

Patent Law

Winter 2020

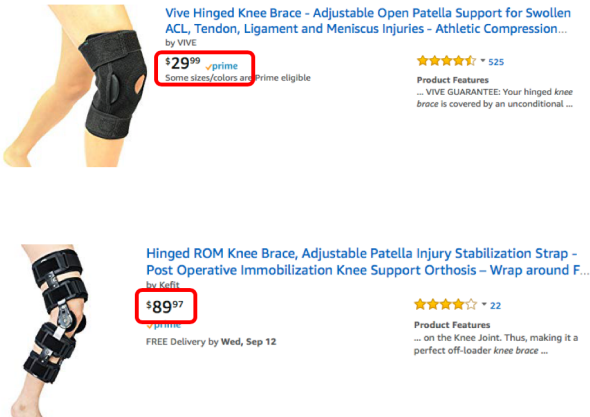
Professor William Fisher and Professor Ruth Okediji

1. This is a four-hour, in-class, open-book examination. It will be administered from 9:00 a.m. to 1:00 p.m. on January 24, 2020.
2. The exam mode is OPEN + NETWORK. This means that, during the exam, you may consult any material you wish. The only thing you may not do is consult in any way with any other person during the exam.
3. The exam contains two questions. Your answer to question #1 may not exceed 2000 words. Your answer to question #2 may not exceed 1500 words.
4. Your answers to the two questions will be given equal weight when determining your final grade.
5. Exam4 will automatically put your Anonymous ID and word count on the exam copy. Do not write your name on any part of your response. To preserve the anonymity of your response, avoid including any information that would enable the instructor to identify you.

DO NOT TURN TO PAGE TWO UNTIL THE PROCTOR TELLS YOU TO BEGIN.

Question #1

As you learned in the first lecture in this course, knee braces are commonly used by athletes to prevent – or compensate for – injuries to their knee ligaments. A wide variety of such braces are currently on sale in the United States, most of them for modest prices. A few are depicted below.



The Armor brace manufactured by Donjoy is widely considered the best knee brace. It is much more expensive than the rest.



DonJoy Armor Knee Support Brace with FourcePoint Hinge: Standard Calf Length, Right Leg, X-Large by DonJoy
★★★★☆ 5 customer reviews | 10 answered questions



About the product



- Treat or prevent moderate to severe ACL, MCL, and LCL instabilities, recovery from ACL reconstructions, and hyperextension prevention
- Combines DonJoy's proven 4-Points-of-Leverage System, along with patented FourcePoint hinge technology
- Designed for athletes involved in extreme or contact sports, who don't want to sacrifice speed

Price: **\$496.32** ✓prime
FREE Delivery Thursday, Sept. 27 - Wednesday, Oct. 17 Details
Usually ships within 1 to 2 months. Ships from and sold by Amazon.com.

2 Styles: Standard Calf Length, Right Leg
 
 \$519.99 ✓Prime \$496.32 ✓Prime

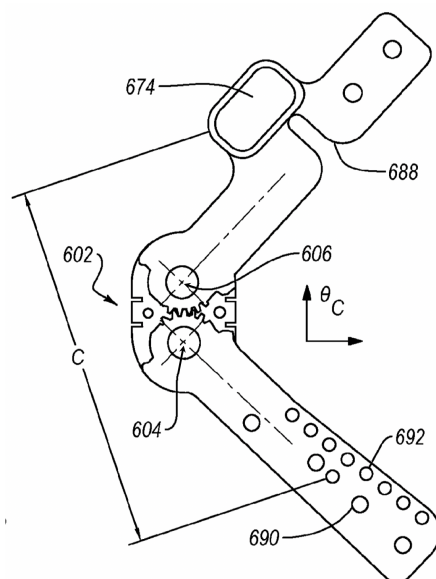
5 Sizes: X-Large
 Small Medium **X-Large** ▾
 \$549.99 \$549.99 ✓Prime **\$496.32** ✓Prime

