UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MURRAY & POOLE ENTERPRISES LTD.,
Petitioner,

v.

INSTITUT DE CARDIOLOGISTOLOGIE DE MONTREAL,
Patent Owner.

Case IPR2023-01064
Patent No. 11,400,063

DECLARATION OF PAUL RIDKER, M.D.

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I. SUMMARY OF OPINIONS

1. Colchicine is an old drug that had been used for various disorders based on its anti-inflammatory properties, sold in U.S. as COLCRYS film coated tablets (EX1016). The '063 patent, filed on November 13, 2020, has claims directed to using low doses of colchicine to treat atherosclerotic cardiovascular patients following a myocardial infarction ("MI") to reduce the risk of secondary cardiovascular events. The same colchicine use, doses, patients, and treatment initiation times had been previously disclosed and was supported by a developed path of cardiovascular research. In my opinion, all claims of the '063 patent are anticipated by and/or would have been obvious from the prior art.

2. First, the '063 patent's *post hoc* time-to-treatment-initiation ("TTI") analysis and method of initiating treatment within about 3 days following an MI was reported in Bouabdallaoui (EX1005), published by a group of two dozen authors in August 2020. I understand that Bouabdallaoui is prior art to claims of the '063 patent, including claims 1 and 8, that require initiating treatment "within about 3 days of the MI," as this feature is not described in its November 2019 and October 2020 provisional applications. In my opinion, Bouabdallaoui anticipates claims 1-13, 17-26, 28, 40-46, 49, and 50.

Anticipation by Bouabdallaoui (EX1005) of claims 1-13, 17-26, 28, 40-46, 49, and 50 with November 2020, priority date

Claims 1 and 8	Bouabdallaoui (EX1005)
1[a], 8[a]: A method of **treating a patient after having a myocardial infarction (MI)**,	✓
1[b], 8[b]: the method comprising initiating the administration of colchicine **at a daily low dose** to the patient,	✓
1[c], 8[c]: wherein the colchicine is administered **without pre-loading** the patient with a higher dose of colchicine before the administration at the daily low dose,	✓
1[d], 8[d]: **within about 3 days** of the MI	✓
1[e] wherein **percutaneous coronary intervention was performed** for treating the patient's MI.	✓
8[e] wherein the patient is **at a lower risk of a cardiovascular event**..., and wherein the cardiovascular event is **resuscitated cardiac arrest, stroke, or urgent hospitalization for angina requiring coronary revascularization**.	✓

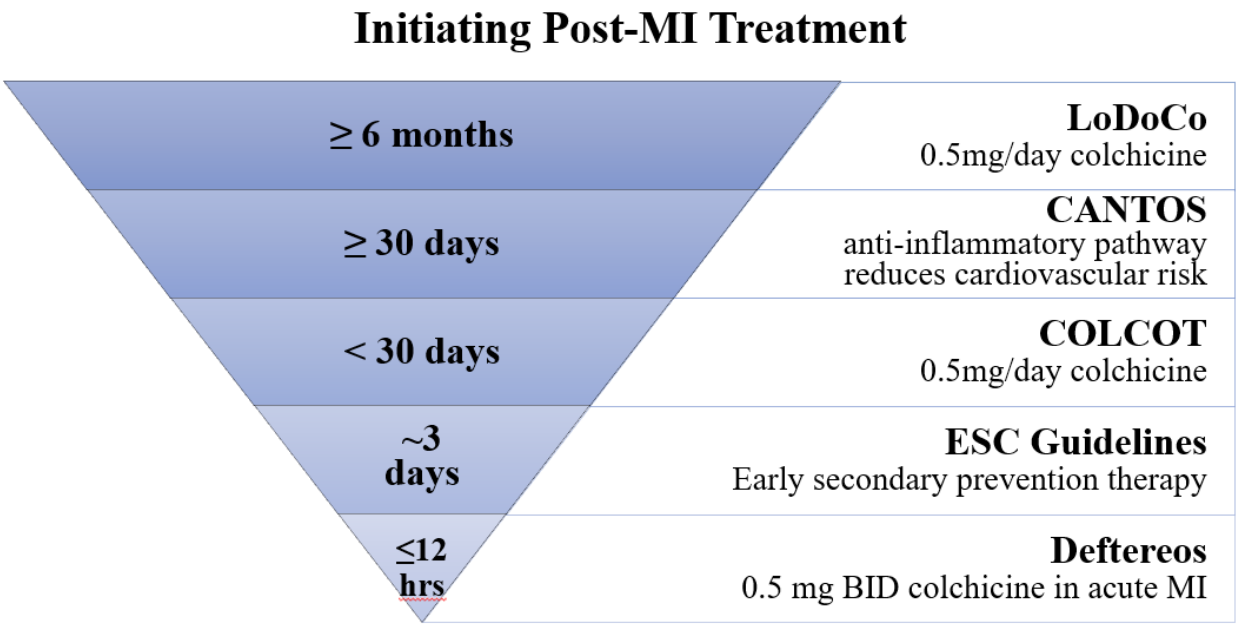
3. Second, other claims of the '063 patent, such as claim 27, require initiating treatment "within 30 days of an MI." These claims require no more than initiating colchicine at low doses (e.g., a dose of 0.5 mg/day) to patients—exactly the same as had already been described in COLCOT Protocol (EX1006). In my opinion, COLCOT Protocol anticipates claims 27, 29-36, and 39 of the '063 patent.

Anticipation by COLCOT Protocol (EX1006) of claims 27, 29-36, and 39 with November 2019, priority date

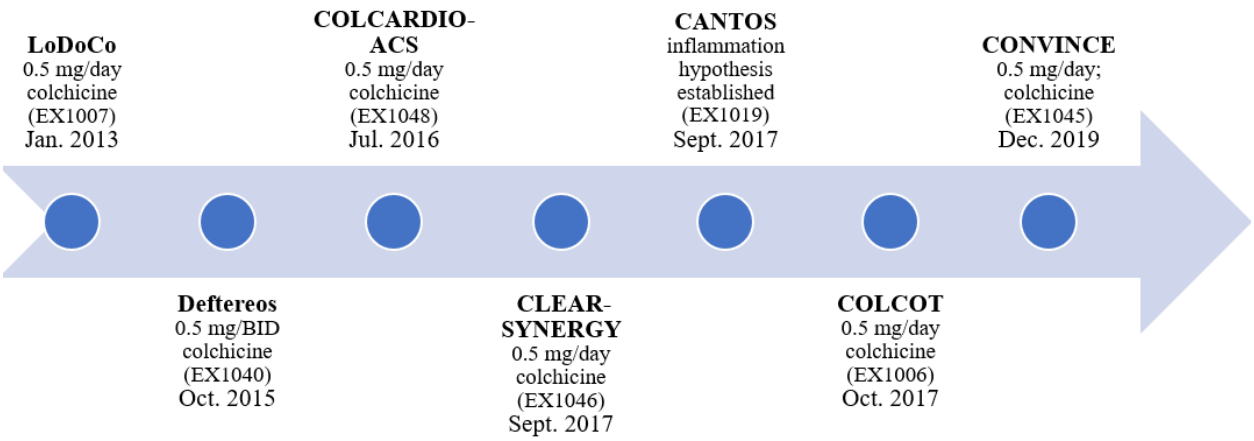
Claim 27	COLCOT Protocol (EX1006)
27[a]: A method of reducing the risk of a stroke in a patient after having an MI,	✓
27[b]: the method comprising initiating the administration of colchicine at a daily low dose to the patient	✓
27[c]: **within about 30 days** of an MI.	✓

4. Third, all claims of the ’063 patent would have been obvious in view of Nidorf (EX1007), COLCOT Protocol (EX1006), ESC Guidelines (EX1009), and COLCRYS (EX1016). The efficacy of 0.5 mg/day colchicine to reduce the risk of secondary cardiovascular events in post-MI patients was shown in the “LoDoCo” study reported by Nidorf. And the mechanisms of action by which anti-inflammatories, such as colchicine, reduce cardiovascular risk had also been established in my “CANTOS” trial (EX1019). COLCOT Protocol taught initiating colchicine treatment with 30 days post MI and it was also common practice, as reflected in ESC Guidelines, to initiate other secondary preventive therapy (such as statins), around the time of hospitalization discharge, typically about 2- 3 days post-MI.

5. Consistent with the direction the art was already going, the skilled cardiologist would have been motivated to shorten the post-MI treatment initiation time from LoDoCo’s original at least 6 months down to CANTOS’ at least 30 days, further down to COLCOT’s within 30 days, and still further down to around 3 days post-MI consistent with standard secondary prevention practice and ESC Guidelines. Indeed, Deftereos (EX1040) had already initiated colchicine treatment within 12 hours post-MI.



Consistent with this trend and building on the results from LoDoCo and CANTOS, by 2019 multiple other low dose colchicine clinical studies aimed at reducing cardiovascular events in patients with recent acute MI or stroke had been registered or initiated, including CONVINCE (EX1045), CLEAR-SYNERGY (EX1046), and COLCARIO-ACS (EX1048). Collectively, these studies show that the field had already recognized the potential benefits of low-dose colchicine for use following an MI to reduce the risk of subsequent cardiovascular events.



6. While the clinical efficacy in reducing the risk of secondary cardiovascular events with 0.5 mg/day colchicine initiated earlier than LoDoCo's at least 6 months had not been reported, efficacy—including for treatment initiated around day 3 post-MI—would have been reasonably expected from the reported success of LoDoCo using the same dose and CANTOS's clinical validation of the mechanisms by which anti-inflammatories treat the underlying atherosclerotic cardiovascular disease in post-MI patients.

7. Fourth, it also would have been obvious to a skilled cardiologist to use oral film-coated colchicine tablets, as taught by COLCRYS, in the method of treatment taught by Bouabdallaoui. Based on the combined teachings of Bouabdallaoui and COLCRYS, claims 1-26, 28, and 40-50 would have been obvious to a skilled cardiologist.

8. Finally, while the main findings of COLCOT are undoubtedly of broad clinical importance as a large-scale placebo-controlled confirmation of earlier

reported colchicine's effectiveness in cardiovascular diseases, efficacy from initiating treatment within 30 days post-MI would have been expected and the COLCOT *post hoc* TTI analysis from Bouabdallaoui does not show unexpected results or superiority for initiating treatment within about 3 days of an MI. Limitations in the *post hoc* nature of this secondary data analysis prevent one from concluding that initiating treatment within this sub-window is different in any clinically significant way from initiating treatment at another time. Even as reported in the '063 patent, the analysis shows that the risk reduction is similar whether treatment is initiated early or late in the 30-day window of the COLCOT Protocol. Further, in the '063 patent as well as in the anticipatory publication from Bouabdallaoui, no statistically significant difference is demonstrated between various clinical outcomes in the time frames of 0 to 3 days, 4 to 7 days, and greater than 8 days that were selected by the authors for analysis on a *post-hoc* basis, nor do the authors present the most basic interaction analyses that would be required to make such claims.

9. Further, the *post-hoc* subgroup analyses of Bouabdallaoui require cardiovascular readers to accept the improbable notion that colchicine 0.5 mg treatment initiated at days 2 to 3 is "beneficial" whereas the same treatment initiated between days 4 and 7 is "not beneficial", yet then becomes "beneficial" again when started after 8 days, even though in all cases the drug is to be continued as therapy

over a period of several years. This kind of non-biologic data analysis is an example of why *post hoc* subgroup analyses cannot be relied upon, particularly when the treatment of interest is designed to be given as a long-term chronic therapy as is clearly the case for colchicine. In fact, we know today that delayed initiation of long-term low-dose colchicine is if anything at least as effective as early initiation. This observation of clear benefit even with a delayed start was initially made in the first LoDoCo trial published in 2013 and has subsequently been reaffirmed in the second LoDoCo trial (LoDoCo2) in which colchicine 0.5 mg daily was shown to lower rates of major adverse cardiovascular events by 31 percent among those with stable atherosclerosis, a magnitude of effect if anything greater than the 23 percent reduction observed following recent myocardial infarction in COLCOT. Moreover, in contrast to the stable phase at day 2 and 3 following MI when patients are getting ready for hospital discharge to home, even today it has not been shown that colchicine is clinically effective in the immediate hours following acute MI, an unstable and dangerous time period when a different set of biologic processes related to coronary reperfusion and restoration of oxygen flow are dominant. Thus, while it is my opinion that the primary results of the main COLCOT trial itself are informative for patient care, it is also my opinion that the secondary *post-hoc* analyses of Bouabdallaoui do not show any unexpected results or superiority for initiating colchicine treatment within about 3 days of an MI.

II. QUALIFICATIONS

10. I am a physician, clinical cardiologist, and cardiovascular disease researcher, and I have the honor of serving as the Eugene Braunwald Professor of Medicine at Harvard Medical School and as Director of the Center for Cardiovascular Disease Prevention at Boston's prestigious Brigham and Women's Hospital. I am also a Professor at the T.C Chan Harvard School of Public Health, also in Boston, Massachusetts.

11. I graduated *magna cum laude* from Brown University in 1981 and received a Bachelor of Science degree. In 1986, I received an M.D. from Harvard Medical School. In 1992, I received an MPH degree from Harvard School of Public Health. From 1986 to 1992, I completed my internship and residency in the Department of Medicine at Brigham and Women's Hospital and Harvard Medical School, including working as a research/clinical fellow in Medicine (cardiovascular disease). In 1988 and 1989, I obtained Board of Registration in Medicine and Diplomate of the American Board of Internal Medicine to practice in Commonwealth of Massachusetts. In 1991, I obtained Diplomate of the American Board of Internal Medicine with subspecialty in cardiovascular disease.

12. Since my group discovered between 1997 (Ridker et al, NEJM 1997;336:973-979) and 2000 (Ridker et al, NEJM 2000;342:836-843) that the inflammatory biomarker C-reactive protein (CRP) and the central signaling cytokine

interleukin-6 (IL-6) are elevated in asymptomatic men and women many years in advance of heart disease and thus that inflammation *precedes* the onset of clinically apparent cardiovascular events much like cholesterol and blood pressure, I have spent virtually all of my investigative career elucidating the inflammation hypothesis of atherosclerosis. Indeed, over the past 25 years, my research unit would additionally be credited for providing the first evidence that statin drugs are both cholesterol lowering and anti-inflammatory (Ridker et al, Circulation 1998;98:839-844); the first FDA-approved diagnostic test for vascular inflammation (high-sensitivity CRP or hsCRP, Rifai et al, Clin Chem 1999; 45:2136-2141); the first evidence that individuals with elevated hsCRP are at high enough risk to benefit greatly from therapies like statins they otherwise would be denied (Ridker et al, NEJM 2002;347:1557-1565; Ridker et al, NEJM 2005;352:20-28, Ridker et al NEJM 2008;359:2195-2207), and ultimately the definitive proof-of-principle of the inflammation hypothesis of atherothrombosis in humans in the CANTOS trial which, using a therapeutic monoclonal antibody targeting interleukin-1β, proved in 2017 that the lowering of low-grade systemic inflammation could indeed lower cardiovascular event rates (EX1019). All of these manuscripts are widely considered to be "citation classics" which drove the field of inflammation and atherosclerosis forward.

13. Based largely on this work and upon my leadership of multiple multi-

national randomized, double-blind, placebo-controlled clinical trials investigating inflammation and heart disease, I have received several honorary degrees and international awards, including as examples designation as a Distinguished Scientist of the American Heart Association (2018) and election to the United States National Academy of Medicine (2020). I am also an elected member of the American Society of Clinical Investigation (ASCI), the Association of American Physicians (AAP), and a Fellow of the American College of Cardiology (FACC). I am asked to lecture on inflammation and atherosclerosis globally; as but a few recent examples I have given the honorary Hugh Sinclair Lecture for the British Atherosclerosis Society at Oxford University, United Kingdom; the R.T. Hall Lectureship for the Cardiovascular Society of Australia and New Zealand; the Antonio Gotto Lecture for the International Atherosclerosis Society, Tokyo, Japan; and the Attilio Maseri Honorary Lectureship, Trieste, Italy. I am the recipient of the Joseph Stokes Lifetime Achievement Award from American Society for Preventive Cardiology and am one of very few individuals to have received all three of the major research awards given by the American Heart Association. Most rewarding, our work has inspired the next generation of vascular biologists and investigative cardiologists to seek novel pathways to lower inflammation, hopefully for the benefit of our patients.

14. I have served as a consultant to numerous pharmaceutical companies, including Novartis, Flame, Agepha, AstraZeneca, Janssen, Civi Biopharm, Glaxo

Smith Kline, SOCAR, Novo Nordisk, Omeicos, Health Outlook, Montai Health, New Amsterdam, Boehringer-Ingelheim, RTI. Zomagen, Cytokinetics, Horizon Therapeutics, and Cardio Therapeutics. I also have minority shareholder equity positions in Uppton, Bitteroot Bio, and Angiowave.

15. A copy of my curriculum vitae is provided as **Appendix A**.

III. MATERIALS CONSIDERED

16. My opinions are based on my education, training, background and experience, the documents I reviewed, and information available to me to date. I have reviewed and considered the documents and materials cited in this declaration, as well as those listed in **Appendix B**. To the extent I am provided with additional documents or information in this proceeding, I reserve the right to modify or expand upon my opinions based on such new information, and in response to any additional reports and testimony.

IV. LEGAL STANDARD

17. I am not an attorney but have been informed of some patent law principles by counsel.

18. I understand that patents are to be interpreted from the perspective of a "a person of ordinary skill in the art" at the time the patent was filed ("POSA"). I provide my opinions on who would qualify to be a POSA for the '063 patent in Section VI.B, below.

19. Regarding the meaning of terms in the claims of a patent, I have been informed by counsel and I understand that they should normally be given the meaning as would have been understood by a POSA at the time the patent was filed, considering the context of the patent specification and its prosecution history.

20. I have been informed by counsel and I understand that claims of a patent are "anticipated" or not novel if a prior art reference discloses every limitation in the claim.

21. I have been informed by counsel and I understand whether the claims of a patent are "obvious" is a factual inquiry, and that the factors guiding the analysis include: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; (4) and any so-called objective secondary factors of nonobviousness (for example, commercial success, long-felt but unmet need, unexpected results, and copying). I further understand that for combinations of references, it is important to consider whether a POSA would have been motivated to combine their teachings with a reasonable expectation of success to arrive at the claimed subject matter.

V. BACKGROUND AND STATE OF ART AS OF 2019

A. Myocardial Infarction and Classic Secondary Prevention Therapy of Post-MI Patients Before 2012

22. Myocardial infarction (MI), or colloquially a heart attack, was recognized as "the most severe manifestation of coronary artery disease," typically

resulting from disruption of a vulnerable atherosclerotic plaque or erosion of the coronary artery endothelium.[1] Although traditionally divided into ST elevation myocardial infarction (STEMI) or non-ST elevation myocardial infarction (NSTEMI), many therapies are similar between the two.[2] Unstable angina—also typically resulting from atherosclerotic coronary artery disease and understood to be a potential imminent precursor to MI—was often grouped with acute MI for disease management.[3]

23. Following an MI, emergency or urgent management (typically within 0 to 12 hours) optimally includes percutaneous coronary intervention (PCI), a standard percutaneous revascularization procedure formerly known as percutaneous transluminal coronary angioplasty (PTCA) or generally coronary angioplasty.[4] PCI is performed using a catheter to open acutely clogged arteries with an aim to restore blood flow as rapidly as possible allowing life-preserving oxygen to be delivered to downstream tissues. PCI is faster and less invasive than coronary artery bypass

[1] EX1017 (Reed 2017), 1; EX1015 (Aday 2018), 1 ("Atherosclerosis is the central disease process underlying most instances of myocardial infarction (MI), ischemic stroke, and peripheral artery disease."); EX1006 (COLCOT Protocol), 4 ("Atherosclerosis is the most common cause of myocardial infarction, stroke, and peripheral arterial disease.").

[2] EX1017 (Reed 2017), 1.

[3] EX1017 (Reed 2017), 1.

[4] EX1021 (1999 Guidelines), 4; EX1010 (Stone 2008), 1.

grafting (CABG) surgery. Other emergency treatments used to rapidly restore blood flow following acute coronary occlusion include agents known as thrombolytic therapy which can dissolve blood clots but come with a significant increase in risks of bleeding.

24. While emergency PCI can open a closed coronary artery and restore downstream blood flow, the procedure itself does nothing to alter the underlying chronic and progressive nature of atherosclerosis that the patient is suffering from. Thus, even following emergency PCI, a patient who had an MI remains at very high risk for recurrent cardiovascular events over their lifetimes, including second heart attacks and stroke, due to continued progression of their coronary artery disease. Post-MI patients are thus treated aggressively with various "secondary prevention" drugs that are designed on a chronic long-term basis to reduce that risk.[5] For example, statin drugs that lower cholesterol are a standard secondary prevention therapy as they had been shown to reduce the risk of future cardiovascular events such as cardiovascular death, non-fatal myocardial infarction, unstable angina requiring hospitalization, coronary revascularization, and non-fatal stroke.[6] Moreover, best practice has long been to initiate statin therapy in-hospital prior to discharge home

[5] EX1017 (Reed 2017), 9; EX1007 (Nidorf), 2:34-36; EX1009 (ESC Guidelines), 31.

[6] EX1017 (Reed 2017), 9.

after myocardial infarction to ensure excellent long term care.

25. However, despite these standard therapies, "patients with atherosclerotic vascular disease continue to be at risk of cardiovascular events, possibly because these treatments fail to target some of the inflammatory pathways implicated in the disease."[7]

B. Anti-inflammatory Agents Had Been Successfully Used to Reduce Risks of Cardiovascular Events As of 2019

26. Colchicine was a well-known anti-inflammatory medication that had been used for the treatment and secondary prevention of gouty arthritis, familial Mediterranean fever (FMF), and Behcet's disease.[8] By 2019, low daily doses of colchicine had also been used successfully as secondary preventive therapy for coronary artery disease and its use was supported by established anti-inflammatory mechanisms of action.

1. The First LoDoCo Trial Design and Results

27. The use of colchicine to reduce the risk of cardiovascular events in patients with coronary artery disease generally, including acute coronary syndrome (ACS) and MI patients, was first evaluated in the "LoDoCo" (Low Dose Colchicine for Secondary Prevention of Cardiovascular Disease) trial using 0.5 mg/day

[7] EX1007 (Nidorf), 2:35-38.

[8] EX1007 (Nidorf), 1:26-28.

colchicine conducted by Dr. Nidorf and colleagues in Australia.[9] The study's primary efficacy outcome was the composite endpoint of ACS, fatal or nonfatal out-of-hospital cardiac arrest, and non-cardioembolic ischemic stroke.[10] In studies such as LoDoCo, a lower number of primary outcome events relative to control indicate a reduced risk.

28. As Dr. Nidorf reported in 2013, "primary outcome occurred in 55 of 532 patients, including 15 of 282 patients (5.3%) assigned to colchicine treatment and 40 of 250 patients (16%) assigned to the control group (HR: 0.33; 95% confidence interval [CI] 0.18 to 0.59; p 0.001; number needed to treat: 11)."[11] LoDoCo demonstrated that "the addition of colchicine 0.5 mg/day to standard therapy in patients with stable coronary disease ***significantly reduced the risk of a cardiovascular event***, including ACS, out-of-hospital cardiac arrest, and noncardioembolic ischemic stroke."[12] The effect of colchicine on the primary outcome was "evident early, and the benefits of colchicine continued to accrue throughout the follow-up period."[13]

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[9] EX1020 (Nidorf 2013), 11, Table 1.

[10] EX1020 (Nidorf 2013), 11.

[11] EX1020 (Nidorf 2013), 13.

[12] EX1020 (Nidorf 2013), 14 (emphasis added).

[13] EX1020 (Nidorf 2013), 13.

29. Results from the first LoDoCo trial are significant because they provide the initial clinical evidence that an anti-inflammatory agent with diverse effects might be useful in the treatment or prevention of cardiovascular disease. LoDoCo also first demonstrated colchicine's role in the prevention of cardiovascular events in patients with underlying established coronary disease.[14] This was recognized in the literature, with the consensus being that LoDoCo showed that "[c]olchicine significantly reduced the incidence of a combined adverse cardiovascular end point."[15]

2. COLCOT Trial Design

30. Following the success of LoDoCo, the confirmatory COLCOT trial (Colchicine Cardiovascular Outcomes Trial) was designed to similarly test long-term use of 0.5 mg/day colchicine to reduce the risk of cardiovascular events in

[14] EX1020 (Nidorf 2013), 14.

[15] EX1042 (Toldo 2018), 9; *see also* EX1043 (Nidorf 2015), 2 ("The potential benefit of long-term colchicine in patients with stable coronary disease … was demonstrated prospectively in the LoDoCo trial in which the same (low) dose of colchcine used for secondary prevention in gout was safely and effectively employed in patients already taking high-dose statins and anti-platelet therapy."); EX1026 (Thompson 2018), 3 ("The 2013 publication of the LoDoCo trial demonstrated in a PROBE design that low-dose colchicine (0.5 mg/day) in patients on high-dose statins was well tolerated and was strongly suggestive of a marked benefit."); EX1044 (Tsivgoulis 2018), 3 ("In the LoDoCo RCT of 532 patients with chronic stable coronary artery disease, low dose of colchicine (0.5mg/day) reduced the risk of major cardiovascular events by 67% over a median follow-up period of 36 months. In this trial, colchicine had an excellent safety profile…").

patients having established underlying coronary disease, specifically an MI patient within 30 days prior to treatment.[16] As the COLCOT Protocol acknowledges, "[c]onsiderable work has highlighted the potential of colchicine in the treatment of cardiovascular diseases mediated by pro-inflammatory processes."[17] COLCOT Protocol built on LoDoCo, noting in reference to LoDoCo that "most recently colchicine has been evaluated for its effect on cardiovascular events in patients with coronary artery disease (CAD)."[18]

31. In addition to using the same 0.5 mg/day colchicine dose as LoDoCo, COLCOT used a similar primary outcome composite of cardiovascular death, resuscitated cardiac arrest, acute myocardial infarction, stroke, and hospitalization for angina requiring coronary revascularization.[19]

32. According to COLCOT Protocol, treatment was initiated within 30 days post-MI but only "after having completed any planned percutaneous revascularization procedures associated with their initial infarction."[20] COLCOT Protocol also excluded patients "with a poorly controlled medical condition," such

[16] EX1006 (COLCOT Protocol), 4-5.

[17] EX1006 (COLCOT Protocol), 4.

[18] EX1006 (COLCOT Protocol), 4.

[19] EX1006 (COLCOT Protocol), 2.

[20] EX1006, (COLCOT Protocol), 1.

as certain types of heart attack, "recent stroke (within the past 3 months)," and patients "currently in cardiogenic shock or with hemodynamic instability" are excluded from the study.[21] This means that the patient's acute MI has been stabilized by clearing the underlying arterial thrombosis and restoring cardiac blood flow prior to treatment initiation.

33. While both LoDoCo and COLCOT provide colchicine as a secondary prevention treatment for MI patients, the studies differed in that (1) COLCOT was limited to MI patients while LoDoCo also included other CAD patients, and (2) COLCOT initiated colchicine treatment to stabilized post-PCI patients within 30 days of the MI while LoDoCo started treatment after CAD (including MI) had been stable for at least 6 months.[22]

3. CANTOS Trial Design and Results

34. Around this same time, specifically in 2017, the so-called "inflammation hypothesis" of cardiovascular disease was proven in the large-scale placebo-controlled CANTOS trial (Canakinumab Anti-Inflammatory Thrombosis Outcomes Study) conducted by my group.

35. In the CANTOS trial, patients with a history of MI at least 30 days

[21] EX1006, (COLCOT Protocol), 5.

[22] *Compare* EX1006 (COLCOT Protocol), 1, 5 *with* EX1020 (Nidorf 2013), 11, Table 1.

before randomization and an increased high-sensitivity C-reactive protein level received a therapeutic monoclonal antibody (canakinumab) directly targeting and specifically inhibiting interleukin-1β, a key mediator of the inflammatory response.[23] The primary efficacy endpoint was the first occurrence of nonfatal myocardial infarction, any nonfatal stroke, or cardiovascular death in a time-to-event analysis.[24] As my 2017 paper reported, "a significant effect for the primary end point, was observed in the 150-mg group (hazard ratio vs. placebo, 0.85; P = 0.02075, with a threshold P value of 0.02115)."[25] The study proved that targeting the inflammatory pathway of those MI patients led to a significantly lower rate of recurrent cardiovascular events.[26] This beneficial effect occurred in the absence of any reduction in cholesterol, blood pressure, or other known therapeutic pathway for atherosclerotic disease. Further, because CANTOS employed a highly specific monoclonal antibody that targeted a single highly specific inflammatory molecule, the trial proved without doubt that direct inflammatory inhibition could in fact benefit patient care. Between 2017 and 2018, editorials and commentaries from

[23] EX1019 (Ridker 2017), 2.

[24] EX1019 (Ridker 2017), 4.

[25] EX1019 (Ridker 2017), 6.

[26] EX1019 (Ridker 2017), 2, 12.

eminent biologists described CANTOS as "a giant leap for vascular biology"[27], "a gigantic proof-of-concept trial"[28], "a new calculus of inflammasome targeting for vascular protection"[29], a study that "validates the inflammatory pathogenesis of atherosclerosis"[30] and a trial that opens "a new chapter in therapeutic targeting"[31].

36. The significance of CANTOS in proving the inflammation hypothesis of CAD is not limited to canakinumab and extended more broadly to several anti-inflammatory secondary prevention treatments of MI patients, particularly those that have direct or indirect impact on the canonical NLRP3 to interleukin-1 to interleukin-6 pathways of innate immunity, such as colchicine.[32] As reflected in the literature, "[w]ith the publication of the CANTOS results, clinicians have definitive evidence that directly targeting inflammation is beneficial for the secondary

[27] EX1033 (Baylis 2017), 1.

[28] EX1032 (Ibañez 2017), 1.

[29] EX1034 (Verma 2018), 1.

[30] EX1035 (Weber 2017), 1.

[31] EX1035 (Weber 2017), 1.

[32] EX1026 (Thompson 2018), 4, Figure 1 (acknowledging that colchicine is involved in inhibition of the assembly of the NLRP3 inflammasome through binding tubulin and that it acts through the IL-1β); EX1041 (Martinez 2015) (demonstrating that colchicine treatment of ACS patients was associated with significantly lower transcoronary release of key inflammatory cytokines IL-1β and IL-18, as well as IL-6).

prevention of cardiovascular disease."[33]

4. LoDoCo, CANTOS, and COLCOT All Initiated Treatment in Patients with Stabilized MI

37. LoDoCo, CANTOS, and COLCOT are all similar in targeting inflammation in stabilized coronary artery disease patients that had experienced an MI.

38. For instance, Nidorf discloses that patients eligible for LoDoCo had angiographically proven coronary disease that had been clinically stable for at least 6 months.[34] Among these, 23% of the enrolled patients had past acute MI or unstable angina.[35] Nidorf further explains:

> "Stable" in the context of the terms "stable cardiovascular disease", "stable coronary disease" or "stable coronary heart disease" is defined as any conditions of diagnosed cardiovascular disease in the absence of acute cardiovascular events. Hence, e.g. stable coronary disease defines the different evolutionary phases of coronary disease, excluding the situations in which coronary artery thrombosis dominates clinical presentation (acute coronary syndrome).[36]

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[33] *E.g.*, EX1017 (Reed 2017), 5.

[34] EX1007 (Nidorf), 18:31-34.

[35] EX1020 (Nidorf 2013), Table 1.

[36] EX1007 (Nidorf), 10:35-43.

39. By way of explanation, coronary artery thrombosis is the underlying arterial blockage causing sudden, reduced blood flow (acute coronary syndrome ("ACS")) that presents clinically as acute MI or unstable angina. Thus, for post-MI patients, "stable" according to Nidorf means that cardiac blood flow has been largely restored and the patient is no longer presenting with ACS generally or acute MI specifically.

40. CANTOS similarly treated post-MI patients that had been stabilized. This is reflected in full name of the CANTOS trial: "A randomized, double-blind, placebo-controlled, event driven trial of quarterly subcutaneous canakinumab in the prevention of recurrent cardiovascular events among ***stable post-myocardial infarction patients*** with elevated hsCRP."[37] More specifically, the CANTOS protocol[38] discloses that eligible participants "suffered a documented acute myocardial infarction at least 30 days before randomization,"[39] which skilled cardiologists also would understand as initiating treatment after the patients with the acute MI event had been stabilized.

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[37] EX1039 (CANTOS Protocol), 10 (emphasis added).

[38] My group provided EX1039 (CANTOS Protocol) to the New England Journal of Medicine along with the manuscript of my 2017 paper on CANTOS to give readers additional information about the CANTOS trial, which was published in the same issue of the journal with my 2017 paper as supplemental material.

[39] EX1039 (CANTOS Protocol), 19.

