Paper II – Practical

(Exploitation of Patents – Drafting, Specification & Patent Writing)

Time: 2 ½ hours. TOTAL MARKS: 60

INSTRUCTIONS TO CANDIDATES

The questions to be interpreted as given and no clarification can be sought from the invigilator.

Draft an Indian Patent Specification for either A or B (any one), based on the respective invention disclosures. Write one independent and one dependent claim. (Figures are not required).

A. Generally catapults have been known in the past to catapult small objects. This invention is about handheld catapults, of slingshot design, which is conceived to catapult a large projectile than previously available.

The development of the slingshot is one, which has been evolving for many years. The first such device was simply a handheld yolk to which was attached an elastic material and a small pouch to hold the missile.

The current slingshot designs are numerous and may contain a variety of bracing devices. These include a simple wrist brace, folding brace, adjustable brace, the removable brace and many alterations thereof.

The present invention provides for a handheld slingshot, which is capable of catapulting a projectile of greater mass than previously available.

Another object of the present invention is to provide protection from the occasional contact between the elastic bands or pouch and the user's fingers. This contact often stings and is uncomfortable.

The catapult herein disclosed is one, which has many applications. The primary objective of the present invention is to provide a handheld catapult to project water balloons. Water balloon wars, being one of America's great summertime activities, will be intensified by the present invention’s ability to catapult water balloons a great distance with a considerable amount of accuracy. Many persons, not possessing a good throwing arm, will find that the present invention "Evens The Odds".

Another use for such a catapult is that of hurling sport balls through the air. Catapulting a baseball into the air for fielding practice, using the present invention, is much easier than throwing with the arm. For skeet shooting, a plastic ball may be catapulted to provide a moving target for practice. Still another use is to catapult rubber balls for games or to train dogs to fetch.

The present invention is manufactured similar to the traditional slingshot but contains alterations, which will allow larger projectiles to be catapulted. The present day slingshot is comprised of 5 basic elements. These elements begin with the yolk, which is connected to a handle, to which is attached a wrist brace of sorts. Referring back to the yolk, elastic tubes are connected to the ends of the yolk and a pouch is connected to the two elastic tube ends. There are possible additions to this basic format, which may include sights, elastic band protectors, and numerous design modifications.

The heart of the present invention is the enlarged projectile pouch and the clearance of the yolk. In addition to the above-mentioned features, an optional hand guard is available if desired. The pouch can be fabricated of many materials, including leather, vinyl, plastic, rubber or any other material, which can be formed into a "cup" to provide support for projectile during launch. The yolk is extended and widened to provide a plurality of projectile size catapults. The hand guard is a protective option, which may be included with the handgrip portion, to provide hand and finger protection from the elastic bands or the pouch upon release of the projectile.

The following description is one embodiment of the essence of the present invention (Reference Figure 1):

The arm brace cushion 1 is attached to the arm brace 2 which is connected to the hand grip 3. The preceding is well known for slingshots and is not necessarily a substantial part of the present invention, but is, in one manufacture or another, essential. The yolk structure 4, being manufactured of most any rigid material such as aluminum, steel, fiberglass, plastic and the like, is specifically designed to provide clearance 6w/6h for the launched projectile. The elastic tubing 7 is held securely by the ribbed portion 5 of the yolk 4. The connection between the elastic tubing 7 and the projectile pouch 9 is obtained by incorporating a ribbed plug 8 which is pulled through the eyelets and inserted into the elastic tube ends. To provide a handle 10 for the pouch 9, an orifice is patterned into the development to allow attachment of pouch handle. Hand protection, from occasional contact between elastic tubes or pouch, is provided by the hand guard 11.

