

## Trick or Treat? How a U.S. Patent Over a Method for Processing Sugarcane Wrongly Alarmed the Colombian Panela Industry

Carter Ostrowski

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TRICK OR TREAT? HOW A U.S. PATENT OVER A METHOD FOR  
PROCESSING SUGARCANE WRONGLY ALARMED THE  
COLOMBIAN PANELA INDUSTRY

*Carter Ostrowski\**

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I. INTRODUCTION

A sweetener with many names — Indian muscovado, Mexican piloncillo, African and Asian jaggery, and Colombian panela — this unrefined, non-centrifugal cane sugar has been a staple product across the world for centuries.<sup>1</sup> No country's constituents appreciate this delicacy

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1. J. Kenji López-Alt, *Making Panela at a Colombian Sugar Mill is Still a Low-Tech Affair*, SERIOUS EATS (Aug. 10, 2018), <https://www.serious eats.com/2015/01/making-panela-colombian-sugar-mill-low-tech.html>.

more than those of Colombia.<sup>2</sup> Colombia is the runner-up in global panela production and the world leader in panela consumption per capita.<sup>3</sup> On average, each Colombian citizen consumes over seventy pounds of panela each year.<sup>4</sup> Beyond its use in cakes, pastries, and coffees, Colombians dissolve panela in hot water to create aguapanela.<sup>5</sup> Served hot or cold, often with lime, aguapanela is a significant source of calories for working Colombians.<sup>6</sup> Additionally, aguapanela mixed with ginger is used for medicinal purposes because of the purported health benefits of its trace vitamins and minerals, which are byproducts of panela's crude production method.<sup>7</sup>

In 2020, the United States Patent and Trademark Office (the "USPTO") issued U.S. Patent No. 10,632,167 ("the '167 Patent") for producing policosanol-rich sugarcane juice, which looks to capitalize on panela's purported health benefits.<sup>8</sup> To produce that juice, the '167 Patent describes a production method that closely resembles traditional methods used to make panela.<sup>9</sup> Because patents grant their owners exclusionary rights over the practices claimed by the patent, Colombian panela producers are concerned that the '167 patent will upend their way of life.<sup>10</sup> This Comment analyzes the validity of the '167 patent and its potential impact on the Colombian panela industry. Part II provides an overview of the Colombian panela industry, the U.S. patent law system, relevant Colombian law, and the '167 Patent. Although Colombian patent law is discussed, this Comment primarily focuses on the U.S. patent law system. Part III discusses why the '167 Patent would likely be upheld if its validity was challenged in a court of law and, if upheld, why the '167 Patent may not affect Colombian panela producers. Finally, Part IV emphasizes the limits of the patent system and the importance of having a sound scientific basis when filing an application for patent.

## II. BACKGROUND

Patent litigation is one of the most expensive types of litigation because

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2. *Id.*

3. *Id.*

4. Kirsten Begg, *Aguapanela: The Truth*, COLOMBIA REPS. (Mar. 12, 2009), <https://colombiareports.com/aguapanela/>.

5. Jennie Erin Smith, *Colombians Ask: Who Would Dare Patent Panela?*, N.Y. TIMES (Jan. 26, 2021), <https://www.nytimes.com/2021/01/26/science/colombia-panela-patent-gonzalez.html>.

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

there are so many layers to each case.<sup>11</sup> The current issue is no exception. Determining whether Colombian panela production would infringe the ‘167 Patent requires analysis of Colombian panela’s deep-rooted, traditional method of production as well as the intricacies of U.S. patent law and overlapping international and foreign law. First, Section A of this Part discusses panela’s significance to Colombians and its traditional method of production. Second, Section B provides a brief overview of the U.S. patent system. Third, Section C summarizes Colombian patent law and other Colombian laws relevant to panela production. Finally, Section D walks through the ‘167 Patent and its controversial scientific foundations.

### A. *The Significance and Production of Panela*

Panela is more than a diet staple to Colombians; it’s an irreplaceable source of income.<sup>12</sup> The panela industry makes up nearly twelve percent of the Colombian workforce and is one of the main sources of income for more than 70,000 Colombian families.<sup>13</sup> Through both its direct and indirect impact, the panela industry affects 350,000 Colombians and accounts for approximately 6.7% of Colombia’s agricultural gross domestic product.<sup>14</sup> Further, it is estimated that over 98% of Colombian panela is consumed domestically, with only around 0.4% exported and the remaining used as input for industrial processes.<sup>15</sup>

The process of making panela has gone essentially unchanged since sugarcane was first brought to South America in the sixteenth century.<sup>16</sup> That process begins in one of the over 200,000 hectares of Colombian sugarcane fields.<sup>17</sup> Couriers, or cutters, chop down mature sugar cane stalks by hand.<sup>18</sup> A *carguero*<sup>19</sup> then stacks the chopped stalks onto the backs of donkeys and mules and accompanies it back to the *trapiche*<sup>20</sup>

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11. JANICE M. MUELLER, *PATENT LAW* 30 (Rachel E. Barkow et al. eds., 6th ed. 2020).

12. Gonzalo Rodríguez et al., *Panela Production as a Strategy for Diversifying Incomes in Rural Area of Latin America*, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS [FAO] (2007), <https://www.fao.org/3/ap307e/ap307e.pdf>.

13. *Id.*

14. *Id.*

15. *Id.*

16. Dennis Bejarano, *Panela’s Bitter Future*, SLOW FOOD (July 23, 2015), <https://www.slowfood.com/panelas-bitter-future>.

17. Begg, *supra* note 4.

18. Smith, *supra* note 5.

19. A *carguero*, or freighter, is an “operator who lifts and accompanies the sugarcane in the transport, which takes it from the batch to the sugar mill, generally it is done on the mules and the sugar cane from the sugar mill to the loading point.” *Carguero*, PANELERO INFO. SYS. (Apr. 2, 2019), <http://www.sipa.org.co/wp/index.php/glossary/carguero/>.