41. COLCOT also taught treating stabilized post-MI patients, as reflected in its eligibility criteria requiring that "[p]atient ***must have completed any planned percutaneous revascularization procedures*** associated with his or her qualifying myocardial infarction."[40] COLCOT Protocol further taught initiating treatment within 30 days post-MI but only "***after having completed any planned percutaneous revascularization procedures*** associated with their initial infarction."[41] As I explained above, this means that acute MI has been stabilized after percutaneous revascularization cleared the underlying arterial thrombosis and restored cardiac blood flow. Reinforcing that the patients are stable, COLCOT Protocol eligibility criteria excluded patients "with a poorly controlled medical condition," such as certain types of heart attack, "recent stroke (within the past 3 months)," and patients "currently in cardiogenic shock or with hemodynamic instability" are excluded from the study.[42]

42. As such, all three studies are directed to the treatment of stable post-MI patients, with each initiating treatment at progressively shorter post-MI time periods.

5. Other Accumulated Knowledge of Colchicine As of 2019

[40] EX1006 (COLCOT Protocol), 5 (emphasis added).

[41] EX1006 (COLCOT Protocol), 1 (emphasis added).

[42] EX1006 (COLCOT Protocol), 5.

43. Before 2019, the therapeutic benefits of colchicine in patients with ACS had been continuously further explored, and knowledge of its clinical benefits were further accumulated. *See* Section V.B., above. These studies demonstrate that the skilled cardiologist was motivated to initiating daily low-dose colchicine following an MI event to reduce the risk subsequent cardiovascular events with a reasonable expectation of successfully reducing such subsequent cardiovascular events.

44. For instance, Verma et al. conducted a meta-analysis of 15 randomized controlled trials to evaluate the benefits of colchicine in patients with both coronary artery and other cardiac diseases and concluded that "in different populations of patients with established cardiovascular disease, colchicine reduces the composite cardiovascular outcome by approximately 60%." [43] Verma further proposed plausible mechanisms to explain "the apparently beneficial effects of colchicine for prevention of cardiovascular events," explaining that "[b]y suppressing neutrophils, colchicine may play a role in stabilizing plaques and preventing fissuring or rupture that can result in the clinical manifestations of acute coronary ischemia or stroke."[44]

45. Referring to Verma's analysis, Nidorf further confirmed that colchicine showed "an overall benefit on cardiovascular risk reduction, in addition to its ability

[43] EX1030 (Verma 2015), 1, 10.

[44] EX1030 (Verma 2015), 11.

to reduce pericarditis."[45]

46. Vaidya et al. further acknowledged in 2018 that "[t]here is increasing evidence supporting a potentially beneficial role for colchicine therapy in prevention of cardiovascular disease (CVD)" and investigated whether colchicine therapy could reduce certain adverse plaque characteristics.[46] Vaidya demonstrates that "regular low-dose colchicine therapy has significantly greater coronary plaque-stabilizing effects than OMT [optimal medical treatment] alone, as evidenced by a significant reduction in both LAPV [low attenuation plaque volume] and hsCRP."[47] Vaidya concluded that "colchicine may be an attractive option to serve this need [for further agents for secondary prevention post-ACS] via further plaque stabilization."[48]

47. After the CANTOS trial results were published, Peter Thompson and Dr. Nidorf published a review article to "summarize[] recent work in finding effective, affordable alternatives to canakinumab" and highlights colchicine's similar impact on the canonical NLRP3 to interleukin-1 to interleukin-6 pathways

[45] EX1043 (Nidorf 2015), 2.

[46] EX1029 (Vaidya 2018), 2.

[47] EX1029 (Vaidya 2018), 7.

[48] EX1029 (Vaidya 2018), 8.

of innate immunity.[49] Drs. Thompson and Nidorf further acknowledged that "[i]n patients with coronary disease, low-dose colchicine rapidly reduces hs-CRP in patients taking statins, and has been shown to reduce coronary atherosclerotic plaque."[50] This review article further noted that the 2013 LoDoCo trial "strongly suggest[ed] a marked benefit" of low-dose colchicine and that the "use of low-dose colchicine is now being explored in trials totalling 15000 patients," including the LoDoCo2 trial and the COLCOT trial.[51]

48. Following results of LoDoCo and other trials showing colchicine's reduction of biomarker levels in stabilized patients, Tsivgoulis et al. taught that "[c]olchicine could be a safe and effective inhibitor of the inflammation cascade induced by extracranial or intracranial atherosclerosis, providing thus an additional therapeutic agent in secondary noncardioembolic stroke prevention." [52] As Tsivgoulis et al. explain, this use was also supported by elucidation of the inflammatory hypothesis by CANTOS:

> The positive results of the CANTOS trial not only show that

[49] EX1026 (Thompson 2018), 4 (acknowledging colchicine's inhibition of the assembly of the NLRP3 inflammasome" and its impairment of "the release of IL-1β into NETs").

[50] EX1026, (Thompson 2018), 4.

[51] EX1026, (Thompson 2018), 4.

[52] EX1044 (Tsivgoulis 2018), 4.

> canakinumab reduces cardiovascular risk in people with a prior heart attack and inflammatory atherosclerosis, but also provide invaluable support to the inflammatory hypothesis of atherothrombosis and expand even further on the contribution of innate immunity to cardiovascular health.

49. Indeed, before 2019, multiple other clinical trials initiating low dose colchicine in MI patients early post-MI had been already registered, initiated, or completed. For instance, Deftereos initiated colchicine treatment in patients with ST-segment–elevation myocardial infarction "⩽12 hours from the onset of chest pain" and reported "a potential benefit of colchicine in ST-segment–elevation myocardial infarction" based on certain biomarkers and infarct size reduction.[53]

50. The CLEAR-SYNERGY (OASIS-9) trial—a large-scale, randomized, and double-blinded multicenter international trial that enrolled about 4000 patients posted before 2019—also tested low dose colchicine in combination of another agent (spironolactone) in patients "with STEMI referred for PCI within 12 hours of symptom onset."[54] Following the results of LoDoCo, the colchicine dose in CLEAR-SYNERGY were decreased from 0.5 mg twice daily to 0.5 mg/daily.[55] The trial's

[53] EX1040 (Deftereos 2015), 5.

[54] EX1046 (CLEAR-SYNERGY Protocol), 2, 3; EX1047 (Nidorf 2019), 6.

[55] *See* EX1047 (Nidorf 2019), 6.

primary outcomes was, similar to LoDoCo and COLCOT, a composite of cardiovascular death and recurrent cardiovascular events such as recurrent Ml, stroke, or ischemia driven target vessel revascularization.[56]

51. The Colchicine Cardiovascular Outcomes in Acute Coronary Syndrome Study (COLCARDIO-ACS) study, another large-scale, randomized, placebo-controlled, double-blind multicenter trial of 3000 patients, was registered in 2016 and was similarly designed to administer 0.5 mg/day colchicine to patients with recent ACS, which are defined to include acute MI patients, with hs-CRP level of equal or greater than 2mg/L.[57] The primary efficacy outcomes of the study are major adverse cardiovascular events (MACE) and a composite of ACS including MI, urgent unscheduled revascularization, CV death, and non-fatal stroke, at 36 months.[58] The COLCARDIO-ACS study does not require any post-MI treatment initiation delay.[59]

52. Administration of 0.5 mg/day colchicine was also already underway in the Colchicine for prevention of Vascular Inflammation in Non- CardioEmbolic

[56] EX1046 (CLEAR-SYNERGY Protocol), 3.

[57] EX1048 (COLCARDIO-ACS Protocol), 2, 4.

[58] EX1048 (COLCARDIO-ACS Protocol), 2.

[59] *See* EX1048 (COLCARDIO-ACS Protocol), 4.

stroke ("CONVINCE")[60] trial for prevention of recurrent stroke and major vascular events.[61] While stroke (cerebral ischemia) differs from coronary artery disease and myocardial infarction, as Tsivgoulis et al. explains they were thought to be commonly linked by underlying arterial atherosclerosis.[62]

53. As Thompson and Nidorf summarized, as of 2018, multiple trials using low-dose colchicine in atherosclerotic-based conditions, including COLCOT, LoDoCo2, as well as the CONVINCE trial and CLEAR-SYNERGY trial, were underway.[63]

Table 2. Trials currently underway to test low-dose colchicine in atherosclerosis

Trial name and PI	Patients	Sample size	Dose	Clinical trial registration
Acute coronary syndromes				
Tardif *et al.*, Canada; COLCOT	Acute coronary syndrome	4500	Colchicine 0.5 mg/day vs. placebo	NCT025510 94
Jolly *et al.*, Canada, CLEAR-SYNERGY OASIS-9	Stent Registry ST elevation myocardial infarction	4000	Colchicine 1 mg/day and/or spironolactone 25 mg/day and/or placebo and/or SYNERGY stent (2 × 2 factorial design),	NCT030488 25
Stable coronary disease				
Nidorf *et al.*, Australia, Netherlands; LoDoCo2	Stable coronary artery disease	5500	Colchicine 0.5 mg/day vs. placebo	ACTRN1261 4000093684
Stroke or high-risk TIA				
Kelly *et al.*, Ireland; CONVINCE	Stroke or high risk transient ischaemic attacks	2623	Colchicine 0.5 mg/day vs. placebo	NCT028986 10

[60] EX1045 (CONVINCE) (CONVINCE entailed 0.5mg/day (no loading dose) for 60 months, administered following ischemic stroke or high-risk transient ischemic attack ("TIA"), without any required treatment initiation delay).

[61] EX1044 (Tsivgoulis 2018), 4.

[62] EX1044 (Tsivgoulis 2018), 2-3.

[63] EX1026 (Thompson 2018), 3-4.

EX1026, Table 2.

6. COLCOT Trial Results

54. Given previously published results from the first LoDoCo trial and from CANTOS, it was highly reassuring to the clinical community when, in 2019, the COLCOT trial reported by Tardif et al (EX1022) confirmed these earlier observations by also showing a reduced risk of cardiovascular events following colchicine 0.5 mg/day administration initiated within 30 days of an MI.

55. Before discussing the data from carrying out COLCOT Protocol, Tardif 2019 acknowledges the earlier success of the LoDoCo trial, noting the LoDoCo trial had shown that "patients with stable coronary disease treated with colchicine at a dose of 0.5 mg once daily had fewer cardiovascular events than those not receiving colchicine."[64]

56. As for COLCOT's results, Tardif 2019 reports that "[a] primary end-point event occurred in 5.5% of the patients in the colchicine group, as compared with 7.1% of those in the placebo group (hazard ratio, 0.77; 95% confidence interval [CI], 0.61 to 0.96; P = 0.02 by the log-rank test)."[65] It concludes that "among patients with a recent myocardial infarction, colchicine at a dose of 0.5 mg daily led to a significantly lower percentage of patients with ischemic cardiovascular events than

[64] EX1022 (Tardif 2019), 3, 10 (citing EX1020 (Nidorf 2013) as Ref. No. 9).

[65] EX1022 (Tardif 2019), 5-6.

placebo."[66]

57. In late August 2020, using data from the COLCOT trial, Dr. Bouabdallaoui and two dozen colleagues published a *post hoc* analysis using three different cut-offs for time-to-treatment-initiation (TTI) that were not pre-specified but rather "were determined based on the usual journey of patients with MI."[67] I was aware of this publication at the time as it was released on-line in the European Heart Journal coincident with its public presentation as part of the European Society of Cardiology's August 29-September 1, 2020, "ESC Congress 2020," which included the presentation of the COLCOT *post hoc* TTI results.[68]

58. Specifically, the 30-day post-MI timeline was divided into day 0 to 3, day 4 to 7, and day 8 to 30, which Bouabdallaoui acknowledges as referring to "in-hospital management," "early post-discharge period," and "late post-discharge period," respectively.[69] This is the same *post hoc* analysis that is described in the '063 patent filed later in 2020.[70]

59. According to Bouabdallaoui, the *post hoc* TTI data show that "early

[66] EX1022 (Tardif 2019), 9.

[67] EX1005 (Bouabdallaoui), 4-5, Table 3.

[68] *See e.g.*, EX1025 (ESC Congress 2020 Report), 36.

[69] EX1005 (Bouabdallaoui), 3.

[70] EX1005 (Bouabdallaoui), 4-5, Table 3.

initiation of low-dose colchicine within the first 3 days after MI is associated with a reduction of 48% in the risk of the primary endpoint consisting of a composite of CV death, resuscitated cardiac arrest, MI, stroke, or urgent hospitalization for angina requiring coronary revascularization, in comparison with placebo."[71] Bouabdallaoui concludes that "[t]he benefits were more marked when treatment was initiated within the first 3 days after MI, as compared with between Days 4 and 30, supporting the strategy of in-hospital initiation of colchicine."[72] Of note, however, no statistical test addressing whether or not there was a true and statistically significant difference in outcomes across these three *post-hoc* time cutpoints is presented. This is an important issue as reliance on this kind of *post hoc* subgroup analysis has long been frowned upon in the interpretation of clinical trials for acute ischemia and secondary prevention therapies of cardiovascular events, ever since the observation was made over 30 years ago in the ISIS-2 trial in which aspirin, an extremely effective drug for treatment of acute coronary ischemia (with an overall P-value < 0.000001), was nonetheless found to be "ineffective" among those born under the zodiac signs of Libra or Gemini, an obvious biologic fallacy.[73]

C. Post-MI Secondary Prevention Treatment

[71] EX1005 (Bouabdallaoui), 5.

[72] EX1005 (Bouabdallaoui), 5.

[73] EX1027 (ISIS-2 1988), 9.

60. Well before 2019, it had been common practice to initiate proven secondary prevention treatment for MI survivors as soon as practical so that it can begin to provide its long-term cardiovascular risk reduction benefit. In particular, secondary prevention treatment treatments were routinely initiated following initial stabilization of the MI and prior to hospitalization discharge, typically no more than 3-day post-MI.[74]

61. For instance, ESC (the European Society of Cardiology) Guidelines for the management of acute MI in patients presenting with ST-segment elevation ("ESC Guidelines") recognized the problems of reduced patient compliance (adherence) to secondary prevention treatments once the patients are discharged from hospitals, pointing out that "[l]ow treatment adherence is an important barrier

[74] EX1014 (Grin 1998), 1 ("Early identification of low risk patients with MI allowed safe omission of the intensive care phase and noninvasive testing, and a day 3 hospital discharge strategy, resulting in substantial cost savings"); EX1011 (Tran 2018), 1 ("The average length of stay (LOS) for patients hospitalized with acute myocardial infarction (AMI) has declined significantly over the past several decades" to about 3 days) ("[p]prior observational studies and randomized clinical trials have shown that the early (⩽72 hours) hospital discharge of patients with an uncomplicated, low risk, AMI is safe and cost-effective"), 4, 6 (average length of stay of around 3 days provided benefits across different subtypes of MI patients); EX1009 (ESC Guidelines), 13, 24 ("studies have shown that low-risk patients with successful primary PCI and complete revascularization can safely be discharged from hospital on day 2 or day 3 after [the] PCI," which was usually performed "within 12 h of symptom onset.").

to achieving optimal treatment targets and is associated with worse outcomes."[75] It was also known that "[d]elayed outpatient follow-up after AMI results in worse short- and long-term medication adherence," further highlighting the importance and potential benefit of initiating treatments after the patients are stabilized and before they are discharged from hospitals.[76] In this context, ESC Guidelines expressly recommended that for statins, which were already a standard of care at the time for post-MI patients for secondary prevention, "treatment should be started as early as possible, as this increases patient adherence after discharge, and given as high-intensity treatment, as this is associated with early and sustained clinical benefits."[77]

62. Consistent with such recommendation, Stenestrand had shown that early initiation of statin treatment in MI patients before or at patient discharge was associated with clinical benefits such as reduced 1-year mortality.[78] Stenestrand concluded that "our findings suggest that initiation of statin treatment before or at the time of hospital discharge should be recommended for AMI survivors" "for statin treatment as secondary prevention."[79]

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[75] EX1009 (ESC Guidelines), 30.

[76] EX1009 (ESC Guidelines), 30.

[77] EX1009 (ESC Guidelines), 33.

[78] EX1008 (Stenestrand), 7, 8.

[79] EX1008 (Stenestrand), 9.

63. As I explained above, before 2019, skilled cardiologists had initiated colchicine treatment early post-MI and prior to hospital discharge in multiple clinical trial studies, including the study described in Deftereos and the CLEAR-SYNERGY (OASIS-9) trial.[80] Deftereos reported based on the study results "a potential benefit of colchicine in ST-segment elevation myocardial infarction."[81]

D. Ground 1-4 References

1. US 10,206,891 ("Nidorf," EX1007)

64. U.S. Patent No. 10,206,891 ("Nidorf") is a patent issued on November 16, 2017.[82] I understand that Nidorf is prior art to all claims of the '063 patent.

65. Nidorf describes colchicine as a well-recognized and validated anti-inflammatory therapy in acute conditions such as acute flares of gouty arthritis.[83] Nidorf teaches administering colchicine, including at doses of 0.5 mg/day, for treating and/or preventing a cardiovascular event.[84]

66. Nidorf further teaches that in some embodiments, "the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, and/or

[80] EX1040 (Deftereos 2015), 1; EX1046 (CLEAR-SYNERGY Protocol), 2, 3.

[81] EX1040 (Deftereos 2015), 1.

[82] EX1007 (Nidorf), 1.

[83] EX1007 (Nidorf), 1:26-28.

[84] EX1007 (Nidorf), 2:56-62, 3:2-6, 17:3-6.

noncardioembolic ischemic stroke."[85] Nidorf explains that "the present invention can be used to treat cardiovascular diseases…including… acute vascular diseases, such as myocardial infarction, stroke" and that such "[t]herapeutic intervention with colchicine" can be used together with other secondary prevention agents such as statins.[86]

67. Nidorf describes the "LoDoCo" trial that "assess[ed] the therapeutic effects" of colchicine in "patients with cardiovascular disease" by administering 0.5 mg/day of colchicine without a preloading dose to patients with clinically stable coronary disease.[87] Patients who were eligible had "angiographically proven coronary disease" and had been clinically stable for at least 6 month.[88]

68. The primary efficacy outcomes of LoDoCo were cardiovascular events such as ACS (acute coronary syndrome), fatal or non-fatal out of hospital cardiac arrest, and non-cardio-embolic ischemic stroke.[89] Nidorf explains that an ACS is defined as either an acute myocardial infarction or unstable angina.[90] Nidorf explains

[85] EX1007 (Nidorf), 2:66-3:2.

[86] EX1007 (Nidorf), 7:62-65, 8:2-7, 12:50-62.

[87] EX1007 (Nidorf), 17:66-18:8.

[88] EX1007 (Nidorf), 18:31-34.

[89] EX1007 (Nidorf), 19:26-29.

[90] EX1007 (Nidorf), 19:6-14.

that "the primary analysis was stratified by … past myocardial infarction, …and therapy with aspirin, … , high dose statin therapy…"[91] The Nidorf 2013 paper (EX1020) that discusses the same LoDoCo trial confirms that 23% of the enrolled patients had "past AMI [acute myocardial infarction] or UA [unstable angina]."[92]

69. Nidorf reports that "[t]he effect of colchicine on the primary outcome was evident early and the benefits of colchicine continued to accrue throughout the follow up period."[93] Nidorf concluded that "[t]his trial demonstrates that the addition of colchicine 0.5 mg/day to standard therapy in patients with stable coronary disease significantly reduces the risk of a cardiovascular event, including an ACS, out of hospital cardiac arrest and non-cardio-embolic ischemic stroke."[94]

2. Bouabdallaoui (EX1005)

70. Bouabdallaoui et al. was published online on August 29, 2020, in the European Heart Journal.[95] I was aware of this publication at the time as it was released on-line in the European Heart Journal coincident with its public presentation as part of the European Society of Cardiology's August 29-September

[91] EX1007 (Nidorf), 20:3-7.

[92] EX1020 (Nidorf 2013), Table 1.

[93] EX1007 (Nidorf), 20:34-36.

[94] EX1007 (Nidorf), 21:55-59.

[95] EX1005 (Bouabdallaoui), 1.

1, 2020, "ESC Congress 2020," which included the presentation of the COLCOT *post hoc* TTI results.[96]

71. I understand that because Bouabdallaoui published August 29, 2020, it is prior art to claims of the '063 patent that have an "effective filing date" of November 13, 2020, when the application for the '063 patent was actually filed. As I explained further in Section VI.C, in my opinion claims 1-26, 28, and 40-50 are not entitled a priority date before November 13, 2020, because limitations of initiating treatment "within about 3 days of the MI" and "within 4 to 7 days of the MI" are not described in earlier provisional applications. Based on this, I understand that Bouabdallaoui is prior art to claims 1-26, 28, and 40-50.

72. Bouabdallaoui discloses the same COLCOT study and the same time-to-treatment *post hoc* analysis as the '063 patent.[97] Bouabdallaoui further discloses, among other things in common with the '063 patent, that

- "[t]he vast majority of patients (93.0%) underwent PCI during the index hospitalization;"
- "[b]ackground therapy included aspirin, a second anti-platelet agent and a statin in 98.8%, 98.0%, and 99.0% of patients, respectively;"

[96] *See e.g.*, EX1025 (ESC Congress 2020 Report), 36.

[97] *Compare* EX1005 (Bouabdallaoui), Table 3 and Figure 2 *with* EX1001 ('063 patent), Table 3 and Figure 2.

- patients received either 0.5 mg once daily colchicine or placebo;
- the 30-day post-MI time "was divided into three independent periods of times and analysed as such: from Day 0 to 3, referring to in-hospital management; from Day 4 to 7, referring to early post-discharge period, and from Day 8 to 30, referring to later post-discharge period;" and
- the primary efficacy end point "was a composite of CV death, resuscitated cardiac arrest, MI, stroke, or urgent hospitalization for angina requiring coronary revascularization."[98]

73. Bouabdallaoui acknowledges that the three periods of time analyzed in the paper, i.e., from Day 0 to 3, from Day 4 to 7, and Day 8 to 30, each refer to "in-hospital management," "early post-discharge period;" and "late post-discharge period," respectively.[99]

74. Bouabdallaoui reports efficacy identical to the '063 patent[100] (EX1001, 11:26-33 and 12:24-33), including that

> A primary endpoint event occurred in 4.3% of patients in the colchicine group, as compared with 8.3% of those in the

[98] EX1005 (Bouabdallaoui), 3-4.

[99] EX1005 (Bouabdallaoui), 3.

[100] EX1001 ('063 patent), 11:26-33 and 12:24-33.

placebo group when TTI was between Days 0 and 3 (N= 1193, HR= 0.52, 95% CI 0.32–0.84, P= 0.007, Figure 3A). Corresponding rates were 6.0% and 5.9% when TTI was between Days 4 and 7 (N=720) and 5.7% and 7.1% when TTI was on Day 8 or after (N=2748). Table 3 also shows the percentages of patients with events and the hazard ratios for the components of the primary endpoint, including CV death (HR = 1.04, 95% CI 0.15–7.37), resuscitated cardiac arrest (HR = 0.33, 95% CI 0.03–3.20), MI (HR = 0.58, 95% CI 0.32–1.05), stroke (HR= 0.21, 95% CI 0.02–1.81), and urgent hospitalization for angina requiring coronary revascularization (HR = 0.35, 95% CI 0.14–0.88).[101]

75. Bouabdallaoui concludes that the results "support[] the strategy of in-hospital initiation of colchicine in order to improve CV outcomes post-MI."[102]

3. COLCOT Protocol (EX1006)

76. COLCOT Protocol is an updated version of the protocol of the COLCOT trial (study No. NCT02551094) published on the clinicaltrial.gov website[103] on March 8, 2017. I understand COLCOT Protocol is prior art to all

[101] EX1005 (Bouabdallaoui), 4.

[102] EX1005 (Bouabdallaoui), 5.

[103] Clinicaltrial.gov is a well-known resource routinely used by skilled cardiologist clinicians including myself to check updated clinical study information. It is my understanding and personal experience that as of 2019, new clinical trials submitted

claims of the ’063 patent.[104]

77. COLCOT Protocol acknowledges that (1) “[a]therosclerosis is the most common cause of myocardial infarction, stroke and peripheral arterial disease;” (2) “[r]esearch has clearly demonstrated that inflammation plays a key role in the initiation, progression and manifestations of atherosclerosis;” and (3) “[i]t is likely that the inflammatory process is responsible for the high rate of cardiovascular events.”[105] COLCOT Protocol further recognizes that “[c]onsiderable work has highlighted the potential of colchicine in the treatment of cardiovascular diseases mediated by pro-inflammatory processes” and that “[m]ore recently, colchicine has been evaluated for its effect on cardiovascular events in patients with coronary artery disease (CAD)” (citing the LoDoCo trial).

78. COLCOT Protocol then discloses the same COLCOT trial described as Example 2 the ’063 patent, explaining that the study evaluates colchicine’s reduction of rates of cardiovascular events in patients after myocardial infarction in “[p]atients who have suffered a documented acute myocardial infarction within the last 30 days” but “after having completed any planned percutaneous revascularization procedures

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to Clinicaltrial.gov were routinely posted on the website and made available to the public in a timely manner.

[104] EX1006 (COLCOT Protocol), 1.

[105] EX1006 (COLCOT Protocol), 4.

associated with their initial infarction."[106] COLCOT Protocol further discloses that it excluded patients with unstable conditions, such as those "with a poorly controlled medical condition, such as New York Heart Association Class III-IV heart failure, a left ventricular ejection fraction of less than 35%, recent stroke (within the past 3 months)" and those "currently in cardiogenic shock or with hemodynamic instability."[107]

79. COLCOT Protocol describes administering a 0.5 mg tablet of colchicine once per day to the patients.[108] COLCOT Protocol discloses classic cardiovascular events as primary outcome measures, which are identical to those recited in the '063 patent claims, including cardiovascular death, resuscitated cardiac arrest, acute myocardial infarction, stroke, and hospitalization for angina requiring coronary revascularization.[109]

4. ESC Guidelines (EX1009)

80. The "2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation" compiled by the Task

[106] *Compare* EX1006 (COLCOT Protocol), 1 *with* EX1001 ('063 patent), 1:66-2:28, 7:22-8:40.

[107] EX1006 (COLCOT Protocol), 5.

[108] EX1006 (COLCOT Protocol), 1, 4.

[109] EX1006 (COLCOT Protocol), 2.

Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC)[110] was published online in August 26, 2017.[111] Since its online publication, ESC Guidelines had been publicly available to POSA, and by 2018, it had been reviewed and cited by clinicians all over the world.[112]

81. ESC Guidelines "summarize and evaluate available evidence with the aim of assisting health professionals in selecting the best management strategies for an individual patient with a given condition."[113] It discusses both emergency care for MI patients, management during hospitalization and at discharge, and long-term therapies for ST-segment elevation myocardial infarction.[114]

82. In discussing urgent care immediately after the MI, ESC Guidelines explain that "[p]rimary PCI is the preferred reperfusion strategy in patients with STMI within 12 h of symptom onset, provided it can be performed expeditiously (i.e.

[110] The European Society of Cardiology is a professional cardiology association that provides education and guidance to cardiologist, and was well-known and respected by skilled cardiologists.

[111] EX1009 (ESC Guidelines), 1-2.

[112] *See e.g.*, EX1023 (Kubica 2018), 8 (published in 2018 and citing ESC Guidelines (EX1009) as Reference No. 3); EX1024 (Ozaki 2018) (published in 2018 and citing ESC Guidelines (EX1009) as Reference No. 20).

[113] EX1009 (ESC Guidelines), 5.

[114] EX1009 (ESC Guidelines), 2.

120 min from STEMI diagnosis, Figures 2 and 3) by an experienced team."[115]

83. ESC Guidelines further acknowledge that "[s]everal studies have shown that low-risk patients with successful primary PCI and complete revascularization can safely be discharged from hospital on day 2 or day 3 after PCI."[116]

84. When discussing long-term therapies for STEMI, ESC Guidelines acknowledge that "[l]ow treatment adherence is an important barrier to achieving optimal treatment targets and is associated with worse outcomes," and that "[d]elayed outpatient follow-up after AMI results in worse short- and long-term medication adherence." [117] Thus, ESC Guidelines recommend that secondary prevention statin treatments "should be started as early as possible, as this increases patient adherence after discharge, and given as high-intensity treatment, as this is associated with early and sustained clinical benefits."[118]

5. COLCRYS (EX1016)

85. The package insert for COLCRYS™ (colchicine, USP) tablets ("COLCRYS") for oral administration to treat gout flares and FMF was published

[115] EX1009 (ESC Guidelines), 13.

[116] EX1009 (ESC Guidelines), 24.

[117] EX1009 (ESC Guidelines), 30.

[118] EX1009 (ESC Guidelines), 33.

in 2009.[119] COLCRYS shows that the tablets are supplied as "film-coated, capsule-shaped tablets)," "containing 0.6 mg of the active ingredient colchicine USP."[120]

VI. THE '063 PATENT

A. The Challenged Claims

86. The '063 patent has three independent claims, claims 1, 8, and 27. Claim 1 recites a method of treating MI patients who had received PCI by administering colchicine at a daily low dose without a preloading dose within about 3 days of the MI. Claim 8 similarly recites a method of treating MI patients by administering colchicine at a daily low dose without a preloading dose within about 3 days of the MI to reduce a risk of one of the recited cardiovascular events. Claim 27 recites a method of reducing stroke risk in MI patients by initiating colchicine administration with a daily low dose within about 30 days of the MI.

87. The dependent claims further recite:

- Additional medication claims: the patient was prescribed a medication or more specifically an antiplatelet agent (or more specifically aspirin) or statin (claims 2-5, 28-32, and 40-43);
- Cardiovascular event claims: the patient is at a lower risk of a cardiovascular event or more specifically an ischemic

[119] EX1016 (COLCRYS), 1.

[120] EX1016 (COLCRYS), 1, 9.

cardiovascular event, relative to a patient not being administered colchicine (claims 6 and 7); the cardiovascular event of claim 8 is myocardial infarction (claim 9), stroke (claim 10), urgent hospitalization for angina requiring coronary revascularization (claim 11), or resuscitated cardiac arrest (claim 50);

- Patient population claims: the patient has atherosclerotic coronary artery disease (claims 12, 33 and 44) or is an adult human (claims 26, 39, and 49);
- "Initiation upon assessment" claims: the administration of colchicine is initiated upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting (claims 13, 36, and 46);
- Tablet claims: the colchicine is a tablet, or more specifically a coated tablet, or more specifically a film-coated tablet (claims 14-16, 37, 38, 47, and 48);
- Dose and frequency claims: the colchicine is administered at more specific doses, including 0.3 to 0.7 mg, 0.4 to 0.6 mg, or 0.5 mg, or more specific dosing frequencies, including once to three times a day, or more specifically once a day (claims 17-25, 35, and 45); and

- Administration initiation time claim: administering colchicine within 4 to 7 days of the MI (claim 28).

88. I am listing the claims and limitations below with added lettering (in square brackets) to identify individual clauses in each independent claim:

Claim limitations
1[a]. A method of treating a patient after having a myocardial infarction (MI), **1[b]. the method comprising initiating the administration of colchicine at a daily low dose to the patient…,** **1[c] wherein the colchicine is administered without pre-loading the patient with a higher dose of colchicine before the administration at the daily low dose,** **1[d] within about 3 days of the MI** **1[e] wherein percutaneous coronary intervention was performed for treating the patient's MI.**
2. The method according to claim 1, wherein the patient was prescribed a medication.
3. The method according to claim 2, wherein the medication is an antiplatelet agent.
4. The method according to claim 2, wherein the medication is aspirin.
5. The method according to claim 2, wherein the medication is a statin.

6. The method according to claim 1, wherein the patient is at a lower risk of a cardiovascular event, relative to a patient not being administered colchicine.
7. The method according to claim 6, wherein the cardiovascular event is an ischemic cardiovascular event.
8[a]. A method of treating a patient alter having a myocardial infarction (MI), **8[b] the method comprising initiating the administration of colchicine at a daily low dose to the patient…,** **8[c] wherein the colchicine is administered without pre-loading the patient with a higher dose of colchicine before the administration at the daily low dose,** **8[d] within about 3 days of the MI** **8[e] wherein the patient is at a lower risk of a cardiovascular event, relative to a patient not being administered colchicine, and wherein the cardiovascular event is resuscitated cardiac arrest, stroke, or urgent hospitalization for angina requiring coronary revascularization.**
9. The method according to claim 6, wherein the cardiovascular event is myocardial infarction
10. The method according to claim 8, wherein the cardiovascular event is stroke.
11. The method according to claim 8, wherein the cardiovascular event is urgent hospitalization for angina requiring coronary revascularization.

12. The method according to claim 1, wherein the patient has atherosclerotic coronary artery disease.
13. The method according to claim 1, wherein the administration of colchicine is initiated upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting
14. The method according to claim 1, wherein the colchicine is in the form of a tablet.
15. The method of claim 14, wherein the tablet is coated.
16. The method of claim 15, wherein the tablet is film-coated.
17. The method according to claim 1, wherein the colchicine is administered at 0.3 to 0.7 mg.
18. The method according to claim 17, wherein the colchicine is administered at 0.4 to 0.6 mg.
19. The method according to claim 18, wherein the colchicine is administered at 0.5 mg.
20. The method according to claim 8, wherein the colchicine is administered at 0.5 mg.
21. The method according to claim 9, wherein the colchicine is administered at 0.5 mg.
22. The method according to claim 10, wherein the colchicine is administered at 0.5 mg.