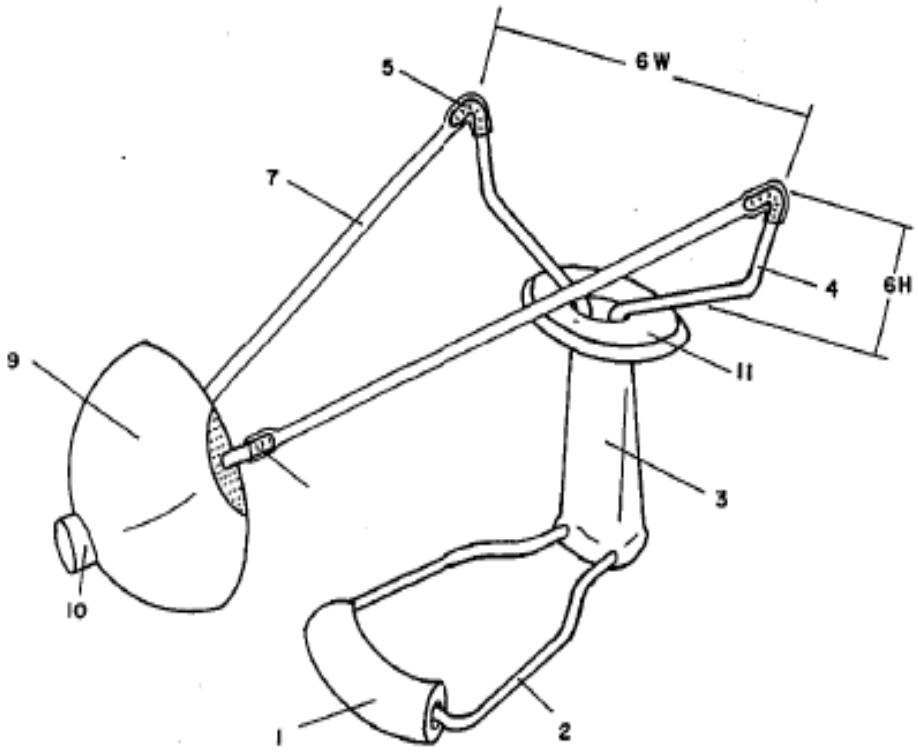

Figure 1

or

B. Invention Description: Diagnosis of Peridontal Diseases

The present invention relates to diagnostic method, kits and products for detecting or evaluating the presence of periodontal diseases, especially gingivitis, in humans or lower animals. These methods comprise measuring the amount of leukocyte esterase present in the oral cavity of the human or lower animal being diagnosed.

To understand the scope of this invention it is important to define a few concepts. For the purposes of this invention “Detecting or evaluating the presence of periodontal diseases" means detecting the presence of, or evaluating the severity of, periodontal diseases. Furthermore, the term "periodontal diseases", as used herein, means inflammatory conditions

of the mouth, whether or not discernible to the naked eye, including such inflammatory conditions as periodontitis, stomatitis, and gingivitis.

Periodontal diseases, such as, for example, periodontitis, gingivitis, stomatitis, and the like, are inflammatory conditions of the mouth characterized by inflammatory oral tissue changes usually due to local irritation. The destructive inflammatory process involves the interaction between bacteria, food debris, oral leukocytes, and the epithelial attachment around the tooth and periodontal membranes. If allowed to progress unchecked, such inflammatory processes can lead to resorption of the supportive bone around the roots of the teeth and eventual loss of teeth. The early detection of such inflammatory conditions is very important to proper dental treatment.

It has been known for many years that at local sites of inflammation the body produces an increased number of leukocytes.

In addition, diagnostic methods for detecting the presence of the inflammatory periodontal disease condition have been developed based on detecting peroxidase enzymes from polymorphonuclear (PMN) leukocytes as described, for example, in "Diagnostic Method for Detecting Periodontal Disease", European Patent Application Publication No. 158796, by Richardson-Vicks Inc., published Oct. 23, 1985, the disclosure of which is incorporated herein by reference in its entirety. Furthermore, Reagents for assessing periodontal diseases by detecting the presence of peroxidases and/or salivary occult blood in the oral cavity are known, having been described in: Tenovuo and Anttonen, "Application of a Dehydrated Test Strip, HEMASTIX®, for the Assessment of Gingivitis", J. of Clinical Periodontology, 5, pages 206-212 (1978).

While there has been much research into methods for detecting periodontal diseases, none of these references disclose or discuss measuring leukocyte esterase as a method for detecting periodontal diseases.