20. A *trapiche* is the place “where sugarcane is processed to turn it into honey or panela.” *Trapiche*

where the panela is made.<sup>21</sup> Most trapiches build a stockpile of chopped stalks for two weeks while workers are hired.<sup>22</sup>

First, the raw sugarcane stalks are processed through hand and water-powered mechanical rollers which grind those stalks into a juice.<sup>23</sup> These hand and water powered rollers are a departure from using mules to power the rollers, a historic practice banned by the Colombian government for sanitation purposes.<sup>24</sup> Next, the juice from the sugarcane stalks streams down into a series of large heated pans.<sup>25</sup> The pans are heated by a furnace fueled with bagasse, the dried carcasses of grinded stalks.<sup>26</sup> As the raw sugarcane juice is heated, workers add a wood pulp to the liquid to separate impurities from the juice.<sup>27</sup> Once the juice begins to boil, workers use massive ladles to skim the surface of the juice and then transfer it to a heating vessel.<sup>28</sup> With each transition, the sugarcane juice reduces, ferments, thickens, and darkens.<sup>29</sup> There is no scientific determination that the sugar has been sufficiently heated or reached the appropriate sugar density; a worker may dip a stick in the heated syrup and cool it in cold water or check it with a wet, bare hand.<sup>30</sup>

The final steps for processing the juice vary from trapiche to trapiche depending on the final product. In one method, the hot syrup-like solution is poured into molds and left to cool and harden.<sup>31</sup> Common mold shapes include rectangular blocks and cones.<sup>32</sup> Another method produces a patty-shaped product. After transferring the thickened, nearly crystalized syrup to a final surface, workers begin to stir the product vigorously for cooling.<sup>33</sup> A pesador<sup>34</sup> then packs the cooling sugar into evenly sized patties. Once the patties fully cool, they begin to harden and are often stamped with the label for eventual sale.<sup>35</sup>

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*panelero*, PANELERO INFO. SYS. (Mar. 20, 2019), <http://www.sipa.org.co/wp/index.php/glossary/trapiche-panelero/>.

21. Smith, *supra* note 5.

22. *Id.*

23. *Id.*

24. Lopez-Alt, *supra* note 1

25. *Id.*

26. *Id.*

27. Smith, *supra* note 5.

28. *Id.*

29. Lopez-Alt, *supra* note 1.

30. Smith, *supra* note 5.

31. Gaston Rings, *Process of making panela, trapiche in Colombia*, YOUTUBE (Aug. 24, 2009), <https://www.youtube.com/watch?v=1K6XKadWWq8>.

32. Smith, *supra* note 5.

33. Lopez-Alt, *supra* note 1.

34. Pesadors are trapiche workers that hand-weigh and shape hot panela into portions at the end of production. Smith, *supra* note 5.

35. Lopez-Alt, *supra* note 1.

Because these trapiches provide so many jobs for Colombians, Colombia issued Law 40 of 1990 (“Law 40”) to regulate the production and exportation of panela.<sup>36</sup> First, Law 40 outlawed large sugar corporations from producing panela in Colombia by limiting panela establishments to a grinding capacity of ten tons per hour.<sup>37</sup> Second, Law 40 allowed the government to regulate the conditions and quantities in which panela is produced.<sup>38</sup> Additionally, Law 40 required that commercial panela producers register with the government and all exported panela be government-approved to guarantee the quality of the product.<sup>39</sup> Lastly, Law 40 set out specific production, health, and quality standards that all panela must meet.<sup>40</sup>

Despite some mechanical improvements to panela production, most trapiches operate a very traditional operation.<sup>41</sup> Although some producers have been able to purchase upgrades like automobiles for sugarcane transport, high efficiency cane rollers, or closed tanks for evaporation, such machines are too expensive for most trapiche owners.<sup>42</sup> Regardless, the ‘167 Patent may jeopardize both traditional and industrial panela producers.<sup>43</sup> Because the process for producing panela, industrialized or not, consists of the same fundamental steps, the exclusionary rights granted by the ‘167 Patent could spell out disaster for Colombian panela producers.<sup>44</sup>

### *B. Introduction to United States Patent Law*

Before an analysis can be done on the potential impact and viability of the ‘167 Patent, a basic understanding of U.S. patent law is necessary.<sup>45</sup> The following Subsections overview patents generally, the major tenants of patentability applied by the USPTO and U.S. courts, and the judicial approach to assessing patent infringement.

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36. L. 40, diciembre 4, 1990, DIARIO OFICIAL [D.O.] (Colom.) [hereinafter Law 40].

37. *Id.*

38. *Id.*

39. *Id.* “It will be understood that the panelero establishment is of a commercial nature when its production exceeds the amount of one tonne per week” *Id.*

40. *Id.*

41. Lopez-Atl, *supra* note 1.

42. *Id.*; Alcaldia Obando, *BIOBANDO*, YOUTUBE (Sept. 8, 2012), <https://www.youtube.com/watch?v=LYQIV4htOdg>.

43. Smith, *supra* note 5.

44. *Id.*

45. This is not intended to be a comprehensive guide to U.S. patent law. Only a basic overview of the major tenants of patentability is provided.

## 1. Patent Overview

Patents are a form of intellectual property geared towards scientific discoveries, inventions, and processes.<sup>46</sup> Like copyrights, trademarks, and trade secrets, patents confer certain intangible rights to their owners.<sup>47</sup> These rights are secured by the Patent and Copyright Clause of Article I of the U.S. Constitution, which states that “[t]he Congress shall have Power...[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>48</sup> In other words, the Patent and Copyright Clause implies exclusionary rights to inventors and authors to incentivize innovation and creativity.<sup>49</sup>

The exclusionary rights that accompany an issued patent allow the patent’s owner to prevent others from making, using, offering to sell, selling, or importing that patented invention throughout or into the United States.<sup>50</sup> By offering avenues for protection and exclusivity for their works, innovators are financially motivated to create.<sup>51</sup> The government only offers these exclusionary rights for a limited time and requires full disclosure of the invention at the time of application for patent.<sup>52</sup> The government limits exclusionary rights to ensure the public benefits from the disclosure of new technologies even if the inventor decides not to put their invention on the market.<sup>53</sup> Once a patent’s limited window of protection expires, the public is free to make, use, sell, and import the expired patent’s claimed invention or method.<sup>54</sup> Further, patents and patent applications are published and made available to the public, ensuring the dissemination of their knowledge and fueling future innovation.<sup>55</sup>

## 2. Statutory Patentability Requirements

Before inventors are granted exclusivity rights in the U.S. over their

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46. MUELLER, *supra* note 11, at 8.

47. *Id.*

48. U.S. Const. art I, § 8, cl. 8.

49. *Id.*

50. 35 U.S.C. § 271(a) (2012).

51. MUELLER, *supra* note 11, at 31.

52. *Id.* A newly issued U.S. patent is valid for at least twenty years from the date of its earliest effective filing date in the U.S. Patent and Trademark Office. Applications that face undue delay in their prosecution process might qualify to have their terms extended. 35 U.S.C. § 154 (2019).