23. The method according to claim 11, wherein the colchicine is administered at 0.5 mg
24. The method according to claim 1, wherein the colchicine is administered once, twice or three times a day.
25. The method according to claim 24, wherein the colchicine is administered once per day.
26. The method according to claim 1, wherein the patient is an adult human.
27 [a] A method of reducing the risk of a stroke in a patient after having an MI, **27 [b] the method comprising initiating the administration of colchicine at a daily low dose to the patient** **27[c] within about 30 days of an MI.**
28. The method according to claim 27, wherein the method comprises administering colchicine within 4 to 7 days of the MI.
29. The method according to claim 27, wherein the patient was prescribed a medication.
30. The method according to claim 29, wherein the medication is an antiplatelet agent.
31. The method according to claim 29, wherein the medication is aspirin.
32. The method according to claim 29, wherein the medication is a statin.

33. The method according to claim 27, wherein the patient has atherosclerotic coronary artery disease.
34. The method according to claim 27, wherein the colchicine is administered at 0.5 mg.
35. The method according to claim 27, wherein the colchicine is administered once per day.
36. The method according to claim 27, wherein the administration of colchicine is initiated upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting.
37. The method according to claim 27, wherein the colchicine is in the form of a coated tablet.
38. The method of claim 37, wherein the tablet is film-coated.
39. The method of claim 27, wherein the patient is an adult human.
40. The method according to claim 8, wherein the patient was prescribed a medication
41. The method according to claim 40, wherein the medication is an antiplatelet agent.
42. The method according to claim 40, wherein the medication is aspirin.
43. The method according to claim 40, wherein the medication is a statin.
44. The method according to claim 8, wherein the patient has atherosclerotic

coronary artery disease.
45. The method according to claim 8, wherein the colchicine is administered once per day.
46. The method according to claim 8, wherein the administration of colchicine is initiated upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting.
47. The method according to claim 8, wherein the colchicine is in the form of a coated tablet.
48. The method of claim 47, wherein the tablet is film-coated.
49. The method of claim 8, wherein the patient is an adult human.
50. The method of claim 8, wherein the cardiovascular event is resuscitated cardiac arrest.

B. Level of Ordinary Skill in the Art ("Skilled Cardiologist")

89. The '063 patent involves treating patients with MI by administrating colchicine. Based on this context, a POSA, which I will also refer to as a "skilled cardiologist," would have an M.D. degree and be board certified with a subspecialty in the treatment of cardiovascular disease. The skilled cardiologist should also have had at least 3-5 years of experience, following board certification, in cardiology and cardiovascular disease treatment and sufficient clinical experience to understand standard good medical practice in patient management. The skilled cardiologist

would have been familiar with acute coronary syndromes, stable coronary diseases, cardiovascular diseases, and their standard treatments, including the acute management and long-term secondary preventions of myocardial infarction. By 2019, the skilled cardiologist would have been aware of research relating to cardiovascular disease progression, including the role of inflammatory pathways in secondary cardiovascular events.

C. Administering Colchicine to MI Patients "Within About 3 Days of the MI" or "Within 4 to 7 Days of the MI" Is Not Disclosed in The Patent's Priority Applications

90. Claims 1-26 and 40-50 require administering colchicine to MI patients "within about 3 days of the MI," and claim 28 requires administering colchicine to MI patients "within 4 to 7 days of the MI."

91. I was asked to review the (1) November 15, 2019, provisional application (EX1004) and (2) the October 20, 2020, provisional application (EX1003) identified in the "Related U.S. Application Data" section on the cover page of the '063 patent to see if a skilled cardiologist would have understood them to disclose initiating colchicine treatment "within about 3 days of the MI" or "within 4 to 7 days of the MI."[121] In my opinion, neither provisional application discloses initiating colchicine treatment within this period.

[121] *See generally* EX1004 (November 15, 2019, provisional application); EX1003 (October 20, 2020, provisional application); EX1001 ('063 patent), (60).

92. Although the November 15, 2019, provisional application discloses "administering colchicine within 5, 10, 15, 20, or 25 days of the MI," it does not mention within "3 days," "about 3 days," or "4 to 7 days" anywhere in the specification.[122] The November 15, 2019, provisional application then further focuses on waiting periods of longer than 5 days before colchicine administration, stating that "the method includes administering colchicine ***within 10 days of the myocardial infarction***. In still other embodiments, the method includes administering colchicine ***within 15 days of the myocardial infarction***. In yet other embodiments, the method includes administering colchicine ***at about 30 days of the myocardial infarction (for example, at 31, 32, or 33 days)***."[123]

93. A skilled cardiologist would not have understood that these longer time periods ("within 5, 10, 15, 20, or 25 days of the MI") had described administering colchicine within a shorter period of about 3 days of the MI or within 4 to 7 days of the MI. Indeed, I noted that when the November 15, 2019, provisional application describes the COLCOT trial, it emphasizes that "[p]atients were enrolled a ***mean of 13.5 days*** after myocardial infarction."[124] This would have further confirmed to a

[122] EX1004 (November 15, 2019, provisional application), 2:32-33.

[123] EX1004 (November 15, 2019, provisional application), 2:33-36 (emphases added).

[124] EX1004 (November 15, 2019, provisional application), 9:2.

skilled cardiologist that the COLCOT study was not specifically designed to test colchicine treatment in patients within 3 days or within 4 to 7 days after the MI.

94. The October 20, 2020, provisional application, which seems to be a manuscript of a paper describing the results of the COLCOT Protocol designed to administer colchicine within 30 days of the MI, also does not disclose initiating colchicine administration within about 3 days or within 4 to 7 days of the MI. Instead, the manuscript describes the COLCOT trial as being conducted in "patients who had a recent MI (⩽30 days)."[125] Nowhere does the manuscript mention or describe an analysis of treatment initiated within a period of about 3 days or within 4 to 7 days of the MI.[126]

95. Thus, in my opinion, neither of the provisional applications would have been understood by a skilled cardiologist to disclose the later added and claimed "within about 3 days of the MI" and "within 4 to 7 days" limitations.

96. I was informed and understand that this means that claims 1-26 and 40-50 reciting this "within about 3 days of the MI" limitation and claim 28 reciting the "within 4 to 7 days" limitation are thus not entitled to an "effective filing date" earlier than the actual filing date of the November 13, 2020, nonprovisional application that

[125] EX1003 (October 20, 2020, provisional application), 5, Table 1.

[126] *See generally* EX1003 (October 20, 2020, provisional application).

was issued as the ’063 patent.

D. Claim Construction

1. “treating”

97. Claims 1-26 and 40-50 all recite “a method of treating a patient after having a myocardial infarction (MI).”[127] Based on my review of the ’063 patent, in my opinion a skilled cardiologist would understand that the claim language “treating” is synonymous with “providing treatment to” and does not require obtaining any clinical results such as any type or degree of clinical efficacy.

98. In its ordinary meaning to a skilled cardiologist, “treat” or “treating” includes providing care to a patient by, for instance, prescribing or administering medication with the objective of managing a medical condition. While the goal of treatment is to improve the patient’s health, a skilled cardiologist would nonetheless consider prescribing or administering medication as “treating” even if not effective.

99. For instance, ESC Guidelines use “treatment” and “treatment strategy” interchangeably and describe “treatment delays.”[128] This usage indicates that “treating” is used to refer to the act of providing medical care with a goal of, but not

[127] EX1001 (’063 patent), claims 1-26 and 40-50.

[128] *E.g.*, EX1009 (ESC Guidelines), 6 (“MI is classified into various types, based on pathological, clinical, and prognostic differences, along with different treatment strategies”), 9 (“This is indicated, but should not delay the reperfusion strategy/treatment”), 10 (“Treatment delays are the most easily audited index of quality of care in STEMI”).

necessarily achieving, efficacy.

100. In my opinion, nothing in the ’063 patent changes this ordinary meaning.

101. For instance, claim 1 is directed to a “method of treating” without specifying any clinical efficacy or including any language that requires a therapeutically effective amount of colchicine. By contrast, claim 8, which is also directed to a “method of treating,” separately states that “the patient is at a lower risk of a cardiovascular event, relative to a patient not being administered colchicine.” A skilled cardiologist would understand from this that the common “method of treatment” language does not require a clinical result such as the “lower risk” results separately recited in claim 8.

102. The ’063 patent also does not define “treating” as requiring any clinical efficacy or otherwise teaches that this term requires any actual treatment. Instead, the ’063 patent only provides definitions of certain cardiovascular events, which do not relate to the claimed “treating” or support requiring any clinical response.[129]

103. The ’063 patent also uses “treat” consistent with its ordinary meaning of “providing treatment to.” For example, it refers to the patient “concurrently being treated with a medication (for example, antiplatelet agent, a statin, aspirin, or a

[129] EX1001 (’063 patent), 5:55-6:40.

combination thereof)"[130] without any implied or required result of the treatment. Similarly, COLCOT Protocol also mentions "treatment" in the context of evaluating potential clinical effects instead of requiring actual clinical efficacy. EX1006, 2 ("evaluat[ing] whether long-term treatment with colchicine reduces rates of cardiovascular events in patients after myocardial infarction.").

2. "a method of reducing the risk of a stroke"

104. Claims 27-39 all recite "a method of reducing the risk of a stroke in a patient after having an MI."[131] In my opinion, a skilled cardiologist would understand this to be the objective of the treatment—the treatment goal. In my opinion, a skilled cardiologist would not understand "a method of reducing the risk of a stroke" in this context as requiring any actual reduction of stroke risk.

105. In its ordinary meaning to a skilled cardiologist, when a medication is used to reduce the risk of a cardiovascular event, it only means that the drug is administered with the hope of being able to achieve reduction of the cardiovascular event risk in the patient. This is due, in part, to the nature of clinical practice in cardiology, where one knows if a treatment in an individual patient was effective to avoid a secondary cardiovascular event. Thus, a skilled cardiologist would understand that "a method of reducing the risk of a stroke" to describe the treatment

[130] EX1001 ('063 patent), 4:23-25.

[131] EX1001 ('063 patent), claims 27-39.

and its goal without requiring actually reducing stoke risk in every patient who received the medication.

106. In my opinion, nothing in the '063 patent changes this ordinary meaning.

107. Similarly, while the '063 patent defines "stroke" as "a condition which occurs when the blood supply to a part of the brain is suddenly interrupted (i.e., ischemic stroke) or when a blood vessel in the brain bursts and releases blood into the spaces surrounding the brain cells (i.e., hemorrhagic stroke)," [132] it does not, provide any definition of "reducing the risk" of the recited stroke or otherwise teaches what constitutes reduction of the risk of stroke.

108. Thus, in my opinion, a skilled cardiologist would understand "a method of reducing the risk of a stroke" as describing the goal or objective of the treatment but not as requiring any actual reduction of stroke risk.

VII. ANTICIPATION OF CHALLENGED CLAIMS

A. Ground 1: Claims 1-13, 17-26, 28, 40-46, 49, and 50 Are Anticipated by Bouabdallaoui

109. Bouabdallaoui contains the same COLCOT *post hoc* analysis relied upon in the '063 patent.[133] As I explain below, Bouabdallaoui anticipates claims 1-

[132] EX1001 ('063 patent), 6:23-40.

[133] *Compare* EX1005 (Bouabdallaoui), Table 3 *with* EX1001 ('063 patent), Example 1.

13, 17-26, 28, 40-46, 49, and 50.[134]

Ground 1 Claims 1, 8

Claim limitations	Bouabdallaoui
1[a], 8[a]: A method of treating a patient after having a myocardial infarction (MI),	Bouabdallaoui discloses that "COLCOT was an international multicentre, randomized, double-blinded trial that randomly assigned patients to receive either low-dose colchicine (0.5mg once daily) or placebo…. Patients were considered eligible if they had a recent MI (<30 days)."[135] A skilled cardiologist would have understood that the method of COLCOT Protocol entailed treating a patient after having an MI.
1[b], 8[b]: the method comprising initiating the administration of colchicine at a daily low dose to the patient,	Bouabdallaoui discloses that "COLCOT was a[]… trial that randomly assigned patients to receive either low-dose colchicine (0.5mg once daily) or placebo."[136] Bouabdallaoui further discloses that "***[c]olchicine at the low dose of 0.5mg daily*** was shown to significantly reduce the risk of ischaemic CV events by 23% compared with placebo when initiated within the first 30 days after MI in the Colchicine Cardiovascular Outcomes Trial (COLCOT)."[137] The 0.5 mg once daily dose disclosed in Bouabdallaoui

[134] I understand that Bouabdallaoui, based on its August 29, 2020, publication date, is prior art to claims 1-13, 17-26, 28, 40-46, 49, and 50 that require initiating treatment "within about 3 days" or "within 4 to 7 days." *See* Section VI.C], above.

[135] EX1005 (Bouabdallaoui), 2-3.

[136] EX1005 (Bouabdallaoui), 2-3.

[137] EX1005 (Bouabdallaoui), 2 (emphasis added).

	meets limitations 1[b], 8[b].[138]
1[c], 8[c]: wherein the colchicine is administered without pre-loading the patient with a higher dose of colchicine before the administration at the daily low dose	*See* limitations 1[b] and 8[b]. A skilled cardiologist would understand that Bouabdallaoui's disclosure of administering 0.5 mg colchicine once daily is a complete dosing protocol that does not involve a higher preloading dose.[139]
1[d], 8[d]: within about 3 days of the MI,	Bouabdallaoui discloses that 604 of the 2322 patients treated with colchicine ("26.0%" of the total colchicine-treated patients) initiated treatment within 0 to 3 days of the MI.[140] Bouabdallaoui discloses that "primary endpoint event occurred in 4.3% of patients in the colchicine group, as compared with 8.3% of those in the placebo group when TTI was between Days 0 and 3."[141] A skilled cardiologist would understand that Bouabdallaoui's disclosures of the number of patients who initiated treatment between 0 to 3 days and efficacy data for those patients teach treating MI patients within about 3 days of the MI.
1[e] wherein percutaneous coronary intervention was performed for treating	Bouabdallaoui teaches that "[a]ll patients enrolled in the trial benefitted from percutaneous coronary intervention whenever indicated and guidelines-directed

[138] According to the '063 patent, a "daily low dose" may be 0.5 mg/day. EX1001 ('063 patent), 2:7-9.

[139] *See* EX1005 (Bouabdallaoui), 2-3.

[140] EX1005 (Bouabdallaoui), Table 1.

[141] EX1005 (Bouabdallaoui), 4.

the patient's MI.	management of CV disease prior to randomization."[142] Bouabdallaoui discloses that 2154 of the total of 2322 patients treated by colchicine in the study, i.e., "92.8%" of the colchicine-treated patients, had "PCI associated with the index event."[143] A skilled cardiologist would understand that the "PCI associated with the index event" would have been performed for urgent management of the patients' MI before their randomization and colchicine administration in the study, meeting limitation 1[e].
8[e] wherein the patient is at a lower risk of a cardiovascular event, relative to a patient not being administered colchicine, and wherein the cardiovascular event is resuscitated cardiac arrest, stroke, or urgent hospitalization for angina requiring coronary revascularization.	Bouabdallaoui teaches that "[t]his analysis of COLCOT shows that early initiation of low-dose colchicine within the first 3 days after MI is associated with a reduction of 48% in the risk of the primary endpoint consisting of a composite of CV death, ***resuscitated cardiac arrest,*** MI, ***stroke***, or ***urgent hospitalization for angina requiring coronary revascularization***, in comparison with placebo."[144] Bouabdallaoui's descriptions of reducing the risks of primary endpoints match the recited lower cardiovascular event risk and teach limitation 8[e].

1. Dependent claims

a. Additional medication claims 2-5, 40-43

[142] EX1005 (Bouabdallaoui), 3.

[143] EX1005 (Bouabdallaoui), Table 1.

[144] EX1005 (Bouabdallaoui), 5 (emphases added).

110. Claims 2-5 and 40-43 further require that the patient was prescribed a medication, or more specifically, a statin or an antiplatelet agent such as aspirin.[145] Bouabdallaoui teaches these limitations, explaining that "[b]ackground therapy included aspirin, a second anti-platelet agent and a statin in 98.8%, 98.0%, and 99.0% of patients, respectively."[146] Bouabdallaoui Table 1 further shows that the vast majority of the treated patients had been previously prescribed statin or aspirin.[147]

[145] EX1001 ('063 patent), claims 2 ("the patient was prescribed a medication"), 3 ("the medication is an antiplatelet agent"), 4 ("the medication is aspirin"), 5 ("the medication is a statin"), 29 ("the patient was prescribed a medication"), 30 ("the medication is an antiplatelet agent"), 31 ("the medication is aspirin"), 32 ("the medication is a statin"), 40 ("the patient was prescribed a medication"), 41 ("the medication is an antiplatelet agent"), 42 ("the medication is aspirin"), 43 ("the medication is a statin").

[146] EX1005 (Bouabdallaoui), 3-4.

[147] EX1005 (Bouabdallaoui), Table 1 (highlights added).

Table I Baseline characteristics according to treatment allocation

Characteristics	All patients (*N* = 4661)	Colchicine group (*N* = 2322)	Placebo group (*N* = 2339)
Age (years), mean ± SD	60.5 ± 10.6	60.6 ± 10.6	60.5 ± 10.6
Male sex, no. (%)	3774 (81.0%)	1861 (80.1%)	1913 (81.8%)
BMI (kg/m^2), mean ± SD	28.3 ± 4.7	28.2 ± 4.8	28.4 ± 4.7
Current smoking, no./total no. (%)	1382/4659 (29.7)	694/2322 (29.9%)	688/2337 (29.4%)
History of hypertension, no. (%)	2377 (51.0)	1160 (50.0)	1217 (52.0)
History of diabetes, no. (%)	942 (20.2)	451 (19.4)	491 (21.0)
Prior MI, no. (%)	751 (16.1)	360 (15.5)	391 (16.7)
Prior PCI, no. (%)	783 (16.8)	382 (16.5)	401 (17.1)
Prior CABG, no. (%)	146 (3.1)	66 (2.8)	80 (3.4)
Prior HF, no. (%)	90 (1.9)	48 (2.1)	42 (1.8)
Prior stroke or TIA, no. (%)	119 (2.6)	53 (2.3)	66 (2.8)
PCI associated with the index event, no. (%)	4336 (93.0)	2154 (92.8)	2182 (93.3)
Medication use, no. (%):			
Aspirin	4605 (98.8)	2291 (98.7)	2314 (98.9)
Other anti-platelet agent	4567 (98.0)	2267 (97.6)	2300 (98.3)
Statin	4615 (99.0)	2297 (98.9)	2318 (99.1)
Beta-blocker	4143 (88.9)	2077 (89.4)	2066 (88.3)

111. Thus, these claims are also anticipated by Bouabdallaoui.

b. Cardiovascular event claims 6-7, 9-11, 28, 50

112. Claims 6-7, 9-11, and 50 address reducing risk of certain cardiovascular events for the colchicine-treated patient.[148] Claim 28 recites reducing the risk of a stroke in a patient after having an MI, comprising initiating the administration of colchicine at a daily low dose to the patient within 4-7 days of an MI.[149] Bouabdallaoui specifically reports that its colchicine patients treated within 3 days post-MI had reduced risks of these recited events relative to an untreated patient and

[148] EX1001 ('063 patent), claims 6, 7; *see also* claim 9 ("the cardiovascular event is myocardial infarction"), 10 ("the cardiovascular event is stroke"), 11 ("the cardiovascular event is urgent hospitalization for angina requiring coronary revascularization"), 50 ("the cardiovascular event is resuscitated cardiac arrest").

[149] EX1001 ('063 patent), claim 28.

that initiating colchicine treatments within 4-7 days of the MI reduced the stroke incidence in MI patients (although the data was not statistically significant).

113. For instance, Table 3 of Bouabdallaoui discloses "the percentages of patients [who received colchicine treatment within 0 to 3 days of the MI] and the hazard ratios for the components of the primary endpoint, including CV [cardiovascular] death (HR = 1.04, 95% CI 0.15–7.37), resuscitated cardiac arrest (HR = 0.33, 95% CI 0.03–3.20), MI (HR = 0.58, 95% CI 0.32–1.05), stroke (HR= 0.21, 95% CI 0.02– 1.81), and urgent hospitalization for angina requiring coronary revascularization (HR = 0.35, 95% CI 0.14–0.88)."[150] Bouabdallaoui concludes that "[e]arly initiation of low-dose colchicine after MI greatly reduced the risk of ischaemic CV [cardiovascular] events compared with placebo."[151]

114. Bouabdallaoui further discloses that when colchicine treatment was initiated within 4 to 7 days of the MI, the rate of stroke dropped from 0.8% in the placebo group to 0.2% in the treatment group, with a high P value of 0.272.[152] As I explained in Section VI.D, claim 28 does not require actual reduction of stroke risks, let alone statistically significant reduction of stroke risks.

115. Thus, Bouabdallaoui expressly teaches lowing risk of the recited

[150] EX1005 (Bouabdallaoui), 4, Table 3.

[151] EX1005 (Bouabdallaoui), 7.

[152] EX1005 (Bouabdallaoui), Table 3.

cardiovascular events and anticipates claims 6, 7, 9-11, 28, and 50.

c. Patient population claims 12, 26, 44, and 49

116. Dependent claims 12 and 44 recite that "the patient has atherosclerotic coronary artery disease."[153] And claims 26 and 49 recite that "the patient is an adult human."[154] These claims are also anticipated by Bouabdallaoui.

117. For instance, Bouabdallaoui teaches treating MI patients where "[m]yocardial infarction (MI) is associated with an acute exacerbation of cardiovascular (CV) inflammation superimposed on the chronic atherosclerosis-related inflammatory process."[155] This is consistent with the prior understanding that "[a]therosclerosis is the most common cause of myocardial infarction, stroke and peripheral arterial disease."[156] Thus, Bouabdallaoui teaches treating MI patients with atherosclerotic coronary artery disease as recited by claims 12 and 44 and anticipates these claims.

118. Similarly, Bouabdallaoui's disclosures that "[p]atients were mostly

[153] EX1001 ('063 patent), claims 12, 44.

[154] EX1001 ('063 patent), claims 26, 49.

[155] EX1005 (Bouabdallaoui), 2.

[156] EX1006 (COLCOT Protocol), 4; EX1015 (Aday 2018), 1 ("Atherosclerosis is the central disease process underlying most instances of myocardial infarction (MI), ischemic stroke, and peripheral artery disease.").

men (81.0%) with a mean age of 60.5 years"[157] anticipate claims 26 and 49 because these are adult human patients as recited in those claims.

d. "Initiation upon assessment" claims 13 and 46

119. Claims 13 and 46 recite that "the administration of colchicine is initiated upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting." [158]

120. These claims are anticipated by Bouabdallaoui, which teaches treating patients in the period "from Day 0 to 3, referring to in-hospital management."[159] Bouabdallaoui concludes that (1) its *post hoc* analysis "support[s] the strategy of in-hospital initiation of colchicine in order to improve CV outcomes post-MI," (2) "[p]atients benefit from early, in-hospital initiation of colchicine after MI," and (3) "[t]hese results support in-hospital initiation of adjunctive anti-inflammatory therapy with colchicine for post-MI prevention. [160]

121. These teachings all show that the administration of colchicine in patients within 0 to 3 days of the MI was initiated after the patients were assessed for eligibility and before they were discharged from hospital. Thus, Bouabdallaoui

[157] EX1005 (Bouabdallaoui), 3.

[158] EX1001 ('063 patent), claims 13, 46.

[159] EX1005 (Bouabdallaoui), 3, 5.

[160] EX1005 (Bouabdallaoui), 2, 5, 7.

meets the additional limitation of initiating administration of colchicine in a hospital setting as recited in claims 13 and 46.

e. Dose and frequency claims 17-25, 45

122. Dependent claims 17-25 and 45 further recite different dose ranges of colchicine and dosing frequencies, which all cover administering 0.5 mg colchicine once daily.[161] Because Bouabdallaoui discloses that the COLCOT trial patients received "low-dose colchicine (0.5mg once daily)," it also anticipates these claims for the same reasons that it anticipates claims 1 and 8.[162]

B. Ground 2: Claims 27, 29-36, and 39 Are Anticipated by COLCOT Protocol

123. COLCOT Protocol discloses the same COLCOT study as the '063 patent and teaches the treatment method as recited in claim 27.[163] As I explain below, COLCOT Protocol anticipates claims 27, 29-36, and 39.

1. Independent Claim 27

[161] EX1001 ('063 patent), claim 17 ("the colchicine is administered at 0.3 to 0.7 mg"), 18 ("the colchicine is administered at 0.4 to 0.6 mg"), 19 ("the colchicine is administered at 0.5 mg"), 20 ("the colchicine is administered at 0.5 mg"), 21 ("the colchicine is administered at 0.5 mg"), 22 ("the colchicine is administered at 0.5 mg"), 24 ("the colchicine is administered once, twice or three times a day"), 25 ("the colchicine is administered once per day"), 45 ("the colchicine is administered once per day").

[162] EX1005 (Bouabdallaoui), 2, 3.

[163] *Compare* EX1006 (COLCOT Protocol) *with* EX1001 ('063 patent), Example 2.

124. The method of claim 27 is directed to "reducing the risk of a stroke in a patient after having an MI" and includes a single active step of "initiating the administration of colchicine at a daily low dose to the patient within about 30 days of an MI."[164] This exact method was published in the prior art COLCOT Protocol[165]. And, as I will explain, the claimed method's intended purpose of "reducing the risk of a stroke in a patient after having an MI" is inherent to—the necessary and inevitable result of—the COLCOT Protocol method.

125. First, as shown in the Ground 2 Claim Chart, COLCOT Protocol identically teaches administering colchicine at a daily low dose (0.5 mg/day) to patients within 30 days of an MI. This is the same as claimed limitations 27[b]-[c].

Ground 2 Chart, Claim 27

Claim limitations	COLCOT Protocol
27[a] A method of reducing the risk of a stroke in a patient after having an MI.	This limitation is anticipated by COLCOT Protocol's disclosure that the COLCOT study "evaluates whether long-term treatment with colchicine reduces rates of cardiovascular events in patients after myocardial infarction," which the "Primary Outcome Measures" section of the Protocol further discloses as including

[164] EX1001('063 patent), claim 27.

[165] EX1006 (COLCOT Protocol), 3-6.

Claim limitations	COLCOT Protocol
	reducing the rate of "stroke."[166]
27[b] the method comprising initiating the administration of colchicine at a daily low dose to the patient	COLCOT Protocol discloses that the MI patients will receive "colchicine (0.5 mg per day)….," which a skilled cardiologist would understand as initiating the colchicine administration at a 0.5 mg daily low dose to the patient.[167] "Arms and Interventions" section of Colchicine Protocol further discloses that "0.5 mg tablet of colchicine [is] taken once a day," confirming its teachings of daily low dose administration.[168]
27[c] within about 30 days of an MI.	COLCOT Protocol expressly discloses that "[p]atients who have suffered a documented acute myocardial infarction within the last 30 days, are treated…," thus, teaches treatment within 30 days of a documented MI.[169] "Inclusion Criteria" section of COLCOT Protocol further teaches that "[p]atient must have suffered a documented acute myocardial infarction within the last 30 days," further supporting that the colchicine treatment is initiated

[166] EX1006 (COLCOT Protocol), 1, 2-3.

[167] EX1006 (COLCOT Protocol), 1.

[168] EX1006 (COLCOT Protocol), 4.

[169] EX1006 (COLCOT Protocol), 1.

Claim limitations	COLCOT Protocol
	within 30 days of the MI.[170]

126. Second, COLCOT Protocol does not itself report any data showing that colchicine reduced risk of a stroke in a patient after having an MI. However, because COLCOT Protocol's treatment of administering 0.5 mg/day colchicine to the claimed patient population within 30 days of an MI is identical with '063 patent Example 2, we know from '063 patent Example 2 that following COLCOT Protocol reduces a risk of stroke.

127. More specifically, according to the '063 patent, "[t]he results of the main COLCOT trial" administering colchicine at a daily dose of 0.5 mg to patients post-MI "support that the use of colchicine in patients who have had a myocardial infarction in the past 30 days significantly improved their quality of life in several ways…." [171] These include "a statistically significant lower risk of ischemic cardiovascular events…. stroke… was also significantly lower…. This reduction in morbidity was particularly prominent… in the ***reduction of severe conditions, such as stroke*** and urgent hospitalization for angina leading to revascularization: ***hazard***

[170] EX1006 (COLCOT Protocol), 5.

[171] EX1001 ('063 patent), 27:33-37.

ratios are 0.26 (95% confidence interval is 0.10-0.70) and 0.50 (95% confidence interval is 0.31-0.81), respectively."[172]

128. The reduced risk of stroke from the method of the COLCOT Protocol is also reported in Table 13 of the '063 patent[173]:

TABLE 13

Major Clinical End-points (Intention-to-Treat Population)

End Point	Colchicine (N = 2366) number (percent)	Placebo (N = 2379) number (percent)	Hazard Ratio (95% CI)	P Value
Primary composite end point	131 (5.5)	170 (7.1)	0.77 (0.61-0.96)	0.02†
Components of primary end point				
Death from cardiovascular causes	20 (0.8)	24 (1.0)	0.84 (0.46-1.52)	
Resuscitated cardiac arrest	5 (0.2)	6 (0.3)	0.83 (0.25-2.73)	
Myocardial infarction	89 (3.8)	98 (4.1)	0.91 (0.68-1.21)	
Stroke	5 (0.2)	19 (0.8)	0.26 (0.10-0.70)	

129. The '063 patent further discloses that "[i]n COLCOT, the risk of the primary composite efficacy end point of death… stroke… was significantly lower among the patients who were randomly assigned to receive 0.5 mg of colchicine

[172] EX1001 ('063 patent), 2:7-23 (emphasis added).

[173] EX1001('063 patent), Table 13 (highlights added).

once daily… predominantly to a lower incidence of strokes…."[174]

130. I note that the '063 patent does not appear to set any specific threshold for the magnitude or level of statical significance for what it means to "reduc[e] the risk of a stroke." What a skilled cardiologist would understand, however, is that the reported hazard ratio of 0.26 (95% confidence interval is 0.10-0.70) is a "reduc[ed] the risk of a stroke" because the '063 patent specifically describes this result as evidence of a reduced risk of stroke.[175] According to the '063 patent, this is the level of risk reduction that results from the method of COLCOT Protocol.

131. Thus, carrying out COLCOT Protocol's treatment step of administering daily low doses (e.g., 0.5 mg/day) of colchicine to the claimed patient population within 30 days of an MI, which is identical with the '063 patent Example 2 and practices the method of claim 27, necessarily reduces stroke risk in those patients, as recited in claim 27.

132. Two other issues are worth noting here. First, in the initial LoDoCo trial published in 2013, a virtually identical hazard ratio of 0.23 was reported for stroke after initiation of colchicine, indicating that effects on stroke were fully anticipated as well by prior clinical trial data. Second, within Bouabdallaoui et al, the reported

[174] EX1001 ('063 patent), 39:11-20.

[175] EX1001 ('063 patent), 2:7-23.

hazard ratios for stroke are 0.21 for the 0 to 3 day time period, 0.28 for the 4 to 7 day time period, and 0.19 for the 8 to 30 day time period. Not only are all of these hazard ratios fully consistent with the previously reported reduction in stroke observed in the initial 2013 LoDoCo trial, but they demonstrate yet again no difference whatsoever by time to treatment.

2. Dependent claims 29-36 and 39

a. Additional medication claims 29-32

133. Claims 29-32 further require that the patient was prescribed a second medication in addition to colchicine, in particular an antiplatelet agent, such as aspirin, or statin.[176] COLCOT Protocol also discloses these additional limitations.

134. Specifically, COLCOT Protocol expressly teaches that enrolled patients "must be treated according to the national guidelines (including antiplatelet therapy, statin…)," and thus, discloses that the patients were prescribed an antiplatelet agent or statins as required by claims 29, 30, and 32.[177]

135. Regarding the claim 31 "aspirin" limitation, because aspirin had been the most common standard antiplatelet therapy for MI patients, a skilled cardiologist would have immediately recognized aspirin from COLCOT Protocol's disclosure of

[176] EX1001 ('063 patent), claim 29 ("the patient was prescribed a medication"), claim 30 ("the medication is an antiplatelet agent"), claim 31 ("the medication is aspirin"), claim 32 ("the medication is a statin").

[177] EX1006 (COLCOT Protocol), 5.

"antiplatelet therapy" according to "national guidelines."[178] Thus, claim 31 is also anticipated by COLCOT Protocol.

b. Patient population claims 33, 39

136. Claim 33 further recites that the patient has atherosclerotic coronary artery disease.[179] COLCOT Protocol also expressly teaches that "[a]therosclerosis is the most common cause of myocardial infarction, stroke and peripheral arterial disease."[180] A skilled cardiologist would have understood that this teaching in COLCOT Protocol is consistent with the prior understanding that the vast majority of MI patients, including those treated by COLCOT Protocol, would have atherosclerotic coronary artery disease.[181] Thus, claim 33 is also anticipated by COLCOT Protocol.

137. Claim 39 further recites that the patient is an adult human.[182] COLCOT Protocol discloses that "[m]ales and females of at least 18 years of age" are included

[178] *See e.g.*, EX1021 (1999 Guidelines), 3; EX1009 (ESC Guidelines), 31.

