SPECIFIC EXAM INSTRUCTIONS TABLE OF CONTENTS

C. Instructions Specific to this Particular Exam

1. Structure

The final examination is designed to be three (3) hours in length. It consists of three sections, each of which presents an independent problem, issue, or opportunity to discuss policy (or, some mixture of all three). Each section has a particular unique focus, and is worth a different amount of the total points available on the examination. The point weights are given in the table of contents immediately above on this page.

2. Suggested Time Allocation

The emphasis of this examination is roughly proportional to the emphasis of the areas of intellectual property law covered in class.

Given the point percentages for the three sections disclosed above, one logical division of time in a three hour (3) examination is to spend 30 minutes reading the examination sections and planning one's answer. Then, the remaining time would be spent as follows: 68 minutes writing the analysis for the first section worth 45% of the points; 45 minutes writing the analysis for the second section worth 30% of the points; and 37 minutes writing the analysis for the third section worth 25% of the points.

If one instead read each section and wrote the answer for that section before going on to the next section, the suggested total time allocation for each section would be: 80 minutes for the first section worth 45% of the points; 55 minutes for the second section worth 30% of the points; and 45 minutes for the third section worth 25% of the points.

3. BlueBook Use

Start a new bluebook before beginning your analysis of each major area or logical subdivision. This means that you should use a new BlueBook (or, if typing and allowed by the exam taking software, use its mechanisms to create a page break) before your analysis of each section.

Remember to put your personal identification number on the cover of each bluebook.

4. Read the Assignment Section in Advance

It is ***highly recommended*** that you read the "Assignment" section first, before reading the other sections of the examination, and before you begin. The "Assignment" section is the portion of the examination made available before the exam date via the class web page.

5. Starting and Stopping the Exam

The actual examination sections describing the case/dispute/problem/issue has six (6) pages.

Without looking at the content of the examination problem(s), please count your pages now to ensure that your examination is complete. If not, notify the proctor immediately.

A proctor will provide "warning" that the end of the exam period is approaching by writing on the board in the exam room(s) the amount of time remaining at approximately the five minute mark.

When time is called, stop writing immediately.

DO NOT TURN THE PAGE UNTIL YOU ARE INSTRUCTED TO DO SO.

II. ISSUE ANALYSIS SECTION (45%)

Under a U.S. law passed in the mid-1990s and codified at 35 U.S.C § 287(c), every U.S. patent issued on an application having an "effective filing date" on or after Sept. 30, 1996, is limited in available remedies if a "medical practitioner" undertakes "medical activity" covered by the patent.

> [T]he term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.[1]

The law exempts "medical practitioners" and "related health care entities" from suit, injunction, damages, and attorneys fees for such "medical activity."[2] However, § 287(c) does

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[1] 35 U.S.C. § 287(c)(2)(A).

In essence, "medical activity" statutorily means certain surgical or other wide-ranging medical processes or procedures, such as, hypothetically: a method of administering anesthesia (assuming the anesthetic compound was not patented – see clause (i) & (ii) of § 287(c)(2)(A)); or a method of making a particular incision in such a way that the natural tissue pattern will keep the incision closed for self-healing without sutures/stitches.

In addition, for the patented use of the patented composition of matter discussed in clause (ii) of § 287(c)(2)(A) to fall into the carve-out from "medical activity," the composition of matter must "directly contribute to achievement of the objective of the claimed method."

Finally, a note on nomenclature: quoted terms used in these footnotes and associated text discussing the § 287(c) issue are statutory phrases/language. The problem envisions that all relevant statutory language has been provided or paraphrased sufficiently to analyze the issue.

[2] Other relevant terms are defined as follows, using paraphrasing of the statutory definitions: (i) "medical practitioner" is a natural person licensed by a State of the U.S. to perform "medical activity;" and (ii) "body" means a human body, or a non-human body used for research. On the other hand, however, "biotechnology" is not defined under § 287(c).

In addition, the following definition may be relevant:

> [T]he term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home,

not apply to any person or entity "engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter." Moreover, it does not apply to any activities: (i) that are "directly related" to such "commercial development, manufacture, sale, importation, or distribution;" and (ii) that are subject to any of several U.S. acts relating to health, drugs and clinical testing, some of which are administered by the U.S. Food and Drug Administration (FDA) in its capacity as the regulator for prescription drugs and medical devices requiring marketing approval.

Worried about loss of rights, the European Medical Association (EMA), a physician-member group, caused the EU to cause the WTO DSB to create a panel to review § 287(c). The EMA alleges that since enacted, § 287(c) has violated TRIPS.