53. MUELLER, *supra* note 11, at 31.

54. *Id.*

55. *Id.* at 73-76.

invention, they must file a patent application with the USPTO.<sup>56</sup> Patent applications must fully disclose the invention such that someone having ordinary skill in the art would be able to use the claimed invention.<sup>57</sup> Once prepared and filed, the application goes through a process called patent prosecution where the USPTO evaluates the application and determines whether the invention is patentable.<sup>58</sup> The determination of patentability revolves around three main requirements: (1) utility; (2) novelty; and (3) non-obviousness.<sup>59</sup>

The first requirement of patentability is utility.<sup>60</sup> For an invention to be useful, or have utility, it need only cross a very low threshold.<sup>61</sup> If the invention is “capable of providing some identifiable benefit,” then it is useful under the law.<sup>62</sup> Despite that low bar, utility is still necessary. For example, in *Brenner v. Manson*, the United States Supreme Court considered a chemist’s patent application for a steroid that claimed to have tumor-inhibiting effects in mice.<sup>63</sup> However, the applicant based these claims entirely on the steroid’s similar make-up to another compound which had actually demonstrated tumor inhibiting effects.<sup>64</sup> The Court agreed with the USPTO and rejected the chemist’s patent application for lack of utility, holding that being similar to a separate useful invention does not prove utility.<sup>65</sup> For the government to grant exclusivity rights, an inventor must disclose a legitimate use for his invention, not merely allude to some potential use for someone else to discover.<sup>66</sup> Additionally, *Brenner* laid the ground work for the “specific, substantial, and credible” standard of patent utility.<sup>67</sup> Patent examiners are told not to impose utility rejections “if the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a ‘specific and substantial utility’) and the assertion would be considered credible by a person of ordinary skill in the art.”<sup>68</sup>

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56. *Id.* at 12.

57. 35 U.S.C. § 112(a) (2019).

58. MUELLER, *supra* note 11, at 66.

59. MUELLER, *supra* note 11, at 67.

60. 35 U.S.C. § 101(a) (2019).

61. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

62. *Id.*

63. 383 U.S. 519, 522 (1966).

64. *Id.*

65. *Id.* at 535.

66. *Id.* This also leans towards another factor, enablement, that is not an issue here regarding panela. 35 U.S.C. § 112(a) (2019).

67. *Brenner*, 383 U.S. at 534-535.

68. MPEP (9th ed., June 2020) § 2107(II)(A)(3). “Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of

The second requirement for patentability is novelty.<sup>69</sup> The Leahy-Smith America Invents Act of 2011 simplified the basic principles of novelty: if a claimed invention has been “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention” anywhere in the world, then the claimed invention is considered to be anticipated and therefore not patentable.<sup>70</sup> Further, for an invention to be anticipated, it must be described in its entirety by the earlier filed patent, patent application, or printed publication (collectively, “prior art”); this is known as the strict identity standard.<sup>71</sup> For example, in *Titanium Metals Corp. v. Banner*, employees of Titanium Metals Corporation of America (“Titanium”) developed a titanium alloy and received a patent on the invention.<sup>72</sup> The patent claimed a “titanium [(Ti)] base alloy consisting essentially by weight of about 0.6% to 0.9% nickel [(Ni)], 0.2% to 0.4% molybdenum [(Mo)], up to 0.2% maximum iron, balance titanium.”<sup>73</sup> Five years earlier, however, an article had been published in a Russian journal featuring a data point corresponding to a Ti-Ni-Mo alloy consisting of 0.75% Ni and 0.25% Mo.<sup>74</sup> When the Titanium patent’s validity was challenged, the United States Court of Appeals for the Federal Circuit held that the patent was wrongly issued because it was anticipated by the alloy disclosed in the Russian journal article and therefore unpatentable for lack of novelty.<sup>75</sup> Alternatively, if the alloy disclosed in the Russian journal article instead comprised of only 0.4% Ni or 0.5% Mo, Titanium’s alloy would not have satisfied the strict identity standard and would have qualified as novel over the previously disclosed alloy.<sup>76</sup>

The third requirement for patentability is non-obviousness.<sup>77</sup> Non-obviousness bars an invention from being a mere variation or combination of prior art that “would have been obvious to a person having ordinary skill in the art” (“PHOSITA”).<sup>78</sup> PHOSITAs are afforded a certain degree of creativity within their fields; as a result, the USPTO commonly rejects

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the applicant’s assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.” *Id.* § 2107(II)(B)(1)(ii).

69. MUELLER, *supra* note 11, at 67.

70. 35 U.S.C. § 102(a) (2019).

71. MUELLER, *supra* note 11, at 242.

72. 778 F.2d 775, 776 (Fed. Cir. 1985).

73. *Id.*

74. *Id.*

75. *Id.* at 782. The “up to 0.2% maximum iron” limitation in Titanium’s claim is interpreted as including 0% iron. Thus, the strict identity standard was satisfied even though the Russian alloy did not include iron. *Id.*

76. *Id.* at 781.

77. MUELLER, *supra* note 11, at 67.

78. 35 U.S.C. § 103 (2019).

the following for being obvious: (1) combinations of analogous prior art; (2) substitutions of elements in a piece of prior art; and (3) situations in which there are only a limited number of possible solutions to a problem.<sup>79</sup> The following is a classic example of obviousness:<sup>80</sup>

A is known in the prior art, and B is known in the prior art. Upon looking at A and then looking at B, would [a PHOSITA] consider A+B to be already known? If the answer is yes, then A+B is obvious. If the answer is no, then A+B is not obvious.<sup>81</sup>

A fourth and less common requirement for patentability is that a patent applicant may only be granted a single U.S. patent on a given invention.<sup>82</sup> This requirement only pertains to inventors with at least one other pending U.S. application or granted U.S. patent.<sup>83</sup> If a patent applicant attempts to receive a second patent over his already patented invention, the USPTO will issue a “double patenting” rejection.<sup>84</sup>

There are two types of double patenting rejections.<sup>85</sup> First, a same invention-type double patenting rejection is when a later-filed application claims the exact same scope as the applicant’s original patent or application.<sup>86</sup> Second, an obviousness-type double patenting rejection exists when the later-filed application claims “a merely obvious variant” of the applicant’s original patent or application.<sup>87</sup> Double patenting rejections are issued by the USPTO and U.S. courts to prevent parties from unjustifiably extending monopolies over already-patented products or processes.<sup>88</sup> Applicants often attempt to circumvent the “one patent per invention” rule by obtaining patents on products used to produce the already patented invention or by obtaining patents on new uses, formulations, or preparations of the invention.<sup>89</sup>

### 3. Patent Infringement

As mentioned above, a patent grants its owner the right to exclude

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79. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 400-403 (2007).

80. Gene Quinn, *Patentability: The Nonobviousness Requirement of 35 U.S.C. 103*, IP WATCHDOG (June 17, 2017), <https://www.ipwatchdog.com/2017/06/17/patentability-nonobviousness-35-usc-103/id=84716/>.