[179] EX1001 ('063 patent), claim 33.

[180] EX1006 (COLCOT Protocol), 4.

[181] EX1015 (Aday 2018), 1 ("Atherosclerosis is the central disease process underlying most instances of myocardial infarction (MI), ischemic stroke, and peripheral artery disease.").

[182] EX1001 ('063 patent), claim 39.

in the study.[183] A skilled cardiologist would have understood that such specific patient population would be adult human patients, as recited in claim 39. Thus, claim 39 is also anticipated by COLCOT Protocol.

c. Dose and frequency claims 34-35

138. Claims 34 and 35 further recite more specific dose or dosing frequency.[184] Both claims, however, still cover a once daily dose of 0.5 mg colchicine, which is taught by COLCOT Protocol as a shown in Ground 2 Chart, element 27[b].[185] Thus, COLCOT Protocol teaches the methods of claims 34 and 35.

d. "Initiation upon assessment" claim 36

139. Claim 36 further recites initiating administration of colchicine "upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting."[186] COLCOT Protocol teaches that the location of its colchicine administration at the "Montreal Heart Institute," which was a well-known hospital facility.[187] COLCOT Protocol further teaches that the study requires an initial

[183] EX1006 (COLCOT Protocol), 5.

[184] EX1001 ('063 patent), claim 34 ("the colchicine is administered at 0.5 mg"), 35 ("the colchicine is administered once per day").

[185] *See also* EX1006 (COLCOT Protocol), 1, 4 ("colchicine (0.5 mg per day)," "0.5 mg tablet of colchicine [is] taken once a day").

[186] EX1001 ('063 patent), claim 36.

[187] EX1006 (COLCOT Protocol), 7.

assessment by the "investigator" (all medical doctors) to determine if the patient is a suitable candidate.[188] A skilled cardiologist would have understood that the assessment by an investigator would occur at a hospital (the study site), emergency department, or medical office setting, as recited by claim 36.

VIII. OBVIOUSNESS OF CHALLENGED CLAIMS

A. Claims 1-50 Would Have Been Obvious Over Nidorf in View of COLCOT Protocol, ESC Guidelines, and COLCRYS

140. Nidorf, COLCOT Protocol, and ESC Guidelines are all in the same field of treating atherosclerotic coronary artery disease and relevant to the methods claimed in the '063 patent because they commonly relate to using secondary prevention therapies, such as colchicine, in post-MI coronary artery disease patients to reduce the risk of secondary cardiovascular events. COLCRYS is also relevant to these references and the '063 patent as it teaches the suitability and use of film-coated colchicine tablets, the active agent common to LoDoCo (Nidorf) and COLCOT Protocol.

141. As I further explain below, consistent with the trend in colchicine studies that had already initiated or report, a skilled cardiologist would have been motivated to combine their teachings to shorten LoDoCo's colchicine treatment

[188] EX1006 (COLCOT Protocol), 6 (describing in exclusion criteria that "[p]atient is considered by the investigator, for any reason, to be unsuitable candidate for the study").

initiation time to within 30 days post-MI, including at around 3 days, with a reasonable expectation of reducing secondary cardiovascular events in those patients. *See also* Section V.B, above. The motivation and expectation of success are reinforced by, among other things, CANTOS teaching the efficacy of initiating anti-inflammatory treatment as early as 30 days post-MI together with the standard practice, multiple ongoing low-dose colchicine clinical studies that initiated treatment without any delay, and known benefits, as reflected in ESC Guidelines, of initiating secondary preventative treatment prior to or concurrent with hospitalization discharge around day 3 post-MI. In my opinion, all claims 1-50 would have been obvious over Nidorf in view of COLCOT Protocol, ESC Guidelines, and COLCRYS.

1. It would have been obvious from Nidorf, COLCOT Protocol, and ESC Guidelines to administer colchicine within about three days post-MI to reduce the risk of cardiovascular events.

142. Like the ’063 patent claims, Nidorf (EX1007) and COLCOT Protocol (EX1006) both describe administering 0.5 mg colchicine daily to stable patients with past MI for secondary prevention. In my opinion, all claims of the ’063 patent would have been obvious to a skilled cardiologist in view of these references together with ESC Guidelines (EX1009) which recommends initiating secondary preventive therapy after MI patients are stabilized prior to or at discharge from hospital at around 3 days of the MI, and COLCRYS (EX1019) teaching the use of film-coated

colchicine tablets.

a. Nidorf and COLCOT Protocol are commonly directed to 0.5 mg/day colchicine for secondary prevention treatment in post-MI stabilized patients

143. Nidorf teaches using colchicine as a secondary preventative therapy to "reduce[] the risk of cardiovascular events in patients with objectively diagnosed and clinically stable coronary disease," and the enrolled patients "had been clinically stable for at least 6 month."[189] It includes data from the LoDoCo trial showing that administering 0.5 mg/daily colchicine to patients with clinically stable coronary disease "significantly reduces the risk of a cardiovascular event, including an ACS, out of hospital cardiac arrest and non-cardio-embolic ischemic stroke."[190] Nidorf further reports that "[t]he effect of adding colchicine became evident early, continued to accrue over time."[191] In other words, Nidorf teaches reducing cardiovascular event risks as recited in claims 8 and 27.[192] *See also* Sections V.B.1, V.B.4, above.

144. A skilled cardiologist would have understood that Nidorf teaches

[189] EX1007 (Nidorf), 17:60-18:8, 18:31-34, 20:25-21:65.

[190] EX1007 (Nidorf), 21:55-59.

[191] EX1007 (Nidorf), 21:63-64.

[192] EX1007 (Nidorf), 21:55-59.

treating stable cardiovascular disease patients generally, including those who have had a previous MI event as is all too common among cardiovascular disease patients. *See also* Section V.B.1, above. This understanding would have been reinforced by Nidorf's disclosure that the primary analysis was stratified by, among other things, diagnosis of "past myocardial infarction"[193] and the related Nidorf 2013 reporting that 23% of the LoDoCo colchicine-treated patients had past acute MI or unstable angina.[194]

145. Thus, the only part of claims 1, 8, and 27 not disclosed in Nidorf is initiating treatment "within about 3 days" (claims 1, 8) or "within 30 days" (claim 27) of the MI. In my opinion, however, following the success of LoDoCo, initiating 0.5 mg/day colchicine within 30 days post-MI as disclosed in COLCOT Protocol, including at around day 3 post-MI, would have been consistent with quality care for other chronic therapies used on a long-term basis to reduce atherosclerotic risk which skilled cardiologists routinely start upon MI patient stabilization and prior to hospital discharge, and would have been obvious, especially in view of COLCOT Protocol and ESC Guidelines. *See also* Sections V.B.3, V.B.4, V.C, above. Essentially, after the success of CANTOS with initiating anti-inflammatory treatment as soon as 30

[193] EX1007 (Nidorf), 20:3-5.

[194] EX1020 (Nidorf 2003), Table 1.

days post-MI, it would have been obvious to the skilled cardiologist to reduce the colchicine post-MI initiation time period to within the COLCOT 30-day window including to around 3 days post-MI as used with other secondary preventive therapy. Indeed, the results of CANTOS had already been specifically relied upon as support for the use of daily low dose colchicine in atherosclerotic contradictions.[195]

146. Similar to LoDoCo, COLCOT Protocol teaches administering 0.5 mg/day colchicine to reduce cardiovascular events in stabilized post-MI patients.[196] For example, as I explained in Section V.B.4 above, COLCOT Protocol is directed to treating stable post-MI patients as it excludes patients who have had unstable conditions and starts colchicine treatment after post-MI emergency management (e.g., PCI) is completed.[197] Relative to LoDoCo, COLCOT Protocol shortened the colchicine treatment initiation time down from at least 6 months after an acute event (including MI) (LoDoCo) to within 30 days of an MI (COLCOT).[198] Initiating treatment within this period would have been obvious, as the next progression following evidence CANTOS' proof that targeting the anti-inflammatory pathway

[195] EX1047 (Nidorf 2019), 3-5; EX1026 (Thompson 2018), 4-5.

[196] EX1006 (COLCOT Protocol), 1, 4.

[197] EX1006 (COLCOT Protocol), 1, 4.

[198] *Compare* EX1007 (Nidorf), 18:31-34 *with* EX1006 (COLCOT Protocol), 1.

was effective when initiated at least 30 days post-MI. [199] *See also* Sections V.B.3 and V.B.4.

b. Obviousness of initiating treatment at around three days post-MI to reduce the risk of cardiovascular events

147. Initiating the 0.5 mg/day colchicine treatment of LoDoCo and COLCOT Protocol at around 3 days of an MI also would have been obvious to a skilled cardiologist as this is (i) already within the 30-day range of COLCOT Protocol and (ii) consistent with routine practice, as recognized in ESC Guidelines, for initiating secondary preventative therapy following an MI. Indeed, there was significant momentum for the use of low dose colchicine as secondary prevention therapy in atherosclerotic-based conditions and the art was already moving in the direction of shorter post-MI colchicine treatment initiation. *See* Section V.B.5, above.

148. For example, ESC Guidelines show that prior to 2019, patients were typically sufficiently stable for hospital discharge within 3 days of an MI, even following a PCI.[200] In my experience, a 3-day post-MI hospitalization stay was common in 2019 as it is today. Consistent with common medical practice at the

[199] EX1039 (CANTOS Protocol), 19.

[200] EX1009 (ESC Guidelines), 24 ("Several studies have shown that low-risk patients with successful primary PCI and complete revascularization can safely be discharged from hospital on day 2 or day 3 after PCI.").

time, ESC Guidelines explains that pre-discharge management included the administration of secondary preventive therapy (in particular statins, which had been approved for this indication) to "increase patient adherence after discharge" and provide "early and sustained clinical benefits."[201]

149. By 2019, a skilled cardiologist would have (i) been motivated to combine the related methods of Nidorf and COLCOT Protocol and the secondary preventative practices as reflected in ESC Guidelines to initiate daily low dose colchicine therapy within 3 days of an MI and (ii) reasonably expected this treatment would reduce the risk of future cardiovascular events. The bases for my opinion in this regard are summarized below and then addressed in further detail in the following sections with respect to specific claims.

150. First, initiating treatment within 3 days is within the 30-day period disclosed in COLCOT Protocol. It would have been obvious to a skilled cardiologist to initiate colchicine treatment as secondary preventive therapy anywhere in stable post-MI patients within this 30-day window, including around 2 or 3 days post-MI. That is, initiating 0.5 mg/day colchicine treatment at around 2 or 3 days post-MI

[201] EX1009 (ESC Guidelines), 24 ("A short hospital stay implies limited time for proper patient education and up-titration of secondary prevention treatments."), 33 ("Therefore, statins are recommended in all patients with AMI…. Lipid-lowering treatment should be started as early as possible, as this increases patient adherence after discharge, and given as high-intensity treatment, as this is associated with early and sustained clinical benefits.").

requires no more than implementing the 30-day period taught by COLCOT Protocol.

151. Second, a skilled cardiologist would have been independently motivated to initiate colchicine as long-term secondary-prevention therapy during the typical 3-day post-MI hospitalization period, specifically following the initial urgent MI management period (roughly the first 12 hours) and before the stabilized patients are discharged. This is based on and consistent with routine practice with other secondary preventive treatments, such as statins.[202] Indeed, it was known from the Deftereos pilot study that initiating colchicine treatment even earlier—i.e, within 12 hours post-MI—was reported to be safe and reduce biomarkers associated with infarct size.[203] And, as previously noted, the art was already moving in this direction with numerous colchicine secondary-prevention trials. *See* Section V.B.5., above.

152. Third, based on the validated general mechanistic link between inflammation and secondary prevention of cardiovascular events by initiating treatment in stabilized MI patients as early as 30 days post-MI (CANTOS trial), the proven efficacy of low-dose colchicine in reducing cardiovascular events from the LoDoCo trial (Nidorf), the focus of COLCOT Protocol on initiating treatment within the 30-day post-MI window, and the reported benefits associated with early in-

[202] EX1009 (ESC Guidelines), 24, 33.

[203] EX10440 (Deftereos 2015), 1.

hospital initiation of other secondary prevention treatments, a skilled cardiologist would have reasonably expected that initiating colchicine treatment within 30-days, including within 3 days, would be effective to reduce a risk of cardiovascular events. This expectation is also reflected in the numerous colchicine secondary-prevention trials that had been at least planned by this time. *See* Section V.B.5., above.

153. Finally, as I explained in section VIII.C below, Tardif 2019 and Bouabdallaoui reported reduction of cardiovascular events in MI patients by initiating colchicine treatment within 30 days (Tardif 2019) and 0-3 days (Bouabdallaoui) of the MI. For claims 1-26 and 40-50 that are not entitled to a priority date earlier than November 2020 (the '063 patent's filing date), the efficacy data reported in Tardif 2019 and Bouabdallaoui would have further reinforced the motivation to initiate colchicine treatment within about 3 days of the MI with a reasonable expectation of achieving reduced cardiovascular events in those patients.

154. My opinions are explained in further detail below with respect to specific claims.

2. Independent claims 1, 8, and 27

a. Claims 1 and 8

155. Nidorf and COLCOT Protocol teach all limitations of claims 1 and 8 except specifically teaching initiating treatment "within about 3 days of the MI." However, based on what was known as of 2019, it would have been obvious for a

skilled cardiologist to initiate colchicine treatment "within about 3 days of the MI."

156. First, as I explained above in Section V.B.4, Nidorf and COLCOT Protocol similarly taught administering colchicine as a long-term secondary prevention therapy for patients who had an MI, with COLCOT Protocol teaching initiating treatment following "myocardial infarction ***within the last 30 days***…."[204]

157. Second, a skilled cardiologist would have been motivated to initiate colchicine as post-MI secondary-prevention therapy following stabilization of acute MI symptoms (typically within the first 12 hours) and prior to discharge from the hospital (typically no more than about 3 days as of 2019 for uncomplicated cases).[205] Initiating treatment prior to discharge from the hospital was specifically recommended and consistent with my own practice for other chronic, secondary preventive therapies such as statins. The benefits included optimized care, minimized delays, and enhanced compliance, which were expected to lead to better

[204] EX1006 (COLCOT Protocol), 1, 5 ("INCLUSION CRITERIA… Patient must have suffered a documented acute myocardial infarction within the last 30 days").

[205] EX1009 (ESC Guidelines), 24 ("Several studies have shown that low-risk patients with successful primary PCI and complete revascularization can safely be discharged from hospital on day 2 or day 3 after PCI."); EX1011 (Tran 2018), 1 ("The average length of stay (LOS) for patients hospitalized with acute myocardial infarction (AMI) has declined significantly over the past several decades" to about 3 days); EX1014 (Grine 1998), Abstract ("Early identification of low risk patients with MI allowed safe omission of the intensive care phase and noninvasive testing, and a day 3 hospital discharge strategy, resulting in substantial cost savings.").

outcomes. It is also common sense that, in general, starting secondary prevention therapy sooner rather than later has the potential to better obtain therapeutic benefits since atherosclerosis is a chronic life-long disorder and neither physicians not their patients have a crystal ball letting them know when the next potentially life-threatening event will occur.

158. For instance, ESC Guidelines recognize several studies showing that low-risks patients are stable for discharge on the second or third day after PCI.[206] ESC Guidelines then note that "[a] short hospital stay [after a MI] implies limited time for proper patient education and up-titration of secondary prevention treatments"[207] and that once discharged, "[l]ow treatment adherence is an important barrier to achieving optimal treatment targets and is associated with worse outcomes.[208]

159. When discussing long-term secondary prevention therapy, ESC Guidelines recommend that for stains, which were already part of the secondary prevention standard of care at the time for post-MI patients, "treatment should be started as early as possible, as this increases patient adherence after discharge, and given as high-intensity treatment, as this is associated with early and sustained

[206] *See* EX1009 (ESC Guidelines), 24.

[207] EX1009 (ESC Guidelines), 24.

[208] EX1009 (ESC Guidelines), 30.

clinical benefits."[209]

160. ESC Guidelines are consistent with and reinforced by Stenestrand, which demonstrates that initiating post-MI statin therapy prior to or at hospitalization discharge [210] showed a more pronounced reduction in 1-year mortality compared to not initiating statin administration at or prior to discharge.[211] Stenestrand concludes that "our findings suggest that initiation of statin treatment before or at the time of hospital discharge should be recommended for AMI survivors with total cholesterol or low-density lipoprotein cholesterol levels above the current guidelines levels for statin treatment as secondary prevention." [212]

161. Indeed, as I summarize in the figure below, initiating colchicine treatment early post-MI had been successfully tested prior to 2019, which would have further motivated skilled cardiologists to start colchicine treatment "within about 3 days of the MI."

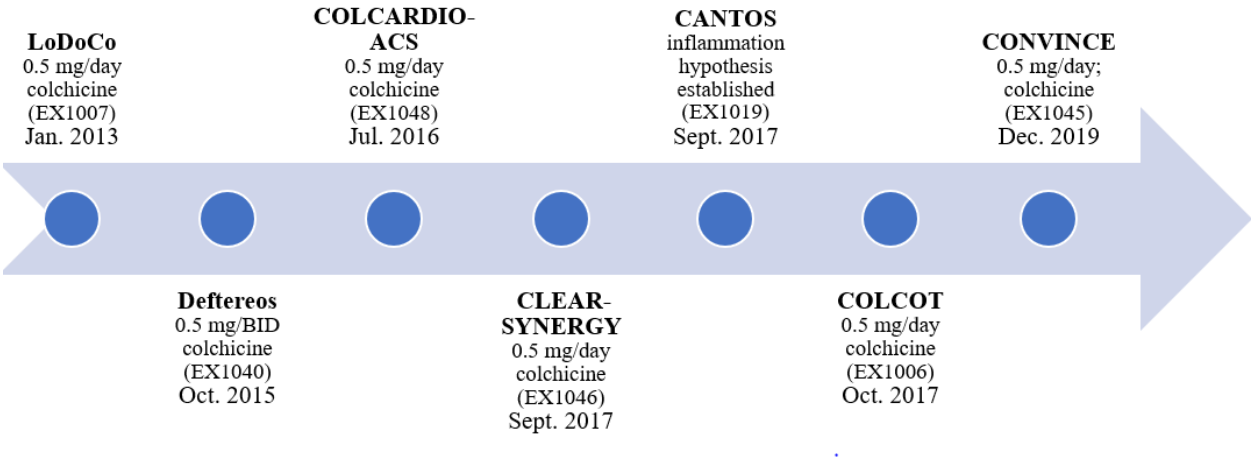
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[209] EX1009 (ESC Guidelines), 33.

[210] Stenestrand is based on a study of Swedish patients from 1995-1998, where the mean hospitalization period was 7.06 days. EX1008 (Stenestrand), 6, 7. By 2019, the post-MI hospitalization period had been reduced to be typically less than about 3 days. EX1011 (Tran 2018), 1 ("The average length of stay (LOS) for patients hospitalized with acute myocardial infarction (AMI) has declined significantly over the past several decades" to about 3 days)).

[211] EX1008 (Stenestrand), 6.

[212] EX1008 (Stenestrand), 9.



162. For instance, Deftereos tested initiating colchicine administration in STEMI patients ⩽12 hours of the MI and reported "a favorite effect of treatment was found in all studied parameters (biomarkers and cardiac MRI."[213] Deftereos concluded that "[t]hese results suggest a potential benefit of colchicine in ST-segment–elevation myocardial infarction." [214] Additionally, as I explained previously, the CONVINCE trial initiated 0.5 mg/day colchicine as secondary preventive treatment following a stroke or TIA—also atherosclerotic-related conditions—without any required post-stroke or post-TIA treatment initiation delay.[215] *See* Section V.B.5, above.

[213] EX1040 (Deftereos 2015), 2, 7.

[214] EX1040 (Deftereos 2015), 1.

[215] EX1045 (CONVINCE Protocol), 3.

163. Also as I explained above in Section V.B.5, the CLEAR-SYNERGY (OASIS-9) trial was also initiated to test the efficacy of low dose colchicine to reduce cardiovascular events in combination of another agent (spironolactone) in patients "with STEMI referred for PCI within 12 hours of symptom onset" and reduced the colchicine dose from 0.5 mg twice daily to 0.5 mg/daily, matching the dose in the successful LoDoCo.[216] The COLCARDIO-ACS study was also designed to administer 0.5 mg/day colchicine as secondary prevention therapy to patients with recent ACS, which are defined to include patients with acute MI.[217]

164. In view of these published trials that had gradually shortened the colchicine treatment initiation time period from at least 6 months of the MI to almost immediately post-MI, by 2019, skilled cardiologists would have recognized the practical and potential therapeutic benefits of initiating long-term secondary prevention therapy as soon as the patient's acute MI has been stabilized and prior to discharge by about day 3 post-MI.

165. Consistent with these teachings and established practices for statins, a skilled cardiologist would have been motivated to initiate colchicine treatments taught by Nidorf and COLCOT Protocol prior to hospitalization discharge—

[216] *See* EX1047 (Nidorf 2019), 6.

[217] EX1048 (COLCARDIO-ACS Protocol), 2.

specifically "within about 3 days of the MI"—to provide the benefits of enhanced patient compliance and earlier long-term therapeutic benefit.

166. Third, a skilled cardiologist would have reasonably expected reduced future cardiovascular events (relative to an untreated patient) following initiating colchicine treatment early, including within about 3 days of a MI.

167. Nidorf had already demonstrated that administering 0.5 mg daily colchicine at longer initiation times "significantly reduces the risk of a cardiovascular event, including an ACS, out of hospital cardiac arrest and non-cardio-embolic ischemic stroke" and that its LoDoCo trial using 0.5 mg daily colchicine achieved "evident" benefit and substantially reduced cardiovascular risks.[218]

168. While Nidorf demonstrated a reduced risk of cardiovascular events in patients having cardiovascular disease that had been stable for at least six months, CANTOS shows that when initiating treatment as early as 30 days post-MI, patients "had a risk of the primary end point [comprising nonfatal myocardial infarction, nonfatal stroke, or cardiovascular death] that was 15% lower than the risk in the placebo group (3.86 vs. 4.50 events per 100 person-years) and a risk of the key secondary cardiovascular end point that was 17% lower than that in the placebo

[218] EX1007 (Nidorf), 21:55-59. 20:34-36.

group (4.29 vs. 5.13 events per 100 person-years)."[219] CANTOS provided "definitive evidence that directly targeting inflammation is beneficial for the secondary prevention of cardiovascular disease."[220]

169. While CANTOS involved the administration of another anti-inflammatory agent (canakinumab), a skilled cardiologist would have understood that its proof of the inflammatory hypothesis was applicable to other agents that are active in the canonical NLRP3 to IL-1 to IL-6 pathway of innate immunity, and this would include colchicine[221], particularly in view of Nidorf's already reported clinical success of 0.5 mg/day colchicine in reducing cardiovascular events.

170. Thus, a skilled cardiologist also would have expected a reduced risk of cardiovascular events following the COLCOT Protocol treatment initiation window of within 30 days of MI, including at around 3 days. That is, a skilled cardiologist would have expected the same overall effect—a reduction in the risk of cardiovascular events—when initiating 0.5 mg/day colchicine treatment anytime following the initial acute MI acute management period (about 12 hours) upon patient stabilization. Indeed, COLCOT is not the first study to shorten LoDoCo's

[219] EX1019 (Ridker 2017), 5, 9.

[220] EX1015 (Aday 2018), 1.

[221] EX1026 (Thompson 2018), 4, Figure 1 (acknowledging that colchicine is involved in inhibition of the assembly of the NLRP3 inflammasome through binding tubulin and that it acts through the IL-1β).

treatment initiation waiting period for stable MI patients—CANTOS had already done that successfully, which would have reinforced the reasonable expectation of success. As I explained in Section V.B.3, CANTOS enrolled patients who "have suffered a documented acute myocardial infarction at least 30 days before randomization"[222] and thus moved LoDoCo's treatment initiation cutoff time from at least 6 months after an acute MI to "at least 30 days" after an MI.

171. The successes of early administration of long-term secondary prevention agents in MI survivors, including LoDoCo, CANTOS, and statin data reported in Stenestrand, would have further reinforced the expectation that initiation of daily colchicine administration upon patient stabilization—whether it is after 6 months of an MI, at 30 days of an MI, within 30 days of an MI, or at around about 3 days of an MI at hospitalization discharge)—would reduce future cardiovascular event risks relative to untreated patients and potentially result in improved client compliance and better secondary prevention relative to patients initiating treatment post-discharge.[223]

[222] EX1039 (CANTOS Protocol), 19.

[223] EX1009 (ESC Guidelines), 33 ("Therefore, statins are recommended in all patients with AMI, irrespective of cholesterol concentration at presentation. Lipid-lowering treatment should be started as early as possible, as this increases patient adherence after discharge, and given as high-intensity treatment, as this is associated with early and sustained clinical benefits."); EX1008 (Stenestrand), 9

172. Thus, it would have been obvious to a skilled cardiologist by 2019 to initiate colchicine administration to patients within 3 days of a MI, as required by claims 1 and 8, in view of the teachings of Nidorf and COLCOT Protocol in view of ESC Guidelines.

b. Claim 27

173. Claim 27 recites a method of reducing stroke risk in patients with MI by initiating colchicine administration at a daily low dose "within 30 days of the MI."[224] As explained above, Nidorf teaches all limitations of claim 27 except initiating treatment "within 30 days of the MI" and COLCOT Protocol teaches every limitation including the "within 30 days of the MI" limitation.

174. As I explained above in Section VIII.A.2.a, it would have been obvious to a skilled cardiologist to initiate daily low dose colchicine administration in patients within the 30-day post-MI window of COLCOT Protocol, including when the patients' conditions are stabilized within the typical about 3-day post-MI hospital stay period or at discharge based on Nidorf's demonstrated success using 0.5 mg daily colchicine to reduce cardiovascular risks including stroke and the known benefits of early secondary prevention treatments as reflected in ESC Guidelines.

("our findings suggest that initiating of statin treatment before or at the time of hospital discharge should be recommended for AMI survivors").

[224] EX1001 ('063 patent), claim 27.

175. Further, as I previously explained in Section VI.D and in Ground 2, a skilled cardiologist would have understood the language "reducing the risk of a stroke in a patient after having an MI" in claim 27 as an intended purpose or goal of the method that does not necessarily require actually reducing a risk of stroke. However, even if the claim requires actually reducing a risk of stroke, for the same reasons as I explained in the context of claims 1 and 8, a skilled cardiologist would have reasonably expected that colchicine 0.5 mg/day initiated within 30-days post-MI would reduce the risk of cardiovascular events including stroke.

176. More specifically, as I further explained in Sections V.B.1 and V.D.1, Nidorf explains that LoDoCo "demonstrates that the addition of colchicine 0.5 mg/day to standard therapy in patients with stable coronary disease significantly reduces the risk of a cardiovascular event, including an ACS, out of hospital cardiac arrest and non-cardio-embolic ischemic stroke."[225] Nidorf further specifically teaches that in the LoDoCo study, "[o]ut of hospital cardiac arrest and ***non-cardio-embolic ischemic stroke*** were infrequent but were also ***reduced in the treatment group***."[226] The '063 patent defines "stroke" as including ischemic stroke, which is

[225] EX1007 (Nidorf), 21:55-59, 20:34-36 (emphasis added).

[226] EX1007 (Nidorf), 20:42-44 (emphases added).

consistent with a skilled cardiologist's understanding.[227] Thus, Nidorf teaches reducing a risk of "stroke" as recited in claim 27.

177. The expectation of a reduction in risk in stroke is reinforced by Nidorf 2013, which also reported the stroke data from the LoDoCo trial showing a reduction in stroke relative to placebo.[228] In fact, Nidorf specifically taught that "the rate of stroke was [] reduced in the treatment group."[229] While the significance of the stroke data standing alone is recognized to be limited by the "small number of events in both control and colchicine-treatment groups," it is directionally consistent with what the skilled cardiologist would have expected from the reduction of composite primary outcome in LoDoCo with an average hazard ratio of 0.33 (0.18–0.59) and a P value of 0.001."[230] The other cardiovascular events in the composite also generally show a concordance of reduction of incidence in the same direction.[231]

178. The same directional concordance of stroke reduction with a composite

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[227] EX1001 ('063 patent), 6:23-27 ("the term 'stroke' refers to a condition which occurs when the blood supply to a part of the brain is suddenly interrupted (i.e., ischemic stroke) or when a blood vessel in the brain bursts and releases blood into the spaces surrounding the brain cells (i.e., hemorrhagic stroke)."

[228] EX1020 (Nidorf 2013), Table 3 (noncardioembolic stroke outcome of 1.6% control, 0.35% colchicine, hazard ratio 0.23 (0.03-2.03), P = 0.184).

[229] EX1007 (Nidorf), 20:43-44.

[230] EX1007 (Nidorf), 20:43-44.

[231] EX1020 (Nidorf 2013), Table 3.

cardiovascular events outcome was also shown in CANTOS.[232] These data further support the expectation that 0.5 mg/day colchicine would reduce stroke incidence when treatment is initiated within 30 days of an MI according to COLCOT Protocol.

179. Thus, the method of claim 27 would have been obvious to a skilled cardiologist based on the teachings of Nidorf, COLCOT Protocol, and ESC Guidelines.

3. Dependent claims 2-7, 9-26, and 28-50

180. As I explain below, the remainder of the claims add features that were expressly taught by Nidorf and COLCOT Protocol or well known in the art. Thus, in my opinion, these claims would also have been obvious for the same reasons as I discussed above for claims 1, 8, and 27 and as further explained below.

a. Cardiovascular event claims 6-7, 9-11, 50

181. Claims 6-7, 9-11, and 50 further recite reducing the risk of a cardiovascular event, such as an ischemic cardiovascular event or a single event already listed in claim 8.[233] These additional requirements do not change my opinion

[232] EX1019 (Ridker 2017), Table 2.

[233] EX1001 ('063 patent), claims 6 ("a lower risk of a cardiovascular event, relative to a patient not being administered colchicine"), 7 ("the cardiovascular event is an ischemic cardiovascular event"), 9 ("the cardiovascular event is myocardial infarction"), 10 ("the cardiovascular event is stroke"), 11 ("the cardiovascular event is urgent hospitalization for angina requiring coronary revascularization"), 50 ("the cardiovascular event is resuscitated cardiac arrest").

that the method would have been obvious to a skilled cardiologist.

182. As I explained above, a skilled cardiologist would have been motivated to initiate administration of daily low dose colchicine to patients within about 3 days of a MI to reduce the risk of cardiovascular events. This includes all the claimed cardiovascular events, which are taught by Nidorf and COLCOT Protocol as part of their clinical trial primary outcome measures.[234]

183. A skilled cardiologist would also have reasonably expected that this treatment would reduce the risk of each category or individual cardiovascular event named in these claims. This would have been the case for the same reasons I previously explained in Section VIII.A.2.a, including based on the efficacy demonstrated in LoDoCo in view of the mechanistic proof of CANTOS.

184. Moreover, Nidorf teaches that in the LoDoCo trial, daily administration of 0.5 mg colchicine "significantly reduces the risk of a cardiovascular event, including an ACS [acute coronary syndrome], out of hospital cardiac arrest and non-cardio-embolic ischemic stroke."[235] Notably, Nidorf then specifically teaches that

[234] EX1006 (COLCOT Protocol), 2-3 (Primary outcome measures of COLCOT trial include "[c]ardiovascular death," "resuscitated cardiac arrest," "acute myocardial infarction," "stroke," and "hospitalization for angina requiring coronary revascularization"); EX1007 (Nidorf), 19:26-29 ("The primary efficacy outcome was the present of a cardiovascular event such as ACS, fatal or non-fatal out of hospital cardiac arrest or non-cardio-embolic ischemic stroke.").

[235] EX1007 (Nidorf), 21:55-59.

"[f]urther analysis confirmed that ***patients randomized to treatment were less likely to present with an ACS*** unrelated to stent disease(9/282 (3.2%) vs. 30/250 (12%) hazard ratio 0.26, 95% CI; 0.12-0.55; p<0.001), ***be it associated with an AMI*** [acute MI] (4/282 (1 .4%) vs. 14/250 (5.6%) hazard ratio 0.25, 95% CI; 0.08-0.76; p=0.014) ***or UA*** [unstable angina] (5/282 (1.8%) vs. 16/250 (6.4%) hazard ratio 0.27, 95% CI; 0.10-0.75; p=0.011)."[236] Nidorf further teaches that "[***o]ut of hospital cardiac arrest*** and non-cardio-embolic ischemic stroke were infrequent but were also ***reduced in the treatment group***."[237].Thus, Nidorf teaches reduction of the risks of each of the cardiovascular events individually recited in claims 6-7, 9-11, and 50.[238]

185. As I explained in Section VII.A, Bouabdallaoui reports reduction of each of the recited cardiovascular events in MI patients by initiating colchicine treatment within 3 days of the MI and concludes that "[e]arly initiation of low-dose colchicine after MI greatly reduced the risk of ***ischaemic CV events*** compared with placebo."[239] Because claims 6-7, 9-11 and 50 are not entitled to a priority date earlier than November 13, 2020 (the '063 patent's filing date), the efficacy data reported in Bouabdallaoui would have further reinforced the motivation to initiate colchicine

[236] EX1007 (Nidorf), 20:50-55 (emphases added).