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Qty: 1 ▾

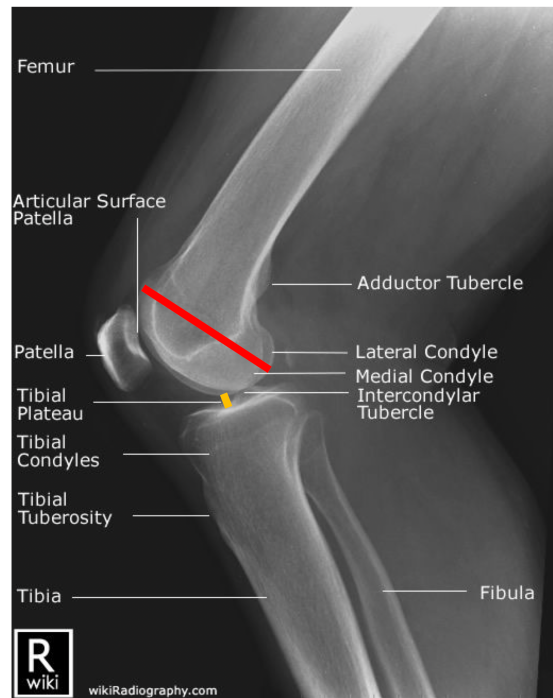
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Donjoy is able to maintain this high price because the essential features of the Armor brace are protected by a patent – specifically, US Patent 6,623,439 (hereinafter, the ‘439 patent). That patent will expire on August 8, 2021. Donjoy fears that, on that date, competitors will begin making braces identical to the Armor and selling them at much lower prices, which in turn will corrode Donjoy’s profits.

In hopes of preserving its market share and profit margin after the expiration of the ‘439 patent, Donjoy has spent several years exploring ways of improving the technology underlying the Armor brace. One avenue of experimentation proved especially fruitful. For many years, most brace makers have included in their products “polycentric hinges” – so called because they incorporate two pivot points instead of one. Interlocking gears coordinate the movement of a polycentric hinge around its two axes. The advantage of this structure is that it enables the rotation of the brace to mimic the natural flexing of the knee more closely than a hinge with a single pivot point. A drawing of such a polycentric hinge appears below. The two pivot points are identified by numbers 604 and 606.



Donjoy’s Armor brace includes such a hinge. All models of the Armor use the same size hinge. In 2015, it occurred to Ingrid, an orthopedist employed by Donjoy, that knees come in various shapes and sizes and thus, ideally, the distance between the pivot points in each brace hinge would match each customer’s physiology. Working closely with 10 members of the US Women’s national soccer team who had suffered knee injuries, Ingrid tried several ways of measuring knees to determine the optimal hinge configuration. By July of 2016, she concluded that the optimal distance between the two pivot points could be determined by (a) measuring the maximum width of the knob at the end of the femur (shown in red in the x-ray below); (b) multiplying that width by 0.38; and then (c) adding the height of the gap between the femur knob and the tibial plateau (shown in orange in the x-ray below).



In August of 2016, Ingrid equipped the 10 players with custom braces, each of which incorporated a hinge built according to the formula set forth above. The players then used the braces in international competition. At the end of the season, all of the players reported that these were the best braces they had ever worn.

On October 1, 2017, Donjoy filed for a US patent embodying the invention. The crucial claim in the application is set forth below.

What is claimed is ... a knee brace for supporting a knee joint, said knee brace comprising a substantially rigid upper member for attachment to a thigh, a substantially rigid lower member for attachment to a calf, and a polycentric hinge joining the upper and lower members;
 wherein the two pivot points of said polycentric hinge are separated by a distance more than 90% and less than 110% of: $[0.38 \times \text{the maximum lateral distance of the lower end of the femur (as shown)}] + [\text{the distance between the lower end of the femur and the tibial plateau (as shown)}]$ of the person upon whom the brace will be used.

While the application was pending, Donjoy began selling custom braces built using Ingrid's formula. (Each customer provided Donjoy with an x-ray like the one set forth above, which Donjoy used to determine the optimal hinge size.) The price of a custom brace is \$2000. Despite the high price, the braces have proven to be popular.

On January 1, 2020, Donjoy's patent application was granted.