81. *Id.*

82. MUELLER, *supra* note 11, at 82.

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.* at 83.

89. *Id.* at 82 n. 264.

others from making, selling, using, or importing the patented invention.<sup>90</sup> When a person violates those rights, it is called patent infringement.<sup>91</sup> A person can either infringe literally or under the doctrine of equivalents.<sup>92</sup> Literal infringement is when a defendant's actions fall directly within the bounds of a patent's claims.<sup>93</sup> For example, in *Titanium Metals Corp. v. Banner*, Titanium's patent was anticipated by the Ti-Ni-Mo alloy (containing 0.75% Ni and 0.25% Mo) disclosed in the Russian journal article.<sup>94</sup> If the article had never been published and Titanium's patent issued, a competitor who subsequently produced the disclosed alloy would be held liable for literal infringement because the produced alloy would fall squarely within the ranges claimed by Titanium's patent.<sup>95</sup> To illustrate further, if in that same scenario the competitor's alloy had comprised only 0.59% Ni and 0.41% Mo, then the competitor would not be held liable for literal infringement.<sup>96</sup> The common law doctrine of equivalents addresses this loophole.<sup>97</sup>

The doctrine of equivalents asks whether potential infringers' actions "perform substantially the same function, in substantially the same way, to achieve the same result"; if so, then there is infringement.<sup>98</sup> This is a fact-specific and unreliable inquiry.<sup>99</sup> For example, if Titanium's hypothetical competitor had produced the Ti-Ni-Mo alloy comprised of 0.59% Ni and 0.41% Mo, then a court would have to determine whether the 0.01% composition changes would produce a substantially similar alloy.<sup>100</sup> If the alloy satisfied the substantial similarity test, it would have been found to infringe under the doctrine of equivalents.<sup>101</sup> But, if the 0.01% composition changes had significantly altered a characteristic, such as the alloy's conductivity or tensile strength, then it would have been unlikely to infringe under the doctrine of equivalents.<sup>102</sup>

An accused patent infringer can generally raise two arguments to avoid penalty: (1) claim that the patent is actually invalid and should never have

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90. *Id.* at 735.

91. 35 U.S.C. § 271(a) (2019).

92. MUELLER, *supra* note 11, at 735.

93. *Id.* at 782.

94. 778 F.2d 775, 776 (Fed. Cir. 1985).

95. *Id.*

96. MUELLER, *supra* note 11, at 782. The ranges of the original Titanium patent were 0.6-0.9% Ni, 0.2-0.4% Mo, up to 0.2% Fe, balance Ti. *Titanium Metals Corp. v. Banner*, 778 F.2d at 776.

97. *Id.* at 783

98. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608 (1950).

99. MUELLER, *supra* note 11, at 787.

100. *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. at 608.

101. *Id.*

102. *Id.*

been issued; or (2) claim that they did not actually infringe.<sup>103</sup> Claiming invalidity forces the court to reevaluate the patent with regard to the requirements of patentability.<sup>104</sup> When the court reevaluates the validity of an issued patent, the defendant must overcome the patent's presumption of validity.<sup>105</sup>

A defendant claiming that it did not actually infringe argues that its actions fall outside of the scope of the patent's claims.<sup>106</sup> Here, the court must interpret the scope of those claims and determine what the patent protects.<sup>107</sup> Once the court has interpreted the patent, it determines whether the defendant's actions fall within the scope of the claims.<sup>108</sup> If the court finds that the defendant's actions fall within the scope of the claims either literally or under the doctrine of equivalents, then there is infringement.<sup>109</sup>

Alternatively, a defendant that has been performing the allegedly infringing activity since before the public disclosure of the issued patent may avail a third defense.<sup>110</sup> Known as prior user rights, an accused infringer may continue its allegedly infringing activity if: (1) "such person, acting in good faith, commercially used the subject matter"; and (2) "such commercial use occurred at least 1 year before the earlier of either...the effective filing date of the claimed invention or the date on which the claimed invention was disclosed to the public."<sup>111</sup> If the court finds that these elements are satisfied, then the accused infringer will prevail.<sup>112</sup>

### C. Introduction to Colombian Patent Law

The Colombian patent system operates on slightly different terms than its U.S. counterpart.<sup>113</sup> Once a patent application is submitted to the Colombian Patent Office ("Division de Nuevas Creaciones"), the invention is evaluated for newness, inventive step, and industrial

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103. MUELLER, *supra* note 11, at 853.

104. *Id.*

105. *Id.* at 959.

106. *Id.* at 750.

107. *Id.*

108. *Id.*

109. *Id.* at 735.

110. *Id.* at 860.

111. 35 U.S.C. § 273 (2015).

112. MUELLER, *supra* note 11, at 861-862.

113. Pamela Bechtel Hwang, *Colombia: gateway to South America's Patent Prosecution Highway*, DLA PIPER (Dec. 10, 2012), [https://www.dlapiper.com/en/us/insights/publications/2012/12/colombia-gateway-to-south-americas-patent-prosec\\_/](https://www.dlapiper.com/en/us/insights/publications/2012/12/colombia-gateway-to-south-americas-patent-prosec_/).

applicability.<sup>114</sup>

First, similar to the novelty requirement under U.S. patent law, a Colombian invention submitted for patent must be new and cannot have been made previously available to the public.<sup>115</sup> Public availability includes any written or oral description, public use, sale, or offer for sale of the invention prior to the application's priority date.<sup>116</sup> Also like U.S. patent law's novelty requirement, publicly disclosed information regarding the Colombian patent application must satisfy the strict identity standard, meaning prior art that does not describe the claimed invention in full cannot destroy novelty.<sup>117</sup>

Second, similar to the non-obviousness requirement under U.S. patent law, a Colombian invention submitted for patent must demonstrate an inventive step.<sup>118</sup> For an invention to be inventive in light of the prior art, it cannot be deemed "obvious or evidently derived from the prior art by a person ordinarily skilled in the art."<sup>119</sup> Further, inventive step is typically assessed according to a problem-solution approach.<sup>120</sup> Under both the Colombian inventive step and U.S. non-obviousness standards, a patent rejected as obvious can be rebutted because of secondary considerations.<sup>121</sup> Examples of secondary considerations include evidence of surprising results, economic success, a longstanding hole in the market, excessive experimentation, and prior art that teaches away from what the invention claims.<sup>122</sup>

Third, similar to the utility requirement under U.S. law, a Colombian invention submitted for patent must have industrial applicability, which requires that the invention be capable of being "produced or used in any type of industry."<sup>123</sup> The term "industry" is defined as "involving any productive activity, including services."<sup>124</sup> The Colombian industrial applicability requirement is therefore nearly interchangeable with the

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114. U.S. COM. SERVICE, U.S. DEP'T COM., INTELLECTUAL PROPERTY RIGHTS TOOLKIT COLOMBIA (2011).