[237] EX1007 (Nidorf), 20:42-44 (emphases added).

[238] EX1007 (Nidorf), 21:55-59.

[239] EX1005 (Bouabdallaoui), 7 (emphasis added), Table 3.

treatment within about 3 days of the MI and expectation of achieving reduced cardiovascular events in those patients.

186. Thus, for the same reasons in Section VIII.A.2.a and the additional reasons stated above, claims 6-7, 9-11 and 50 would also have been obvious over Nidorf and COLCOT Protocol in view of ESC Guidelines.

b. Additional medication claims 2-5, 29-32, 40-43

187. Claims 2-5, 29-32, and 40-43 further require that the patient "was prescribed a second medication," in particular an antiplatelet agent, such as aspirin, or statin, before colchicine administration.[240] These additional requirements do not change my opinion that the method would have been obvious to a skilled cardiologist.

188. First, as I explained already in Section VII.B, it was standard practice to use aspirin and statin as secondary prevention therapies for cardiovascular disease patients and common knowledge that a high percentage of such patients would have been treated with aspirin and/or statin.[241] These claims are, therefore, simply

[240] EX1001 ('063 patent), claim 2 ("the patient was prescribed a medication"), claim 3 ("the medication is an antiplatelet agent"), claim 4 ("the medication is aspirin"), claim 5 ("the medication is a statin"), claim 29 ("the patient was prescribed a medication"), claim 30 ("the medication is an antiplatelet agent"), claim 31 ("the medication is aspirin"), claim 32 ("the medication is a statin"), claim 40 ("the patient was prescribed a medication"), claim 41 ("the medication is an antiplatelet agent"), claim 42 ("the medication is aspirin"), claim 43 ("the medication is a statin").

[241] EX1009 (ESC Guidelines), 33 ("The benefits of statins in secondary prevention have been unequivocally demonstrated"), 31 ("Aspirin is recommended

describing the ordinary cardiovascular disease patient.

189. Second, Nidorf discloses that the primary analysis of the LoDoCo trial was stratified by factors including "therapy with ***aspirin***, clopidogrel or both, high dose ***statin*** therapy" and further shows that aspirin and/or statin had been used to treat the patients before the colchicine treatment began.[242] As shown below, the Nidorf 2013 article further confirms that a high percentage of the enrolled patients had been treated with aspirin or statin.[243]

indefinitely in all patients with STEMI"); EX1007 (Nidorf), 7:36-41, 18:3-4 (acknowledging that aspirin as a well-known antiplatelet agent and "standard secondary [cardiovascular event] prevention therapies [include] aspirin and high dose statins").

[242] EX1007 (Nidorf), 20:6-9 (emphases added), 21:25-54 (showing the numbers of patients in the colchicine-treatment group that had been treated with aspirin and/or statins).

[243] EX1020 (Nidorf 2013), Table 1 (highlights added).

Table 1 Study Population

	Control	Treatment
Total	250	282
Mean age, yrs	67 ± 9.2	66 ± 9.6
Male	222 (89)	251 (89)
Diabetes	69 (28)	92 (33)
Smoker	14 (6)	10 (4)
Past AMI or UA	61 (24)	64 (23)
CABG	39 (16)	62 (22)
PTCA	138 (55)	169 (60)
Aspirin and/or clopidogrel	235 (94)	262 (93)
DAPT	24 (10)	38 (13)
High-dose statin	235 (94)	271 (96)
Beta-blocker*	178 (71)	176 (62)
Calcium channel blocker†	25 (10)	52 (18)
ACE inhibitor	150 (60)	155 (55)

190. COLCOT Protocol also discloses that the enrolled patients "***must be treated*** according to the national guidelines (including antiplatelet therapy, statin…)."[244] Because aspirin had been the most common standard antiplatelet therapy for patients with MI as of 2019, a skilled cardiologist would have immediately recognized that COLCOT Protocol's disclosure of antiplatelet therapy recommended in national guidelines as suggesting concurrent treatment with aspirin.[245] Nidorf further teaches that

> primary outcome was less in patients receiving colchicine and at least one antithrombotic agent (4.5%) than in patients

[244] *See* EX1006 (COLCOT Protocol), 1.

[245] *See e.g.*, EX1021 (1999 Guidelines), 3; EX1009 (ESC Guidelines), 31.

> receiving at least one antithrombotic agent but not colchicine (16%). Moreover, primary outcome was less in patients receiving colchicine and at least aspirin (4.67%) than in patients receiving at least aspirin but no colchicine (14.7%).[246]

Based on these data, Nidorf concludes that

> the addition of colchicine to patients receiving at least one antithrombotic agent, such as aspirin, further reduces the incidence of a primary outcome such as acute coronary syndrome, fatal or non-fatal out of hospital cardiac arrest or non-cardio-embolic ischemic stroke.[247]

191. As such, Nidorf's success in reducing cardiovascular events in patients that had been prescribed and receiving aspirin or statin would have supported an expectation that, in patients already treated with aspirin or statin, administering daily low dose colchicine within about 3 days post-MI would have reduced future cardiovascular risks.

192. Thus, these claims would also have been obvious over Nidorf and COLCOT Protocol in view of ESC Guidelines.

c. Patient population claims 12, 26, 33, 39, 44, 49

193. Claims 12, 33, and 44 further recite that "the patient has atherosclerotic

[246] EX1007 (Nidorf), 21:11-17.

[247] EX1007 (Nidorf), 21:17-22.

coronary artery disease."[248] These claims are simply identifying an entirely common cardiovascular disease patient, and the additional requirement does not change my opinion that the method would have been obvious to a skilled cardiologist.

194. A skilled cardiologist would have known by 2019 that atherosclerosis is the most common cause of myocardial infarction and that the vast majority of MI patients would have atherosclerotic coronary artery disease.[249]

195. Consistent with the prior knowledge, Nidorf teaches that "patients with atherosclerotic vascular disease continue to be at risk of cardiovascular events," including acute coronary syndromes such as acute MI, and specifically claims a method of treating and/or reducing the risk of a cardiovascular event "wherein the subject has the symptoms of or is diagnosed with atherosclerotic vascular disease."[250] Thus, Nidorf also teaches and suggests treating patients with acute MI that have underlying atherosclerotic coronary artery diseases. Indeed, Nidorf's LoDoCo study enrolled patients with "angiographically proven coronary disease,"

[248] EX1001 ('063 patent), claims 12, 33, and 44.

[249] EX1015 (Aday 2018), 1 ("Atherosclerosis is the central disease process underlying most instances of myocardial infarction (MI), ischemic stroke, and peripheral artery disease."); EX1006 (COLCOT Protocol), 1 ("Atherosclerosis is the most common cause of myocardial infarction, stroke, and peripheral arterial disease.").

[250] EX1007 (Nidorf), 2:35-36, 19:6-8, claims 1 and 22.

some of which also had past MI.[251]

196. The acknowledgement in COLCOT Protocol that "[a]therosclerosis is the most common cause of myocardial infarction, stroke and peripheral arterial disease" also suggests treating MI patients with atherosclerotic coronary artery diseases.[252]

197. For all the same reasons that I have already addressed, Nidorf's success in reducing cardiovascular events in these patients would have provided a reasonable expectation that daily low dose colchicine treatment in patients with past MI and underlying atherosclerotic vascular disease, when initiated early within about 3 days of the MI, would reduce future cardiovascular risks.

198. Claims 26, 39, and 49 further recite that "the patient is an adult human."[253] As I explained, Nidorf discloses that the LoDoCo trial enrolled patients "aged 35 to 85 years."[254] COLCOT Protocol similarly discloses that "[m]ales and females of at least 18 years of age" are included in the study.[255] A skilled cardiologist would have understood that such specific patient populations would be adult human

[251] EX1007 (Nidorf), 18:32-33; EX1020 (Nidorf 2013), Table 1.

[252] EX1006 (COLCOT Protocol), 1.

[253] EX1001 ('063 patent), claims 26, 39, and 49.

[254] EX1007 (Nidorf), 18:33.

[255] EX1006 (COLCOT Protocol), 5.

patients, as required by claims 26, 39, and 49.

199. For all the same reasons I have already addressed, Nidorf's success in treating these adult human patients would have provided a reasonable expectation that daily low dose colchicine treatment in adult human patients with past MI, when initiated early within about 3 days of the MI, would reduce the risk of future cardiovascular events.

d. "Initiation upon assessment" claims 13, 36, 46

200. Claims 13, 36, and 46 add that "the administration of colchicine is initiated upon assessment in (a) an emergency department (ED), (b) the hospital, or (c) a medical office setting."[256] These additional requirements do not change my opinion that the method would have been obvious to a skilled cardiologist.

201. First, as I explained for claims 1, 8, and 27, it would have been obvious to initiate treatment prior to discharge from the typically about 3-day post-MI hospitalization period. This corresponds to the claimed "the administration of colchicine is initiated upon assessment in … (b) the hospital."

202. Second, Nidorf discloses that the LoDoCo study was supported by "the Heart Research Institute of Western Australia," which was also a recognized hospital setting.[257] Similarly, as I explained in Ground 2, COLCOT Protocol teaches the

[256] EX1001 ('063 patent), claims 13, 36, 46.

[257] EX1007 (Nidorf), 18:10-11.

"[l]ocation[]" of the study is at the "Montreal Heart Institute," which was a well-known hospital facility.[258] COLCOT Protocol further teaches that the study requires an initial assessment by the "investigator" (all medical doctors) to determine if patient is a suitable candidate.[259] Based on these disclosures, a skilled cardiologist would have understood that the assessment by an investigator would occur at a hospital (the study site), emergency department, or medical office setting, as recited by claims 13, 36, and 46.

203. Finally, assessing the patients at a hospital, emergency department, or medical office setting would have been standard practice for a skilled cardiologist as of 2019. Indeed, these three venues are simply those where the skilled cardiologist would have ordinarily practiced.

204. Thus, a skilled cardiologist would have been motivated to assess MI patients in a hospital, emergency department, or medical office setting and would have reasonably expected that the subsequent initiation of daily low dose colchicine treatment within about 3 days of the MI during the hospital stay would reduce a risk for future cardiovascular events such as stroke.

e. Dose and frequency claims 17-25, 34-35, and 45

[258] EX1006 (COLCOT Protocol), 7.

[259] EX1006 (COLCOT Protocol), 5 (describing in exclusion criteria that "[p]atient is considered by the investigator, for any reason, to be unsuitable candidate for the study").

205. Claims 17-25, 34-35, and 45 further recite administering colchicine at more specific doses and in more specific dosing frequencies.[260] These additional dose and dosing frequency limitations still all cover administering 0.5 mg once daily colchicine that was disclosed in Nidorf and COLCOT Protocol. Thus, in my opinion, these claims still would have been obvious to a skilled cardiologist for all the same reasons as addressed for claims 1, 8, and 27 above.

f. Tablet claims 14-16, 37-38, and 47-48

206. Claims 14-16, 37-38, and 47-48 further recite using colchicine in tablet form, more specifically a coated-tablet, and more specifically a film-coated tablet form.[261] These additional requirements do not change my opinion that the methods would have been obvious to a skilled cardiologist as it was common knowledge that colchicine was routinely formulated as film-coated tablets.

207. Nidorf teaches that "[t]he active ingredient colchicine as well as its

[260] EX1001 ('063 patent), claim 17 ("the colchicine is administered at 0.3 to 0.7 mg"), 18 ("the colchicine is administered at 0.4 to 0.6 mg"), 19 ("the colchicine is administered at 0.5 mg"), 20 ("the colchicine is administered at 0.5 mg"), 21 ("the colchicine is administered at 0.5 mg"), 22 ("the colchicine is administered at 0.5 mg"), 24 ("the colchicine is administered once, twice or three times a day"), 25 ("the colchicine is administered once per day"), 34 ("the colchicine is administered at 0.5 mg"), 35 ("the colchicine is administered once per day"), 45 ("the colchicine is administered once per day").

[261] EX1001 ('063 patent), claim 14 ("the colchicine is in the form of a tablet"), 15 ("the tablet is coated"), 16 ("the tablet is film-coated"), 37 ("the colchicine is in the form of a coated tablet"), 38 ("the tablet is film-coated"), 47 ("the colchicine is in the form of a coated tablet"), 48 ("the tablet is film-coated").

tablet formulation is listed in various national and international pharmacopeias such as the United States Pharmacopeia (USP)," demonstrating the routineness of tablet formulations of colchicine even as of 2013.[262] Nidorf further teaches that "[i]n all known indications, [colchicine] is generally administered orally as solid tablets in strengths of 0.5-0.6 mg/tablet (e.g. Europe and United States, respectively)," further affirming that the tablet limitations in the '063 patent claims had been routine and obvious.[263] The 2015 USP lists commercial colchicine "tablets," confirming Nidorf's teachings.[264] Similarly, COLCOT Protocol expressly teaches administering colchicine as "0.5 mg tablet."[265]

208. COLCRYS further discloses that colchicine could be administered effectively in the form of film-coated tablet.[266] While the film-coated tablets of COLCRYS were 0.6 mg colchicine, using this same type of film-coated tablet dosage form with 0.5 mg colchicine would have been obvious to implement the methods of LoDoCo and COLCOT. Indeed, skilled cardiologists would have recognized advantages associated with film-coated colchicine tablets, including

[262] EX1007 (Nidorf), 6:26-29.

[263] EX1007 (Nidorf), 6:40-43.

[264] EX1036 (Colchicine USP), 4.

[265] EX1006 (COLCOT Protocol), 4.

[266] EX1016 (COLCRYS), 4.

improved appearance, taste, and ease of use by the patient.

209. Thus, in view of the teachings of Nidorf, COLCOT Protocol, and COLCRYS, a skilled cardiologist would have been motivated to administer film-coated colchicine tablets as a convenient means of treatment with which patients could easily comply, and would have expected success at least given the efficacy reported in Nidorf.

g. "Within 4 to 7 days" claim 28

210. Claims 28 narrows the "within about 30 days" period of claim 27 to a narrower "within 4 to 7 days."[267] In my opinion, this method also would have been obvious.

211. First, as I explained for the "within about 3 days" limitation of claims 1 and 8, it would have been obvious to a skilled cardiologist to select any post-PCI time point within the COLCOT Protocol 30-day range to start treating the target stabilized MI patients.[268] And, as I discuss in Section VIII.C below, there is nothing unique or unexpected in initiating colchicine treatment within 4-7 days of the MI.

212. Second, while there had been clear reasons to initiate treatment during the typical 3-day post-MI hospital period, it would have also been obvious to initiate

[267] EX1001 ('063 patent), claim 28 ("administering colchicine within 4 to 7 days of the MI").

[268] EX1006 (COLCOT Protocol), 1, 5 ("INCLUSION CRITERIA… Patient must have suffered a documented acute myocardial infarction within the last 30 days").

colchicine treatment shortly after discharge, e.g., within days 4-7 post-MI, during follow-up care if the treatment had not already been started during hospitalization.

213. For example, ESC guidelines recommend that patients

> should have early post-discharge consultations with a cardiologist, primary care physician, or specialized nurse scheduled and be rapidly enrolled in a formal rehabilitation programme, either in-hospital or on an outpatient basis.[269]

Consistent with my clinical practice experience, by 2019 a skilled cardiologist would understand that such an "early post-discharge consultations" would commonly occur with the 4-7 post MI window.

214. Similarly, there was a well-publicized "See you in 7" program to ensure that post-MI patients receive follow-up care within 7 days post-discharge.[270] The rationale for this program was that once the patients are discharged from hospitals, "[d]elayed outpatient follow-up after AMI results in worse short- and long-term medication adherence." [271]

215. Based on the above and consistent with my own experience, a skilled cardiologist would have understood the importance of timely follow-up care, during

[269] EX1009 (ESC Guidelines), 24.

[270] EX1013 (Baker 2015), 1.

[271] EX1009 (ESC Guidelines), 30.

which the cardiologist can evaluate the patient's condition and provide needed medical care, including initiating secondary prevention therapy. For post-MI patients who did not initiate secondary prevention treatment during the typical 3-day hospital stay period, a skilled cardiologist would have been motivated to initiate the treatment during the closely monitored early post-discharge time period.

216. Finally, a skilled cardiologist would have reasonably expected that daily low dose colchicine treatment in patients with past MI, when initiated during an early post-discharge period of 4 to 7 days, would reduce the risk of stroke for all the same reasons as addressed for claims 1, 8, and 27.

B. Claims 1-26, 28, and 40-50 Would Have Been Obvious Over Bouabdallaoui in View of COLCRYS

217. As I explained above in Section VII.A, Bouabdallaoui is prior art to claims 1-13, 17-26, 28, 40-46, 49, and 50 and discloses every limitation in those claims. These claims would have been obvious over the teachings of Bouabdallaoui for the same reasons as I already explained.

218. Claims 14-16, 47, and 48 further recite administering colchicine in a tablet, more specifically coated tablet or film-coated tablet form. A skilled cardiologist would have been motivated to follow Bouabdallaoui's method of initiating treatment within about 3 days or within about 4-7 days using film-coated colchicine tablets as taught by COLCRYS. As I explained in Section VIII.A.3.f COLCRYS's disclosure of colchicine "film-coated" tablets for oral administration

as well as the known advantages of film-coated tablets would have motivated skilled cardiologists to administer colchicine in a film-coated tablet form as recited in those claims with a reasonable expectation of success.

219. Thus, in my opinion, claims 1-26, 28, and 40-50 would have been obvious over Bouabdallaoui in view of COLCRYS.

C. The *post hoc* COLCOT TTI data do not show any unexpected results

220. While the main findings of COLCOT are undoubtedly of clinical importance for its confirmation of colchicine's effectiveness in cardiovascular diseases in a large-scale placebo-controlled clinical study, it is also my opinion that the *post hoc* COLCOT "Time-to-Treatment Initiation" (TTI) data in the '063 patent (previously published in Bouabdallaoui[272]) are not surprising and do not show any unique effect for initiating treatment within 0-3 days of an MI event.[273] As I will discuss, for several reasons the TTI data is not sufficient to make between-group comparisons or conclusions as to relative superiority of one time period over another. In particular, in the '063 patent as well as in the anticipatory publication from

[272] EX1005 (Bouabdallaoui), Table 3.

[273] There is also nothing unexpected or surprising for claims 1-26 and 40-50 that recite treatment initiation periods different from "within about 30 days of an MI" since these claims are not supported in the provisional applications (see Section VI.C) and the *post hoc* COLCOT data were already published in Bouabdallaoui. (e.g, EX1005 (Bouabdallaoui), Table 3).

Bouabdallaoui, no statistically significant difference is demonstrated between various clinical outcomes in the time frames of 0 to 3 days, 4 to 7 days, and greater than 8 days that were selected by the authors for analysis on a *post-hoc* basis, nor do the authors present the most basic interaction analyses that would be required to make such claims. Indeed, the *post hoc* COLCOT TTI analysis does not include any statistical between-group comparisons.

221. The ’063 patent also does not show any unexpected reduction in a risk of stroke by initiating colchicine treatment within 30 days of the MI, as stated in claim 27. Instead, the reported effect on stroke reduction of 1.6% to 0.4% with a hazard ratio of 0.25 is nearly the same as the stroke reduction of 0.7% to 0.2% with a hazard ratio of 0.23 reported in LoDoCo.[274]

222. Thus, in my opinion, the ’063 patent does not show unexpected superiority of initiating treatment within 0-3 days of the MI. Nor does the patent demonstrate improved reduction of stroke risk by initiating colchicine treatment within 30 days of the MI compared to the prior art LoDoCo trial.

1. The *post hoc* COLCOT TTI data

223. The *post hoc* COLCOT TTI results are provided in Tables 3-7 and Figures 2-3 of the ’063 patent.[275] They are described as showing:

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[274] *Compare* EX1001 (’063 patent), Table 10 *with* EX1020 (Nidorf 2013), Table 3.

[275] EX1001 (’063 patent), 11:24-18:43.

- "A primary endpoint event occurred in 4.3% of patients in the colchicine group, as compared to 8.3% of those in the placebo group when TTI was between days 0 and 3 (N=1193, HR=0.52, 95% CI 0.32-0.84, p=0.007, FIG. 3A). Corresponding rates were 6.0 and 5.9% when TTI was between days 4 and 7 (N=720) and 5.7 and 7.1% when TTI was on day 8 or after (N=2748), but these differences between groups did not reach statistical significance."[276]

- "This TTI analysis of COLCOT shows that early initiation of low-dose colchicine within the first 3 days after MI is associated with a reduction of 48% in the risk of the primary endpoint consisting of a composite of CV death, resuscitated cardiac arrest, MI, stroke, or urgent hospitalization for angina requiring coronary revascularization, in comparison with placebo. This result was due to a lower incidence of MIs, strokes and urgent hospitalizations for angina leading to coronary revascularization. The secondary efficacy endpoint consisting of a composite of CV death, resuscitated cardiac arrest, MI or stroke was also significantly reduced by 45% with early initiation of low-dose colchicine. The benefits were more marked when treatment was initiated within the first 3 days after MI, as compared to between days 4 and 30, supporting the strategy of in-hospital initiation of colchicine in order to improve CV outcomes post-MI."[277]

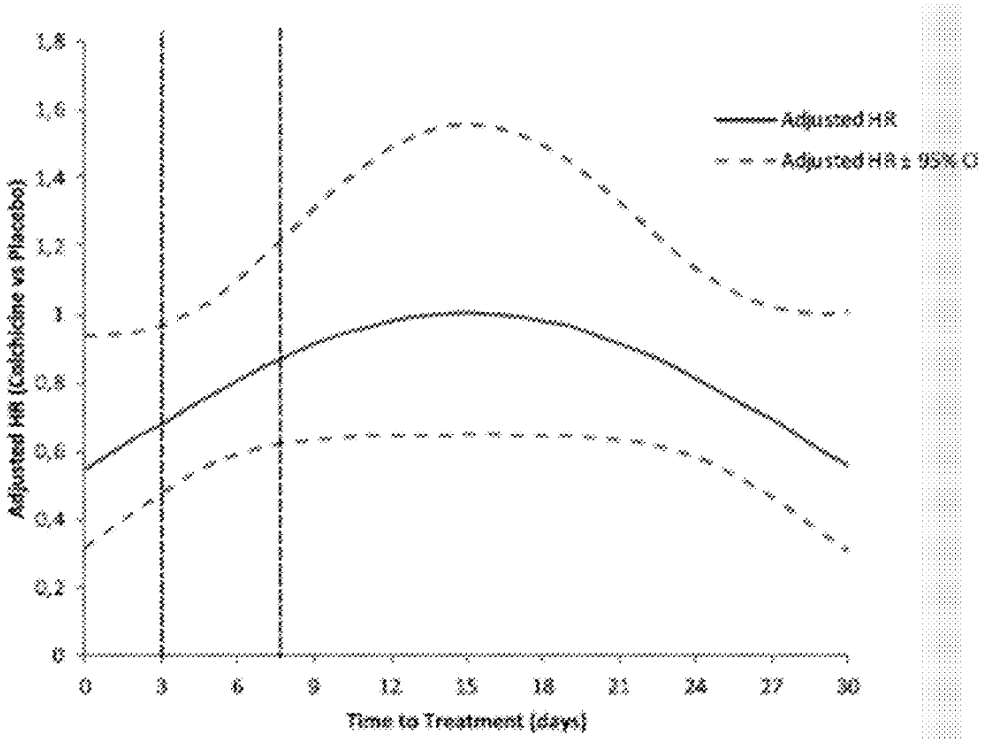
224. Figure 2 in the '063 patent, reproduced below, is described as "a graph of the association between the time-to-treatment initiation and the adjusted hazard ratio (solid line) with the 95% confidence intervals of the adjusted hazard ratio (dashed line)"[278] and as showing "[t]he effects of colchicine on the primary endpoint

[276] EX1001 ('063 patent), 11:27-34, 12:24-25.

[277] EX1001 ('063 patent), 17:25-40.

[278] EX1001 ('063 patent), 6:47-51.

according to TTI…."[279]



2. Initiating treatment "within about 3 days of the MI" is not necessary for efficacy and does not show any unique results

225. It is my opinion that these *post hoc* COLCOT TTI subgroup data do not provide any convincing evidence that time of initiation of low dose colchicine is an important determinant of clinical benefit. Rather, my reading of these data and that of the field as a whole indicates that the benefits of low dose colchicine are of similar magnitude and persist over very long treatment periods, irrespective of timing of a prior acute coronary syndrome (ACS). In other words, the patent data does not

[279] EX1001 ('063 patent), 11:26-27.

establish differences (beyond chance) between the TTI subgroups.

226. First, in the ‘063 patent as well as in the anticipatory publication from Bouabdallaoui, no statistically significant difference is demonstrated between various clinical outcomes in the time frames of 0 to 3 days, 4 to 7 days, and greater than 8 days that were selected by the authors for analysis on a *post-hoc* basis, nor do the authors present the most basic interaction analyses that would be required to make such claims.

227. Second, the *post-hoc* subgroup analyses of Bouabdallaoui requires cardiovascular readers to accept the improbable biologic notion that colchicine 0.5 mg treatment initiated at days 2 to 3 is “beneficial” whereas the same treatment initiated between days 4 and 7 is “not beneficial”, yet then becomes “beneficial again” when started after 8 days, even though in all cases the drug was to be continued as therapy over a period of several years, and the vast majority of clinical events avoided in comparison to those allocated to placebo occurred well after the 30-day initiation period had ended. This kind of non-biologic data analysis is an example of why *post hoc* subgroup analyses cannot be relied upon, particularly when the treatment of interest is designed to be given as a long-term chronic therapy as is clearly the case for colchicine. The further fact that there is no statistical difference demonstrated across these various *post-hoc* time points is an important issue as reliance on this kind of *post hoc* subgroup analysis has long been frowned upon in

the interpretation of clinical trials, ever since the observation was made over 30 years ago in the ISIS-2 trial that aspirin, an extremely effective drug for treatment of acute coronary ischemia (with an overall P-value < 0.000001) was nonetheless found to be "ineffective" among those born under the zodiac signs of Libra or Gemini, an obvious biologic fallacy.[280]

228. Third, even if one accepts the notion that subgroup data can be informative, the data from the '063 patent as well as in the anticipatory publication from Bouabdallaoui still do not support this idea. For example, while the authors seek to convince readers without a test for statistical significance between groups that initiation of treatment in the 0 to 3 day time window is "superior" to initiating therapy in other time windows, their own data in Figure 2 above shows the magnitude of benefit was just as large when colchicine was started much later within the 30-day window as compared to 0 to 3 days.

229. Fourth, data regarding the benefits of low dose colchicine on stroke are informative in this discussion. As described above in the sections on anticipation and shown in the '063 patent itself, in the initial LoDoCo trial published in 2013, a hazard ratio of 0.23 was reported for stroke after initiation of colchicine which is fully consistent with the benefits found for stroke in the COLCOT trial data presented in

[280] EX1027 (ISIS-2 1988), 9.

2019.[281] In other words, the '063 patent does not show any unexpected superiority in reducing stroke risks by initiating treatment within a 30 day window compared to the prior art LoDoCo trial that initiated treatment much later in time.

TABLE 10

Study efficacy outcomes								
	LoDoCo[11]		COLCOT[10]		COPS[13]		LoDoCo2[12]	
	Colchicine N = 250	Control N = 282	Colchicine N = 2366	Placebo N = 2379	Colchicine N = 396	Placebo N = 399	Colchicine N = 2762	Placebo N = 2760
Primary composite outcome: Cardiovascular mortality, myocardial infarction, ischemic stroke, urgent revascularization								
Ischemic stroke								
Events, N (%)	1 (0.4%)	4 (1.6%)	4 (0.2%)	16 (0.7%)	2 (0.5%)	6 (1.5%)	16 (0.6%)	24 (0.9%)
HR (95% CI)	0.23 (0.03-2.03)		0.25 (0.08-0.75)		0.34 (0.07-1.70)		0.66 (0.35-1.25)	

230. These same stroke data, however, further argue against the suggestion that time to treatment matters since, as shown below, within Bouabdallaoui et al, the reported hazard ratios for stroke are 0.21 for the 0 to 3 day time period, 0.28 for the 4 to 7 day time period, and 0.19 for the 8 to 30 day time period.[282] Not only are all of these hazard ratios fully consistent with the previously reported reduction in stroke observed in the initial 2013 LoDoCo trial, they demonstrate yet again no

[281] EX1001 ('063 patent), Table 10 (partial Table 10 with added highlights).

[282] EX1005 (Bouabdallaoui), Table 3 (highlights added).

difference whatsoever by time to treatment. In other words, the data does not show that initiating treatment within 3 days of the MI achieved unexpectedly enhanced stroke reduction compared to initiating treatment anytime later than 3 days.

Table 3 Efficacy endpoints according to time-to-treatment initiation (*N* = 4661, colchicine vs. placebo)

Endpoints	TTI 0–3 days, *N* = 1193 Colchicine vs. placebo, no. (%) HR (95% CI); *P*	TTI 4–7 days, *N* = 720 Colchicine vs. placebo, no. (%) HR (95% CI); *P*	TTI ≥ 8 days, *N* = 2748 Colchicine vs. placebo, no. (%) HR (95% CI); *P*
Primary composite endpoint	26 (4.3%) vs. 49 (8.3%)	22 (6.0%) vs. 21 (5.9%)	77 (5.7%) vs. 99 (7.1%)
	0.52 (0.32–0.84); *P* = 0.007	0.96 (0.53–1.75); *P* = 0.896	0.82 (0.61–1.11); *P* = 0.200
CV death	2 (0.3%) vs. 2 (0.3%)	2 (0.5%) vs. 4 (1.1%)	15 (1.1%) vs. 18 (1.3%)
	1.04 (0.15–7.37); *P* = 0.970	0.45 (0.08–2.46); *P* = 0.356	0.89 (0.45–1.76); *P* = 0.734
Resuscitated cardiac arrest	1 (0.2%) vs. 3 (0.5%)	2 (0.5%) vs. 1 (0.3%)	2 (0.1%) vs. 2 (0.1%)
	0.33 (0.03–3.20); *P* = 0.340	1.90 (0.17–20.95); *P* = 0.600	1.02 (0.14–7.22); *P* = 0.986
MI	17 (2.8%) vs. 29 (4.9%)	16 (4.4%) vs. 9 (2.5%)	52 (3.8%) vs. 59 (4.2%)
	0.58 (0.32–1.05); *P* = 0.071	1.67 (0.74–3.78); *P* = 0.218	0.93 (0.64–1.35); *P* = 0.710
Stroke	1 (0.2%) vs. 5 (0.8%)	1 (0.3%) vs. 3 (0.8%)	2 (0.1%) vs. 11 (0.8%)
	0.21 (0.02–1.81); *P* = 0.156	0.28 (0.03–2.71); *P* = 0.272	0.19 (0.04–0.84); *P* = 0.029
Urgent hospitalization for angina requiring coronary revascularization	6 (1.0%) vs. 17 (2.9%)	4 (1.1%) vs. 6 (1.7%)	15 (1.1%) vs. 26 (1.9%)
	0.35 (0.14–0.88); *P* = 0.026	0.63 (0.18–2.24); *P* = 0.476	0.61 (0.32–1.16); *P* = 0.131
Secondary composite endpoint	20 (3.3%) vs. 36 (6.1%)	18 (4.9%) vs. 16 (4.5%)	67 (4.9%) vs. 77 (5.5%)
	0.55 (0.32–0.95); *P* = 0.031	1.04 (0.53–2.03); *P* = 0.919	0.92 (0.66–1.28); *P* = 0.629
All-cause death	6 (1.0%) vs. 6 (1.0%)	8 (2.2%) vs. 7 (2.0%)	26 (1.9%) vs. 31 (2.2%)
	1.03 (0.33–3.19); *P* = 0.962	1.03 (0.37–2.84); *P* = 0.957	0.90 (0.53–1.51); *P* = 0.684
All coronary revascularizations	33 (5.5%) vs. 51 (8.7%)	25 (6.9%) vs. 18 (5.1%)	72 (5.3%) vs. 94 (6.7%)
	0.63 (0.40–0.97); *P* = 0.037	1.41 (0.76–2.61); *P* = 0.275	0.81 (0.59–1.10); *P* = 0.172

231. Fifth, neither in the original LoDoCo trial from 2013, nor in the affirming COLCOT or LoDoCo2 trials, has there been any evidence of a difference in benefit across periods of time.

232. Sixth, in contrast to the stable phase at roughly days 2 and 3 following MI when patients are getting ready for hospital discharge to home, it has not been shown even today as to whether colchicine is clinically effective in reducing secondary cardiovascular events in the immediate hours following acute MI, an unstable and dangerous time period when biologic processes related to coronary

reperfusion and restoration of oxygen flow are dominate. Even today, giving colchicine immediately are unknown and several clinical trials are ongoing which will address whether the potential benefits of an immediate treatment approach. And the ’063 patent does not show any data supporting that initiation treatment within 1 day of the MI (in its claimed “within about 3 days” range) achieved reduction of any cardiovascular event risk, much less unexpected superior benefit compared to initiating treatment after 3 days of the MI.[283] This is another reason why the patent data do not show anything unexpected or superior about initiating treatment “within about 3 days of the MI.”

