was totally occluded. After 6 min of either standard CPR including ventilation with a patent airway or chest compressions-only with a totally occluded airway, no difference in 24 h survival was found (10/10 vs. 9/10). As anticipated arterial blood sases were not as sood, but hemodynamics produced were better with chest compression-only CPR (P < 0.05). Chest compression-only CPR, even with a totally occluded airway, is as good as standard CPR for successful outcome following 6.5 min of cardiac arrest. Such a strategy for the first minutes of cardiac arrest, particularly before professional help arrives, has several advantages including increased acceptability to the lay public. © 1998 Elsevier Science Ireland Ltd. All rights reserved.

Keywords: Mouth-to-mouth; Chest compression-only CPR; Hemodynamics

The importance of bystander CPR is well known and has been shown to improve the outcome of out-of-hospital cardiac arrest [1,2]. Unfortunately, current reports indicate that bystander CPR is declining. Recent studies from suburban Pittsburgh, PA and Tucson, AZ suggest the current rate of bystander CPR is only 20-30%, or approximately half of what it was 10 years ago [3.4]. Questioning potential rescuers including American Heart Association basic life instructors [5], house staff

\*Corresponding author. Tel.: +1-520-6262477; fax: +1-520-6262909; e-mail: kernk@u.arizona.edu.

[6], physicians and nurses [7], and the lay public [8] about their willingness to perform bystander CPR on strangers has resulted in a consistent message that many are afraid of contracting a contagious disease from mouth-to-mouth contact. This fear, though illfounded, is one that many of our current basic life support courses often perpetuate with their emphasis on barrier devices [9].

An additional impediment to bystander CPR is the difficulty that the average lay person has in learning, retaining, and performing this complex psychomotor task. Donnelly and colleagues studying recently trained lay persons found that, only a minority could perform BLS CPR (according to the European Resuscitation

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#### Weisfeldt



[54] INTEGRATED SYSTEM FOR CARDIOPULMONARY RESUSCITATION AND CIRCULATION SUPPORT [75] Inventors: Myron I., Weisfeldt. Baltimor

Joshua E. Tsitlik, Reisterstown; Nisha Chandra, Towson, all of Md. [73] Assignee: The John Hopkins University, Baltimore, Md

[22] Filed: Mar. 23, 1981

Weisfeldt et al.

[51] Int. Cl.<sup>3</sup> ... [52] U.S. Cl. ... [58] Field of S References Cited

U.S. PATENT DOCUMENTS OTHER PUBLICATIONS

"Proceeding 8th Annual Northeast Bioengineering Conserence '; Instrumentation for Caratopulmonary Re-suscitation; pp. 275–278.
"Cardiology"; Time; p. 29; Jan. 8, 1965.
Abstract of: Carotid. Flow During Cardiopulmonary

Aug. 9, 1983 Resus.; Am. Jur. Card., vol. 43, p. 422; Feb. 1979; by

4,397,306

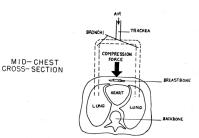
Applicants.
Full Text of: Carotid. Flow; Am. Jur. Card., vol. 48, p. Primary Examiner-Richard J. Apley