Traditionally, in the U.S., there was scant litigation against medical practitioners asserting patented method claims, although medical procedure patents have issued from the U.S. PTO for over 100 years, and during the 1990s at an estimated rate of fifteen per week to doctors.[3] Although litigation has been scant, § 287(c) arose from the publicity associated with a case of one doctor suing another in the early 1990s over a patented procedure used in cataract surgery.

Practices in Europe, in contrast to the U.S., have been different: the rate of patenting surgical/medical procedures is three times that in the U.S., adjusted to a per-physician basis; and litigation to exclude others' use of the claimed procedures is commonly successful. However, this occurs in an environment where most physicians work as employees, rather than as independent practitioners, which is the dominant model in the U.S. Also potentially relevant is that the American Medical Association (AMA) has had a long-standing working group lobbying in the U.S. for laws or regulations prohibiting chiropractors, nurse practitioners and physicians assistants ("Lesser-Practitioners") from undertaking most medical procedures, on the alleged policy grounds that their training is insufficient to safely perform the procedures. An internal

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hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic. § 287(c)(2)(C).

[3] Most physicians obtain these patents as an outgrowth of their research, which they undertake primarily to enhance their reputation and obtain referrals.

document of the AMA working group from the early 1990s (before § 287(c) was enacted) advocated the strategy of encouraging physicians to obtain more patents on medical procedures, and then enforce them against Lesser-Practitioners (but not against other doctors) in order to guarantee patient safety. Among the group of Lesser-Practitioners and doctors, Lesser-Practitioners comprise approximately 15% of the total in the U.S.[4]

Finally, one universally respected commentator, discussing § 287(c), noted the following.

> The overwhelming majority of patents in [the fields related to "medical activity"] are owned by the biotechnology and pharmaceutical industry, and the companies in that industry do not sue medical practitioners performing medical activities, as those terms are defined in the new subsection. . . .
>
> Significantly, the agreed-upon compromise will have no effect on what is patentable under 35 U.S.C §101 and no effect on what constitutes an infringement under 35 U.S.C §271. Moreover, the new subsection (c) to 35 USC §287 appropriately and specifically exempts the commercial activities of biotechnology, diagnostic and pharmaceutical companies and does not limit in any manner their ability to enforce their patents against their competitors.

Articulate the likely analysis of the § 287(c) WTO dispute by a DSB panel, discussing arguments from the multiple relevant party-perspectives on the issue.[5]

III. DOCTRINE-APPLICATION "IRAC" SECTION (30%)

ACME-Hobart Corp. (AHC) manufactures writing instruments. It is headquartered in France but distributes its products in many countries in Europe and the Americas. For many years in France it has sold a pen under the mark "Créature." Besides the word mark on the pen, customers world-wide identify the AHC Créature pen by a smiling, bright-pink,

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[4] Even if you know that the facts recited in this paragraph are not the true real-world situation or views of the recited groups, take these facts as true for this examination problem.

[5] Do not factor into the analysis any possibility of contributory infringement by, or inducement of infringement by, the "medical practitioner" user.

monster-resembling creature molded into the length and shape of the pen body.[6] The monster-resembling creature ran the length of the pen; it was as if one was writing with a petrified version of the creature, except on one end there was a ball point pen, and a "clicker" on the other end to retract/extend the ball point. In Europe, the pen was popular with professionals and teenagers alike, the former group using it as a symbol of being "hip." AHC has distributed the pen throughout Canada in large volume for many years under the mark Créature, but prior to 2002 it never obtained trademark registration for either the word mark or the monster-resembling creature in either Canada or the U.S. (although it had both registrations in France and many other countries).[7] In Canada, the main purchasers were teenagers, who delighted in the pink monster-resembling creature. Reliable surveys show that approximately 15-20% of the pens distributed in Canada made their way into the U.S. via travelers across the busy U.S.-Canadian border.

In late 2001, to enter the U.S. market for the first time, AHC negotiated a distribution agreement with a U.S. distributor. It made its first shipment of pens to the distributor in August 2002, and sales to U.S. teenagers proceeded at a brisk pace in September 2002. Shortly thereafter, in October 2002, AHC filed for a U.S. trademark registration for the word mark Créature as applied to the pen.

The U.S. PTO held up AHC's registration when it discovered another pending application for pens for the word mark e-Criture.[8] The application was held by Novelty Pens,

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[6] In a reliable survey of every country where AHC distributed the pen during the 1990s, using a statistically significant sample of the relevant market, when customers were shown AHC's monster-resembling creature apart from a pen apparatus, but in the same approximate size, customers responded as follows when asked what came to their mind when they saw the creature: 85% said they thought of the pen; 12% said they thought of some type of animal (including lizards, mongooses, and many others); and 3% said they were unsure. In a similar reliable survey to the same markets showing customers the word mark Créature: 45% thought of the pen; 35% exclaimed in alarm "I don't see any creature!;" and 20% said they were unsure.