233. Thus, while it is my opinion that the primary results of the confirmatory COLCOT trial are informative and important for patient care, it is also my opinion that the secondary *post-hoc* analyses of Bouabdallaoui et al do not show any unexpected results or superiority for initiating colchicine treatment within about 3 days of an MI.

234. My opinion is not an isolated one but is consistent with that of many other experts in the field. As one example, the *post hoc* COLCOT TTI data have also been carefully addressed by Dr. Aernoud Fiolet and his senior mentor Dr. Jan Hein Cornel, a well-known and well-respected expert in cardiovascular disease

[283] *See* EX1001 (’063 patent), Table 1.

treatment.[284] Drs. Fiolet and Cornel's observations of the COLCOT *post hoc* data, which I discuss further below, are consistent with my own opinions.

235. First, Drs. Fiolet and Cornel also note that the TTI data is a *post hoc* analysis based on later identified (i.e., not pre-specified) patient COLCOT subgroups. What this means is that the newly defined subgroups may not be sufficiently randomized, which undermines between-group comparisons and conclusions as to relative superiority. Drs. Fiolet and Cornel pointed this out, noting that "[a]n important caveat in the interpretation of this finding is that not all unequally distributed characteristics were used in adjustment of these estimators."[285] For example, as shown in Table 2 below (highlights added), patients in the TTI 0-3 group started with a lower history of hypertension number, MI number, and stroke or TIA number as compared to the TTI 4-7 day and TTI ≥8 day patient groups.[286] Consequently, patients in the TTI 0-3 day subgroup would be potentially less prone to developing post-MI cardiovascular events independent of colchicine treatment effects. The patient number in the TTI ≥8 day treatment group is also more than 2-fold that of the TTI 0-3 day treatment group (1193 v. 2748), bringing in additional

[284] EX1012 (Fiolet 2021), 5-6.

[285] EX1012 (Fiolet 2021), 6.

[286] EX1001 ('063 patent), Table 2.

potential size effect artifact.[287]

TABLE 2

Baseline characteristics according to TTI

Characteristics	TTI 0-3 days N = 1193	TTI 4-7 days N = 720	TTI ≥ 8 days N = 2748	p*	p**
Age (years)-mean ± SD	59.1 ± 10.8	60.1 ± 11.0	61.3 ± 10.4	<0.0001	<0.0001
Male sex- no. (%)	980 (82.2%)	605 (84.0%)	2189 (80.0%)	0.014	0.071
BMI (kg/m^2)-mean ± SD	28.1 ± 4.6	27.7 ± 4.6	28.6 ± 4.8	<0.0001	0.004
Current Smoking-no. (%)	522 (43.8%)	306 (42.6%)	554 (20.2%)	<0.0001	<0.0001
History of Hypertension-no. (%)	490 (41.1%)	343 (47.6%)	1544 (56.2%)	<0.0001	<0.0001
History of Diabetes no. (%)	208 (17.4%)	130 (18.1%)	604 (22.0%)	0.001	0.001
Prior MI-no. (%)	170 (14.3%)	111 (15.4%)	470 (17.1%)	0.070	—
Prior PCI no. (%)	182 (15.3%)	107 (14.9%)	494 (18.0%)	0.035	0.037
Prior CABG-no. (%)	34 (2.9%)	30 (4.2%)	82 (3.0%)	0.218	—
Prior HF-no. (%)	14 (1.2%)	12 (1.7%)	64 (2.3%)	0.046	0.017
Prior Stroke or TIA-no. (%)	20 (1.7%)	21 (2.9%)	78 (2.8%)	0.084	—
PCI associated with the index event-no. (%)	1143 (95.8%)	685 (95.1%)	2508 (91.3%)	<0.0001	<0.0001
Medication use-no. (%)					

236. Second, as shown below in Table 3 of the patent (highlights added), the data for multiple cardiovascular events (e.g., resuscitated cardio arrest and stroke) are from single-digit numbers of patients and not statistically significant over the placebo.[288] This again undermines making any between-group comparisons or conclusions as to relative superiority.

[287] EX1001 ('063 patent), Table 2.

[288] EX1001 ('063 patent), Table 3 (highlights added).

TABLE 3

Efficacy endpoints according to TTI (N = 4661, colchicine vs. placebo)

Endpoints	TTI 0-3 days, N = 1193 Colchicine vs. placebo no. (%) HR (95% CI); p	TTI 4-7 days, N = 720 Colchicine vs. placebo no. (%) HR (95% CI); p	TTI ≥ 8 days, N = 2748 Colchicine vs. placebo no. (%) HR (95% CI); p
Primary composite endpoint	26 (4.3%) vs. 49 (8.3%) 0.52 (0.32-0.84); p = 0.007	22 (6.0%) vs. 21 (5.9%) 0.96 (0.53-1.75); p = 0.896	77 (5.7%) vs. 99 (7.1%) 0.82 (0.61-1.11); p = 0.200
CV death	2 (0.3%) vs. 2 (0.3%) 1.04 (0.15-7.37); p = 0.970	2 (0.5%) vs. 4 (1.1%) 0.45 (0.08-2.46); p = 0.356	15 (1.1%) vs. 18 (1.3%) 0.89 (0.45-1.76); p = 0.734
Resuscitated cardiac arrest	1 (0.2%) vs. 3 (0.5%) 0.33 (0.03-3.20); p = 0.340	2 (0.5%) vs. 1 (0.3%) 1.90 (0.17-20.95); p = 0.600	2 (0.1%) vs. 2 (0.1%) 1.02 (0.14-7.22); p = 0.986
MI	17 (2.8%) vs. 29 (4.9%) 0.58 (0.32-1.05); p = 0.071	16 (4.4%) vs. 9 (2.5%) 1.67 (0.74-3.78); p = 0.218	52 (3.8%) vs. 59 (4.2%) 0.93 (0.64-1.35); p = 0.710
Stroke	1 (0.2%) vs. 5 (0.8%) 0.21 (0.02-1.81); p = 0.156	1 (0.3%) vs. 3 (0.8%) 0.28 (0.03-2.71); p = 0.272	2 (0.1%) vs. 11 (0.8%) 0.19 (0.04-0.84); p = 0.029

237. Specifically, as the highlights above show, for the resuscitated cardio arrest endpoint, each of the TTI groups only contain one or two colchicine-treated patients and one to three placebo-treated patients. Unsurprisingly given the small number of events, the variations of hazard ratios broad and P values calculated for this endpoint are not statistically significant.

238. More specifically, for patients with a TTI of 0-3 days, the variation of hazard ratio for resuscitated cardiac arrest is in a wide range of 0.03 to 3.20, and the high P value of 0.340 is not statistically significant.[289] The data for the stroke

[289]EX1001 ('063 patent), Table 3.

endpoint are similar.[290] One patient receiving colchicine treatment is included in this data group, and the hazard ratio range is from 0.02 to 1.81 with a P value of 0.156. Consequently, one cannot conclude that the effects in the 0-3 day group are or are not different from the other groups.

239. Thus, at least for claims 10 and 50 that specifically require reducing risks of stroke or resuscitated cardio arrest, respectively, the '063 patent does not establish any actual difference or provide unexpected results to support their nonobviousness.

240. Third, the *post hoc* TTI data does not include analyses showing statistical significance ***between primary endpoint data for TTI 0-3 days and TTI 4-30 days*** or otherwise demonstrate that colchicine's clinical benefit is unique to or could only be achieved by treatment initiated within about 3 days. Instead, the patent data shows that there are not statistically significant differences between the groups with respect to the primary endpoint.

241. More specifically, the primary composite endpoint for patients with TTI 0-3 days has a hazard ratio range that overlaps with those of the patients with TTI 4-7 days and 8-30 days.[291] For each individual cardiovascular event in Table 3,

[290] EX1001 ('063 patent), Table 3.

[291] EX1001 ('063 patent), Table 3.

the large hazard ratio ranges for each TTI group substantially overlap with each other, many of which have high P values.[292] This type of data are insufficient to support a conclusion that initiating colchicine treatment within 3 days in the COLCOT study achieved superiority over other treatment initiation periods. Drs. Fiolet and Cornel similarly noted that "[t]he authors of [Bouabdallaoui] did not report whether the differences in observed effect size between strata were statistically significant."[293]

242. Finally, even accepting the *post hoc* COLCOT TTI results as they are presented, Drs. Fiolet and Cornel also note that the Figure 2 graph shows an apparent parabolic effect for treatments initiated early and late in the overall 30-day window. What this means is that initiating treatment within 0-3 days does not provide any different result or benefit relative to initiating treatment late in the 30-day window, e.g., by around day 27 during the last three days of the window.

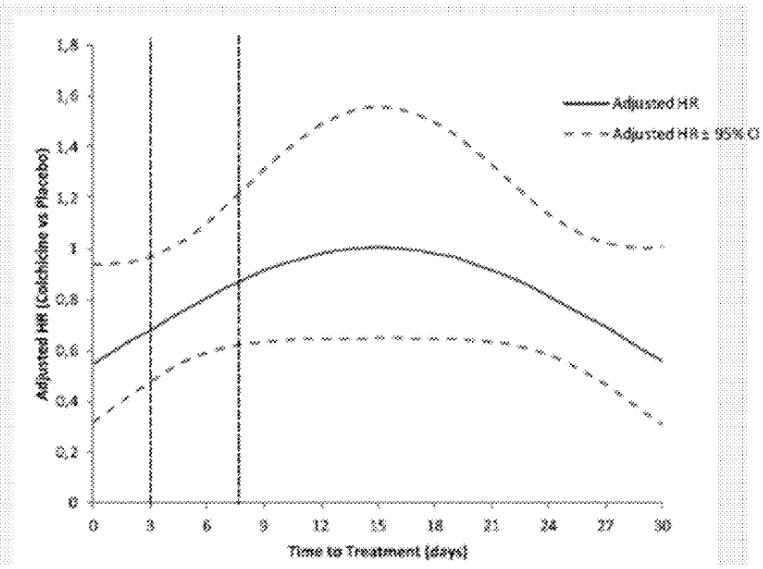
243. Indeed, as shown by Figure 2 of the patent, instead of achieving superior adjusted HRs (hazard ratios) over all TTI 4-30 days patients, the HRs of TTI 0-3 days patients are almost at the same level as those for TTI 27-30 days.[294]

[292] EX1001 ('063 patent), Table 3.

[293] EX1012 (Fiolet 2021), 6.

[294] EX1001 ('063 patent), Fig. 2.

FIG. 2



244. As Drs. Fiolet and Cornel concluded, "whether this parabolic relation of treatment initiation and effect size—with greater effect size seen in both very early (<3 days) and very late (>21 days) treatment initiation—reflects separate biologic mechanisms of the drug or is ***a play of chance*** cannot be distinguished from these data."[295]

245. Based on their independent analysis, Drs. Fiolet and Cornel conclude that "[t]he effect of colchicine persists throughout prolonged treatment, irrespective of timing of a prior acute coronary syndrome (ACS)" and that "the play of chance

[295] EX1012 (Fiolet 2021), 6 (emphasis added).

cannot be distinguished from these data."[296] Thus, like myself, Drs. Fiolet and Cornel also agree that in the absence of a plausible biological mechanism, a skilled cardiologist would interpret this parabolic data as reflecting an artifact of the *post hoc* analysis rather than an actual treatment effect.

3. The Patent Data Do Not Support the Claim Scope

246. The '063 patent includes claims with three different treatment initiation periods: (1) "within about 3 days of the MI" (e.g., claims 1, 8), (2) "within 4 to 7 days of the MI" (claim 28), and (3) "within about 30 days of an MI" (e.g., claim 27). In addition to my opinions above regarding the 0-3 day period, the COLCOT *post hoc* TTI data is not described as showing, and in my opinion does not show, unexpected benefits or unique effects the latter initiation time periods of claims 27 and 28.

247. I noted that even the '063 patent itself recognizes that its *post hoc* TTI data for the primary end point "did not reach statistical significance" for either days 4-7 or day 8 and after[297] and that the effects on the secondary endpoint "were more marked when treatment was initiated within the first 3 days after MI, as compared to between days 4 and 30, supporting the strategy of in-hospital initiation of

[296] EX1012 (Fiolet 2021), 6

[297] EX1001 ('063 patent), 11:31-12:26.

colchicine in order to improve CV outcomes post-MI."[298]

248. Thus, the data from the *post hoc* TTI analysis as described in the '063 patent does show any unexpected benefit or unique effect when treatment is initiated on day 4 or later post-MI.

IX. CONCLUSION

249. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true. I further declare that all statements made herein were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code.

Date: June 14, 2023 By: 

Paul Ridker, MD, MPH

[298] EX1001 ('063 patent), 17:36-40.

Appendix A

CURRICULUM VITAE

PART I: General Information

DATE PREPARED: June 15, 2022

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Place of Birth: St. Louis, Missouri

Education:

1981	BS	Brown University, Providence, RI
1986	MD	Harvard Medical School, Boston, MA
1992	MPH	Harvard School of Public Health, Boston, MA (Quantitative Methods and Epidemiology)

Honorary Degrees:

2009	Doctorem Honoris Causa, University of Utrecht, The Netherlands
2009	Doctorem Honoris Causa, Universidad Abierta Interamericana, Argentina

Postdoctoral Training:

Internship and Residency

1986-89	Intern/Resident, Department of Medicine, Brigham and Women's Hospital, Boston, MA
1989	Rotating Chief Medical Resident, Brockton-West Roxbury Veteran's Administration Hospital, Boston, MA

Clinical and Research Fellowships

1984-85	Sinclair-Kennedy Fellow, Harvard University, Boston, MA (Field work in Epidemiology in Zimbabwe, Zambia, Kenya)
1986-89	Clinical Fellow in Medicine, Harvard Medical School, Boston, MA
1989-92	Research Fellow in Medicine, Harvard Medical School, Boston, MA
1989-91	Research/Clinical Fellow in Medicine (Cardiovascular Disease), Brigham and Women's Hospital, Boston, MA

Licensure and Certification:

1988	Board of Registration in Medicine, Commonwealth of Massachusetts
1989	Diplomate of the American Board of Internal Medicine
1991	Diplomate of the American Board of Internal Medicine, Subspecialty in Cardiovascular Disease

Academic Appointments:

1992-93	Instructor in Medicine, Harvard Medical School, Boston, MA
1993-97	Assistant Professor of Medicine, Harvard Medical School, Boston, MA
1997-02	Associate Professor of Medicine, Harvard Medical School, Boston, MA
2002-	Professor of Medicine, Harvard Medical School, Boston, MA
2003-	Professor of Public Health, Harvard School of Public Health, Boston, MA
2003-	Eugene Braunwald Professor of Medicine, Harvard Medical School, Boston, MA

Hospital and Affiliated Institution Appointments:

1991-2	Associate Physician, Brigham and Women's Hospital, Boston, MA
1992-	Consulting Cardiologist, Southern Jamaica Plain Health Center, Boston, MA
2005-	Senior Physician, Brigham and Women's Hospital, Boston, MA
2005-	Consulting Cardiologist, Dana-Farber Cancer Institute, Boston, MA
2007-	Senior Cardiologist, Brigham and Women's Hospital, Boston, MA

Hospital and Health Care Organization Service Responsibilities:

1992-	Attending Cardiologist, Clinical Service, Brigham and Women's Hospital, Boston, MA
1992-	Attending Cardiologist, Echocardiography Unit, Brigham and Women's Hospital, Boston, MA
2011-	Consulting Staff, Dana Farber Cancer Institute, Boston, MA

Major Administrative Responsibilities:

1992-97	Director of Clinical Trials, Division of Preventive Medicine, Brigham and Women's Hospital Boston, MA
1994-97	Co-Director, Cardiovascular Research, Division of Preventive Medicine, Brigham and Women's Hospital, Boston, MA
1997-02	Co-Director, Blood Studies, Division of Preventive Medicine, Brigham and Women's Hospital, Boston, MA
1997-03	Director, Cardiovascular Research, Division of Preventive Medicine, Brigham and Women's Hospital, Boston, MA
1997-04	Chairman, PREVENT Trial, NHLBI
1999-	Program Director, Cardiovascular Epidemiology Training Program, NHLBI/NRSA
1999-2001	Chairman, PRINCE Trial
2000-08	Co-Director, Leducq Center for Molecular and Genetic Epidemiology of Cardiovascular Disease, Brigham and Women's Hospital
2000-	Director, Center for Cardiovascular Disease Prevention, Brigham and Women's Hospital
2003-10	Co-Director, Donald W. Reynolds Center for Cardiovascular Research, Harvard Medical School
2003-07	Chairman, ValMARC Trial
2004-10	Chairman, JUPITER Trial
2007-	Director, Women's Genome Health Study (WGHS)
2007-10	Chairman, LANCET Trial

2009-2015	Chairman, JUPITER Genome Wide Association Study
2011-18	Chairman, CANTOS Trial
2011-20	Chairman, Cardiovascular Inflammation Reduction Trial (CIRT), NHLBI
2013-2018	Co-Chair, Executive Committee, SPIRE trials
2015-	Co-Chair, PROMINENT Trial
2016-	Executive Director, BWH Center for Community Wellness
2020-	Chairman, ACTIV-4B COVID-19 Outpatient Thrombosis Prevnetin Trial (NHLBI, Operatioin Warp Speed)
2021-	Co-Chair, Steeering Committee, Ziltivekimab Cardiovascular Outcomes Study (ZEUS)

Major Committee Assignments:

1990-96	Steering Committee, International Studies of Infarct Survival (ISIS), Oxford, England
1992-	Steering Committee, Women's Health Study (WHS), Boston, MA
1993-95	Steering Committee, American Studies of Infarct Survival (ASIS), Boston, MA
1993-00	Steering Committee, Women's Antioxidant Cardiovascular Trial (WACS), Boston, MA
1994-04	Council on Thrombosis, American Heart Association
1994-	Council on Epidemiology and Prevention, American Heart Association
1995-99	Endpoints Committee, ACHIEVE Trial, Philadelphia, PA
1996-99	Cardiology Advisory Board, Owen Health Care
1997-00	Board of Directors, Central Boston Division, American Heart Association
1997-99	Medical Advisory Council, Alcoholic Beverage Medical Research Foundation
1997-04	Chairman, Steering Committee, PREVENT Trial, Boston, MA
1998-03	Ad Hoc Reviewer, Clinical Trials Review Committee, National Heart, Lung, and Blood Institute
1998-02	American Heart Association, Committee on Cardiovascular Prevention
1999-01	Advisory Committee, International Society on Thrombosis and Haemostasis
1999-01	International Advisory Committee, Fibrinogen & Inflammation, Paris, France
1999-02	American Heart Association, Liaison for Population Biology
1999-2001	Chairman, Steering Committee, PRINCE trial, Boston, MA
1999-01	Reviewer, Special Emphasis Panel on Inflammation, National Heart, Lung, and Blood Institute, Bethesda, MD
1999-04	American Heart Association, Cardiovascular Epidemiology, Council
2000-04	Genetics Advisory Panel, Harvard Medical School
2000-04	Steering Committee, High Throughput Genotyping Center, Brigham and Women's Hospital
2000-04	Operations Committee, Tissue and Blood Repository, Brigham and Women's Hospital
2000-05	Advisory Board to the Office of Corporate Sponsored Research and Licensing, Partners HealthCare
2001-05	Associate Editor, Seminars in Vascular Medicine
2001-06	Joint Steering Committee, Partners HealthCare/ Millennium Pharmaceuticals Collaborative
2001-06	Reviewer, Medical Council, Doris Duke Charitable Foundation
2001-04	Advisor, National Health Lung and Blood Institute, Specialized Centers of Clinically Oriented Research (SCCOR)
2002-07	Leadership Committee, Council on Epidemiology and Prevention, American Heart Association
2003-07	Data and Safety Monitoring Board, HOST Trial, US Veterans Administration

2003-11	Chairman and Principal Investigator, JUPITER Trial
2003-09	Scientific Board, Stanley J Sarnoff Endowment for Cardiovascular Science
2003-07	Chairman, Valsartan-Managing Blood Pressure Aggressively and Evaluating Reduction in CRP Trial (Val-MARC)
2006-10	Chairman, Steering Committee, LANCET Study
2006-2010	Executive Advisory Board, Harvard Institute for Global Health (HIGH)
2006-2013	Pharmacogenetics and Risk of Cardiovascular Disease Network (PARC), NHLBI
2006-2017	Board of External Advisors (BEE), National Heart Lung and Blood Institute
2008-	Chairman, Steering Committee, JUPITER GWAS
2011-2015	Reviewer, NHLBI Extramural Loan Repayment Program (LRP)
2011-	Chairman, Steering Committee, CANTOS Study
2011-2016	Chairman, Genetics Informatics Trial (GIFT) Data Safety Monitoring Board (DSMB), NHLBI
2011-	Chairman, Steering Committee, Cardiovascular Inflammation Reduction Trial (CIRT), NHLBI
2012-2016	Data and Safetly Monitoring Board, ACELERATE
2012-2015	Co-Chair, NHLBI HIV/AIDS CVD Working Group / Workshop, Bethesda, MD
2012-2016	NHLBI Science Moving towards Resaerch Tranlsation and Therapy (SMARTT) Review Panel, Bethesda, MD
2013-2014	NHLBI Special Emphasis Panel, NHLBI Institutional Training SEP, Bethesda, MD
2013	Joint Review Panel, Medical Research Council (MRC), British Heart Foundation (BHF), United Kingdom Cancer Research, Oxford England
2013	Committee on Publications (New England Journal of Medicine), Massachusetts Medical Society, Boston, MA
2013-	Executive Committee, STRENGTH
2013-2018	Co-Chair, Executive Committee, Studies of PCSK9 Inhibition and the Reduction of vascular Events (SPIRE)
2014-	Executive Committee, AEGIS
2015-2017	Co-Chair, NHLBAC Working Group on Clinical Trials
2015-2017	Co-Chair, NHLBI Working Group on HIV and Cardiovascular Disease
2017	USFDA Cardiorenal Advisory Panel
2017	Member, Peter Munk Scientific Advisory Board, UHN Toronto, Canada
2018	British Heart Foundation Review Panel, University of Oxford, United Kingdom

Professional Societies:

1985-91	Peabody Society, Harvard Medical School, Boston, MA
1992-	American College of Physicians
1993-	American College of Cardiology (FACC)
1993-	American Heart Association
1994-04	International Society of Thrombosis and Hemostasis
1994-04	North American Antithrombotic Consortium
1995-	American Federation of Clinical Research
1999-	American Society for Clinical Investigation (ASCI)
1999-02	American Association for the Advancement of Science
2000-05	New York Academy of Sciences
2000-05	American Epidemiological Society (AES)
2002-	American Association of Physicians (AAP)
2004-09	National Lipid Association (NLA)
2005-	American Heart Association (Fellow, FAHA)
2011-	Association of University Cardiologists (AUC)
2012-	American Clinical and Climatological Association

Editorial Boards:

1995-05	Journal of Thrombosis and Thrombolysis
1997-02	American Journal of Medicine
1998-06	Circulation
1999-09	Preventive Cardiology
1999-09	Harvard Heart Letter
2000-05	Current Controlled Trials in Cardiovascular Medicine
2000-05	American Journal of PharmacoGenomics
2001-04	Journal of the American College of Cardiology
2001-03	Seminars in Vascular Medicine (Associate Editor)
2001-05	Korean Journal of Cardiovascular Diseases
2001-06	Circulation (Consulting Editor)
2003-09	American Heart Hospital Journal
2003-11	Metabolic Syndrome and Related Disorders
2004-09	Diabetes & Vascular Disease Research
2006-11	European Heart Journal
2013-19	Circulation Research (Associate Editor)

Selected Awards, Named Lectures, and Honors:

1980	Phi Beta Kappa, Brown University, Providence, RI
1981	Sigma Xi Science Honors, Brown University, Providence, RI
1981	Magna Cum laude, Brown University, Providence, RI
1982	National Institutes of Health Student Research Award, Bethesda, MD
1984	Soma Weiss Research Award, Harvard Medical School, Boston, MA
1984-85	Sinclair-Kennedy Fellowship, Harvard University, Boston, MA
1990-92	National Heart, Lung, and Blood Institute Trainee Award in Cardiovascular Epidemiology (National Research Service Award)
1992-94	Merck Academic Development Postdoctoral Fellowship Award, Rahway, NJ
1992-97	Clinician Scientist Award, American Heart Association, Dallas, TX
1993	Elected Fellow, American College of Cardiology (FACC)
1997-99	SmithKline Beecham Faculty Development Award
1997-02	Established Investigator Award, American Heart Association
1999	Elected Member, American Society of Clinical Investigation (ASCI)
2000	Elected Member, American Epidemiological Society (AES)
2000	Linus Pauling Lecture and 2000 Prevention Award, American College for Advancement in Medicine (ACAM)
2000	Doris Duke Distinguished Clinical Scientist Award
2001	Honorary Lecture on Population Sciences, European Society of Cardiology, Stockholm, Sweden
2001	"America's Best, Science and Medicine", TIME, August 2001
2001	Consulting Editor, Circulation, American Heart Association, Dallas, TX
2001	Elected Fellow, Council on Arteriosclerosis, Thrombosis, and Vascular Biology, American Heart Association, Dallas TX (FAHA)
2002	Elected Member, Association of American Physicians (AAP)
2003	Eugene Braunwald Professor of Medicine, Harvard Medical School
2003-07	Reynolds Investigator, Donald W. Reynolds Foundation, Las Vegas, NV
2004	Top 30 Teachers Award, American College of Cardiology
2004	James Herrick Lecture, American Heart Association, Chicago IL
2004	"The Time 100", TIME, April 2004
2005	A. E. Diamond Lectureship, University of Toronto, Toronto, Canada
2005-	Harvard School of Public Health 2005 Alumni Award of Merit, Boston, MA

2005-	National Institutes of Health, NIH Director's Astute Clinician Award, Bethesda, MD
2007-	Distinguished Fellow, International Atherosclerosis Society, Milan, IT
2007-18	Board of External Advisors (BEE), National Heart Lung and Blood Institute
2008	Populations Science Lectureship, Japan Atherosclerosis Society
2009	Doctorem Honoris Causa, University of Utrecht
2009	Calabresi Lecture, Yale University
2009	Daniel D. Savage Memorial Science Award, Association of Black Cardiologists
2009	Outstanding Achievement Award, International Society Atherosclerosis
2009	Honoree, The VF Society, New York, NY
2009	XXVII Leccion Memorial Lecture, Fundacion Fernandez-Cruz, Madrid, Spain
2009	Doctorem Honoris Causa, Universidad Abierta Interamericana, Argentina
2010	Lectura Magistrale, Perugia, Italy
2011	Elected Member AUC
2012	Elected Member, American Clinical and Climatological Association
2013	Landmark Distinguished Scientist Lecture, Toronto, Canada
2013	Linton Distinguished Lecture, New England Society for Vascular Surgery
2013	Distinguished Scientist Award, Amercan Heart Association
2015	Mikamo Lecture, 79th Annual Scientifc Meeting of the Japanese Circulation Society, Osaka Japan
2017	Keenan Lecture, University of Toronto, Toronto Canada
2017	Robert J. Burns Memorial Lecture, Canadian Cardiovascular Society, Canadian Society of Cardiovascular Nuclear and CT Imaging, Vancouver, Canada
2018	Distinguished Biomedical Scholar Award Lecture, University of Iowa, IO
2018	Distinguished Lecture, ATVB, San Francisco, CA
2018	Distinguished Scientist Lecture, American Heart Association, Chicago IL
2018	Agepha Cardiovascular Research Award, Vienna, Austria
2019	Eugene Braunwald Keynote Lecture, American College of Cardiology, New Orleans
2019	Attilio Maseri Lecture, ATBV Spring Meetings, Trieste Italy
2019	Paul Dudley White Keynote Lecture, American College of Cardiology, New York, NY
2019	Keynote Lecture, European Atherosclerosis Society, Maastricht
2020	Elected Member, National Academy of Medicne (NAM)
2020	R.T. Hall Lecutereshp, CSANZ Australia
2020	Joseph Stokes Lifetime Achievement Award, American Society for Preventive Cardiology

Part II: Research, Teaching, and Clinical Contributions:

A. Narrative Report Research Activities

Dr. Paul M Ridker is the Eugene Braunwald Professor of Medicine at the Harvard Medical School and Director of the Center for Cardiovascular Disease Prevention at the Brigham and Women's Hospital in Boston, MA. Dr. Ridker additionally serves as Professor of Public Health at the T.C. Chan Harvard School of Public Health in Boston, MA. A board-certified internist and cardiologist, Dr. Ridker has joint appointments in the Division of Cardiovascular Diseases and the Division of Preventive Medicine, both at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA.

Dr. Ridker's primary research focus has involved inflammatory mediators of heart disease and the molecular and genetic epidemiology of inflammation and thrombosis, with particular interests in biomarkers for coronary disease, "predictive" medicine, and the underlying causes

and prevention of atherosclerotic disease. Dr. Ridker's research brings together classical tools of population-based epidemiology with emerging genetic and molecular techniques designed to improve our ability to predict and prevent thrombotic occlusion. Dr. Ridker's best known work has centered on inflammatory markers of thrombosis, the clinical use of C-reactive protein (hsCRP) to predict risk of cardiovascular disease and diabetes, the ability of statin therapy to both lower CRP and vascular event rates among individuals identified at inflammatory risk, and the genetics of vascular inflammation. The 2017 CANTOS clinical trial, designed and conducted by Dr. Ridker, provided crucial proof-of-principle for the inflammation hypothesis of atheorthrombosis.

Dr. Ridker has served as the Principal Investigator of multiple investigator-initiated RO1 grants funded by the National Heart, Lung, and Blood Institute (NHLBI) and has served for 20 years as Program Director for an institutional National Research Service Award (NRSA) for Research Training in Cardiovascular Epidemiology. Dr. Ridker's research efforts have additionally been supported by a Clinician Scientist Award (1992-1997), an Established Investigator Award (1997-2002), and a Distinguised Scientist Award (2013) from the American Heart Association; a Distinguished Clinical Scientist Award from the Doris Duke Charitable Foundation (2000-2005); and through philanthropic research grants from the Leducq Foundation (2000-2006) and the Donald W Reynolds Foundation (2003-2009). Dr. Ridker lists among his honors elected membership into the American Society for Clinical Investigation (ASCI), the American Epidemiological Society (AES), and the American Association of Physicians (AAP), as well as Honorary Degrees from the University of Utrecht (Netherlands) and Universidad Abierta Interamericana (Argentina). Citing his work on inflammation, CRP, and atherothrombosis, Time Magazine honored Dr. Ridker as one of America's Ten Best Researchers in Science and Medicine in 2001 and as one of the "Time 100" in 2004. In 2018/2019, Dr. Ridker delivered the prestigious Distinguished Scientist Lecture at the annual American Heart Association meetings, the Eugene Braunwald Keynote Lecture for the American College of Cardiology, the Attilio Maseri Lecture in Trieste Italy, the Distinguished Lecture for ATVB North America, and the Paul Dudley White Keynote Lecture for the American College of Cardiology.

Dr Ridker served over a decade on the Board of External Experts for the National Heart Lung and Blood Institute (NHLBI) and has served on multiple US FDA review panels. In addition to his work in cardiovascular epidemiology and his roles in the NIH-funded Physician's Health Study (PHS) and Women's Health Study (WHS), Dr Ridker has been the Principal Investigator or Study Chairman of several investigator-initiated, multinational, randomized clinical trials including PREVENT, PRINCE, Val-MARC, LANCET, and JUPITER, as well as the CANTOS and CIRT trials directly evaluating the role of inflammation inhibition as a novel method for vascular protection. Dr Ridker is also the Principal Investigator of the ongoing Women's Genome Health Study (WGHS) and JUPITER-GWAS, two comprehensive genome wide association studies being conducted among more than 35,000 initially healthy American men and women. Dr. Ridker co-chaired the SPIRE PCSK9 development program internationally, and currently serves as Trial Chairman for PROMINENT, a 10,000 particiant study of selective PPAR-a inhibition for vascular protection.

Dr. Ridker is the author of over 900 original reports, 150 reviews and book chapters, and 5 textbooks related to cardiovascular medicine. Dr. Ridker is a co-inventor on patents held by the Brigham and Women's Hospital that relate to the use of inflammatory biomarkers in cardiovascular disease and diabetes.

According to the ISS Web of Science (January 2020), Dr. Ridker's scientific publications have been cited more than 300,000 times (h-index > 220).