Assistant Examiner—David Brown Attorney, Agent, or Firm—Cushman, Darby & Cushman

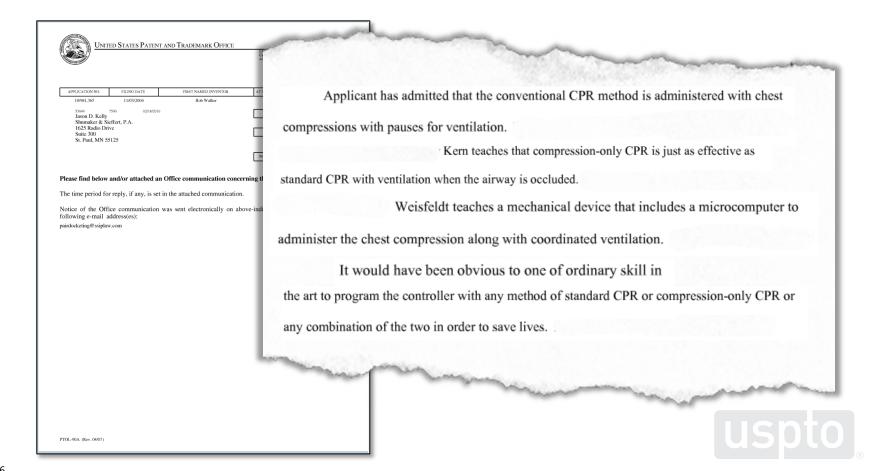
ABSTRACT

An integrated system for cardiopulmonary resuscitation and circulation support comprising chest compression means adapted to be positioned over the patient's ster-num and operable to compress the sternum at desired intervals and to a desired degree, lung ventilating means including (1) a high pressure ventilator for ventilating simultaneously with chest compression; (2) a low pressimultaneously with chest compression; (2) a low presure ventilator for inflating the lungs at low pressure between a selected number of compression cycles; and (3) a negative pressure ventilator for defiating the lungs are considered to the compression of the compression cycles and the compression consistency of the indicated ventilators at any one time, means for restricting the addonent to exert pressure on the abdominal wall; and control means for selectively operating the chest compression means, the lung ventilating means, valve means and for the cred of time desired.

9 Claims, 7 Drawing Figures



### Examiner's rejection on obviousness



### Appellant's arguments on obviousness

PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
irst Named Inventor. Robert G. Walker Confirmation No. 6764

Kern et al. fails to include any suggestion that changing CPR techniques during a CPR administration period may be beneficial to a patient. Instead, Kern et al. provides a discussion comparing the relative efficacy of compression-only CPR to compression and ventilation CPR. The disclosure of Kern et al. actually maintains an assumption that CPR with ventilation is superior to compression-only CPR if ventilation is possible. In no manner does Kern et al. suggest practicing both techniques during a single CPR administration period



### **Board decision on obviousness**

We conclude that the rejection's evidence and reasoning supports a prima facie case for the obviousness of applying both known methods of administering CPR to a patient in need of resuscitation. The hoped for result is the patient's revival, and it would have been reasonable to expect that combining the known methods would have achieved that result at least as effectively as either method used alone.



### **Appellant's Request for Reconsideration**

DOCKET NO.: PHYS-0004 (PB10123.00)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

The PTAB misapprehended this argument stating that claim 19 is open to its first step including CPR with compression and ventilation. That is true but does not answer the posited argument that Kern teaches compression only CPR should be performed first, opposite to the claimed subject matter.

#### to arrive at the claimed subject matte

Since chest compression-only CPR is a well-known to improve hemodynamics or reperfusion and is an alternative method of providing CPR that is just as effective, there appears to be no unobviousness to one of ordinary skill in the art to use either or both methods in an attempt to provide cardio pulmonary resuscitation to a patient. The most important issue is that the patient be administered one form or another of the conventional CPR with ventilation and/or compression-only CPR whatever it

- 1 -

[uspto]

### **Board decision on Request for Reconsideration**

On reconsideration, we agree with Appellant that the reasoning relied on in the Decision improperly treated Appellant's arguments regarding Kern's preference to initiate resuscitation with compression. We find that Kern does not support, without more, a finding that CPR with compression and ventilation should precede compression-only CPR. In this regard, the Examiner has pointed to nothing in the cited prior art that would have suggested the specific order required by the Examiner's combination.

### **Notice of allowance**

Notice of Allowability  - The MAILING DATE of this communication a	Examiner Quang D. Thanh	Art Unit 3771	AIA (First Inventor to File) Status
- The MAIL ING DATE of this communication a			No
1. ☑ This communication is responsive to <u>a decision on Reco</u>		Appeal Board date	d 7/24/2013.
☐ A declaration(s)/affidavit(s) under 37 CFR 1.130(b) v  2. ☐ An election was made by the applicant in response to a requirement and election have been incorporated into thi	restriction requirement set forth dur	ring the interview or	n; the restriction