115. CARLOS R. OLARTE ET AL., GETTING THE DEAL THROUGH – PATENTS 52 (Stuart J. Sinder eds., 10th ed., 2013).

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

122. *Id.* "Teaching away" means that the piece of prior art suggests or requires an invention only work in a way opposite or contrary to that of the newly claimed invention. *Id.*

123. Subregional Integration Agreement (Cartagena Agreement), Decision 486—Common Provisions on Industrial Property art. 19, Sept. 14, 2000, available at: <https://www.wipo.int/edocs/lexdocs/laws/en/can/can012en.pdf> [hereinafter Decision 486].

124. *Id.*

U.S. utility requirement.<sup>125</sup>

Ownership of a Colombian patent gives the owner the right to prevent third parties from manufacturing, selling, offering to sell, importing, and, in the case of a method claim, using the patented invention.<sup>126</sup> Under Colombian law, for a party to infringe on a patent, it must do so literally.<sup>127</sup> Unlike the U.S., Colombia runs on a civil law system.<sup>128</sup> Civil law systems do not rely on case law; instead, courts lean heavily on statutes, codes, treaties, and other types of written laws.<sup>129</sup> Because there is no written doctrine of equivalents in Colombian patent law, a patent owner cannot rely on the infringer's actions being substantially similar to its patent to prevail on an infringement claim.<sup>130</sup> A patent owner's success in infringement actions therefore depends on whether courts interpret patent claims broadly enough to find literal infringement.<sup>131</sup>

Prior user rights are also recognized in Colombia.<sup>132</sup> A party qualifies for Colombian prior user rights if the party "in good faith and before the priority date or the filing date of the application on which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparations for such use or exploitation."<sup>133</sup> Unlike its U.S. counterpart, Colombian prior user rights are not limited to those who practiced an issued patent more than one year prior to its disclosure.<sup>134</sup>

#### *D. The Claims and Prosecution History of Patent No. 10,632,167*

On April 28, 2020, the '167 Patent was issued to Jorge Enrique Gonzalez Ulloa ("Mr. Gonzalez").<sup>135</sup> The '167 Patent's title, "System and method for processing raw sugarcane maximizing the preservation of policosanols during production of a shelf stable potable cholesterol-reducing product," is deceiving.<sup>136</sup> At first glance, the patent merely discloses a process for manufacturing a pharmaceutical, but a closer

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125. FREDERICK M. ABBOTT ET AL., INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY 218 (Rachel E. Barkow et al. eds. 4th ed. 2019).

126. Decision 486, *supra* note 123.

127. Olarte, *supra* note 115, at 51.

128. *What is the Civil Law?*, LSU LAW (last visited Apr. 17, 2021), <https://www.law.lsu.edu/clo/civil-law-online/what-is-the-civil-law/>.

129. *Id.*

130. Olarte, *supra* note 115, at 51.

131. *Id.*

132. Decision 486, *supra* note 123.

133. *Id.*

134. *Id.*

135. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

136. *Id.*

examination reveals a strong resemblance to panela production.

The '167 Patent claims a process for producing a policosanol-rich sugarcane juice product.<sup>137</sup> Policosanol is an alcohol derived from the waxy part of plants that the '167 Patent claims is “an effective remedy for the treatment of unhealthy elevated blood cholesterol levels in humans.”<sup>138</sup> But, the studies that support these alleged benefits were produced by a single research group whose results have since been unrepeatable.<sup>139</sup> Moreover, the '167 Patent faced double-patenting and obviousness rejections during patent prosecution but was able to overcome the rejections by emphasizing its policosanol-centered disclosure.<sup>140</sup> The following paragraphs explain policosanol and its uncertain standing in the scientific community, describe the process claimed by the '167 Patent, and breakdown the '167 Patent's prosecution history.

### 1. The Uncertainties of Policosanol

In the early 2000's, a Cuban research group released its findings on the therapeutic effects of a sugarcane wax-based policosanol supplement.<sup>141</sup> The Cuban research group's findings showed that the supplement was an efficacious treatment for various cardiovascular-related ailments, particularly hypercholesterolemia.<sup>142</sup> The research group claimed that a daily intake of the supplement lowered overall cholesterol levels by increasing the liver's ability to process low-density lipoproteins (“LDL”) and decreasing HMG-CoA reductase activity.<sup>143</sup> These findings were significant because the prescription medications normally used to treat high cholesterol can have harmful side effects.<sup>144</sup> In contrast, the

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137. *Id.*

138. *Id.*

139. Christopher P. F. Marinangeli et. al, *Policosanols as Nutraceuticals: Fact or Fiction*, CRITICAL REVIEWS IN FOOD SCIENCE AND NUTRITION, Mar. 2010, at 259.

140. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017), *Non-Final Office Action* dated May 21, 2019, p. 3, 5 [hereinafter *Non-Final Office Action*].

141. Marinangeli, *supra* note 139.

142. *Id.* “Despite low bioavailability, numerous studies originating in Cuba have shown PC supplements to be efficacious treatments for various cardiovascular-related ailments including hypercholesterolemia, poor arterial function, poor antioxidant status, and intermittent claudication.” *Id.* at 260.

143. *Id.* LDL is commonly referred to as “bad cholesterol” and HMG-CoA reductase inhibitors make-up most common cholesterol lowering drugs. *LDL and HDL Cholesterol: “Bad” and “Good” Cholesterol*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Jan. 31, 2020), [https://www.cdc.gov/cholesterol/ldl\\_hdl.htm](https://www.cdc.gov/cholesterol/ldl_hdl.htm); Agam B. Bansal & Manouchkath Cassagnol, *HMG-CoA Reductase Inhibitors*, NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION (Nov. 4, 2020), <https://www.ncbi.nlm.nih.gov/books/NBK542212/>.