B. Funding Information

Report of Past Research Activities

1984-85	Harvard University Sinclair-Kennedy Fellowship	Recipient
1990-92	NIH (HL07575) Institutional National Research Service Award NHLBI Trainee Award Cardiovascular Epidemiology	Recipient
1991-01	NIH/NCI (CA47988) Blood Collection Substudy, Women's Health Study	Co-Investigator
1991-03	NIH/NCI (CA40360) Physicians' Health Study: Continued Follow-up	Co-Investigator
1991-14	NIH/NHLBI (RO1 CA047988 - Buring) Women's Health Study: Continued Follow-up	Co-investigator
1992-94	Merck, Sharpe and Dohme Academic Development Postdoctoral Fellowship	Recipient
1992-97	Clinician Scientist Award American Heart Association Dallas, TX	Principal Investigator
1993-95	Miles, Inc. Inhibition of Platelet Function	Principal Investigator
1993-95	Alcoholic Beverage Research Foundation Effects of Alcohol on Fibrinolytic Function	Principal Investigator
1993-97	Hoechst-Roussel DCC Healing and Early Afterload Reducing Therapy	Co-Principal Investigator,
1993-06	NIH/NHLBI (HL46959) Trial of Antioxidant Therapy of CVD in Women	Co-Investigator
1994-95	University of Pennsylvania Decision Analysis of Thrombolysis	Principal Investigator
1994-96	Behringwerke AG First American Study of Infarct Survival (ASIS)	Co-Principal Investigator
1996-97	Dupont Merck Pharma Randomized Trial of Low Dose Warfarin in the Secondary Prevention of Venous Thromboembolism: Pilot Feasibility Study	Principal Investigator
1997-99	Abbott Pharmaceuticals Inflammation and Vascular Risk	Principal Investigator
1997-00	SmithKline Beecham Faculty Development Program	Principal Investigator
1998-01	NIH/NHLBI (RO1 HL58755) Inflammation, Infection, and Cardiovascular Risk	Principal Investigator

1998-02	Established Investigator Grant American Heart Association	Principal Investigator
1998-04	NIH/NHLBI (RO1 HL57951) Secondary Prevention Trial of Venous Thrombosis Among Patients with and without Factor V Leiden	Principal Investigator
1999-04	NIH/NHLBI (R01 HL63293) Thrombotic, Inflammatory, & Gene Marker of CVD in Women	Principal Investigator
2000-01	Merck, Inc. Inflammatory Biomarkers in AFCAPS/TexCAPS	Principal Investigator
2000-02	Dade Behring, Inc. Clinical Applications of hs-CRP	Principal Investigator
2000-02	Bayer Corporation, Inc. Dose-dependent Effects of Aspirin on hs-CRP	Principal Investigator
2000-03	Bayer Corporation, Inc. hs-CRP, Low Dose Aspirin, and the Primary Prevention of Cardiovascular Disease in Women	Principal Investigator
2000-04	Leducq Foundation, Paris, France Leducq Center for Molecular and Genetic Epidemiology of Cardiovascular Diseases	Co-Director
2000-05	NIH/NHLBI Blood Factors and Peripheral Arterial Disease Outcomes	Principal Investigator (subcontract)
2000-06	Bristol-Myers Squibb Pravastatin Inflammation CRP Evaluation (PRINCE)	Principal Investigator/ Trial Chairman
2002-03	Pharmacia Hypertension and hs CRP	Principal Investigator
2002-03	Variagenics Genetic Polymorphisms and Lipid and Inflammatory Changes	Principal Investigator
2003-05	Novartis Valsartan-Managing Blood Pressure Aggressively and Evaluating Reduction in CRP (VaL-MARC) Trial	Principal Investigator
2000-07	Doris Duke Charitable Foundation Doris Duke Distinguished Clinical Scientist Award Molecular and Genetic Approaches to Cardiovascular Disease Prevention	Principal Investigator
2003-10	Donald W. Reynolds Foundation Cardiovascular Clinical Research Center	Co-Director
2005-07	Aventis HbA1c Levels in the Women's Health Study	Principal Investigator

2007-9	Merck Investigator Initiated Grants	Principal Investigator	
2006-8	Abbott Prospective Analysis of Plasma Triglycerides and CVD	Principal Investigator	
2005-12	NIH/NHLBI (HL080467 - Buring) Women's Health Study: Continued Follow-up	Co-Investigator	
2003-12	AstraZeneca Justification for the Use of statins in Prevention: An Intervention Trial Evaluating Rosuvastatin (JUPITER)	Principal Investigator	
2005-15	NIH/NHLBI (UO1 HL069757 - Krauss) Pharmacogenetics and Risk of CVD	Co-Investigator	
2005-11	Leducq Foundation, Paris France Leducq Trans-Atlantic Networking of Excellence for Cardiovascular Research Program	Principal Investigator	
2006-11	Sanofi-Aventis A Randomized Clinical Trial of Lantus for C-Reactive Reduction in Type 2 diabetes (LANCET)	Principal Investigator	
2006-11	Women's Genome Health Study (WGHS) NIH/NHLBI/Amgen	Principal Investigator	
2007-12	NIH/NHLBI (RO1 HL081153 - Krumholz) Young Women with AMI (subcontract)	Co-Investigator	
2008-14	NIH/NHLBI (HL091069 – C Albert) DETERMINE: Biologic Markers and MRI SCD	Co-investigator	PRE-
2009-13	AstraZeneca JUPITER Genome Wide Association Study	Principal Investigator	
2010-13	Celera A Candidate Gene Study of Predictors of Vascular Risk and Statin Response	Principal Investigator	
2010-14	NIH/NHLBI (RO1 HL103742 – Pradhan) Mechanisms of Statin Induced DM	Co-investigator	
2011-15	NIH/NHLBI (UO1 HL108630 – Loscalzo) Pathophenotype Landscape of Complex Disease	Co-Investigator	
C.	Report of Current Research Activities		
2005-19	NIH/NHLBI (T32 HL07575 – Ridker/Buring) Institutional National Research Service Award (NRSA) for Research Training in Cardiovascular Epidemiology	Program Director	
2011-19	Novartis Canakinumab Anti-Inflammatory Thrombosis Outcomes Study (CANTOS)	Principal Investigator	
2011-19	NIH/NHLBI (U01 HL101422 - Ridker) Cardiovascular Inflammation Reduction Trial (CIRT)	Principal Investigator	
2017-2020	Merck		

	Post-Doctoral Program in Health Literacy	Principal Investigator
2016-2019	Pfizer CRSA: Lipid Lowering Trials (SPIRE-1, SPIRE-2)	Principal Investigator
2014-2021	Kowa Pemafibrate Cardiovascular Events (PROMINENT)	Principal Investigator
2019-	Amarin – Inflammatory Biomarkers in REDUCE-IT	Principal Investigator

C. Report of Teaching

1. Local Contributions:

a. HARVARD MEDICAL SCHOOL / HARVARD SCHOOL OF PUBLIC HEALTH

1992-1996	Harvard Medical School HCP 701.0 Introduction to Principles and Methods of Analytic Epidemiology Lecturer 70 – 150 Medical Students, 5 contact hours/ 15 preparation hours/year
1997-1999	Harvard Medical School AC 701.0 Critical Reading of the Medical Literature Lecturer 130 medical students, 2 contact hours/4 preparation hours/year
1995-02	Harvard Medical School Cardiovascular Pathophysiology Lecturer 150 medical students, 2 contact hours/4 preparation hours/year
1995-08	Harvard School of Public Health Epi 212a Epidemiology of Cardiovascular Disease Lecturer, 60 students, 3 contact hours/6 preparation hours/year
1993-97	Harvard Medical School Introduction to Clinical Medicine Tutorial leader, 6 students, 30 contact hours/10 preparation hours/year
1992-97	Harvard Medical School/ BWH Cardiology Rotation Cardiology/Echocardiography/ECG Tutorials Attending and Tutorial Leader 20 students, 12 contact hours/6 preparation hours/year
2000-13	Harvard Medical School HST 030 Human Pathology Lecturer 60 students, 2 contact hours/4 preparation hours
2002-6	Harvard Medical School IN 708.OMI Cardiovascular Pathophysiology Lecturer 120 students, 2 contact hours
2002-09	Harvard School of Public Health ID 228 Principles of Screening Lecturer 40 students, 3 Contact hours
2002-	Harvard School of Public Health EPI 208 Lecturer 40 students, 3 Contact hours
2007-2016	Harvard Medical School Intensive Training in Translational Medicine, 3 Contact hours

2007--2015	Harvard Medical School SCSP Introduction to Human Investigation/Scholars in Clinical Science, 3 Contact hours
2007-	Harvard Medical School Harvard Catalyst Colloquium Series, 3 Contact hours
2010-	Harvard Medical School Harvard Catalyst / Harvard Clincal and Translational Science Center Introduction to Clinical Investigation and Translational Medicine
2014-	HST 030 Fall Research Frontiers Lecture
2018-	Harvard Medical School, Clinical Scholars / Research Scholars Program

b. HARVARD MEDICAL SCHOOL CONTINUING MEDICAL EDUCATION

1997-ongoing	Department of Continuing Medical Education, Harvard Medical School Thrombosis and Thromboembolism: New Strategies for Improved Patient Care Course Co-Director, 300 physicians and students 20 contact hours/60 preparation hours/15 administrative hours/year
1998-05	Department of Continuing Medical Education, Harvard Medical School Intensive Review of Internal Medicine Lecturer – Lipid Symposium, 600 physicians and students 2 contact hours/6 preparation hours/year
1997-03	Department of Continuing Medical Education, Harvard Medical School Review of Primary Care Lecturer - Risk Factors for Coronary Artery Disease, 400 physicians and students 2 contact hours/4 preparation hours/year
1994-07	Department of Continuing Medical Education, Harvard Medical School Comprehensive Review of Cardiology Lecturer Risk Factors for Coronary Artery Disease, Primary and Secondary Prevention Inflammation and Vascular Disease, Lipid Lowering Strategies (workshop) Echocardiography (workshop), 350 physicians and students
1999-05	Department of Continuing Medical Education, Harvard Medical School Lipid Disorders in Vascular Medicine Lecturer, Atherosclerotic Risk Factors: Established and Emerging 120 physicians and students, 2 contact hours/4 preparation hours/year
2003-19	Department of Continuing Medical Education, Harvard Medical School Cardiovascular Medicine: Review and Update for Practitioners (invited lecturer)
2003-19	Department of Continuing Medical Education, Harvard Medical School Office Practice of Primary Care Medicine (invited lecturer)
2003-19	Department of Continuing Medical Education, Harvard Medical School Intensive Review of Internal Medicine (invited lecturer)
2007-19	Department of Continuing Medical Education, Harvard Medical School Internal medicine: Comprehensive Review and Update (invited lecturer)

c. LOCAL INVITED TEACHING PRESENTATIONS - SELECTED

1993 Cardiovascular Grand Rounds, New England Deaconess Medical Center
1994 Cardiovascular Grand Rounds, Framingham Heart Study/Boston University
1995 Cardiovascular Grand Rounds, Brigham and Women's Hospital
1996 Cardiovascular Grand Rounds, Massachusetts General Hospital
1997 Medical Grand Rounds, West Roxbury VA Medical Center/BWH
1997 Obstetrical and Gynecologic Grand Rounds, Beth Israel Medical Center
1997 Medical Grand Rounds, Brigham and Women's Hospital
1998 Cardiovascular Grand Rounds, Boston University Medical Center
1998 Cardiology Grand Rounds, Massachusetts General Hospital
1999 Anesthesia Grand Rounds, Brigham and Women's Hospital
2000 Medical Grand Rounds, Beth Israel Medical Center
2000 Cardiology Grand Rounds, New England Medical Center
2000 Combined Pathology Grand Rounds, Brigham and Women's Hospital
2001 Medical Grand Rounds, West Roxbury VA Medical Center
2001 Medical Grand Rounds, Brigham and Women's Hospital
2002 Medical Grand Rounds, New England Medical Center
2002 Cardiovascular Grand Rounds, Brigham and Women's Hospital
2003 Anesthesia Grand Rounds, Brigham and Women's Hospital
2004 Primary Care Grand Rounds, Brigham and Women's Hospital
2004 Rheumatology Grand Rounds, Brigham and Women's Hospital
2005 Medical Grand Rounds, Beth Israel/Deaconess Medical Center
2005 Cardiovascular Grand Rounds, Massachusetts General Hospital
2007 Cardiovascular Grand Rounds, Beth Israel Deaconess Medical Center
2007 Harvard Medical School Alumni Association Lectureship
2007 Dana Farber Cancer Institute / Harvard Cancer Center Statistical Lectures
2008 Cardiovascular Grand Rounds, Massachusetts General Hospital
2008 Cardiovascular Grand Rounds, Brigham and Women's Hospital
2009 Medical Grand Rounds, Brigham and Women's Hospital
2009 Medical Grand Rounds, Beth Israel Medical Center
2012 Medical Grand Rounds, Brigham and Women's Hospital
2012 Harvard Catalyst, Harvard Scholars in Clinical Science Program
2013 Cardiovascular Grand Rounds, West Roxbury VA Medical Center
2014 Pathology Grand Rounds, Brigham and Women's Hospital
2014 Center for Cardiovascular Sciences, Harvard Medical School
2016 HMS/HST Research Frontiers, Harvard Medical School
2016 Harvard T.C. Chan School of Public Health
2017 Medical Grand Rounds, Brigham and Women's Hospital (Inflammation Biology)
2017 Cardiology Grand Rounds, Brigham and Women's Hospital (PCSK9)
2017 Cardiology Grand Rounds, Brigham and Women's Hospital (CANTOS)
2017 Cardiology Grand Rounds, Massachusetts General Hospital
2018 Rheumatology Grand Ruonds, Massachestts General Hospital
2019 Cardiology Grand Rounds, Brigham and Women's Hospital (CIRT)

d. TEACHING LEADERSHIP ROLES

1999-2019 Program Director
NHLBI (T32) / Fellowship Training Program in Cardiovascular Epidemiology
Division of Preventive Medicine

1997-2019 Course Co-Director
Department of Continuing Medical Education, Harvard Medical School
Thrombosis and Thromboembolism: New Strategies for Improved Patient Care

e. TRAINEES/ ADVISEES

Name	Years	Current Position
Christopher O'Donnell, MD, MPH	1993-1995	Associate Professor of Medicine, Chief, U.S. Department of Veterans Affairs
Abraham Ariyo, MD, MPH	1995-1996	Dallas Regional Medical Center
Kathryn Rexrode, MD, MPH	1995-1997	Associate Professor, Harvard Medical School
Daniel Price, MD	1995-1997	Cardiologist, Yale New Haven Hospital
Louis Rhode, MD	1997-1998	Universitad Federal do Rio Grande del Sul
Debra Schaumberg, OD, ScD	1997-1999	Ophthalmology Vice President, Epidemiology and Optholmology, Evidera
Lynn Amowitz, MD	1997-2000	World Health Organization
Joseph Miles, MD	1998-2000	Assistant Professor of Medicine, Hospitals of the University of Pennsylvania-Penn Presbyterian
Elizabeth Jackson, MD, MPH	1998-2000	Professor, University of Alabama at Birmingham
Howard Sesso, ScD	1998-2000	Associate Professor, Harvard Medical School
Simin Lui, MD, ScD	1999-2000	Professor of Medicine, Alpert Medical School, Brown University, Providence RI
David Morrow, MD, MPH	1999-2001	Professor, Harvard Medical School
Michelle Albert, MD, MPH	1999-2002	Professor, and Dean of Admissions University of California at San Francisco
Gavin Blake, MBBS, MPH	1999-2003	Cardiologist, Dublin, Ireland
Aruna Pradhan, MD, MPH	1999-2001	Associate Professor, Harvard Medical School
Edmund Bermudez, MD, MPH	1999-2002	Interventional Cardiologist, Venice, FL
Peter Mason, MD	2000-2001	Associate Professor, Medical College of Wisconsin, Milwaukee, WI
Brian Ference, MD	2001-2002	Assistant Professor, Medicine Wayne State University School of Medicine
Jennifer Pai, PhD	2000-2004	Director of Data Sciences, Strategy, and Platforms at Merck & Co.
Robert Ostfeld, MD	2002-2003	Associate Professor, Albert Einstein College of Medicine and Associate Director, Cardiology Fellowship at Montefiore-Einstein
Chethan Gangireddy, MD	2002-2003	Assistant Professor, Medicine, Lewis Katz School of Medicine at Temple University
Jose Torres, MD	2002-2006	Assistant Professor, Department of Neurology, NYU Langone Hospitals

Sarah Rosner, PhD	2002-2005	Associate Professor of Biostatistics, Boston University School of Public Health
Jacqueline Suk Danik, MD, MPH	2002-2011	Assistant Professor of Medicine, Harvard Medical School, Clinical Director of Echocardiography at Massachusetts General Hospital
Christopher Newton-Cheh, MD	2002-2004	Assistant Professor of Medicine, Harvard Medical School, Cardiologist at Massachusetts General Hospital
Fidencio Saldana, MD, MPH	2003-2005	Dean of Students and Assistant Professor, Harvard Medical School
Stephanie Chiuve, MD	2003-2006	Director of Epidemiology AbbVie
Daniel Chasman, PhD	2004-2006	Associate Professor, Harvard Medical School
Sanjay Shrivastava, MD	2004-2006	Cardiologist, Atrius Health
Samia Mora, MD	2004-2006	Associate Professor, Harvard Medical School
Brendan Everett, MD	2005-2007	Associate Professor, Harvard Medical School
Sandeep Bansal, MD	2005-2007	Cardiologist, Penn Medicine
Jessica Mega, MD, MPH	2006-2008	Chief Medical and Scientific Officer, Verily
Isabella Kardys, MD, PhD	2006-2007	Erasmus MC, Department of Cardiology, Rotterdam
David Conen, MD	2006-2008	Associate Professor, McMaster University
Guillaume Pare, MD	2006-2008	Associate Professor, McMaster University
Nina Paynter, PhD	2007-2009	
Linda Peelen, PhD	2009-2011	Associate Professor Epidemiology, UMC Utrecht
Steven Lubitz, MD	2008-2010	Assistant Professor of Medicine, Harvard Medical School, Cardiologist at Massachusetts General Hospital
Jessica Pena, MD, MPH	2009-2012	Assistant Professor, Weill Cornell Medicine
Audrey Chu, PhD	2010-2014	Scientific Leader in Human Genetics, GSK
Akintunde Akinkuolie, MD	2011-2016	Cardiology Fellow, UCLA
Elizabeth Barnett, PhD	2011-2016	Senior Research Scientist, Community Health
Patrick Lawler, MD, MPH	2013-2017	Assistant Professor of Medicine, University of Toronto
Amit Khera, MD	2015-2017	Instructor in Medicine, Massachusetts General Hospital

Aaron Aday, MD	2016-2018	Instructor in Medicine, Vanderbilt University Nashville, TN
Eddie Duran, MD	2017-2020	Cardiology Fellow, University of Wisconsin
Oluremi Ajala, MD	2017-2020	Cardiology Fellow, University of Illinois
Hasan Siddiqi, MD	2018-2020	Instructor in Medicine, Vanderbilt University, Nashville, TN

f. SELECTED REGIONAL, NATIONAL, OR INTERNATIONAL CONTRIBUTIONS

1992 Greater Boston Interventional Cardiology Forum, Boston, MA

1993 Cardiology Forum 1993, Honolulu, HI
Visiting Professor Program/Memorial Medical Center, Savannah, GA

1994 First International Symposium of the North American Antithrombotic Therapy Consortium, Boston, MA
Visiting Professor Program/The Reading Hospital and Medical Center, Reading, PA
Gordon Research Conference on Thrombosis and Fibrinolysis, Ventura, CA
European Cardiovascular Congress (ECC), Nice, France
1st Annual Society of Cardiovascular Management (SCM) Conference, Society for Cardiovascular Management, Washington, DC
Thomas R. Mulroy Memorial Lecture, Northwestern University, Chicago, IL
Framingham Heart Study, Framingham, MA
46th Annual Cardiological Society of India, Rajastan, India

1995 Medical and Cardiovascular Grand Rounds, Vanderbilt University Medical Center, Nashville, TN
Cardiovascular Grand Rounds, Yale University School of Medicine, New Haven, CT
Medicine Update 1995, Keystone, Colorado
Forum on Outcomes Research: Strategies to Compete in Today's Managed Care Environment, Cambridge, MA
Cardiovascular Grand Rounds and Research Rounds, McMaster University, Hamilton, Ontario, Canada
Cardiovascular Grand Rounds, Wilford Hall Air Force Base, San Antonio, TX
American Society of Hematology, Seattle, WA
American Heart Association Fellowship Symposium, Anaheim, CA
Interventions in the Treatment of Heart Disease, the New York Cardiological Society, New York, NY
Grand Rounds, Martin Luther King Hospital/Drew University School of Medicine, Los Angeles, CA

1996 Thrombosis Research Center, University of Massachusetts, Worcester, MA
Cardiovascular Grand Rounds, Massachusetts General Hospital, Boston, MA
Second International Cooperative Pulmonary Embolism Registry (ICOPER) Investigators Meeting, Rome, Italy
Medicine Update 1996, Copper Mountain, Colorado
36th Annual American Heart Association Conference on Cardiovascular Disease Epidemiology and Prevention, San Francisco, California
Third International Fibrinogen Symposium: Hemostasis, Inflammation, Cardiovascular Disease, Ulm, Germany

Annual Innisbrook Seminar in Cardiology and Cardiovascular Surgery, Tarpon Springs, FL

1997
19th Annual Conference of the Biomedical Association (BMA), Boston, MA
Medicine Update 1997, Salt Lake City, Utah
XI International Symposium on Atherosclerosis, Paris, France
4th International Conference on Preventive Cardiology, Montreal, Canada
XVIth Congress of the International Society on Thrombosis and Haemostasis, Florence, Italy
Joint Congress on Molecular Diagnostics, German Society of Clinical Chemistry and Laboratory Medicine, Munster, Germany
Hemostatic Variable in Atherothrombosis, 1997, Marseilles, France
Cardiovascular Grand Rounds, Boston University Medical Center, Boston, MA
First Annual Scientific Meeting of the Heart Failure Society of American, Baltimore, MD
Thrombosis Research Institute, London, England
American Society of Hematology, San Diego, California

1998
Cardiovascular Grand Rounds, Dartmouth Medical School
Edna G. Kynett Memorial Lecture, Abington Memorial Hospital
14th Annual Cardiovascular Conference at Lake Louise, Alberta, Canada
American College of Cardiology Plenary Session, Atlanta, GA
Annual Meeting of the Society for Vascular Medicine and Biology, San Diego CA
American Federation of Clinical Research, Washington, D.C.
Julius Litter Memorial Lecture, Framingham, MA
Medical Grand Rounds, Columbia University, New York, NY
Second Annual Bove Lecture, Maine Medical Center, Portland, ME
34th Annual Robert Jeresaty Cardiovascular Symposium, Hartford, CT
American Diabetes Association National Meeting, Chicago, IL
International Symposium on Pulmonary Embolism, Yokkaichi, Japan
Cardiovascular Grand Rounds, Massachusetts General Hospital, Boston, MA
50th Annual Conference of the American Association of Clinical Chemistry, Chicago, IL
Cardiovascular Grand Rounds, Johns Hopkins University Medical Center, Baltimore, MD
Infection, Inflammation, and Coronary Disease, Centers for Disease Control Atlanta, GA
Third Annual Symposium on Thrombosis, Thrombolysis and Anticoagulation, Boston, MA
Prevention Conference V: Beyond Secondary Prevention, American Heart Association, San Francisco, CA
American College of Cardiology, New Techniques and Concepts in Cardiology, Washington, DC
American Society of Hematology, Miami, FL

1999
Vascular Biology Working Group, New Orleans, LA
American College of Cardiology, New Orleans, LA
IVth International Fibrinogen Symposium, Paris, France
Biomarkers and Surrogate Endpoints: National Institutes of Health, Bethesda, MD
American Thrombosis Association, Denver, CO
Association for Lipid and Atherosclerosis Research, Detroit, MI
Invited Debate, 39th Annual Conference on Cardiovascular Disease Epidemiology and Prevention, Orlando, FL

Medical Grand Rounds, Beaumont Hospital, Detroit, MI
Second Annual Symposium Cardiac Care for Women, Falls Church, VA
Medical Grand Rounds, University of Massachusetts, Worcester, MA
17th Annual Bellin Cardiovascular Seminar, Green Bay, WI
Plenary Speaker, European Society of Cardiology, Barcelona, Spain
Invited Speaker, American College of Physicians/American Society of Internal Medicine (ACP/ASIM) Meetings, Dartmouth College, NH
Invited Speaker, American College of Cardiology, Sante Fe Colloquium on Cardiovascular Therapy, Sante Fe, NM
Invited Speaker, American Association of Clinical Chemistry, Washington, D.C.
Invited Speaker, Joint AHA/AACC Summit on Markers in Cardiology, Louisville, KY
Plenary Speaker, American Heart Association, Atlanta, GA
American College of Rheumatology/Inflammation Study Group, Boston, MA
International Conference on Infection and Atherosclerosis, Washington, D.C.
16th Annual Advances in Heart Disease, American College of Cardiology, University of San Francisco, CA

2000

Simon Dack Visiting Professor, Mount Sinai Medical Center, New York, NY
DeStevens Lecture, Northwestern University Medical Center, Chicago, IL
Lipid 2000, Boca Raton, Florida
Cardiology Grand Rounds, Yale University School of Medicine
International Conference on Biomarkers in Cardiovascular Disease, Paris, France
BIO 2000 International Biotechnology Meetings, Boston, MA
Plenary Session, American College of Cardiology, Anaheim, CA
Cardiology Grand Rounds, New England Medical Center, Boston, MA
Invited Speaker, IVth Annual Thrombosis and Thromboembolism Review, Henry Ford Medical Center, Detroit, MI
Plenary Speaker, Cardiovascular Disease 2000, Tokyo, Japan
Cardiology Grand Rounds, Albert Einstein School of Medicine, New York
Frontiers in Lipoprotein and Vascular Disease Research, American College of Clinical Chemistry, St. Louis, MO
Linus Pauling Lecture, American College for Advancement in Medicine, Dallas, TX
Plenary Speaker, 7th Annual Symposium of the Preventive Cardiovascular Nurses Association, Washington, D.C.
Interdisciplinary Lipid Council, New York, NY
Plenary Speaker, American College of Rheumatology, Philadelphia, PA
Invited Speaker, Women's Health Initiative, NHLBI, Washington, DC

2001

24th Annual Gold Coast Conference, Miami, FL
State-of-the-Art Plenary Session, American College of Cardiology, Orlando, FL
International Symposium on Atherosclerosis: Genomics and Therapeutic Perspectives, Montreal, Canada
28th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA
Office Practice of Primary Care Medicine, Boston, MA
Cardiology Grand Rounds, Columbia University, New York, NY
Cardiology Grand Rounds, LDS/University of Utah, Salt Lake City, UT
37th Annual Robert M. Jeresaty Cardiovascular Symposium, Hartford, CT
9th Annual American College of Cardiology Update, San Antonio, TX
Oklahoma Heart Institute Update, Oklahoma Heart Foundation, Tulsa, OK
DeStevens Atherosclerosis Lecture, Northwestern University, Chicago, IL

Annual Scientific Meetings, Doris Duke Charitable Foundation, Newport, RI
12th Annual Meeting, Society for Vascular Medicine and Biology, Baltimore, MD
XVIII Congress The International Society on Thrombosis & Haemostasis, Paris, FR
2nd International Congress on Heart Disease, Washington, DC
Honorary Lecture on Population Sciences, European Society of Cardiology, Stockholm, Sweden
XIV International Symposium on Drugs Affecting Lipid Metabolism, New York
International Task Force for Prevention of Coronary Heart Disease, New York
Fourth Annual Joint Summit on Markers in Cardiology, Louisville, KY
Spingarn Lecture, Beth Israel Hospital/Albert Einstein Medical School, NY
34th NY Cardiovascular Symposium, American College of Cardiology, New York

2002

Medical Grand Rounds, New England Medical Center, Boston, MA
Medical Grand Rounds, Montefiore Medical, Albert Einstein Medical School, NY
Visiting Professor, Medical and Cardiovascular Grand Rounds, Emory University, Atlanta, GA
23rd Annual Office Practice of Primary Care Medicine, Harvard Medical School, Boston, MA
Plenary Symposium, 51st American College of Cardiology, Atlanta, GA
CDC/AHA Workshop on Inflammation and Cardiovascular Disease, Atlanta, GA
4th Heart Disease in Women Conference, American College of Cardiology, Bethesda
Advances in Cardiovascular Medicine and Surgery, Texas Heart Institute celebration for the opening of the Denton A Cooley Building, Houston, TX.
6th Annual Symposium on Prevention of Cardiovascular Disease, West Palm, FL
Xth Simposio Internacional de Cardiopatia Isquemica, Sociedad Espanola de Cardiologia, Bilbao, Spain
First Annual Symposium: Genomics and Cardiovascular Disease, Philadelphia, PA
13th Annual Symposium, Cardiovascular Disease: State of the Art 2002, Ocean Edge, MA
American Heart Association, Atherosclerotic Vascular Disease Conference, Boston, MA
48th Scientific/Standardization Meeting, International Society of Thrombosis and Haemostasis, Boston, MA
Robert Turner Memorial Conference on Diabetes, Carlsbad, California
Plenary Symposium, European Society of Cardiology, Berlin, Germany
Plenary Symposium, TCT 2002, Washington, D.C.
Canadian Cardiovascular Society, Toronto, Canada
Cardiovascular Grand Rounds, University of Iowa, IO
19th Annual ACC/Santa Fe Colloquium on Cardiovascular Therapy, Santa Fe, NM
Plenary Session, American Heart Association, Chicago, IL
Grand Rounds, Medical College of Ohio, Toledo, OH
20th Anniversary Symposium, Jean Mayer USDA Human Nutrition Research Center
on Aging at Tufts University, Boston, MA

2003

2nd Annual David H Spodick Symposium, Worcester, MA
Medical Grand Rounds, Duke University Medical Center, Durham, NC
Plenary Symposium, American College of Cardiology, Chicago, IL
Dr. Daniel D Savage Memorial Lecture, 16th Annual Scientific Session of the Association of Black Cardiologists, Chicago, IL
23rd Annual Scientific Meeting, Stanley J Sarnoff Endowment for Cardiovascular Science, Washington, D.C.

Seventh Annual Symposium on Prevention of Cardiovascular Disease, Miami, Fl
3rd Annual American Heart Association Special Populations Symposium, Los Angeles, CA.
Cardiovascular Update 2003: Harvard Medical School CME, Boston, MA
Northern New England Cardiovascular disease Study Group, Portsmouth, NH
2nd Annual Genomics and Cardiovascular Disease Symposium, Philadelphia, PA
Genes, Environment, and Disease: National Institute of Environmental Health Sciences Genome Project, Boston, MA
63rd Annual Meeting, American Diabetes Association, New Orleans
Edna G. Kynett Memorial Lecture, Jefferson Medical College, Thomas Jefferson University, Philadelphia, PA
23rd Annual Cardiology State-of –the Art, Lahey Clinic, MA
International Symposium on Triglycerides, Metabolic Disorders, and Cardiovascular
Disease, Lorenzini Foundation, New York, NY
American Association of Clinical Chemistry, Philadelphia, PA
26th Annual Intensive Review of Internal Medicine, Harvard Medical School, Boston, MA
Plenary Lecture, TCT 2003, Washington D.C.
36th Annual New York Cardiovascular Symposium, American College of Cardiology,
NY

2004 Visiting Professor and Cardiovascular Grand Rounds, John Hopkins Medical Center,
Baltimore MD
American Heart Association Young Investigators Mentoring Meetings, Boston, MA
Visiting Professor and Medical Grand Rounds, University of Massachusetts Medical
Center, Worcester, MA
State-of-the-Art Lecture, Physicians Day, Partners HealthCare, Boston, MA
Fred Ownby Lectureship, Vanderbilt University, Nashville, TN
James Herrick Lecture, American Heart Association, Chicago, IL
Visiting Professor and Cardiovascular Grand Rounds, Yale University Medical Center, New Haven, CT
Plenary Symposium, American College of Cardiology, New Orleans, LA
Cardiology Grand Rounds, Dartmouth College Medical Center, Hanover, NH
Visiting Professor and Cardiovascular Grand Rounds, Brown University, Providence,
RI
Distinguished Lecturer Series, Dayton Heart Center, Dayton, OH
Advances in Treatment of Coronary Artery Disease, New York Presbyterian Hospital, NY
Plenary Symposium, American Heart Association, New Orleans, LA

37th Annual New York Cardiovascular Symposium, American College of Cardiology,
NY

2005 Cardiology Grand Rounds, New York University, New York, NY
Cardiovascular State of the Art Lecture, Tampa, FL
Plenary Symposium, American College of Cardiology, Orlando, FL

Medical Grand Rounds, University of Massachusetts, Worcester, MA
Medical Grand Rounds, Beth Israel Deaconess Medical Center, Boston, MA
3rd Chicago Cardiovascular Symposium, Chicago, IL.
Medical Grand Rounds, Brown University, Providence, RI.
Federation of Clinical Immunology Societies, 5th Annual Meeting, Boston, MA.
A. E. Diamond Lectureship, University of Toronto, Toronto, Canada.
The Seventh Annual John F. Lee, MD Memorial Lecture, Boston, MA
4th Dr Marcus Baker Memorial Lecture, St Vincent's Regional Heart and Vascular Center, Bridgeport, CT
Cardiovascular Disease: New Horizons in Prevention and Treatment, Massachusetts Medical Society, Boston, MA
Cardiovascular Grand Rounds, Montreal Heart Institute, Montreal, Canada
Cardiovascular Biomarkers and Surrogate Endpoints Symposium, Bethesda, MD.
38th Annual New York Cardiovascular Symposium, American College of Cardiology, NY
Plenary Symposium, Trends in Cardiovascular Therapeutics, Washington, DC.
Plenary Lecture, Canadian Cardiovascular Congress, Montreal, CN.
Franklin D Johnston Professorship Lecture, University of Michigan, Ann Arbor, MI.
Cardiovascular Grand Rounds, Massachusetts General Hospital, Boston, MA.