Sturdy Sports (“Sturdy”) manufactures and sells knee braces in the United States. The managers of Sturdy have long admired the Donjoy braces and envied Donjoy’s market share and profits. They plan to begin manufacturing and distributing braces identical to the Armor brace as soon as the ‘439 patent expires. But they are worried that they will not be able to compete effectively with Donjoy unless they can also employ Donjoy’s new business model of offering custom braces with hinges sized to match each customer’s knees. Against this backdrop, Sturdy’s managers are currently considering two courses of action:

- (a) Starting on August 8, 2021, make and sell custom braces using the same formula and the same procedure now being used by Donjoy for its custom braces; or
- (b) Starting on August 8, 2021, sell replicas of the Armor brace with five different hinge sizes, permitting customers to try them on and select the model that best fits their individual knees.

You are working for a law firm that specializes in patent litigation. The General Counsel of Sturdy has asked a partner in the firm for an opinion letter concerning the likelihood that one or both of the plans being considered by Sturdy will give rise to liability for patent infringement in the United States. The partner has asked you to prepare the first draft of the opinion letter and to address any additional concerns you might have. If you need additional information to analyze any of the issues you think are implicated by this case, say what that information is and why it matters. Your draft may not contain more than 2000 words.

(This narrative is an altered version of a real set of business practices. If you know or learn anything concerning the true state of affairs, you should ignore that knowledge when preparing your answer.)

Question #2

In an essay containing no more than 1500 words, answer one and only one of the following two questions:

A.

In view of recent reports suggesting a decline in US technological competitiveness in key areas such as wind and solar technology, and with increasing concern over China's rising administrative sophistication in patent matters, Congress has determined that changes to US innovation policy are needed to strengthen US leadership in a rapidly changing global environment. A congressional committee has been formed to suggest proposals for, among other things, improving the US patent system.

Members of Congress have advised the President that any effort to amend US patent law must address the question of appropriate protection for genetic resources and traditional knowledge (GRs/TK), an issue on which the US has mounted significant opposition at the World Intellectual Property Organization (WIPO).

Two issues have been particularly controversial at WIPO: (i) whether patents with claims based on unauthorized access and use of GRs/TK should be revoked and; (ii) whether there should be a new mandatory obligation for patent applicants to disclose the origin (DOO) of the GRs/TK utilized in an invention.

The US pharmaceutical industry is vehemently opposed to both agenda items. The industry argues that recognition of exclusive rights to GRs/TK will undermine US innovation for the foreseeable future. Industry leaders argue that the US should treat this knowledge as prior art but with no patent defeating effect. They further oppose the idea that international GRs/TK holders or Native American tribes should be entitled to benefit sharing from patent royalties.

The Chair of the congressional committee has written to the USPTO concerning these matters. Her letter notes that a number of OECD countries have adopted a DOO requirement for patent applicants and that the committee "is curious to hear from the USPTO whether such an obligation is also needed in US patent law to improve transparency and reduce the incidence of erroneously granted patents." The letter further asks the USPTO to provide an opinion on aspects of the GRs/TK negotiations at WIPO that might usefully be leveraged to catalyze desirable changes in US innovation policy.

You are the senior policy officer at the USPTO overseeing the Office's response to the congressional committee. Members of your staff have pointed out an irony in the longstanding US position: the world is losing biodiversity at an alarming rate and many drugs derive from natural substances. New drug development is reliant on fairly unfettered access by scientists to biological resources. The staff opine that it is important to incentivize countries to provide such

access, and consequently that economic returns to GRs/TK holders should be part of a negotiating package at WIPO that the US should support.

As to the DOO issue, the staff point to examples of disclosure obligations in US law. For example, the Bayh-Dole Act includes a disclosure requirement, found in 35 U.S.C. §202(c)(6), that requires federal funding agreements to include:

“[a]n obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, *a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.*”

The staff believe that a DOO is consistent with this and other existing disclosure obligations related to US patent applications.

If the US agrees to a mandatory international DOO obligation, should it be designed as a property or liability regime? What tradeoffs are likely to be involved for US innovation policy? What alternative policy levers might the US consider for these two questions?

B.

The winner of the 2020 presidential election is deeply concerned about the state of US innovation policy, and is interested in implementing changes that will stimulate the development of technologies that will benefit the environment (e.g., wind and solar power), reduce the costs of pharmaceutical drug development, and in general restore US dominance in technological innovation.

Review the diagram on the following page depicting various policy levers that might be deployed by the US government. Which of these levers would you propose that the new administration prioritize to accomplish the objectives outlined above?



Management of the pace and direction of innovation

Red = rules or policies; Green = lines of influence; purple = tangible benefits