144. Marinangeli, *supra* note 139, at 265.

policosanol supplement presented zero adverse side effects.<sup>145</sup>

Despite the promise of a natural and side-effect-free method of lowering cholesterol, the scientific community has met the Cuban studies with skepticism.<sup>146</sup> This skepticism grew as researchers were unable to produce even mildly similar results to the original Cuban study.<sup>147</sup> Researchers outside Cuba attempted to recreate the original experiments, but not a single experiment showed significant changes in patients' cholesterol levels.<sup>148</sup> When the adverse findings were released, the original Cuban researchers claimed that the policosanol used in their study had “unique properties.”<sup>149</sup> Interestingly, the Cuban group used a sugarcane-based supplement, whereas the external research groups used policosanols derived from plants other than sugarcane and prepared them with different methods.<sup>150</sup> Despite those differences, the policosanols used by the external groups had purity levels and alcohol chain lengths similar to those of the original Cuban policosanol supplement.<sup>151</sup> Further, the original Cuban supplement was later tested by a different research group and it presented no signs of lowering cholesterol.<sup>152</sup> Ultimately, even though there are a number of studies that refute the results of the original Cuban research group, more research must be conducted before definitively stating that the original studies were falsified.<sup>153</sup>

## 2. The Claims of U.S. Patent No. 10,632,167

The '167 U.S. Patent claims a process of producing a policosanol-rich sugarcane juice.<sup>154</sup> Trademarked in the U.S. as “Policane,” the product is intended to be a beverage for everyday consumption.<sup>155</sup> Policane is comparable to Colombian aguapanela and the processes for producing them are nearly identical.<sup>156</sup>

The '167 Patent's process begins with harvesting raw sugarcane by

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145. *Id.*

146. *Id.* at 259.

147. *Id.* at 260.

148. *Id.*

149. *Id.* at 260.

150. *Id.* at 262.

151. *Id.*

152. *Id.*

153. *Id.* at 265.

154. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

155. Smith, *supra* note 5.

156. *Id.*

hand.<sup>157</sup> Next, the unwashed cane is chopped into small pieces.<sup>158</sup> Then, the chopped cane is softened with cool water and juiced in a series of mechanical rollers at the lowest possible rate and a pressure of about 1,500 pounds per square inch.<sup>159</sup> The policosanol-rich juice is collected only from the first two rollers.<sup>160</sup>

This policosanol-rich juice is then filtered to remove larger unwanted particles.<sup>161</sup> Next, the pH and sugar density levels of the juice are managed in a series of clarification, heating, and inversion steps. First, calcium hydroxide is added to lower the pH level of the juice.<sup>162</sup> Second, the juice is heated to no more than seventy degrees Celsius to preserve the policosanols.<sup>163</sup> Flocculates are then added to the juice to collect impurities.<sup>164</sup> These sink to the bottom of the vats and are vacuumed out.<sup>165</sup> Bubbles are then pumped through the vat to push the flocculates to the top of the vat where the impurities are skimmed off the top.<sup>166</sup> Finally, the juice is evaporated to increase its sugar density, the remaining syrup is inverted with citric or phosphoric acid to reduce the pH, and a sugar vacuum is used to once again increase the sugar density before it is left to cool.<sup>167</sup>

### 3. The Prosecution History of U.S. Patent No. 10,632,167

Like most other patent applications, the '167 Patent's application was initially rejected by the USPTO and deemed unpatentable by an examiner.<sup>168</sup> Patent prosecution allows for an applicant to make changes to an application or introduce arguments as to why the USPTO examiner should not have rejected the application.<sup>169</sup> The '167 Patent's application faced two rejections.<sup>170</sup> The first rejection was an obviousness-type double patenting rejection related to a separate patent owned by Mr. Gonzalez, U.S. Patent No. 6,245,153 ("the '153 Patent").<sup>171</sup> The examiner

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157. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017). Mechanical harvesting of sugarcane typically employs a burning mechanism which reduces policosanol levels. *Id.*

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.*

167. *Id.*

168. *Non-Final Office Action*, *supra* note 140.

169. MUELLER, *supra* note 11, at 68.

170. *Non-Final Office Action*, *supra* note 140.

171. *Id.* at 3.

also rejected the ‘167 Patent’s application as obvious over the ‘153 Patent.<sup>172</sup>

The ‘153 Patent disclosure is extremely similar to the ‘167 Patent’s disclosure.<sup>173</sup> Titled “Method for producing sugar cane juice,” the ‘153 Patent claims a process for producing juice from sugarcane stalks.<sup>174</sup> The ‘153 Patent process is nearly identical to the process claimed by the ‘167 Patent’s application, except it takes no steps to preserve the policosanols in sugarcane stalks and does not even mention the compound.<sup>175</sup> Further, the examiner stated that despite the ‘153 Patent failing to teach a policosanol-rich bagasse, the ‘153 Patent process “would inherently produce policosanol-rich bagasse” because similar stalks were passed through similar rollers in both processes.<sup>176</sup> In conjunction with the shared inventorship between the ‘153 Patent and the ‘167 Patent’s application, these similarities led the examiner to make an obviousness-type double patenting rejection.<sup>177</sup>

The obviousness rejection was supported with multiple references to the ‘153 Patent specification.<sup>178</sup> These references point out the nearly identical juice extraction, filtration, heating, clarification, flocculation, and evaporation steps between the two claimed processes.<sup>179</sup> In the absence of evidence to the contrary, the examiner found that the ‘167 Patent’s application as a whole was obvious to a PHOSITA in light of the ‘153 Patent.<sup>180</sup>

Mr. Gonzalez successfully rebutted both rejections with a three-part argument focused on the preservation of policosanols.<sup>181</sup> First, the ‘167 Patent application called for specific limitations in the sugarcane juice production process explicitly designed to preserve policosanols.<sup>182</sup> The steps mentioned by Mr. Gonzalez to preserve policosanols include: (1) not cleaning the cut cane stalks; (2) heating the pH-stabilized juice without reaching a temperature that would evaporate policosanols; and (3) filtering and re-adding the froth from the clarification step back into the juice.<sup>183</sup> Second, the ‘153 Patent discloses steps that would destroy

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172. *Id.* at 5.

173. U.S. Patent No. 6,245,153 (filed August 8, 1999).

174. *Id.*

175. *Id.*

176. *Non-Final Office Action*, *supra* note 140, at 4.

177. *Id.* at 3-4.

178. *Id.* at 4-7.

179. *Id.* at 5-6.

180. *Id.* at 6-7.

181. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017), *Amendment* dated Nov. 21, 2019, p. 8, 11-12 [hereinafter *Amendment*].

182. *Id.* at 8.