The method of the present invention is particularly useful for detecting the presence of gingivitis which is not readily discernible to the naked eye, and for evaluating the severity of gingivitis whether or not discernible to the naked eye. Thus, the methods of the present invention are especially suited for predicting the onset of gingivitis and/or for quantitatively or semi-quantitatively indicating the degree of the severity of gingivitis. As a result of this early

detection, early dental treatment can be initiated to ensure rapid return to proper dental health.

"Measuring the amount of leukocyte esterase present in the oral cavity", as used herein, means either simply detecting the presence of leukocyte esterase; or quantitatively or semi-quantitatively measuring the concentration of leukocyte esterase in the oral cavity. These measurements can be made either at one or more particular oral sites (preferably at gingival sites, and most preferably at the gingival margin), or in the saliva generally. Products and/or reagents which may be utilized for measuring the amount of leukocyte esterase present in the oral cavity are described more fully hereinafter.

The methods of the present invention may be carried out in many ways, including, but not limited to: (1) in vivo or in vitro measurement of a saliva sample; (2) in vitro measurement of a sample from a specific gingival site or sites; and (3) in vivo measurement of the leukocyte esterase activity at a specific gingival site or sites. Each of these procedures is further elaborated immediately hereinafter to illuminate and exemplify the methods of the present invention.

In vitro measurement of the leukocyte esterase activity in saliva samples is preferably accomplished by utilizing commercially-available leukocyte esterase reagent strips suitable for in vitro evaluation of leukocyte esterase activity. The saliva sample may be expectorated directly onto the strip, or, preferably, is diluted in water to a certain volume and tested by dipping the reagent strip in the dilute saliva sample. It is further preferred that the subject to be diagnosed not eat within one hour prior to the sample collection.

Examples of commercially-available leukocyte esterase reagent strips are CHEMSTRIP® 9 and CHEMSTRIP® LN (both sold by Bio-Dynamics, Indianapolis, Ind.); and MULTISTIX® 2 Reagent Strips and AMES LEUKOSTIX® (both available from Ames, Division of Miles Laboratory, Elkhart, Ind.). Techniques for using these commercially-available leukocyte esterase reagent strips are well known.

All of these commercially-available leukocyte esterase reagent strips contain an indoxyl carbonic acid ester which is hydrolyzed to indoxyl by leukocyte esterase. The indoxyl thus formed reacts with a diazonium compound in the strip to produce a color which indicates the presence of the leukocyte esterase. The degree of darkening of the strips is a semi-

quantitative indication of the amount of leukocyte esterase present in the saliva sample, and hence for the methods of the present invention is an indication of the severity of the periodontal disease. The presence of color change when no periodontal diseases are readily evident to the naked eye may indicate the onset of gingivitis.

In vitro measurement of a sample obtained from a specific gingival site is a preferred method of the present invention. The sample collection may be accomplished in many ways, but preferred is flushing a region with fluid and then micropipetting a sample of fluid directly from the site of the gingival surface, or more preferably swabbing the gingival site. It is also preferred for these in vitro measurements that the subject to be diagnosed rinses his mouth or brushes his teeth within one hour prior to sample collection. The sample collected may be applied directly to a commercially-available leukocyte esterase reagent strip but preferably the sample is diluted to a certain volume and then the dilute sample is tested by dipping the reagent strip into the solution or by applying some of the solution to the reagent strip.

In vivo measurements of leukocyte esterase present in the oral cavity may be accomplished by testing the saliva in the mouth or by measuring the leukocyte esterase activity at specific gingival sites. These in vivo measurements are preferably accomplished by utilizing a diagnostic product of the present invention or a suitable diagnostic kit of the present invention, both described more fully hereinafter. The in vivo measurement of saliva typically involves placing the diagnostic product of the present invention, or the appropriate component of the diagnostic kit of the present invention, into the mouth so that it is bathed with saliva. The in vivo measurement of specific gingival sites preferably involves contacting the diagnostic product of the present invention, or the appropriate component of the diagnostic kit of the present invention, with the gingival site being evaluated. Typical in vivo contact time is about 0.1 to about 60 seconds followed by removal of the diagnostic product or kit component for observation (e.g., for a color change) or further manipulation (e.g., in the case of a kit, preferably to develop a color change).