3. The allowed claim(s) is/are 19-22,26-34,69-74,76-79,88-105, 108-111.

Identifying indicia such as the application number (see 37 CFR 1.84(c each sheet. Replacement sheet(s) should be labeled as such in the h	<ul> <li>should be written on the drawings in the front (not the back) of eader according to 37 CFR 1.121(d).</li> </ul>
<ol> <li>DEPOSIT OF and/or INFORMATION about the deposit of BIOL- attached Examiner's comment regarding REQUIREMENT FOR T</li> </ol>	
Attachment(s)	5. ☐ Examiner's Amendment/Comment
<ol> <li>☑ Information Disclosure Statements (PTO/SB/08),</li> </ol>	Examiner's Statement of Reasons for Allowance
Paper No./Mail Date .    Examiner's Comment Regarding Requirement for Deposit of Biological Material .   Interview Summary (PTO-413), Paper No./Mail Date	7.  Other
/Quang D. Thanh/ Primary Examiner, Art Unit 3771	
I.S. Patent and Trademark Office	
TOL-37 (Rev. 08-13) Notice of	of Allowability Part of Paper No./Mail Date 201401



### Compare: Filed vs issued claims

#### Claim as-filed

- 1. A method for controlling the delivery of chest compressions in cardiopulmonary resuscitation (CPR) through a mechanical CPR device comprising the steps of:
  - delivering chest compressions with the mechanical CPR device through a first cycle frequency; and
  - subsequently delivering chest compression with a the mechanical CPR device through a second cycle frequency, wherein the second cycle frequency is different from the first cycle frequency.

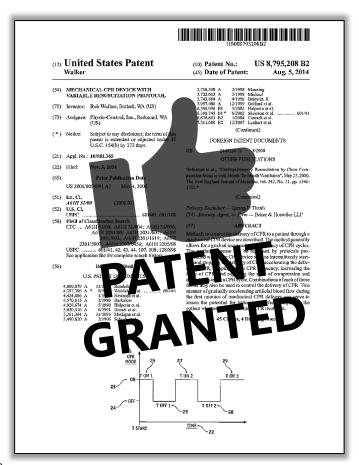
#### **Claim as-allowed**

Claim 19 (Currently Amended): A method of controlling the administration of cardiopulmonary resuscitation (CPR) to a patient through a mechanical CPR device during a CPR delivery period according to a CPR protocol programmed in a controller of the mechanical CPR device, the CPR protocol comprising:

alternating between a period of delivery of chest compressions to the patient with the mechanical CPR device and a period of non-delivery of chest compressions to the patient for an initial portion of the CPR delivery period; and

after the step of alternating between the period of delivery of chest compressions and the period of non-delivery of chest compressions, delivering an uninterrupted series of chest compressions to the patient with the mechanical CPR device for the remainder of the CPR delivery period, wherein the remainder of the CPR delivery period is longer than the period of delivery of chest compressions during the initial portion of the CPR delivery period.

# **Takeaways**



A rejection, even a final one, is not the end of your options

Patent prosecution may take a while, so be patient

How you claim your invention is of paramount importance

Appealing to the PTAB may result in the Examiner allowing the claims

Rehearings are an option

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# PTAB hearings webpage



- www.uspto.gov/patents/ptab/hearings
- Information regarding PTAB oral hearings including
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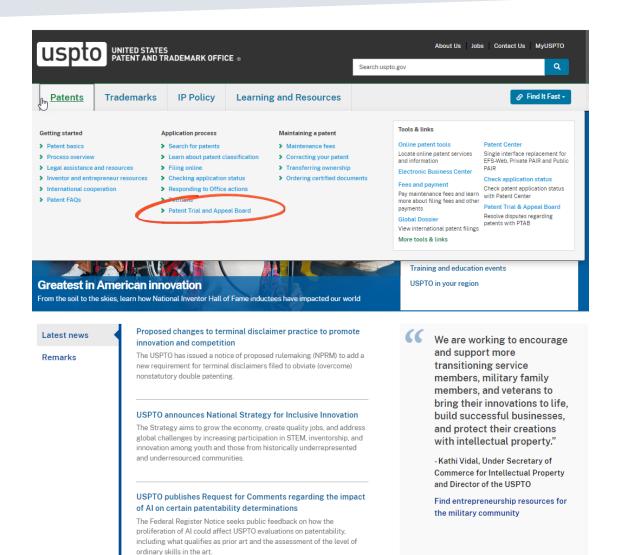
Cynthia Hardman, Administrative Patent Judge