183. *Id.* at 8-10.

policosanols, including the cleaning of the cut cane stalk, excessive heating of the juice, and removal of policosanol-rich froth.<sup>184</sup> Lastly, Mr. Gonzalez argued that it took “over five years of continuous research and experimentation to arrive at a modified version of [the] original process.”<sup>185</sup>

Ultimately, Mr. Gonzalez was successful in rebutting the examiner’s rejections and was granted the patent.<sup>186</sup> Because of this, the ‘167 Patent would be given a presumption of validity if challenged in a court of law.<sup>187</sup> However, just because a patent is presumed valid does not mean it cannot be found invalid.<sup>188</sup>

### III. DISCUSSION

Unfortunately, if the ‘167 Patent is challenged in an infringement lawsuit in the U.S., the court would likely deem it valid. This does not mean that Colombians should be concerned about their way of life being upended. First, Section A of this Part breaks down why the ‘167 Patent would likely be upheld. Second, Section B discusses why, regardless of its validity, the ‘167 Patent would not impact the Colombian panela industry.

#### A. U.S. Patent Validity

If challenged in a U.S. court of law, the ‘167 Patent’s validity would likely be upheld. Of the main U.S. criteria for patentability, a lack of utility presents the strongest argument for the ‘167 Patent’s invalidity. Although they would be weak, novelty and obviousness arguments can also be made against validity.

The strongest argument against the ‘167 Patent’s validity is for lack of utility. Even though the utility threshold is low, all patentable inventions must be useful.<sup>189</sup> The issue lies with the efficacy of policosanols. As shown through the ‘167 Patent’s prosecution history, the ‘167 Patent is only patentable over the ‘153 Patent because of the process changes it implements to preserve policosanols in the final juice product.<sup>190</sup> Without these changes, the ‘167 Patent would be unpatentable for obviousness and

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184. *Id.*

185. *Id.* at 8.

186. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017), *Notice of Allowance* dated Feb. 26, 2020, p. 1 [hereinafter *Notice of Allowance*].

187. MUELLER, *supra* note 11, at 959.

188. *Id.*

189. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999).

190. *See Amendment*, *supra* note 181, at 7-13; *Notice of Allowance*, *supra* note 186.

double patenting.<sup>191</sup> Because the policosanols comprise the novel and non-obvious portion of the ‘167 Patent, it is the policosanols that must have utility; if there is no utility in the preservation of policosanols, then the only other utility is in producing a sugarcane juice product, a feat already accomplished by the ‘153 Patent.<sup>192</sup>

There is little research and increased skepticism regarding the true effects of policosanols, especially the effects boasted by the ‘167 Patent.<sup>193</sup> According to the ‘167 Patent, policosanols are a side-effect-free alternative to blood cholesterol pharmaceuticals such as Lipitor, Crestor, and Lescol; it even claims that policosanols are just as, if not more, effective than these leading brands.<sup>194</sup> The ‘167 Patent asserts that policosanols “are remarkably effective” in reducing a component of cholesterol known to cause a slew of health-related problems.<sup>195</sup> The scientific community, however, is skeptical of policosanols’ purported health benefits because the original results indicating that policosanols are a miracle compound have been unrepeatable.<sup>196</sup>

This unrepeatability implies that the utility of policosanols is not yet known. At the very least, the attempted recreations of the Cuban studies indicate that policosanols, outside of the exact conditions and preparation methods of those studies, have no proven utility.<sup>197</sup> This situation can be equated to the *Brenner* case.<sup>198</sup> Like the similar steroid homologues in *Brenner*, the policosanols derived by the ‘167 Patent will be of at least similar purity levels and alcohol chain lengths as the original Cuban policosanols supplements because of their shared sugarcane base.<sup>199</sup> But, as determined in *Brenner*, similar chemical make-ups are not a sufficient basis for utility.<sup>200</sup> Here, if the ‘167 Patent’s policosanols do not actually lower cholesterol, the true utility of the sugarcane juice is left to be discovered by someone else. Therefore, because the policosanols have no established utility, the issued patent would be invalid.<sup>201</sup>

Unfortunately, even though there is no conclusive evidence of the ‘167 Patent’s utility, the limited studies available are unlikely to overcome the ‘167 Patent’s presumption of validity. With this presumption of validity

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191. See *Amendment*, *supra* note 181, at 7-13; *Notice of Allowance*, *supra* note 186; *Non-Final Office Action*, *supra* note 140, at 2-6.

192. U.S. Patent No. 6,245,153 (filed August 8, 1999).

193. Smith, *supra* note 5.

194. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

195. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

196. Marinangeli, *supra* note 139, at 259.

197. *Id.* at 265.

198. *Brenner v. Manson*, 383 U.S. 519 (1966).

199. *Id.* at 531-532.

200. *Id.* at 535.

201. 35 U.S.C. § 101 (2019).

follows the presumption of credibility of source.<sup>202</sup> Although current research appears to question the credibility of Mr. Gonzalez's assertions, it is not the job of the patent examiners at the USPTO to conduct extensive research into the validity of utility claims.<sup>203</sup> Rather, the USPTO "must treat as true a statement of fact made by an applicant in relation to an asserted utility."<sup>204</sup> To overcome this presumption, a significant amount of evidence would be necessary to prove that the original studies were so wrong that the patent should be invalidated.<sup>205</sup> Because this evidence simply does not yet exist, it is unlikely that an attack on the credibility of the underlying utility of the '167 Patent would be sufficient for a court to invalidate the patent.

A second argument against the '167 Patent's validity is for lack of novelty, and in the alternative, for being obvious, over the traditional methods of producing panela that have been practiced for centuries.<sup>206</sup> Because of the '167 Patent's narrowness and having already overcome similar rejections during patent prosecution, this argument is likely to fail.<sup>207</sup> As mentioned above, the novelty standard requires prior art satisfy the strict identity standard to anticipate the claimed invention.<sup>208</sup> Therefore, for the '167 Patent to be invalidated for lack of novelty, it must be shown that the claimed method for producing the policosanol-rich sugarcane juice is identical to any current or former method of producing panela.

At their core, the '167 Patent's claims are made up of the following nine steps: (1) hand-cut raw sugarcane; (2) shred the unwashed sugarcane; (3) run the shredded sugarcane through a series of roller mills designed to extract the sugarcane juice from the stalks; (4) filter the resulting juice; (5) stabilize the pH of the filtered juice; (6) heat the stabilized juice; (7) clarify the heated juice via flocculation; (8) concentrate the sugar content via evaporation; and (9) extract the evaporated juice concentrate.<sup>209</sup> When comparing these steps to the traditional process used in Colombia, there seems to be a strong case for anticipation. In both processes, sugarcane is hand-cut, subjected to a series of rollers and a pH management step, clarified via natural flocculants, heated, evaporated, and cooled.<sup>210</sup>

Even though there are striking similarities between these two

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202. MUELLER, *supra* note 11, at 959.

203. *Id.* at 497.

204. *Id.*

205. *Id.* at 959. Although not statutorily established, the standard of proof for the invalidity of an issued patent is "clear and convincing." *Id.*

206. *See supra* Part II.A.