[7] In every jurisdiction, AHC has disclaimed any copyright protection that might attach to the monster-resembling creature.

[8] In its report on AHC's application, in discussing the e-Criture mark, the PTO noted that in the French language the word "écriture" means "a writing."

Inc. (NPI),[9] who applied in July 2002, asserting a date of first use during May 2002. NPI's pen under the e-Criture mark was a bright red, monster-resembling animal shaped very similar to AHC's creature. The pen had electronic capabilities, thus the "e-" designation at the beginning of NPI's claimed mark: the pen would sound out a monster howl every time the user clicked the clicker to retract/extend the ball point.

Realizing that its Créature mark is experiencing difficulty in registration, AHC sues NPI under § 43(a) of the Lanham act for infringement of its alleged mark in the monster-resembling creature shape.[10]

Articulate the probable analysis of the likelihood of confusion inquiry: (i) that the PTO must undertake for the word mark and whether it should find barriers to protection of AHC's word mark in the U.S.; and (ii) that the court must undertake for the shape mark infringement suit.

IV. POLICY ANALYSIS SECTION (25%)

Law Professor Lance Protecian has two proposals relating to U.S. and international copyright and related (neighboring) rights law. Protecian has been increasingly concerned with his perception that IP rights have expanded without bounds principally to the benefit of large multinational industrial and commercial conglomerates or cartels. He is sure that authors and artists have been unable to take advantage of this expansion of IP rights, and that the large commercial entities principally use the expanded rights to harvest from the public domain that which they did not sow (at least in full) – enclosing the intellectual commons into a pay-per-access/use model.

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[9] NPI is a two-store operation, one located in Florida and the other in Michigan. It specializes in creating and selling pens in the shape of animals, both real and imaginary. It primarily sells from its stores, but it makes some shipments via mail to other locations all over the U.S. Reliable surveys in Florida and Michigan of the word mark "e-Criture" showed that only 6% of the relevant market identified the mark with NPI's pen. Reliable surveys over the entire U.S. dropped the recognition percentage to 1%.

[10] In the suit, NPI waives the defense that the creature shape is functional because NPI hopes to emerge victorious as the senior U.S. user of both the word and shape mark, and it does not want to be on record as arguing that the shape is functional if it later has to sue others.

Protecian proposes two measures to react against this trend he sees as disturbing:

(i) Protecian is worried that the recently proposed U.S. database bill[11] will be enacted into law, further expanding IP rights and allowing further exploitation of those rights by those with extensive financial resources. Protecian wants to blunt the effect of the bill should it be enacted. He reasons that one of the main purposes of the bill is for U.S. nationals to be able to obtain protection under the database protection laws of European countries.[12] Thus, Protecian reasons, why not simply have the database bill apply in the U.S. only for databases owned by foreign nationals. To satisfy Europe, database protection need not extend to U.S. nationals. Thus, at least some of the worlds' databases will remain "free" and unencumbered by over-expansive IP protection.[13]

(ii) To help the "little guy" author and artist, Protecian proposes an amendment to TRIPS Art. 9(1). It currently exempts compliance with Berne 6bis. Protecian would amend TRIPS Art. 9(1) to require that countries implement Berne Art. 6bis so that authors and artists have the power to protect the attribution and integrity of their works. Protecian reasons that this will change the bargaining power between authors and artists and the large conglomerates, enabling less concentration of IP rights and therefore, while providing greater IP protection overall, less abuse of it by large entities with the power to consolidate and exploit IP rights.

Critique from a policy perspective each of Protecian's proposals. Would you endorse his proposals, reject them, or implement them in altered form?, and if so, how would you alter them? Will they solve, in part or in whole, the problems that concern Protecian?

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11 The "Database and Collections of Information Misappropriation Act of 2003" from class.

12 The EU database directive conditions protection in European countries for foreign nationals on reciprocal protection for works of European nationals in the country of the foreign national seeking protection.

13 Under Protecian's logic, a similar mechanism currently exists in U.S. copyright law – while U.S. nationals must register a copyrighted work before bringing suit, foreign nationals need not do so, and this arrangement is in compliance with Berne, and Berne as incorporated by TRIPS (indeed – it is in-part demanded by Berne's prohibition against formalities).

V. THE ASSIGNMENT

Write an analysis for each of the issue(s) raised by the facts or information enumerated in the examination sections. At the end of each section the focus or "call" of the question is given in a short paragraph enclosed in a rectangle.