The present invention also relates to diagnostic products useful in vivo for detecting or evaluating the presence of periodontal diseases in humans. These diagnostic products comprise at least one agent useful in detecting the presence of leukocyte esterase, and a carrier material. Furthermore, since these diagnostic products are to be utilized in vivo in humans, these diagnostic products must be sterile and safe for in vivo contact with the tissue of the oral cavity, especially gingival tissue, of a human.

The term "agent useful in detecting the presence of leukocyte esterase", as used herein, means an organic or inorganic compound, composition, or combination thereof which is changed by the action of leukocyte esterase or is bound by leukocyte esterase or is otherwise modified in the presence of leukocyte esterase such that the presence of leukocyte esterase can be detected, preferably quantitatively or semi-quantitatively, as a result of this change, binding, or other modification.

Preferred agents useful for detecting the presence of leukocyte esterase are esters hydrolyzable by leukocyte esterase. More preferred are esters which are hydrolyzable by leukocyte esterase to produce a color or change color. This color or color change may be the result of either: (a) one or more of the ester hydrolysis products themselves; or (b) one or more of the ester hydrolysis products combining with one or more other materials (which may or may not be present in the diagnostic product) to produce a color or color change. Most preferred are indoxyl carbonic acid esters which are hydrolyzed by leukocyte esterase to form indoxyl. Such esters are utilized in the commercially available leukocyte esterase reagent strips.

By the diagnostic products of the present invention being "safe for in vivo contact with the tissue of the oral cavity of a human", as used herein, is meant that the agents useful in detecting the presence of leukocyte esterase and the carrier materials are safe to be in contact with the tissue in the oral cavity of a human, or if not safe to be in contact with the tissue in the oral cavity of a human then they are safely isolated within the diagnostic product so that they cannot contact the tissue in the oral cavity of a human, as determined by sound medical judgment (at a reasonable risk/benefit ratio). Most preferred is that all the agents useful in detecting the presence of leukocyte esterase and all the carrier materials themselves are safe.

The present invention further relates to diagnostic kits useful for detecting or evaluating the presence of periodontal diseases in humans. These kits comprise separate means for collecting a sample of fluid at one or more oral tissue sites (especially gingival sites) in a human being diagnosed, and means for measuring the amount of leukocyte esterase present in the sample collected.

The phrase "means for collecting a sample of fluid", as used herein, means any device or apparatus or product which is useful for removing a sample of fluid (which may also include solid tissue matter) from the oral cavity for further analysis without adversely affecting the

ability to detect the presence of leukocyte esterase activity in the sample of fluid collected. Non-limiting examples of such means are swabs, pipettes, syringes, absorbent tapes, absorbent gauzes, absorbent strips, scoops, suction bulbs, and aspirators. Preferred means are swabs and absorbent strips. Absorbent strips useful in the kits of the present invention may also be diagnostic products of the present invention which contain the agent useful in detecting the presence of leukocyte esterase, but which must be mixed with a chromogenic material after removal from the mouth to indicate the presence of leukocyte esterase activity. Thus, a kit of the present invention may comprise one or more diagnostic products of the present invention.

The phrase "means for measuring the amount of leukocyte esterase", as used herein, means a machine or product or device or combination thereof which is capable of showing the presence of leukocyte esterase in a sample of fluid collected as described hereinbefore. Preferably, such means are capable of quantitatively, or more preferably semi-quantitatively (especially by color change), indicating the amount of leukocyte esterase present in the sample collected. Non-limiting examples of such means are leukocyte esterase reagent strips comprising indoxyl carbonic acid esters; and solutions containing chromogenic material.

The kits of the present invention are manufactured such that the means for collecting a sample of fluid and the means for measuring the amount of leukocyte esterase are separate components in the kits, and these essential components plus any optional components to be utilized with the kits (e.g., test tubes for diluting samples in; bottles containing dilution fluid for diluting samples; instruction sheets; etc.) are combined into one package. An example of such a package is a box which is shrink wrapped with plastic.