2006

Update in Clinical Cardiology 2005: Harvard Medical School CME, Boston, MA.
Plenary Lecture, Inflammation and Atherosclerosis, Pri-Med, Houston, TX.
Israeli Atherosclerosis Society, Tel Aviv Israel.
Israeli Heart Society, Tel Aviv Israel.
Cardiovascular Grand Rounds, Columbia University Medical Center, New York, NY.
42nd Annual Robert Jeresaty Cardiovascular Symposium, Hartford, CT.
Central American Cardiovascular Update 2006, Panama City, Panama.
Plenary Lecture, American College of Cardiology, Atlanta, GA.
39th Annual New York Cardiovascular Symposium, American College of Cardiology, NY
Cardiovascular Grand Rounds, John Hopkins Medical Center, Baltimore, MD.
Plenary Lecture, American Society of Hypertension, New York, NY.
Plenary Lecture, 66th Annual Scientific Sessions, American College of Osteopathic Internists, Phoenix, AZ
Invited Lecturer, Inflammation and Aging, Jean Mayer USDA Human Nutrition Research Center, Boston, MA

2007

Evans Lecture, Boston University Medical Center, Boston, MA
Plenary Lecture, Renal Physicians Association, Baltimore, MD
Cardiovascular Disease Prevention 5th Annual Comprehensive Symposium, Miami, FL
Simon Dack Visiting Professor, Mt Sinai School of Medicine, New York, NY
Keynote Speaker, Joan and Julius Jacobsen Research Initiatives in Vascular Disease, Conference, Society for Vascular Surgery, Washington DC
Invited Speaker, American College of Cardiology, New Orleans, LA
Invited Speaker, national Lipid Association, Chicago, IL

Invited Speaker, Inflammation and Atherosclerosis, Harvard University, Boston, MA
Cardiovascular Grand Rounds, Washington Hospital Center, Washington DC
Cardiovascular Grand Rounds, Beth Israel - Deaconess Hospital, Boston, MA
Office Practice of Primary Care Medicine, Harvard Medical School, Boston, MA
Keynote Speaker, 8th Annual US-Japan Dialogue on Cardiovascular Disease, Tokyo, Japan
Dana-Farber Cancer Institute, Statistics in Medicine 2007, Boston, MA
7th Texas Update in Cardiovascular Advancements, Houston TX
Visiting Professor, University of Ehime, Matsuyama, Japan
Visiting Professor, Kyoto University Graduate School of Medicine, Kyoto, Japan
Cardiovascular Medicine Review and Update for the Practitioner, Boston, MA
Invited Speaker, Texas Heart Institute Symposium on Inflammation and Atherothrombosis 2007, Houston, TX
North American Thrombosis Forum, Boston, MA
PRI-MED Updates in Cardiology 2007, Washington, DC
French-American Innovation Day (FAID), Cardiovascular Biomarkers 2007 and Beyond, Boston, MA
Plenary Lecture, American Neurological Association, Washington, DC.
Invited Speaker, XVI Drugs Affecting Lipid Metabolism (DALM), New York, NY
Plenary Speaker, American College of Rheumatology, Boston, MA

2008 Cardiovascular Grand Rounds, University of Massachusetts Medical Center
Cardiovascular Disease Prevention 6th Annual Comprehensive Symposium, Miami,
FL
Invited Speaker, American Academy of Periodontology, Boston, MA
Invited Speaker, High Risk Plaques: Detection and Management, CIMIT, Boston, MA
Keynote Speaker, PRI-MED Updates in Cardiology, New York, NY
6th Annual Comprehensive Symposium on Cardiovascular Disease Prevention 2008, Coral Gables, FL
Invited Speaker, Cardiovascular Disease 2008: Prevention and Treatment, Joslin Diabetes Center, Boston, MA
29th Annual Office Practice of Primary Care Medicine, Harvard Medical School, Boston
Plenary Lecture, SEACAM, Birmingham, AL
8th Texas Update in Cardiovascular Advancements, Houston, TX
Plenary Speaker, National Symposium on Inflammation and Disease Progression, Wayne State University, Detroit MI
Cardiology Grand Rounds, Cornell University, New York, NY
Invited Lecture, 19th Annual Cardiovascular Disease State of the Art 2008, Lahey Clinic, MA,
7th Ramzi S. Cotran Lecture, Children's Hospital, Harvard Medical School, Boston, MA
Invited Speaker, China-America Project for Cardiologists Academic Exchange Chinese Society of Cardiology, Hong Kong
Isadore Rosenfeld Visiting Professor, New-York Presbyterian Hospital, Weill Cornell
Medical College, New York, NY

Plenary Lecture, American Heart Association/ABC, From Genomics to Therapeutics,
Chicago, IL
Plenary Lecture, 4th Annual Biomarkers in Heart Disease. University of California, San Diego, CA
Plenary Lecture, Future Forum Japan, Tokyo, Japan
Invited Lecture, Faculty of Pharmacy, Paris-Descartes University, Paris FR
Plenary Speaker, 40th Japan Atherosclerosis Society Annual Meeting, Tsukuba, Japan
Invited Lecture, The Global Clinic, Healthcare Management for Physician Executives
2008, Harvard Medical School, Boston, MA
Invited Speaker, Canadian Cardiovascular Society, Toronto, ON
35th Annual Williamsburg Conference on Heart Disease, Williamsburg, VA
Plenary Lecture, Cardiometabolic Health Congress 2008, Boston, MA
Plenary Lecture, Canadian cardiovascular Society, Toronto Ontario
PRI-MED Updates in Cardiology 2008, Miami, FL

2009

6th Annual Peter F Cohn Lectureship, Stony Brook University Medical Center, NY
Invited Lecturer, Legacy and Innovation, Cleveland Clinic, Cleveland OH
Cardiology Grand Rounds, Boston University
Plenary Speaker, XIX Societe Francaise de Cardiologie, Paris FR
Opening Lecture, 2009 American Academy of Periodontology, Boston, MA
University of Utrecht Master Class, The Netherlands
Plenary Speaker, Inflammation, CV Risk, and Connective Tissue Diseases, NY
20th Calabresi Lectureship, Yale University, New Haven, CT
Plenary Speaker, American College of Cardiology, Orlando, FL
Plenary Speaker, XV International Symposium on Atherosclerosis, Boston MA
7th Annual Comprehensive Symposium: CVD Prevention 2009
Plenary Speaker, North American Thrombosis Forum, Boston, MA
Plenary Speaker, National Lipid Association, Chicago, IL
Invited Lecturer, Cambridge University, United Kingdom
Office Practice of Medicine 2009, Boston, MA
Annual Cardiovascular Conference, Lake Louise, Alberta
Cardiovascular/Medical Grand Rounds, Dartmouth Hitchcock Medical Center, NH
Invited Lecture, Harvard Initiative for Global Health, Cambridge, MA
Edna G. Kynett Lecture, Jefferson Medical College, Philadelphia, PA
Daniel Savage Lectureship, Association of Black Cardiologists
Plenary Lecture, XXII Congress International Society on Thrombosis and Haemostasis
Plenary Lecture, International Society for Thrombosis and Haemostasis
James T Willerson Lecture, University of Texas, Houston
Keynote Presentation, Cardiometabolic Health Congress 2009, Boston, MA
XXVIII Leccion Memorial Lecture, Madrid, Spain
Honorary Lecture, Argentine Congress of Cardiology, Buenos Aires, Argentina.

2010

27th Annual Advances in Heart Disease, University of California, San Francisco
Plenary Speaker, American Association of Clinical Chemistry, N England Section
Medical Grand Rounds, Rhode Island Hospital, Brown University, Providence RI
Lettura Magistrale, Congresso Il Laboratorio Clinico E L'aterotrombosis, Perugia, Italy

Invited Lecture, Inflammation: Shared Mechanisms of Disease, Biomedical Research
Institute, Boston, MA
Keynote Presentation, Cardiometabolic Health Congress 2010, Boston, MA
Invited Speaker, NIH/NHLBI Infection, Immunity, Inflammation and Atherothrombosis:
New Directions for Improving Patient Care, Boston, MA
Plenary Lecture, World Congress of Cardiology, Beijing, China
Visiting Professor and Dean's Distinguished Lecture, Case Western Reserve University School of Medicine, Cleveland, OH
Keynote Lecture, XLIII Congreso Venezolano de Cardiologia, Caracas, Venezuela
Keynote Lecture, Sociedade de Cardiologia do Estado De Sao Paulo, Brazil
Keynote Lecture, National Meetings, American Association of Clinical Chemistry, Anaheim, CA
Invited Lecture, CRT 2010, Washington DC
Invited Lecture, Canadian Cardiovascular Research Network, Toronto, Ontario
Invited Lecture, North American Thrombosis Summit 2010, Boston, MA
Keynote Lecture, Asia Pacific Cardiovascular Summit 2010, Kuala Lumpur, Malaysia
Plenary Lecture, 21st Annual Sessions Society of Vascular Medicine, Cleveland, OH
8th Annual Biomarkers & Surrogate Endpoints Symposium, Bethesda, MD
27th Annual Advances in Heart Disease, University of California, San Francisco, CA

2011 Visiting Professorship: Institute for Translational Medicine and Therapeutics, University of Pennsylvania, Philadelphia, PA
Cardiology Grand Rounds, The University of Texas Southwestern Medical Center, Dallas, TX
Ninth Annual Comprehensive Symposium, Cardiovascular Disease Prevention, Coral Gables, FL
Clinical Implications of Inflammation, Cleveland Clinic, Cleveland OH
Contemporary Strategies for Practice Excellence in Cardiovascular Disease, Inova Heart and Vascular Institute Cardiovascular Symposium 2011, Falls Church, VA
19th Annual Miriam Lemberg Visiting Professorship In Cardiovascular Disease, University of Miami Health Systems, Miami, FL
Cardiology Grand Rounds, Montefiore Medical Center, Bronx, NY
Invited Lecture, Advanced Preceptorship in Cardiovascular Disease (APCAD), Boston, MA
Invited Speaker: PCNA 17th Annual Symposium, Cardiovascular Risk Reduction, Lake Buena Vista, FL
Medicine Grand Rounds, Temple University, Philadelphia, PA
Medicine Grand Rounds, Guller Family Lecture, Washington University School of Medicine, St. Louis, MO
Annual Invited Professor Lecture in Cardiology, Quebec Heart and Lung Institute (QHLI), Quebec, Canada
Plenary Lecture Arteriosclerosis, Thrombosis and Vascular Biology (ATVB), Chicago, IL
Cardiovascular Medicine: Update for the Practitioner, Atherosclerosis Inflammation,
and Risk Factors, Boston, MA
Invited Speaker, National Lipid Association (NLA)
Plenary Lecture, 26th Annual International Conference, ISHIB, Boston, MA

Visiting Professor, Quebec Heart and Lung Institute, Quebec Canada
Heart Institute Grand Rounds, Cedars-Sinai Medical Center, Los Angeles, CA
Cardiovascular Grand Rounds, Intermountain Medical Center, Murray, UT
Invited Speaker, Symposium celebrating the scientific contributions of Dr. Michael Gimbrone, Boston, MA
Invited Speaker, Cardiovascular Institute, Drexel University College of Medicine
Plenary Lecture, 201 Cardiometabolic Health Congress, Boston, MA
6th Annual Comprehensive Cardiovascular Symposium, Miami Heart Center, FL
Plenary Lecture, Shaping the Future of CV Care, Cleveland Clinic, Cleveland OH
Keynote Lecture, Cardiovascular Society of Chile, Santiago, Chile

2012 Invited Lecture, 125th Meeting of the American Clinical and Climatological Association
Medical Grand Rounds, Brigham and Women's Hospital, Boston, MA
Cardiovascular Grand Rounds, Columbia University, NY, NY
Keynote Lecture, Canadian Cardiovascular Society
Invited Lecture, Association of University Cardiologists
Keynote Lecture, American College of Oseopathic Internsits, Orlando, FL
Invited Lecture, CVD in Autoimmune Disorders, Columbia University
Invited Lecture, Progress in CVD 2012, 9th Annual Barnabas HealthCV Symposium
Plenary Lecture, European Society of Cardiology Congress, Munich, GM
Invited Lecture, National Institiute of Aging (NIA), Bethesda, MD
Invited Lecture, National Human Genome Resaerch Institute, Bethesda, MD
Course Faculty Lecture, The Jackson Laboratory / Johns Hopkins, 53rd Short Course on Mamalian Genetics, Bar Harbor, MA
Faculty, 35th Intensive Review of Internal Medicine, Harvard Medical School, Boton, MA
Visiting Professor, Cardiological Scieity of India, Mumbai
Course-Director, Arterial and Venous Thrombosis, Boston, MA
Invited Lecture, Loyola University Stritch School of Medicine, Chicago, IL
Plenary Lecture, 72nd Scientific Sessions, American Diabetes Association, Philadelphia PA
Invited Lecture, Inova Heart and Vascular Insititute, VA
Plenary Lecture, XXXIII Congress of the Cardiology Society of the State of Sao Paulo, Brazil
Invited Lecture, Cardiology in the Capital, Mayo Clinic, Washington DC

2013 Cardiovascular Grand Rounds, Tufts University, Boston, MA
Visiting Professor, University of Utrect, Netherlands
Vascular Grand Rounds, University of Leuven, Belgium
Invited Lecture, Cardiometabolic Health Congress, Boston, MA
Invited Lecture, Inova Heart 2013 Cardiovascular Symposium, Fairfax, Virginia
Harvard Medical School, Cardiovascular Medicine for the Practitioner, Boston, MA
Invited Lecture, 207th Meeting of the Interurban Clinical Club, Boston, MA
Grand Rounds, Cardiovascular Institute of New Jersey, Robert Wood Johnson Medical School, New Brunswick, NJ
Invited Speaker, CVM Council, Paris France
Plenary Lecture, 77th Annual Scientific Meeting of the Japanese Circulation Society, Yokohama, Japan
Cardiology Grand Rounds, Boston, VA Medical Center, Boston, MA
Invited Lecture, 11th Annual Cardiovascular Disease Prevention International Symposium, Miami, Florida

Keynote Address, 4th Annual Reaserch Retreat, University of Massachusetts Center for Clincal and Translational Science, Worcester, MA
Plenary Lecture, National Lipid Association Scientific Sessions 2013, Las Vegas
Invited Lecture, 2nd Annual Diabetes Symposium, Jefferson University, Phyiladelphia, PA
Invited Lecture, Frontiers in Medicine: Therapeutic Challenges for he 21st Century, Beth Israel Deaconess Medical Center, Boston
Plenary, 2013 Cardiometabolic Health Congress, Boston,MA
2013 Linton Distinguished Lecture, New England Society for Vascular Surgery
Landmark Lectureship, University of Toronto, Toronto Ontario

2014

Invited Speaker, New York Heart Resaerch Foundation, NY, NY
Pathology Grand Rounds, Birhgma and Women's Hospital, Boston, MA
Keynote Lecture, 5th Annual State of the Heart, CCRN, Toronto, Ontario
Invited Speaker, Center for Interdisciplinary Cardiovascular Sciences, Boston, MA
50th Annual Robert Jeresaty Cardiovascular Symposium, Hartford, CT
2nd Annual J.B. Johnson Distinguished Cardiovascular Lecture, Washington DC
Invited Speaker, 4th Annual Yale Cardiovascular Research Center Symposium, New Haven CT
CICS Seminar, Kowa Institute, Boston MA
Medical Grand Rounds, Northwestern University, Chicago, IL
Current Treends in Cardiology, Harvard Medical School, Boston MA
Keynote Lecture, Milan Cardiology, Oespedale San Raffaele, Milan Italy
Cardiology Grand Rounds, University of Chicago, Chicago, IL
Plenary Lecture, Advances in Cardiology, Icahn School of Medicine at Mount Sinai, NY
9th Annual CHMC Cardiometabolic Health Congress, Boston MA
Plenary Lecture, Twenty Years of CRP in Cardiology, Universita Cattolica del Sacro Cuore, Rome, Italy
Intensive Review of Internal Medicine, Harvard Medical School, Boston MA

2015

Heart and Vascular Institute Grand Rounds, Cleveland Clinic, OH
Invited Lecture, National Lipid Association, Denver CO
Course Director and Lecturere, Thrombosis and Thromboembolism, Boston MA
Seminar, Jean Mayer Human Nutrition Research Center, Boston MA
Invitede Lecture, Diabetes CTU, Li K Shing Knowledge Institute, St. Michael's Hospital, Toronto ON
NHLBI AIDS Working Group in Heart Lung and Blood Research, Bethesda, MD
13th Annual Advances in Cardiology, Canadian Cardiovascular Society, Toronto
Plenary Lecture, PCSK9. European Society of Cardiology, London, UK
Plenary Lecture, Inflammation and Atherosclerosis, European Society of Cardiology, London UK.
Invited Lecture, 12th World Congress on Inflammation, Boston, MA
Invited Lecture, Centro Nacional de Investigaciones Cardiovasulares Carlos III, Vulnerable Patient Meeting, Madrid Spain
Mikamo Lecture, 79th Annual Scientifc Meeting of the Japanese Circulation Society, Osaka Japan
Harvard Cardiovascular Update 2015, Boston MA
Keynote Address, 17th International Symposium on Atherosclerosis, Amsterdam, The Netherlands
Invited Lecture, Diabetes Update + 2015, British Columbia, Canada
Plenary Session, ISA, Amsterdam, The Netherlands

Invited Lecture, 15th Controversies in the Treatment of Cardiovascular Disease, Beverly Hills, CA

2016
Keynote, Advances in Lipidology, Harvard Medical School Boston MA
Organizer and Invited Plenary Lecture, Milan Cardiology, Milan Italy
Invited Lecture, Guaging the Guidelines, Toronto, ON Canada
Guest Plenary Lecture, REPRIEVE IM, NHLBI, Boston, MA
Plenary Lecture, Yankee Dental, Boston MA
Invited Lecture, INVOA Cardiovascualr Symposium, McLean VA
Endocrinology Grand Rounds, Brown University, Providence RI
Plenary Lecture, 2nd Annual Bredenberg Vascular Symposium, Maine Medical Center, Portland, ME
Plenary Lecture, 64th Annual Scientific Session of the Japanese College of Cardiology, Tokyo, Japan
Plenary Lecture, European Socidty of Cardiology, Rome, Italy
Invited Lecture, American Heart Association, New Orleans, LA
Invited Lecture, 13th Global CardioVascular Clinical Trialists Forum, Washington
Best of ACC Cardiovascular Medicine, Chennai, India
Best of ACC Cardiovascular Medicine, Mumbai, India
Best of ACC Cardiovascular Medicine, Kathmandu, Nepal
Best of ACC Cardiovascular Medicine, Dhaka, Bangladesh
Opening Plenary Lecture, 19th International Vascular Biology Meeting (IVBM) / North American Vascular Biology Organization (NAVBO), Boston, MA
Plenary Lecture, Managing Inflammation, 11th Annual Cardiometabolic Health Congress, Boston, MA
Invited Lecture, Diabetes Clinical Trials Update, Toronto Ontario
Invited Lecture, Unraveling Vascular Inflammation: From Immunology to Imaging. NHLBI, Bethesda, MD
Invited Lecture, Contemproary Issues in Cardiology and Diabetes, Canadian Cardiovascular Congress, Montreal CA
Invited Lecture, Intensive Review of Internal Medicine, Harvard Medical School, Boston, MA
Visiting Professor, Jewish Hospital, Institute of Molecular Cardiology, University of Louisville, Louisville, KY
Invited Lecture: PCSK9 and Vascular Disease, University of Montreal, Montreal CA

2017
Invited Lecture: New York Cardiovascular Symposium, New York, NY.
Invited Lecture: 14th Global CVCT Forum, Washington, DC
Keenan Lecture and Visiting Professor, University of Toronto, Toronto, Canada
Invited Lecture: Vascular Biology Working Group, AHA, Anaheim California
Plenary Lecture, European Ahterosclerosis Society, Prague, Czech Republic
Medical Grand Rounds, Brigham and Women's Hospital (Inflammation biology)
Cardiovascular Grand Rounds, Brigham and Women's Hospital (PCSK9)
Cardiovascular Grand Rounds, Brigham and Women's Hospital (CANTOS)
Cardiovascular Grand Rounds, Massachusetts General Hospital
Visiting Professor and Cardiology Grand Rounds, University of Califoria San Francisco
Invited Lecture, Landmark Symposium, North American Thrombosis Forum, Boston, MA
Keynote Address, Montefiore Preventive Cardiology Conference, Bronx, NY
Robert J. Burns Memorial Lecture, Canadian Cardiovascular Society, Canadian Society of Cardiovascular Nuclear and CT Imaging, Vancouver, Canada

Plenary Lecture, 12th Annual Cardiometabolic Health Congress, Boston, MA
Plenary Lecture, European Society of Cardiology, Barcelona, Spain
Plenary Lecture, American College of Cardiology, Washington, DC
Plenary Lecutre, Americn Heart Association, Anaheim, California
Invited Lecture, Cardiovascular Medicine 2017 Updates for the Practitioner, Harvard Medical School, Boston, MA
Cardiology Grand Rounds, MedStar Washington Hospital Center, Washington, DC
Invited Speaker, 2017 Spring Program, North American Thormbosis Forum, Boston, MA
Invited Lecture, ONO 300th Anniversary, Tokyo, Japan
Invited Lecture, 2nd Annual Cardiometabolic Disease Sympsoium, Toronto, Canada
Invited lecture, TARGET Meeting, NHLBI, Bethesda, MD
Invited Speaker, Deuel Conference on Lipids, Monterey, California
Keynote Address, 12th MSDA, Pavlov Hall, Federal Almazov NW Research Centre, St. Petersburg, Russia
Invited Speaker, World Medical Innovation Forum, Boston, MA
Keynote Address, 4th International Cardiology SPACE, Prague, Czech Republic
Visiting Professor, Heart and Vascualr Institute Grand Rounds, Cleveland Clinic, Cleveland, OH
Cardiology Grand Rounds, Weill Cornell Medical Center, New York, NY
Cardiology Update 2017, ACC, Mumbai, India

2018 Distinguished Lecture, ATVB, San Francisco, CA
Distinguished Scientist Lecture, American Heart Association, Chicago IL
12th Annual Meridith S. and John A. Oates Lecture in Clinical Pharmacology, Vanderbilt University, Nashville, TN
Louis Rakita Lecture, Case Western Reserve University, Cleveland OH
Keynote Lecture, 26th Annual Meeting, ACC Connecticut, Monroe CT
Distingished Biomedical Scholar Lecture, University of Iowa, IO
Invited Lecture, ACC New York Cardiovascular Symposium, New York, NY
Invited Lecture, 2nd Annual Heart in Diabetes, Philadelphia, PA
Cardiology Grand Rounds, St. Lukes' Health / Texas Heart Institute, Houston, TX
Invited Lecture, Keystone Symposia, Atherosclerosis, Taos, NM
NHLBI Biomedicine Lecture Series, NHLBI, Bethesda, MD
Invited Lecture, Jobs for Massachusetts, Federal Reserve Bank, Boston, MA
Invited Lecture, New York Cardio-Endo-Renal Collaborative, New York, NY
Plenary Lecture, NY Academy of Sciences, Resolution of Inflammation, NY
Cardiovascular Grand Rounds, University of Pennsylvania, Philadelphia PA
15th Key Symposium: Invited Lecture, Innate Immunity, Oxford, United Kingdom
John O. Parker Lectureship, Queen's University, Kingston, Ontario, Canada
Cardiology Rounds, McGill University Health Centre, Montreal, Canada
Invited Lecture, Frontiers in Science and Medicine Symposium, NYU Langone Health, New York, NY
Invited Lecture, 13th Annual Cardiometabolic Health Congress, Boston, MA
7th Bi-Annual Thrombosis and Thrombembolism, Boston, MA
XVIIIth International Symposium on Atherosclerosis (IAS), Toronto CA
12th Annual Update on Cardiovascular Disease, Cleveland Clinic, Cleveland OH
Rheumatology Grand Rounds, Massachusetts General Hospital, Boston, MA
Plenary Lecture, 70th Annual AACC Annual Scientific Meetings, Chicago, IL
Diabetes Specialist Working Group, Li Ka Shing Knowledge Institute, Toronto
Imel-Demots Lectureship, Knight Cardiovascular Institute, OHSU, Portland OR

9th Annual State of the Heart, CCRN, Toronto, ON
Medical Grand Rounds, Memorial Sloane Kettering Cancer Center, New York, NY
54th Annual Robert M Jeresaty Cardiovascular Symposium, Hartford CT
Cardiology Grand Rounds, UT Southwestern Medical Center, Dallas, TX
Invited Lecture, CRT 2018, Washington DC
Plenary Speaker, Sarnoff Annual Scientific Meeting, Boston, MA
14th Annual Leahey Lectureship, Columbia University Medical Center, NY

2019

Eugene Braunwald Keynote Lecture, ACC, New Orleans
Attilio Maseri Lecture, ATBV Spring Meetings, Trieste Italy
Paul Dudley White Keynote Lecture, ACC, NY
Keynote Lecture, European Atherosclerosis Society (EAS), Maastricht
Arthur Ancowitz Memorial Lecture, New York University, New York NY
James E. Crockett Lectureship Award, Kansas City, Kansas
Invited Lecture, New York Cardiovascular Symposium, ACC, New York, NY
Speaker, 14th Annual ITMAT Symposium, University of Pennsylvania, Philadelphia
Burton E. Sobel Visiting Professor, CVRI, University of Vermont, Burlington VT
Rose Weiss Visiting Professor, Lahey Health Medical, Burlington, MA
42nd Annual Intensive Review of Internal Medicine, Harvard Medical School
Plenary Lecture, 51st Annual Meeting Japan Atherosclerosis Society, Kyoto Japan
Invited Lecture, 94th Annual Robert D Conn Heart Conference, Kansas City
Plenary Lecture, 7th International Conference Nutrition in Medicine, Washington
Irwin D Mandel Advances in Cardiovascular Risk Reduction, NYU, New York NY
Invited Lecture, Joint Meeting AAP/ASCI/APSA, Chicago IL
Invited Lecture, Thrombosis & Thromboembolism, Harvard Medical School
Invited Lecture, Cardiovascular Medicine: Update 2019, Harvard Medical School
Plenary Lecture, American Association for Cancer Research, Atlanta GA
Plenary Lecture, CVRM Internal Science Symposium, Gothenburg, Sweden
Distinguished Lecture, 66th Annual Conference of the Israel Heart Society, Tel Aviv
Invited Lecture, Inflammation & Chronic Diseases, Hadassah University, Tel Aviv
Invited lecture, 15th Annual PEGS-BOSTON Protein Engineering Summit, Boston
Cardiology Grand Rounds, Kansas University Medical Center, Kansas
Cardiology Grand Rounds, Cleveland Clinic, Cleveland Ohio

2020

NIH Visiting Scientist, Inflammation Biology 2021, Bethesda MD
27th Annual William L. Winters Lecture, Debakey Heart & Vascular Center, Houston TX
Grand Rounds, National Institutes of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Bethesda MD
Joseph Stokes Lifetime Achievement Award, American Society for Preventive Cardiology (virtual)
Horan-Flowers Lectureship, Gill Heart and Vascular Institute, University of Kentucky (virtual)
Plenary Lecture, American College of Cardiology (Virtual)
Invited lecture, NYT Academy of Science, Resolving Inflammation, NY (virtual)
Medicine Grand Rounds, University of Colorado, Denver (virtual)
Invited Lecture, Canadian Society for Clinical Chemists (virtual)
R.T. Hall Honorary Lecture, CSANZ, Australia (virtual)
Invited Lecture, Cleveland Clinic, OH (virtual)
Grand Rounds, Northwell Cardiovascular Disease Symposium, New York (virtual)
Plenary Lecture, European Society of Cardiology, Amsterdam (virtual)
Invited Lecture, EMBO, The Inflammasomes, Berlin (virtual)

Invited lecture, 4th Annual Cardiovascular Update, Northwell Heart, NY (virtual)
Plenary Lecture, 15th Annual Cardiometabolic Health Congress (virtual)
Invited Lecture, American Heart Association, Dallas TX (virtual)
Medical Grand Rounds, Methodist Hospital, Houston TX (virtual)
Cardiovascular Grand Rounds, Brigham and Women's Hospital, Boston (virtual)
Plenary Speaker, Janet Rowley Research Symposium, University of Chicago, Illinois (virtual)
Invited Lecture, World Forum on Chronic Inflammation, Boston, MA (virtual)
Invited Lecture, Inflammation and Atherosclerosis, Korean Society of cardiology (virtual)
Grand Rounds, Lankenau Hospital, Philadelphia (virtual)
43rd Annual Intensive Review of Internal Medicine, Harvard Medical School (virtual)
Invited Lecture, cardiovascular Medicine: Update 2020, Harvard Medical School (virtual)

2021 Medical Grand Rounds, Stanford University, Palo Alto CA (virtual)
Invited Lecture, NIH/NHLBI Workshop, Early Treatment in High Lifetime Risk in CVD, Bethesda MD (Virtual)
Plenary Lecture, Japanese Society of Cardiology, Osaka, Japan (virtual)
Plenary Lecture, Portuguesa Congress of Cardiology, Lisbon, Portugal (virtual)
Plenary Lecture, Cardiovascular Society of Korea (virtual)
Grand Rounds, BI Deaconess Hospital, Boston USA (virtual)
Late Breaking Plenary Lecture, American College of Cardiology, New Orleans (virtual)
Invited Debate, American College of Cardiology, New Orleans (virtual)
5th International Vatican Conference, Vatican City and New York (virtual)
Invited lecture, Brazilian Cardiology Society, Sau Paulo (virtual)
Invited Lecture, Society for Epidemiologic Research (virtual)
Cardiovascular Teaching Rounds, West Roxbury VA Hospital, Boston, MA
44th Annual Intensive Review of Internal Medicine, Harvard Medical School (virtual)
Invited Lecture, Cardiovascular Medicine: Update 2021, Harvard Medical School (virtual)
Invited Lecture, Canadian Cardiovascular Congress (virtual)
Invited Lecture, 19th International Symposium on Atherosclerosis (IAS), Kyoto, Japan (virtual)
Invited Lecture, Japanese Circulation Society 2021 (Tokyo (virtual)
Invited Lecture, European Society of Cardiology, Paris FR (virtual)
Keynote Lecture, NYU Langone Health: Management of Cardiometabolic Risk in Inflammatory Conditions, NY (virtual)
Plenary Lecture, Inflammation in Diabetes, American College of Cardiology (virtual)
Keynote Lecture, EMBO The Inflammasomes, Martinsried Germany (virtual)
Invited Lecture, South African Heart Associaton 2021 Master Class (virtual)
Invited Lecture, Cardiometabolic Health and Metabolism Congress, Washington DC (virtual)
Invited Lecture, Global Inflammation Think Tank, NY, NY (Virtual)
Pleanary Lecurer, 12th Annual Emirates Cardiac Society, Dubai (Virtual)

Report of Clinical Activities

Dr. Ridker is a Senior Attending Cardiologist at the Brigham and Women's Hospital in Boston, MA, with primary clinical responsibilities in the Echocardiography Laboratory and on the inpatient clinical services. Dr. Ridker also serves as a consulting cardiologist and maintains an active outpatient cardiology clinic at the Southern Jamaica Plain Health Center, a community outreach public health clinic affiliated with the Brigham and Women's Hospital.

PART III: Bibliography

Original Reports

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Patents Filed/Pending:

1. U.S. Application Serial No 09/054,212. Systemic Inflammatory Markers as Diagnostic Tools in the Prevention of Atherosclerotic Diseases and as Tools to Aid in the Selection of Agents to be Used for the Prevention and Treatment of Atherosclerotic Disease (Inventors: Paul M Ridker / Charles H Hennekens)
2. International Application NO PCT/US98/06613. Means of Ascertaining an Individuals Risk Profile for Atherosclerotic Disease (Inventors: Paul M Ridker / Charles H Hennekens)
3. U.S. Provisional Patent Application 60/255,632. Inflammation Markers As Tools in the Detection and Prevention of Diabetes Mellitus and As Tools to Aid in the Selection of Agents to be Used for the Prevention and Treatment of Diabetes (Inventors: Paul M. Ridker/JoAnn E. Manson)
4. U.S. Provisional Patent Application 60/338,841. Soluble CD40L (CD 154) as a prognostic marker of atherosclerotic diseases. (Inventors: Uwe Schoenbeck, Paul M Ridker, Peter Libby).

Appendix B

Appendix B

Exhibit	Description
1001	U.S. Patent No. 11,400,063 B2 to Tardif ("the '063 patent")
1003	Provisional Application 63/093,988 (October 20, 2020, Provisional Application)
1004	Provisional Application 62/935,865 (November 15, 2019, Provisional Application)
1005	Nadia Bouabdallaoui et al., *Time-to-treatment initiation of colchicine and cardiovascular outcomes after myocardial infarction in the Colchicine Cardiovascular Outcomes Trial (COLCOT)*, 41 Eur. Heart J. 4092-99 (2020)
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