Organize your written answer logically by the three sections of the examination. Your written answer does not need a general introduction. Proceed immediately to analyzing the issues, problems or questions in each section

The sections vary in the degree to which they suggest incorporating policy analysis. One section, the third, overtly suggests policy analysis. Another, the second, explicitly suggests traditional IRAC analysis: Issue, Rule, Application and Conclusion. The first section calls for elements of both types of analysis within a particular framework studied in class.

1. "Policy" Analysis

The policy oriented section is designed to allow one to employ some of the various policy arguments that arose during the class. These arguments include, without limitation: institutional considerations for the various treaties, structures and organizations underlying the international IP system; effects and causes of these structures and systems; efficacy, reliability, fairness and justification of the international IP system; and the impact of all this on individuals, companies, countries, and regional trade groupings or other regional divisions. This listing, however, is not necessarily a good way to organize the analysis. A productive organization of the analysis depends on the context of the problems, disputes or questions posed in the policy-oriented section.

Application and deployment of these and other arguments is the emphasis of the "policy" section. Some may view the question(s) in the "policy" section as having two "sides" along political or other ideological lines. Even assuming this view, however, an answer does not earn points by picking the "right" or "best" side of the issue, but rather by effectively marshalling arguments for the two (or many) facets of the issue.

The "policy" section, however, is not completely divorced from the doctrine studied in class. Question(s) in the "policy" section may require the application of, or recognition of, the doctrine studied in class to specific fact patterns.

2. Issue and IRAC Analysis

The analysis in these sections should communicate the following as briefly as possible based on the facts available and the law, principles and policy discussed in class: (i) discuss the arguments, positions or IP rights that should be asserted, or have been asserted,[1] by the parties; (ii) evaluate the arguments and substantive merits from each party's perspective, articulating

[1] The examination question in certain sections is written in such a way that certain issues are clearly "in" the problem or case/dispute because they have been articulated or strongly suggested by the facts. You should analyze these issues, but there may be other issues to be analyzed as well that are not yet asserted by either side. In addition, the examination question in these sections may also indicate that certain other possible issues are "out" and not to be analyzed because the parties disclaim certain issues or protections.

defenses and counter-arguments each should/might assert; (iii) assess the strength of each party's arguments; and (iv) determine for each issue who is likely to prevail and explain why. Your written answer, however, should not be organized according to these four points.

Rather, for each issue, your analysis should communicate the issue, and then state/apply the law (element by element) to the issue's facts (applying counterarguments as well), and then conclude on the issue. An exception to this is that there is no need to restate a legal test that has already been stated; simply refer to the previous statement of the rule. For example, if there is a second trademark infringement issue, and you have already related the infringement likelihood of confusion factors for an earlier issue, you can abbreviate your analysis by directly applying the law to the facts and concluding. Another way to say this is that if a second issue arises where there is a need to apply a legal test already related and discussed, you may analyze the second issue by exception, i.e., discussing the differences in application and outcome.

If you believe that there are any additional critical yet unsupplied facts that would materially impact the outcome of a particular issue, you should note what such facts would be. In such case, ***briefly*** describe how such critical facts might impact the outcome, i.e., indicate ***at most one and only one*** differing result that would ensue from different reasonable factual assumptions about such unsupplied facts.[2]

In addition, as a general matter, discuss any invalidity/protectability issues that may be presented before any infringement issues. For example, if you find yourself discussing a patent law infringement issue, discuss any invalidity issues before any infringement issues.

If the facts note that any issues are to be adjudicated in a U.S. court, the location of final jurisdiction and/or venue for the expected case/dispute is unknown at this time, except that it will be in federal court.

You should analyze clearly presented (either explicitly, or by the facts) infringement issues in the case/dispute even if your analysis determines that the relevant item of intellectual property is invalid, unenforceable or not properly the subject matter of protection. An example of this principle in trademark law is the assertion of product shape/design as a mark, but where the trademark defendant might have a functionality defense. In a real court opinion, if the court holds that the defendant wins on the functionality issue, the court might not analyze the likelihood of confusion test to determine if the accused product shape infringes the product shape/design allegedly functioning as a mark. Your analysis, however, unless the facts clearly indicate otherwise, should evaluate both the functionality defense and infringement if clearly presented: even if you conclude that the shape/design is functional and thus not the proper subject matter of protection as a mark, go on to analyze whether the likelihood of confusion test is met for infringement of the shape/design mark. Similar examples exist within other areas of IP.

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[2] Please note that if you find yourself discussing alternative outcomes for supposedly critical yet unsupplied facts for every issue you analyze, you are probably engaging in too much analysis of such alternative outcomes.