207. *See supra* Part II.D.3.

208. MUELLER, *supra* note 11, at 242.

209. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

210. Smith, *supra* note 5.

processes, the '167 Patent implements specific limitations within each step.<sup>211</sup> These specific limitations include: (1) not cleaning the cut cane stalks; (2) heating the pH-stabilized juice without reaching a temperature that would evaporate policosanols; and (3) filtering the froth resulting from the use of flocculants during the clarification process and re-adding it to the juice.<sup>212</sup> Further, the '167 Patent is based on the use of industrial technology.<sup>213</sup> Conversely, the traditional method of panela production is much less specific.<sup>214</sup> For example, the proper heating temperatures and evaporation steps of the traditional method are all performed manually and without specific ranges.<sup>215</sup> While it is conceivable that at some point a Colombian trapiche has kept temperatures below seventy degrees Celsius, the total combination of policosanol-preserving steps has likely never been performed. Therefore, a lack of novelty argument is likely to fail.

The final argument against the '167 Patent's validity is that it would have been obvious to a PHOSITA to produce cane juice as claimed by the patent.<sup>216</sup> The '167 Patent was originally rejected for obviousness, but the rejection was rescinded upon further argument by Mr. Gonzalez.<sup>217</sup> Mr. Gonzalez was able to work around these rejections by identifying the '167 Patent's additional measures to preserve policosanols and the extensive testing performed to perfect those measures.<sup>218</sup> Therefore, because the obviousness arguments have already been tried and reversed, this argument is not likely to prove invalidity.

Ultimately, for the '167 Patent to be ruled invalid, the most persuasive argument is that the policosanols have no actual utility. Because the novelty and obviousness arguments have essentially been exhausted, it is unlikely they would prevail without the surfacing of additional relevant prior art. Luckily for Colombians, the validity of the '167 Patent should not cause alarm.

### *B. The Effect of U.S. Patent No. 10,632,167 on the Colombian Panela Market*

While at first glance the '167 Patent may appear disastrous for the Colombian panela industry, it is unlikely to cause any changes. First, the

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211. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

212. *Id.*

213. *Id.*

214. Lopez-Alt, *supra* note 1.

215. *See supra* Part II.A.

216. *See supra* Part II.B.2.

217. *See Non-Final Office Action, supra* note 140; *Amendment, supra* note 181; *Notice of Allowance, supra* note 186.

218. *Amendment, supra* note 181.

exclusionary rights granted by a patent are limited by the geographic borders of the country in which it was issued.<sup>219</sup> Second, the '167 Patent only prevents producers from processing sugarcane under the exact method claimed by the patent. Third, the Colombian government is not likely to allow a single entity to upend one of the most important industries within its borders.

The exclusionary rights of patents are generally not enforced extraterritorially.<sup>220</sup> Even if the '167 Patent is valid in the U.S., its exclusionary rights would not apply in Colombia unless a patent is also granted there.<sup>221</sup> Given that only 0.4% of Colombian panela becomes destined for export, the 98% that is consumed domestically would be unaffected.<sup>222</sup>

The '167 Patent's claims and prosecution history reveal the impact the patent is likely to have on the Colombian panela industry. For the '167 Patent to exclude panela producers, those producers would need to follow the patent exactly.<sup>223</sup> Because the standard method of panela production does not incorporate the precise method detailed in the '167 Patent, traditional panela producers would not be liable for infringement. First, the panela produced in Colombian trapiches is typically a solid product, whereas the '167 Patent covers the production of a liquid.<sup>224</sup> Second, Mr. Gonzalez did not file the '153 Patent in Colombia; the '153 Patent was a broader version of the current patent, so Mr. Gonzalez likely knew it would waste resources to file an application where the patent would not be granted or, at the very least, profitable.<sup>225</sup>

Further, because the '167 Patent's claims are narrow, if granted in Colombia, they are unlikely to cover traditional panela production. Colombian patent law does not recognize the doctrine of equivalents and proving literal infringement of the '167 Patent's narrow claims would be a difficult task.<sup>226</sup> But, even if the patent is granted in Colombia and a Colombian court somehow finds that traditional panela production literally infringes the '167 Patent, the infringing producer would be able to claim prior user rights by pointing to panela's extensive history, thereby avoiding sanctions.

Lastly, the Colombian government would not allow a single entity to turn its panela industry upside down. Under Law 40, even current

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219. MUELLER, *supra* note 11, at 1095-1096.

220. *Id.*

221. *Id.*

222. Rodriguez et al., *supra* note 12.

223. *See supra* Part II.C.

224. U.S. Patent No. 10,632,167 (filed Nov. 3, 2017).

225. U.S. Patent No. 6,245,153 (filed August 8, 1999).

226. Olarte, *supra* note 115, at 51.

producers of centrifugal sugar cannot fully intrude on the panela market when their own market becomes saturated.<sup>227</sup> Panela producers are held to a high standard and are strictly regulated to maintain the over 350,000 jobs that are directly and indirectly related to the industry.<sup>228</sup> Therefore, even if Mr. Gonzalez is somehow able to enter the market alongside traditional trapiches, he would face strict regulations on the quantity of product he would be able to produce and business for the traditional trapiches would continue as usual.<sup>229</sup>

#### IV. CONCLUSION

In conclusion, the '167 Patent would likely be found valid if challenged in a U.S. court of law. The strongest argument against its validity is that it lacks utility because the Cuban studies that make up its basis of utility have questionable credibility.<sup>230</sup> If challengers to the '167 Patent were to make this argument, they should produce additional studies to fully discredit the Cuban studies and prove that policosanols have neither the utility claimed nor any other use.<sup>231</sup>

Fortunately for Colombians, the '167 Patent is unlikely to have any major impact on Colombia's panela market regardless of whether the patent is valid. The scope of the '167 Patent's claims is narrow and would only prevent panela producers from operating within very specific means. Further, because only 0.4% of Colombian panela is used for export, and because U.S. patents only prevent U.S. production and importation, the Colombian market will be virtually unaffected by the U.S. patent.<sup>232</sup> Colombians should therefore be unalarmed by the '167 Patent and its Colombian counterpart and continue to enjoy the regional delicacy.

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227. L. 40, diciembre 4, 1990, DIARIO OFICIAL [D.O.] (Colom.).

228. Rodriguez et al., *supra* note 12.

229. See *supra* Part II.A.

230. MPEP (9th ed., June 2020) § 2107(II)(A)(3).

231. If another use is found between now and the time the studies are sufficiently discredited, then new use will stand to meet the utility requirement. MUELLER, *supra* note 11, at 497.

232. Rodriguez et al., *supra* note 12.