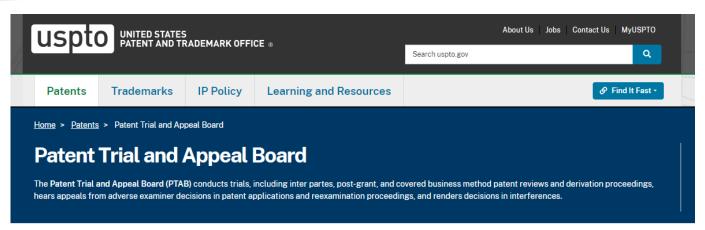


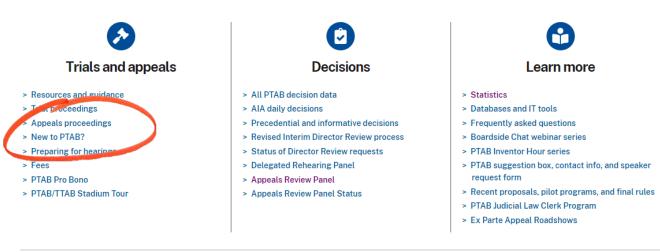
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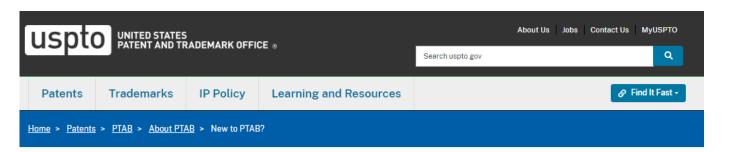












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#### What is PTAB?

PTAB is a tribunal within the USPTO that reviews rejections made by examiners in proceedings called ex parte appeals and decides patentability questions for issued patents raised by third parties in proceedings called AIA trials.

- > More about PTAB
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#### Ex parte appeals

If a patent examiner twice rejects or issues a final rejection in a patent application, the applicant can seek review of the rejection by the Board.

- > What are ex parte appeals?
- > Free legal help for ex parte appeals



#### AIA proceedings

A third party who is not the patent owner, called a petitioner, may challenge the validity of the claims in an issued patent in an AIA proceeding before the Board.

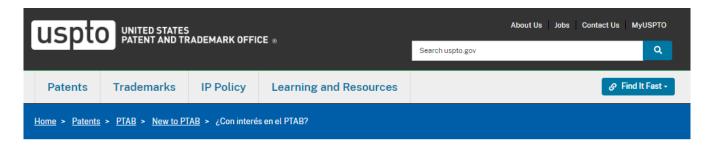
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#### ¿Con interés en el PTAB?

**English** 

Los inventores independientes, los profesionales recientes y otros pueden explorar los enlaces a continuación para comprender mejor el papel que juega el Tribunal de Apelación y Juicio de Patentes (PTAB, por sus siglas en Inglés) en el proceso de obtener una patente de invención.



#### ¿Qué es PTAB?

PTAB es un tribunal administrativo dentro de la USPTO que revisa los rechazos definitivos realizados por los examinadores en procedimientos llamados apelaciones ex parte y resuelve las cuestiones de patentabilidad de las patentes emitidas planteadas por terceros en procedimientos contenciosos bajo la Ley "América Inventa" (AIA, por sus siglas en Inglés).

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Si un examinador de patentes rechaza dos veces o emite un rechazo definitivo en una solicitud de patente, el solicitante puede buscar revisión con respecto al rechazo ante el PTAB a través de una apelación ex parte.

> ¿Qué son las apelaciones ex parte?



#### Procedimientos bajo la AIA

Un tercero que no sea el titular de la patente, llamado peticionario, puede impugnar la validez de las reivindicaciones de una patente emitida en un procedimiento contencioso bajo la AIA ante el PTAB.

Más información sobre los procedimientos bajo la AIA



#### ¿Alguna pregunta?

Haga contacto con PTAB o lea detenídamente las preguntas frecuentes disponibles para su conveniencia.

> Obtenga asistencia (en Inglés)

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# **Questions?**

## **Future programs**

### **Inventor Hour, Episode 30**

Thursday, July 25, 2024 noon (ET)

### **Inventor Hour, Episode 31**

Thursday, Aug. 22, 2024 noon (ET)





